Kemler MA, Barendse GAM, et al. Spinal Cord Stimulation in Patients With Chronic Reflex Sympathetic Dystrophy. N Engl J Med 2000;343:618-24.

Design: Randomized clinical trial

Population/sample size/setting:

- 54 patients (17 men, 37 women, mean age 38) treated for chronic regional pain syndrome (CRPS-I) at a university hospital in the Netherlands
  - Inclusion was based upon IASP criteria for CRPS (pain, impaired function, cold/warm feeling in affected area, symptoms beyond area of trauma), pain score at least 5 on VAS from 0 to 10, confined to extremity but affecting the entire hand or foot, lasting at least 6 months, but not responding to PT, sympathetic blocks, medication, or TENS
  - Exclusion criteria included Raynaud's disease, neurological abnormalities unrelated to CRPS, coagulation abnormalities, cardiac pacemaker use, and a score of 200 or more on the Symptom Check List-90, a standardized psychological test
  - Most patients had severe functional deficits on entry; 20 of 33 hand patients were unable to perform activities of daily activity with the hand, and 13 used a splint; 10 of 21 foot patients used a wheelchair for mobility, and 8 used crutches

Main outcome measures:

- Randomized to either spinal cord stimulation with physical therapy (SCS, n=36) or to physical therapy alone (PT, n=18)
- All patients randomized to SCS had a 7 day trial implant, in which a positive response was considered to be a 50% reduction in pain score, or if there was a score of at least 6 (much improved) on a 7 point global perceived effect scale
- Of the 36 patients randomized to SCS, 24 had a positive trial implant and received a permanent SCS implant; the other 12 were treated with the same PT as the control group
- PT consisted of graded exercises administered for 30 minutes twice per week for 6 months
- The principal outcome was the reduction in pain scores 6 months after baseline on a scale from 0 to 10
- For patients randomized to SCS, the mean reduction pain score reduction was 2.4 points; the pain score increased by a mean of 0.2 points in the PT group
- For patients who actually received an SCS permanent implant, the mean reduction in pain score was 3.6 points
- For SCS, a global perceived effect of "much improved" was recorded in 14 of 24 implant recipients at 6 months, but only 1 of 18 PT patients were much improved at 6 months
- Functional scores (strength, range of motion, etc) did not improve in either treatment group between baseline and 6 months
- SCS was complicated by dural puncture in 4 patient during the testing phase, and in 1 patient, the test needle could not be placed in the epidural space

- Permanent SCS implantation was complicated by dural puncture in 2 patients, and 4 SCS implant recipients had other complications: 1 with a suspected infection (not confirmed by culture), 2 with painful pulse-generators requiring modification, and 1 requiring replacement of a defective lead; in addition, 5 patients had unsatisfactory positioning of the electrode, requiring operative repositioning

Authors' conclusions:

- SCS was effective in reducing pain and enhancing quality of life, but not in improving function in patients with CRPS-I
- The lack of functional improvement may be due to the fact that the patients with refractory CRPS had chronic anatomic changes such as muscle atrophy and contractures
- SCS treats pain but not the underlying disorder
- The success of SCS depends on strict selection criteria, such as exclusion of patients with psychiatric disorders and on full coverage of the affected area with paresthesias during the testing phase

Comments:

- Risk of bias is well-controlled, except for the inevitable risk that arises when blinding cannot be done
- Study size was small, probably due to difficulties in recruiting large numbers of patients into the trial
- Although the description of the PT program was satisfactory, the participation of the patients in this program was not described; since there was a high level of functional disability in the patient population, it is likely that many did not complete two 30 minute visits twice per week for 6 weeks
- The average duration of symptoms was more than 3 years; this may support the authors' hypothesis that functional improvements were unlikely when advanced disease placed limits on functional gains

Assessment: Adequate for some evidence that SCS plus physical therapy alleviates pain better than physical therapy alone in the short term