The Effects of Spinal Cord Stimulation in Neuropathic Pain Are Sustained: A 24-month Follow-up of the Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation

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Purpose

- To present 24-month outcomes of failed back surgery syndrome (FBSS) patients enrolled in the PROCESS study, which evaluated the effectiveness of spinal cord stimulation (SCS) plus conventional medical management (CMM) vs. CMM alone.

Methods

- Prospective, international, multicenter, randomized controlled trial (SCS+CMM vs. CMM only) conducted outside of the United States
- Follows 42 SCS (Medtronic Synergy™) patients with predominant radiating pain in the leg (60% male, mean age 48.8±9.5 yrs) at 1, 3 ,6, 9, 12, 18 and 24 months

Results

- Compared with baseline, SCS+CMM patients at 24 months:
  - Lower levels of leg pain ($p<0.0001$)
  - Better functional capacity ($p=0.0002$)
  - Improvement to health-related QOL ($p\leq0.01$) [7 of 8 dimensions of the Short-Form Health Survey-36]
  - No difference in back pain ($p=0.21$)
- Of the 72 patients who received SCS as the final treatment, 47% achieved primary outcome (≥50% leg pain relief) vs. only 7% CMM patients ($p=0.02$).
- When asked at 24 months:
  - 66% patients were satisfied with their pain relief
  - 93% patients said they would repeat the experience
- 19/42 (45%) patients experienced 34 SCS-related complications.
  - 13/42 patients (31%) required a device-related surgical revision
  - Most occurred in the first year and were benign, reversible, and not incapacitating.

Author Conclusions

- In selected FBSS patients, SCS treatment resulted in pain relief that was sustained at 24 months and was associated with patient satisfaction and clinically important improvements in functional capacity and health-related QOL.

Article Summary

Failed Back Surgery Syndrome

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