Kumar K, Taylor RS, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomized controlled trial in patients with failed back surgery syndrome. Pain 2007;132:179-188.

Reviewed, one additional condition added to conclusions, January 2017

Design: Randomized clinical trial

Population/sample size/setting:

- 100 patients (51 men, 49 women, mean age 51) with failed back surgery syndrome (FBSS) treated in 12 centers in Europe, Canada, Australia, and Israel
- FBSS defined as neuropathic pain of radicular origin, radiating in L4, L5, S1 dermatomes with intensity of at least 50 on a 100 mm VAS for at least 6 months following an anatomically successful operation for a herniated disc
- Exclusion criteria were another clinically significant source of pain, expected inability to operate the spinal cord stimulation (SCS) system, coagulation disorders, lupus, diabetic neuropathy, rheumatoid arthritis, ankylosing spondylitis, active psychiatric disorder, pregnancy, or life expectancy less than 1 year

Main outcome measures:

- Randomized to SCS (n=52) or conventional medical management (CMM, n=48)
- Patients randomized to SCS had a screening trial, in which a positive response was defined as at least 80% overlap of pain with stimulation-induced paresthesia, and at least 50% reduction in leg pain
- Of the 52 patients randomized to SCS, 43 had positive screening trials and were implanted with a stimulator; however, of the 9 who had negative screening trials, 5 requested stimulators, and these 5 were implanted also; a total of 48 stimulators were implanted in that group
- Patients randomized to CMM received oral medications (opioid, NSAID, antidepressant, anticonvulsant), nerve blocks, epidural steroids, PT and psychological rehab, and chiropractic care; invasive interventions such as surgery or intrathecal drugs, was excluded from the CMM protocol
- At 6 months, 2 of the 52 SCS patients and 4 of the 48 CMM patients withdrew consent to continue with the trial
- At the 6 month point, crossovers were permitted; 5 of the 50 SCS patients crossed to CMM; 4 were for insufficient pain relief and 1 due to an “allergic reaction”
- In contrast, 32 of the CMM patients asked to cross over to SCS; 4 of these had negative stimulator screening tests, and 28 were implanted with a stimulator
- The primary outcome of 50% pain relief at 6 months was achieved by 24 of 50 SCS patients and by only 4 of 44 CMM patients; a sensitivity analysis excluding the 5 SCS patients who received implants in spite of a negative screening test did not affect the group outcome

- In addition to the primary outcome analysis, the SCS group had higher quality of life scores on the SF-36 and lower scores on the Oswestry Disability Index (44.9 vs. 56.1) than the CMM group at 6 months
- Complications and adverse events were common in the SCS group; at 12 months, 32% of the patients who received an electrode during the trial had one or more device-related complications, and 24% required surgery to correct them; electrode migration, infection, and loss of paresthesia were the most common complications
- At 12 months, drug adverse events or other non-device complications occurred in 35% of the SCS group and in 52% of the CMM group; the nature of the drug-related complications is not elaborated
- Use of morphine, other opioids, NSAIDs, and antidepressants did not differ between groups; the CMM group used more anticonvulsants (50% vs. 26)
- Return to work was infrequent in both groups; it occurred in 1 CMM patient and 4 SCS patients

Authors' conclusions:

- Compared to CMM alone, SCS improves pain relief, quality of life, and functional capacity in patients with FBSS
- The 6 month follow-up may have been insufficient to detect whether SCS can reduce opioid use, since weaning from these drugs may require many months

Comments:

- Overall, the study was well reported and well conducted; since blinding cannot be done, there may have been an unavoidable risk of bias, especially if many of the crossovers from CMM to SCS were among patients who enrolled in the trial with the expectation that they would be eligible for SCS after the 6 month point
- The interventions in the CMM group may have been a continuation of the interventions which had previously been attempted without success; it consisted of therapy which was "reviewed and actively managed" by the study investigator according to local practice, which may have varied across the 12 study sites, but further elaboration would be necessary in order to make the comparison of interventions more meaningful
- Although pain relief and Oswestry functional scales improved, return to work was an uncommon event in both groups
- The nature of the screening for SCS is not clear from the article; the description of the procedure is referenced, but is in a textbook and not in a readily available published study
- There is a supplementary table in the online journal which reports medication for pain "prior to baseline" and medication "at baseline;" there was a significant change in medication use for both CMM and SCS groups for all medication categories
- For example, prior to baseline, opioid use was recorded in 81% of CMM and 79% of SCS patients; at baseline, the percentages were 58% and 65% respectively; for NSAID, the percentages were 94% for CMM and 87% of

SCS patients prior to baseline, with percentages at baseline of 48% and 29% respectively

- Even larger decreases between "prior to" and "at baseline" seem to have occurred for non-drug therapy; "physical rehabilitation" for CMM and SCS decrease from 87% and 79% to 4% and 2%
- Therefore, it cannot be determined whether it is a good idea to do SCS or a bad idea to discontinue physical rehabilitation
- No information is presented about the time interval between "prior to" and "at baseline;" presumably, the former was recorded during recruitment and the latter recorded after randomization
- The medication use and non-drug therapy at 6 months in Table 2b is very close to the use "at baseline" for both treatment groups; the large decrease between recruitment and randomization is unexplained, but something seems to have happened during this unknown time interval which ought to be explained (author has been e-mailed)

Assessment: Adequate for evidence that spinal cord stimulation yields better pain relief and functional outcomes than conventional medical management (the description of CMM is not sufficient to reproduce that group's actual intervention), but inadequate for evidence that SCS is likely to succeed in returning patients to productive work