Clinical Area: Spinal Cord Stimulators for Intractable Pain
Keywords: spinal cord stimulation, reoperation, failed back surgery syndrome, pain
Reference: North, RB, Kidd, DH, Piantadosi, S. Spinal cord stimulation versus reoperation for failed back surgery syndrome: A prospective, randomized study design. Acta Neurchir 1995; 64: 106-108.

Study Type: Randomized controlled trial

Outcomes

- *Primary:* Crossover to the alternate treatment

Design

- *N* = 27
- *Description of sample:* No demographic information.
- *Inclusion criteria:* Patients with failed back surgery syndrome who meet the following criteria: 1) Surgically remediable disease which can explain their complaints of radicular pain; 2) Meet standard clinical and radiographic criteria for surgical intervention for lumbosacral spine disease; 3) Diagnosis confirmed by second opinion (neurosurgeon or spine surgeon).
- *Exclusion criteria:* 1) Major of disabling neurologic deficit in the distribution of nerve root or roots with surgically remediable compression; 2) Radiographically critical neural compression (patients who meet exclusion criteria 1 or 2 undergo reoperation); 3) Radiographic evidence of gross instability requiring fusion; 4) Significant untreated dependency on prescription narcotic analgesics or benzobiazepenes; 5) Major psychiatric comorbidity evident clinically or on routine psychological testing; 6) The presence of any other clinically significant or disabling chronic pain conditions.; 7) A chief complaint of axial (low back) pain, exceeding radicular pain i.e. buttock and leg pain.
- *Power:* Not discussed.
- *Method of randomization:* Not discussed.
- *Intervention:* Random assignment to: 1) reoperation by one or more of several study surgeons; or 2) spinal cord stimulation (SCS). SCS patients received temporary percutaneous placement of an electrode (3487A Pisces Quad, Medtronics) for a 2 ½ day trial. For patients who reported at least 50% estimated pain relief and showed stable or improved medication intake and improved physical activity, a permanent implant (3487A-56, 3470 Xtrel) was offered. If these criteria are not met, the patient is offered early crossover. Patients were contacted 6 months after the initial treatment and interviewed with a standardized questionnaire. Patients are reminded of their crossover option .
- *Blinding:* Outcome assessor was blinded.
- *Length of follow-up*: 6 months
- *Completeness of follow-up:* Study is ongoing. At the time the manuscript was written, 51/81 (63%) consented to randomization. 27 patients had reached their 6 month assessment point. 30/81 eligible patients opted for reoperation outside the study.

Validity

- *Is the study type appropriate for the questions being asked?* Yes
- *Was the study population typical of patients with this disease?* Did not discuss
- *Were the treatment/control groups comparable at baseline?* Did not discuss
- *Was the intervention compared to placebo and/or best accepted intervention?* Yes
- *Was there compliance with the intervention?* Did not discuss
- *Was there equal intensity of observation of study and control subjects?* Yes
- *Was the process of observation likely to effect the outcome?* Reminding patients about the opportunity of crossing over may have led some to do it.
- *Intention to treat analysis?* Unclear.
- **Conclusions regarding validity of methods:**

About 40% of eligible patients choose not to be randomized and almost all of these chose reoperation—this lack of willingness for eligible patients to be randomized can introduce selection bias. The outcome chosen, treatment crossover, may not reflect the efficacy of the intervention i.e. patients may be dissatisfied with treatment, but might not choose the other treatment. If there were systematic differences between the two groups in willingness to chose the other treatment, this could bias the results. In addition, the study had a very small sample size for a randomized controlled trial and power to detect differences between the groups was not discussed.

Results

10/15 (67%) patients assigned to reoperation opted for crossover to SCS
2/12 (17%) patients assigned to SCS opted for crossover to reoperation
(p=.0018)

Authors' Conclusions

"The interim results of this study, which is the first prospective, randomized comparison of SCS with any other treatment for pain, indicate that the role of spinal cord stimulation can be expanded, as an alternative to reoperation."

Reviewer's Conclusions

Preliminary results of this RCT show that more patients assigned to reoperation choose to crossover to SCS than patients assigned to SCS opt for reoperation. It is not known from this study whether actual pain relief is greater for SCS than reoperation.