

North RB, Kidd DH, et al Spinal Cord Stimulation versus Repeated Lumbosacral Spine Surgery for Chronic Pain: A Randomized, Controlled Trial. Neurosurgery 2005;56:98-107.

Design: Randomized clinical trial

Population/sample size/setting:

- 60 patients (30 men, 30 women, mean age 50) treated for persistent pain after back surgery at Johns Hopkins Hospital
- Eligibility criteria were persistent radicular pain and surgically remediable nerve root compression following one or more lumbosacral spine operations, confirmed by a second opinion from a neurosurgeon or spine surgeon
- Exclusion criteria were indications for immediate reoperation (foot drop, neurogenic bladder, cauda equina syndrome, gross instability necessitating fusion), untreated dependency on prescription narcotics, axial back pain greater than leg pain, psychiatric comorbidity, or other disabling pain problem

Main outcome measures:

- Randomized to spinal cord stimulation (SCS, n=30) or to reoperation (laminectomy and/or foraminotomy and/or discectomy with or without fusion, with or without instrumentation, n=30)
- SCS patients received a 3 day trial with a temporary electrode; a positive response was a 50% pain reduction; patients randomized to SCS who had a negative trial could immediately cross over to surgery
- Patients randomized to surgery were eligible to cross over to SCS 6 months after their reoperation
- Success at 6 months was defined as at least 50% pain relief and an affirmative response to a question asking whether the patient would have the same treatment again
- 24 Workers' Compensation patients were enrolled in the study and randomized to either SCS or reoperation, but 9 were not treated because their insurance carrier refused authorization, leaving 15 WC patients in the analysis
- 50 patients in the randomized trial received insurance authorization for participation, 24 for SCS and 26 for reoperation
- Of the 24 randomized to SCS and treated, 5 had negative SCS trials and were crossed over to reoperation; 2 were lost, and 17 received an SCS implant
- Of the 26 participants randomized to reoperation and treated, 14 crossed over to SCS after 6 months due to unsatisfactory results of surgery
- 19 patients randomized to SCS were available for long term (mean of 2.9 years, range from 1.8 to 5.7 years) follow-up; 9 of the 19 had at least 50% pain relief and were classified as successes (intention to treat analysis)
- 26 patients randomized to reoperation were available for long term follow-up; only 3 were successes (intention to treat analysis)
- 4 patients who crossed over from SCS to reoperation were available for long term follow-up; none of the 4 was a success

- 14 patients who crossed over from reoperation to SCS were available for long term follow-up; 6 of the 14 were successes
- A per-protocol analysis was done: 15 patients who were randomized to SCS and received an implant were available for long-term follow-up; 9 of these were successes; however, of 12 patients who were randomized to reoperation and did not cross over, only 3 were successes
- An as-treated analysis was done: 15 of 29 patients who eventually received SCS were successes; only 3 of 16 patients having only reoperation were successes
- Opioid use increased more often in patients randomized to reoperation (42%) than in patients randomized to SCS (13%)
- Most (52%) of the study population was retired or permanently disabled at the time of entry to the study; the two treatment groups did not differ in ability to return to work
- 3 SCS patients had hardware revisions because of electrode migration or malposition, and 1 SCS patient had an infection at the receiver site; this required removal of the system and antibiotic therapy

Authors' conclusions:

- In patients with persistent radicular pain following lumbosacral spine surgery, SCS is more successful than reoperation
- SCS has an advantage over reoperation in having a screening trial which can select appropriate patients for the procedure; the selection for reoperation does not have a similar selection procedure
- The patient selection in this trial did not include all patients with failed back surgery syndrome; all patients had a specific anatomic explanation for their pain complaint; all were treated in a setting with a multidisciplinary treatment program, and all had exhausted all reasonable alternative therapies

Comments:

- While randomization and concealment of allocation provide protection from selection bias, lack of blinding is an inevitable source of potential assessment bias
- Figure 1 is difficult to interpret; however, the author has clarified by e-mail that in the long-term portion of the figure, the left half shows 9 successes and 6 failures for patients randomized to SCS and implanted (far left diamond), and also shows 6 successes and 8 failures for patients who crossed over to SCS (second diamond from the far left); this adds up to 15 successes and 14 failures in all 29 patients who were actually implanted with SCS
- Similarly, the right half of Figure 1 shows 4 failures and 0 successes in patients randomized to SCS but crossed over to reoperation, (second diamond from the right), and shows 9 failures and 3 successes for patients randomized to reoperation who remained in that group (far right diamond) ; this adds up to 13 failures and 3 successes in all patients who had reoperation without SCS

- The intention to treat analysis is not readily apparent from Figure 1, but from the text it is apparent that this is 9/19 successes for SCS and 3/26 for reoperation

Assessment: Adequate for evidence that SCS yields a higher success rate (approximately 50%) than reoperation of patients with failed low back syndrome