NEW RESEARCH SPOTLIGHT

Summary and Assessment of a Recently Published, Noteworthy Study
Developed for IPSIS Members by the Research Division

Jones CM, Maher CG, Buchbinder R, Harris IA, Lin CC, Hayes C, Gorelik A. Spinal cord stimulation patterns of care, re-interventions, and costs for private health insurers, Australia, 2011–22: a retrospective observational study. *Med J Aust.* 2025 Sep 1;223(5):243-247. doi: 10.5694/mja2.70001. Epub 2025 Jul 14. PMID: 40660620; PMCID: PMC12399048.

Reviewed by: Anthony Schwarzer, MB BS, PhD, and Sean Fox, MD

SUMMARY

TYPE OF STUDY: Retrospective observational study

OBJECTIVE: To investigate spinal cord stimulation patterns of care, the proportions of people who require unplanned surgical interventions after receiving definitive spinal cord stimulator implants, and the costs to private health insurers in Australia.

TREATMENT ASSESSED: Spinal cord stimulation

INCLUSION CRITERIA:

- People admitted to the hospital for spinal cord stimulation-related surgical procedures between January 11, 2011, and April 13, 2022, with full or partial cost coverage by five general private healthcare insurers.
- All twenty insurer members of Private Health Australia were invited to submit records of benefit payments for spinal cord stimulation-related services for pain treatment (excluding out-of-pocket costs for patients).
- Five private health insurers, representing 76% of patients with private health insurance, submitted de-identified data between January 11, 2011, and April 13, 2022. 90% of all spinal cord stimulators are inserted in private health care (approximately 50% of people in Australia are privately insured).

EXCLUSION CRITERIA: Admission in which neither a generator nor a lead was recorded as being used.

TOTAL NUMBER OF PATIENTS: 5,839

OUTCOME MEASURES:

- Patterns of care
  Demographics and patterns using the definitions below:
  - "Admissions" were defined as a hospital admission during which a billable spinal cord stimulation-related procedure was undertaken, including trials without a generator being implanted, definitive implantation, and surgical procedures after implantation.
  - "First procedures" was defined as the first recorded procedure (trial or definitive implantation).

  - "Trial" was defined as the use of either a trial lead (wire) or a definitive lead without an implanted generator.
  - "Definitive implantation" was defined as the implantation of a generator.
  - "Re-intervention" was defined as definitive implantation of a generator.
    - Subanalysis was performed for 3 different time frames: January 11, 2011 - December 31, 2014; January 1, 2015 - December 31, 2018; or January 1, 2019 - April 13, 2022.
- Proportions of people with stimulator implants who subsequently required surgical reintervention overall and within 36 months of receiving definitive implants
- Costs to the insurer for the trial
- Costs for definitive implantation
- Costs for re-intervention

KEY FINDINGS:

- A total of 12,535 admissions with 6,283 people for spinal cord stimulation-related procedures
- 11,452 admissions in 5,839 people after excluding those with neither a generator nor a lead used
  - 1,478 people (25.3%) had trials but never proceeded to definitive implants
  - 4,361 people (74.7%) had definitive stimulators implanted
- Mean age at first admission: 60.2 years (SD 15.4 years)
- Women 63.7%; Men 36.3%
- Median follow-up time 48 months (IQR 33-72 months)
- Definitive stimulators were implanted in 4,361 people (74.7%)
  - 3,244 had previously had at least one stimulation trial (74.3% had one trial)
  - 3,813 were implanted from January 1, 2015 - April 13, 2022 (87.4%)
- At least one surgical intervention was required by 1,011 people with definitive implants (23.2%)
- Median time to first re-intervention was 16.8 months
- Cumulative probability of requiring surgical re-intervention at 36 months was 0.35
- "Among patients who underwent index procedures between 2011 and 2014, the proportion requiring re-interventions within 36 months of receiving a definitive implant was higher (157 of 548, 28.7%) compared with those who had index procedures between 2015 and 2018 (497 of 2,227, 22.3%)."

