**Yao E, Gerritz PK, Henricson E, and et al. Randomized Controlled Trial Comparing Acupuncture With Placebo Acupuncture for the Treatment of Carpal Tunnel Syndrome.**

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**Design:** Prospective, randomized, placebo-controlled, double-blinded trial

**Objective:** To compare the effectiveness of needle acupuncture combined with a wrist brace to placebo needle acupuncture combined with a wrist brace in reducing symptoms and improving functionality in patients for the treatment of mild to moderate carpal tunnel syndrome (CTS).

**Population /sample size/setting:**

* A total of 41 acupuncture-naïve adult patients (mean age 51 years, 30 females, 11 males) with clinical and electrodiagnostic evidence of mild or moderate CTS were recruited in the clinic at Davis Medical Center, University of California, Department of Physical Medicine and Rehabilitation in Sacramento between May 2009 and September 2010.
* After screening and consent, the 41 subjects were randomly assigned in a 1:1 ratio by computer to one of 2 groups: group 1 (n = 21) received acupuncture and a wrist brace; group 2 (n = 20) received placebo acupuncture and a wrist brace.
* Inclusion criteria included mild or moderate carpal tunnel syndrome on the basis of symptoms and electrodiagnostic study, and at least a 3-month duration of CTS symptoms.
* Exclusion criteria included evidence of severe CTS on the basis of physical examination or electrodiagnostic testing, previous carpal tunnel release, a history of wrist or hand fracture on the affected side, a current pregnancy or 3 months postpartum status, treatment with a corticosteroid injection in the carpal tunnel within the past 3 months, a history of generalized peripheral neuropathy or mononeuropathy multiplex, a history of other neurologic disorders that may cause confusion with the diagnosis of CTS (including but not limited to stroke, cervical radiculopathy, myelopathy, brain tumor, inflammatory articular disease, or tendonitis of the hand or wrist), a history of other disorders known to predispose to CTS, and being the recipient of workman’s compensation.

**Methods/Interventions/Outcome Measures:**

* Study design was a prospective, randomized, placebo-controlled, double-blind study.
* Two physician acupuncturists who were not blinded to the subject randomization treated subjects in both groups, but were not involved in the collection of outcome measurements or data analysis. One acupuncturist was trained in medical acupuncture, and the other in a Traditional Chinese Medicine Masters program. Both had 3 years of experience. Neither the assessors nor the patients were informed of the treatment assignments. Subjects in both groups were physically blinded with an opaque cover over their eyes during the treatment sessions.
* Subjects were tested at baseline and underwent 6 weekly treatments. Repeat outcome measures were performed post-treatment immediately after the last and 6th treatment, and at 2 weeks and 3 months after the last treatment.
* The acupuncture group was asked to indicate a “de-qi” sensation. In the placebo acupuncture group, the acupuncturist used a Streitberger placebo acupuncture needle and stopped manipulating the needle after 2 seconds. Total needle retention time was 20 minutes.
* Subjects in both groups were given wrist splints and were instructed to wear the splint nightly for the 6 week treatment period. Compliance with wrist splint use was monitored at the end of the study.
* The primary outcome measurement was subject reported change in the Carpal Tunnel Self Assessment Questionnaire (CTSAQ) Symptom and Function scales immediately after the last treatment and at 2 weeks and 3 months after the final treatment. The questionnaire scale has 11 questions on symptoms and 8 questions on hand function, with a minimum score of 0 and a maximum score of 5 for each item. Scores are averaged for each scale. A decrease of 1.04 or more in the CTSAQ average score indicates a clinically important improvement in a patient’s state of health. The secondary outcomes included tip and key pinch strength and combined sensory index using a dynamometer.
* Two sample *t*-tests were used to detect pre-existing differences in participant characteristics and pretreatment and post-treatment outcome measure scores between treatment groups. Change in the primary and secondary outcome measures were analyzed with the use of a one-way repeated measures analysis of variance from baseline to the 3-month post-treatment evaluations for both groups. The significance level of the study was set at *p* < 0.05. All participants were included according to intent-to-treat analysis.

**Results:**

* Thirty-four subjects completed the study. The study had 7 dropouts, 3 in the acupuncture group and 4 in the placebo group. Four dropouts did not complete all sessions because of personal issues, 2 were lost to follow-up, and one cited acupuncture as being too painful.
* No significant differences were observed between the 2 groups for all the baseline demographic characteristics. Average duration of CTS symptoms was about 6 years in the acupuncture group and about 4 years in the placebo acupuncture group.
* Baseline outcome measurements before any treatments for all the electrophysiological parameters were not significantly different between the 2 groups.
* Both groups demonstrated statistically significant improvements at all time points compared to baseline in CTSAQ symptom scale scores (*p*< 0.05). Subjects in the acupuncture group had a 0.58 improvement (*p=0*.03) on the CTSAQ Symptom Scale score at 3 months after the last treatment, versus 0.81 improvement (*p=0*.001) in the placebo acupuncture group.
* Only the placebo acupuncture group demonstrated statistically significant improvements at all time points compared to baseline in CTSAQ Function Scale scores. At 3 months after the last treatment, the placebo acupuncture group had a 0.48 improvement (*p*=0.02) on the CTSAQ Function scale. For the acupuncture group, immediate post-treatment CTSAQ Function Scale scores showed a statistically significant improvement of 0.55 (*p*=0.05), but at 3 months after the last treatment, the improvement of 0.45 points was no longer statistically significant (*p*=0.17).
* No statistically significant differences between groups were found in CTSAQ symptom or function scores at 3 months post-treatment.
* For the secondary outcome measures of tip pinch, key pinch, and combined sensory index, no statistically significant differences between groups were found at baseline or 3 months after the last treatment.
* Average nightly use of wrist splints was 4 to 5 nights per week, with no significant difference between groups. Bracing compliance did not affect the variability of the outcomes.
* No serious adverse effects for either group were reported.

