Ebenbichler GR, Resch KL, et al. Ultrasound treatment for treating the carpal tunnel syndrome: randomised “sham” controlled trial. BMJ 1998;316:731-5.

PMID:9529407

Design: Randomized Clinical Trial

Purpose of study: to assess the efficacy of ultrasound treatment for mild to moderate carpal tunnel syndrome

Population/sample size/setting:

* 45 adults (mean age 51) with bilateral idiopathic electrophysiologically defined CTS with symptoms 3 months or more treated at a PM&R clinic at the University of Vienna
* Exclusion if secondary neuropathy, systemic disease, axonal neuropathy of median nerve, past CTS treatment with surgery, steroids, or ultrasound

Interventions:

* Both wrists treated in all patients; dominant wrist randomized to ultrasound or sham treatment, with opposite wrist receiving other treatment for 6 weeks (20 sessions), follow-up evaluation done at 2 weeks, end of treatment, and 6 months
* US was administered for 15 minutes per session at a frequency of 1 MHz at an intensity of 1.0 W/cm2, with an Aquasonic gel as the couplant

Outcomes:

* Primary outcome measures for each wrist were based on (1) the sum of scores of subjective complaints and sensory loss, and (2) changes in distal motor latency and in antidromic sensory nerve conduction velocity
* 4 separate subjective variables were measured, each on a scale in which 0 is no complaint and 10 is the maximum complaint
* The 4 variables were a score of all subjective symptoms, a main complaint, a worst complaint, and reported sensory loss
* 11 of 45 subjects dropped out early, 8 for not keeping appointments, 3 for excessive pain requiring additional treatment; 34 completed study
* Patients, therapists, and investigators were blinded
* Changes in subjective symptoms were analyzed as paired differences between ultrasound and sham treated wrists at 2 weeks, at the end of treatment, and again at 6 months
* The ultrasound-treated wrists recorded greater average symptomatic improvements than the sham-treated wrists at all three followup assessments; at 6 months, the paired difference for the main patient complaints was 2.26 points; for mean changes in worst complaints, the difference was 3.83 points; for change in sensory loss, the difference was 1.53 points
* Hand grip strength improved in ultrasound over sham wrists at end of treatment and 6 months; pinch strength showed advantage at 6 month followup
* For hand grip, the difference was 7.43 kg; for pinch strength the difference was 0.71 kg
* No side effects reported; 3 patients were off work during treatment; 8 took oral analgesics

Authors’ conclusions:

* 20 sessions of ultrasound were better than sham US for mild to moderate CTS
* Ultrasound is safer than repeated steroid injection

Comments:

* Inclusion criteria of “mild to moderate pain” for >3 months; not clear what “pain” means when numbness/paresthesias are classic chief complaints
* The study suffers from lacking a well-defined primary outcome
* The principal problem is that the outcome is not based on a validated scale such as the Boston Carpal Tunnel Questionnaire, which was available since 1993; the system of scoring “main complaint” and “worst complaint” appears to be contrived
* 8 patients dropped out due non-compliance with appointments; because both wrists were treated, this necessarily means equal attrition between US and sham treatments, but these 8 withdrawals may have been because US was not effective in the patients who were non-compliant with follow-up
* These withdrawals may mean that the reported results overstate the effectiveness of US for CTS
* Because both wrists were treated, and because the responses of one wrist are correlated with the response of the opposite wrist, there is a potential for an error in unit of analysis if this is not taken into account
* A Cochrane review (Page et al 2013), addressing this point, asserts that the author was contacted and that this contact “confirmed that the correlation between wrists was not accounted for in the analysis (therefore a unit of analysis error occurred”
* However, the wrists were treated in a paired analysis, such as is done in crossover studies, and this analysis is appropriate for studies in which patients serve as their own controls; the criticism that a unit of analysis error occurred does not appear to be warranted
* One problem with the analysis is that the comparison was made in terms of change scores, and that the average baseline score for the US treated wrist was slightly worse than the sham-treated wrist; the analysis should have used analysis of covariance to account for the baseline difference

Assessment: Inadequate for evidence of ultrasound effectiveness (poorly defined outcome and possibility that it could have been created post hoc)

Reference:

Page MJ, O’Connor D, et al. Therapeutic ultrasound for carpal tunnel syndrome. Cochrane Database of Systematic Reviews 2013, Issue 3. Art. No.: CD009601