
Design: Randomized clinical trial

Population/sample size/setting:
- 116 patients (62 women, 54 men, mean age 51) treated for carpal tunnel syndrome at four academic and three private practice centers in Seattle and in New Hampshire
- Eligibility clinical criteria were symptoms for at least 2 weeks in median nerve distribution, with a classic, probable, or possible CTS on pain diagram, failure for at least 2 weeks of conservative treatment, including a trial of wrist splints; if electrodiagnostic tests were normal, night pain alleviated by shaking the wrist was also required
- Exclusion criteria were severe CTS (thenar wasting, abnormal static 2-point discrimination, or EMG denervation), previous CTS surgery on the same hand, any wrist or hand surgery in past 6 months, arthritis, tumor, mass, or deformity of the affected hand, pregnancy, or evidence of diffuse peripheral neuropathy or cervical radiculopathy

Main outcome measures:
- Randomized to CTS surgery (n=57) or non-surgical treatment (n=59)
- Surgery was open or endoscopic according to surgeon preference
- Non-surgical treatment initially consisted of NSAID plus 6 visits with a hand therapist; these visits focused on ligament stretching, tendon gliding, and review of splint use; if unimproved after 6 weeks, therapeutic ultrasound was offered for up to 12 sessions over 6 weeks
- Primary outcome measure was the 9-item functional scale of the CTS Assessment Questionnaire (CTSAQ)
- Secondary outcome measure was the 11-item symptom scale on the CTSAQ
- Other secondary outcomes included hand or wrist pain intensity and the effect of CTS on work days lost and days of limited activity; the SF-36 was used to assess general health
- Two exploratory analyses were done in addition: the authors looked for differences between open and endoscopic CTS release, and for whether the outcome of treatment was affected by either the nerve conduction studies or by the presence or absence of abnormal median nerve signal on MRI
- Functional CTSAQ scores improved in both groups at 6 months and 12 months, with a small advantage for the surgical group when analyzed according to intention-to-treat
- Symptom CTSAQ scores also showed an advantage for surgical group over the non-surgical group at 12 months using intention-to-treat
- Days of lost work or reduced work did not differ significantly between groups
- A large number of crossovers occurred in both groups; 23 of the 59 patients randomized to non-surgical treatment had surgery within 12 months of
randomization, and 13 patients randomized to surgery did not have surgery within 12 months of randomization
- Because of the large numbers of crossovers, a second analysis was done according to the treatment actually received; this “as treated” analysis showed an even larger advantage for the surgical intervention
- In the supplementary analysis of surgical approach, there was no difference between the open and endoscopic CTS operations
- The analysis of the effect of distal median motor latency on outcome showed that surgery was not more beneficial than non-surgical treatment for patients with latency scores of less than 5.0 ms, but for patients with latency scores of 5.0 ms or more, surgical treatment had a large advantage over non-surgery
- Less than half of the patients had an MRI; surgery was more successful than non-surgery (90% vs. 47%) in those with normal or moderately abnormal median nerve signal, but surgery was less successful than non-surgery (45% vs. 64%) when the median nerve signal was severely abnormal

Authors’ conclusions:
- In patients with CTS without denervation, surgery modestly improves hand symptoms and function compared with multimodal nonsurgical treatment
- Median nerve motor latency is associated with the response to surgery; surgery is more clearly beneficial than non-surgery when motor latency is greater than 5.0 ms
- The MRI data, showing that an enhanced median nerve signal worsens the response to surgery, should be regarded as preliminary, since only half of the patients had MRI prior to treatment

Comments:
- As with the SPORT trial of spine surgery, the large number of crossovers produces a modest benefit of surgery in the intention-to-treat analysis and a larger benefit in the as-treated analysis
- Only 1 patient in each group had steroid injection during treatment
- Neither Table 1 nor Table 4 show the number of patients who had median motor latency less than 0.5 ms, preventing an estimate of the power of the study to detect a difference between surgery and non-surgery in that subgroup; since the mean latency was 5.3 ms in Table 1, a minority of patients had motor latency less than 0.5 ms, and the power may have been insufficient to show a difference between surgery and non-surgery

Assessment: High quality (concealment of randomization, accounting for crossovers, presenting both intention-to-treat and as-treated analyses, comparison with multi-modal nonsurgical treatment and not only with splinting). Will support a statement that there is good evidence that surgery is likely to yield greater symptom relief and functional benefit than nonoperative treatment of CTS with prolonged motor latency; it is less likely to support a recommendation that surgery should be a first line of treatment in all CTS cases. It does not support a recommendation that MRI be used for evaluation of CTS.