**Authors’ conclusions:**

* This study demonstrated that both acupuncture and placebo acupuncture improved chronic symptoms of CTS 3 months after the last treatment that typically is not observed in the natural history of CTS. Traditional needle acupuncture was not shown to be superior to placebo acupuncture when used in conjunction with bracing in the treatment of chronic mild to moderate CTS.
* In the natural history of CTS, 20% to 40 % of subjects with mild to moderate CTS might improve in a follow-up period lasting up to 9 years. In this study, 88% of subjects in both groups had symptomatic improvement, which is significantly higher than that observed in the natural history of CTS, suggesting that both acupuncture and placebo acupuncture may have exerted a positive effect. The improvements may also be attributable in part to the placebo effect or the Hawthorne effect, although it is notable that the symptom improvement was maintained to 3 months after the last treatment, with minimal interaction with subjects during that 3 months after treatment. The underlying mechanism for this substantial improvement in CTS symptoms is unclear and cannot be determined from this study.
* One challenge of acupuncture research is the selection of an appropriate control. Different acupuncture control groups (wait list, placebo needles on actual points, placebo needles on sham points) can lead to different outcomes. It is plausible that the placebo acupuncture needles used in this study are not in fact inert when placed and manipulated on actual acupuncture points making them simulate real acupuncture. This could also account for the symptom improvement in both groups.
* Further studies with longer follow-up periods may be needed to examine the unexpected finding of greatly improved chronic symptoms of CTS 3 months after the last treatment in both acupuncture and placebo acupuncture subjects.

**Comments:**

* This study supports the conclusion that needle acupuncture is not superior to placebo acupuncture and neither are clinically effective in reducing symptoms or improving function as part of the conservative treatment of patients affected by CTS. No statistically significant differences between the 2 groups were observed for any of the primary or secondary outcome measures at the end of the 6 week treatment or 3 months later.
* All reported improvements in symptoms and function for both groups over all follow-up time points were below the stated minimal clinically important reduction of 1.04 points or more on the CTSAQ average score. Both the acupuncture group and the placebo acupuncture group do not show clinically significant improvements in function or severity symptoms.
* Strengths of this study included outcomes assessor and patient blinding, the inclusion of a placebo control group, monitoring of splint compliance, intention to treat analysis, and primary outcome clearly stated.
* An important limitation of the study was the exclusion of reporting the raw scores (means and standard deviations) and mean differences with p values for between group differences at baseline and each follow-up time point for the CTSAQ symptom and function scores. The simple graphs and lack of reporting of means and significance levels in the text or in a table made it difficult to determine significant between group differences at all time points. This exclusion limits the interpretability of the results.
* Another limitation of this study was the relatively small number of patients included and a sizeable drop-out rate (17%).
* Both groups showed small improvements after 6 weeks of treatment. The significant reduction in subjective symptom severity may be attributable to wearing the hand splints for 6 weeks. Future studies should include a third comparison group that uses only nightly wrist bracing. This additional group would allow researchers to determine whether improvements are attributable to wrist bracing alone or to the effects of acupuncture or placebo acupuncture.
* Future studies should include subjects with more severe CTS. In this study, baseline CTSAQ symptom and function scores were in the range of 1.8 to 2.5. Including subjects with more severe CTS baseline scores would allow for more room for clinical improvement and the ability to detect greater overall differences avoiding the “floor effect”.
* One important baseline characteristic that was noticeably different between the 2 groups, though not statistically different, was the duration of CTS symptoms. The acupuncture group had CTS symptoms an average of 6 years at the start of the study and the placebo acupuncture group an average of 4 years. Since the acupuncture group endured CTS symptoms 2 years longer, it may be more difficult for subjects in this group to improve.
* Sample size calculations were not presented. It is unknown whether the sample size was large enough and the study adequately powered to detect significant differences in all the outcome measures. This decreases our confidence in the internal validity of the study.
* Since the acupuncturists that administered the treatments to the participants could not be blinded to group allocation, this could introduce performance bias. In addition, the 2 acupuncturists were trained differently in acupuncture, one in a traditional Chinese Masters program, and the other in medical acupuncture. Even though both treated subjects in both groups, no information was given to determine if each acupuncturist treated an equal number of subjects in each group, thus equalizing any performance bias specific to one acupuncturist.

**Assessment*:***

This adequate study provides some evidence that there are no differences between needle acupuncture combined with a wrist brace and placebo needle acupuncture combined with a wrist brace and neither treatment is clinically effective in improving function in patients with mild or moderate carpal tunnel syndrome.