CONCLUSION:

- Close to one in four people (23.0%) require surgical re-intervention within 36 months after receiving definitive spinal cord stimulation as the first procedure.
- The costs are very high, and the cost of a spinal cord stimulator to insurance, including device, medical, and hospital costs for the initial procedure and re-interventions, averaged $55,635.

CRITIQUE

- There is no conflict of interest: none of the investigators was employed by industry.
- Nonconsecutive patients: data from 24% of people with private health insurance were omitted. It is unknown how many patients with implants were excluded from the study.
- Reviewers were not involved in performing the procedures.
- All data from five insurers were included.
- Inclusion criteria were clear.
- The description of the spinal cord stimulation technique was not relevant to this study.
- Statistical data were clear.
- Validated outcome measures were used.
- Both continuous and categorical data were provided.
- Duration of follow-up was adequate.

ASSESSMENT

Do you agree with the authors' conclusions? Why or why not?

- This study is observational only.
- The conclusions are fair and reasonable, based on the available data.
- The costs for the intervention are highlighted and based on data as provided by the insurers.
- The intention of the study was not to determine the efficacy of spinal cord stimulation, though the discussion commented on the lack of literature supporting the efficacy of spinal cord stimulation.
- It is possible that with the advancement of technology, spinal cord stimulators are now more effective.

What recommendations would you make to these and other investigators for future studies on this topic?

- Further studies investigating the reasons for re-intervention (e.g., lead migration, spinal cord injury, dural puncture) would be useful. Such data could shed light on possible preemptive measures that could be employed to prevent such complications. If the causes are difficult to prevent, it would support the authors' claim that the costs are high and not commensurate with the benefit.
- More unbiased studies on efficacy
    - A placebo-controlled randomized controlled trial with two- to five-year follow-up without industry sponsorship, accompanied by economic evaluation
    - A series of N-of-one studies can be undertaken to determine the efficacy of spinal cord stimulation: the device can be switched on and off with blinding (only for high-frequency stimulators).

ASSESSMENT

- Observational studies to determine the relative efficacy of spinal cord stimulation in both patients with back pain and patients with lower limb pain, especially neuropathic pain: there may be a difference in efficacy between these patient groups
- The efficacy should be considered for specific causes of pain, as they may respond differently to spinal cord stimulation (e.g., neuropathy from spinal cord injury vs. peripheral neuropathy vs. phantom limb pain).

- We need more long-term follow-up data: what proportion of devices lose efficacy over time?
- This is an Australian study only. Such studies must also be undertaken in North America and Europe, where the majority of spinal cord stimulators are implanted.

Why is this study important for members of the IPSIS community?

- The strength of this study is the objective data it provides regarding overall rates of re-intervention after spinal cord stimulator implantation. However, the study was unable to assess the reasons for re-implantation.
- This study raises concerns about the use of spinal cord stimulation.
- The study highlights the significant costs of spinal cord stimulation.
- The study highlights the high rate of re-implantation, which suggests that many implantations fail. We don't know the proportion of patients in whom an initially successful implantation becomes ineffective.
- The study importantly does not assess the efficacy of spinal cord stimulation, but the discussion highlights the lack of evidence to support its use: two Cochrane reviews state that spinal cord stimulation may provide limited to no benefit in people with chronic pain, including back pain, neck pain, neuropathic pain, and complex regional pain syndrome. On the other hand, spinal cord stimulation could cause harm.
- There are many industry-sponsored studies in this area with the potential for significant bias. There is, therefore, a need for independent studies that are not sponsored by industry.
- IPSIS members must carefully select patients. Steps such as ensuring that there is at least 90% relief of the index pain before proceeding to permanent implantation may improve the efficacy of the permanent implant.
- More data on the efficacy of spinal cord stimulation are required, and this is an area of research that IPSIS can take up.
- Patients should be counselled that if a spinal cord stimulator is implanted, there is a 25% chance that at least one additional surgery will be required in the first three years after implantation.
- In the absence of convincing evidence of efficacy, the use of spinal cord stimulation should be reconsidered.