
Design: Randomized clinical trial

Population/sample size/setting:
- 45 patients (sex distribution unclear, mean age 52) treated for lateral epicondylitis at a university physical medicine department in Germany
- Eligible if they had unilateral epicondylitis for at least 3 months; excluded if they had analgesics or NSAID in past 2 weeks, radial nerve entrapment, inflammatory rheumatic disease, CNS disease, osteoarthritis, or past treatment of epicondylitis with either surgery or acupuncture
- Epicondylitis defined by lateral elbow pain exacerbated by active extension of the wrist or by gripping, with tenderness of lateral epicondyle and aggravation of pain during resisted extension of middle finger

Main outcome measures:
- Randomized to either true acupuncture (n=23) or sham acupuncture (n=22)
- True acupuncture received twice weekly treatment with six needles inserted to the musculature at classical acupuncture points for 25 minutes per session, for a total of 10 treatments
- Sham acupuncture replicated the schedule of true acupuncture, with needles placed 5 cm away from classical acupuncture points
- A blinded observer in the department of physical medicine examined patients three times: at baseline, 2 weeks after treatment, and 2 months after treatment
- Principal outcome was pain on a scale from 0 to 30; groups were similar at baseline (about 17/30), but true acupuncture was better than sham at the 2 week assessment (8/30 vs. 12/30); at 2 months, group differences were not significant (6/30 vs. 8.7/30)
- Isometric strength (peak force of forearm extensors) was similar at baseline, was better in true acupuncture at 2 weeks, and groups were again similarly improved at 2 months
- DASH disability was similar at baseline in true and sham acupuncture (38 vs 33.7 points); true acupuncture had advantage over sham at 2 weeks (14.4 vs. 25.1 points) and this continued at 2 months (11.1 vs. 18.9 points)
- One subgroup analysis was done; patients were divided into two groups defined by their work demands (heavy or repetitive vs. light or non-repetitive)
  - Real acupuncture led to similar improvements in the two subgroups
  - Sham acupuncture led to less improvement in the heavy/repetitive subgroup than in the light/non-repetitive subgroup

Authors’ conclusions:
- Classical Chinese acupuncture appears more effective than sham acupuncture for treatment of lateral epicondylitis
- The recruitment of patients through press advertisement may have caused a bias in selection
- The natural history of epicondylitis may make the interpretation of the results at 2 months more difficult than the results at 2 weeks after treatment, where the treatment effect of acupuncture may be more apparent

Comments:
- Randomization was done with a list of random numbers generated by the biostatistics department at the university; it is not completely clear that this is equivalent to concealment of allocation, since an unbiased random number list may be compromised if its concealment is not adequate
- The subgroup analysis (physical job strain vs. no job strain) is not convincing, since there is no indication in the methods section that it was preplanned, and there was no reporting of an interaction term (to rule out chance) in the analysis
- As the authors point out, the methods for control acupuncture have not been standardized; they placed the control needles in the same dermatomes as the true needles, which makes it unlikely that counter-irritation explains the analgesic effect of classical acupuncture

Assessment: adequate for evidence that acupuncture improves pain and function more than sham acupuncture for lateral epicondylitis