

A stimulating tale about spinal cord implants for managing chronic pain

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When I tell a patient that I do not have a surgical solution for their back pain, the most frequent desperate reply is: “what am I going to do?” I would be happy to say, “Well, one option is to look into a spinal cord stimulator,” if I could believe that they worked. However, the caveat is that any (interventional) treatment should work well, be of low risk, and be affordable and accessible to all who need it.

Since the first commercially available spinal cord stimulator became available in 1968,¹ developments in evidence-based device safety and efficacy have been rapidly outpaced by technological advances. Subsequent updates by manufacturers have been all about the hardware and software: a marketer’s dream. It was not until 2021 that the Cochrane review of implanted spinal neuromodulation for chronic pain in adults was published; it found “very low-certainty evidence” that spinal cord stimulation “may not provide clinically important benefits on pain intensity compared to placebo stimulation”, and that it “is associated with complications including infection, electrode lead failure/migration and a need for reoperation/re-implantation.”² It was too late to put a brake on the burgeoning industry: the efficacy of spinal cord stimulation might not have been proven, but our device regulators surely also practise *primum non nocere*? The 2022 analysis of adverse effects of spinal cord stimulators reported to the Therapeutic Goods Administration (TGA) by implant providers and patients found that four devices were being removed for every ten implanted.³ Is this why the TGA only subsequently commenced a post-marketing review of spinal cord stimulation devices?

In 2023, the authors of the Cochrane review of spinal cord stimulation for low back pain concluded that “moderate-certainty evidence suggests there is probably no benefit of [spinal cord stimulation] over placebo on pain, function, or health-related quality of life in the medium term.”⁴ Both PainAustralia and the Medical Technology Association of Australia responded in December 2023 — the former with a consumer experience report,⁵ the latter in a media statement titled “spinal cord stimulator implants vital to chronic pain”⁶ — by arguing that some patients do benefit, but they did not cite any objective outcomes. In January 2024, the TGA imposed conditions on the use of eighteen devices.⁷ In April 2024, the ABC aired the Four Corners episode “Pain factory”;⁸ and by December 2024 the TGA had cancelled its approval of twelve spinal stimulation devices and imposed conditions on the use of 84 of the other 91 devices.⁹

In this issue of the *MJA*, Jones and colleagues report the findings of their retrospective study of Australian privately insured patients in whom spinal cord stimulators were implanted between January 2011 and April 2022.¹⁰ Their aims were to investigate patterns of care, rates of surgical re-intervention, and the cost to private health care providers. They did not investigate the efficacy of spinal stimulation, but their study shines light on questions of *noxa* (harm, for the patient) and *sumptus* (cost, for society). Only five of twenty insurer members of Private Health Australia provided data for the study, but the five cover 76%

of people with private health insurance. Jones and colleagues analysed data for 11 541 hospital admissions of 5839 individuals: a considerable number of people receiving a large number of interventions. Definitive stimulators were implanted in 4361 people;¹⁰ although the authors did not explicitly comment on this facet, 1117 (25%) were implanted without first undertaking trial procedures, widely regarded as the appropriate first step when considering spinal stimulation.

Of the 4361 people who received definitive stimulator implants, 1011 (23.2%) underwent at least one subsequent surgical intervention, most within three years of implantation surgery. The authors could not classify the interventions, but they cleverly undertook a sub-analysis of the situation at three years.¹⁰ One device manufacturer states that their stimulator can simply be turned off if no longer required,¹¹ and, as batteries do not need changing for five to ten years (depending on the type), it is not unreasonable to assume that adverse events are an important cause of removals within three years of implantation. Jones and colleagues report that the probability of requiring surgical intervention by three years was 0.35. Would deviating from usual practice 25% of the time be considered acceptable for the surgical approach I employ for chronic pain relief, or having a return to theatre rate of 20–30% within less than half the expected time of therapeutic benefit?

Finally, only one fund provided data to Jones and colleagues for their assessment of the costs of spinal stimulation.¹⁰ Despite this limiting the accuracy of their mean cost estimates, it is unlikely that the costs for other health funds would deviate more than the variance of “tens of thousands” of dollars for those of the fund that reported data. Their numbers are therefore probably a good reflection of market prices. Highlighting these costs at least puts this information in the public arena for discussion and raises the question of value.

Jones and her colleagues should be congratulated for undertaking their challenging analysis. Using the limited data available, they have asked the right questions and could clearly show that more needs to be done to determine whether spinal cord stimulators are low value care items. A randomised controlled trial would be ideal, but difficult. Instead, an independent (not managed by manufacturers) prospective collection of patient-reported outcomes would be a good start, together with better information from the TGA for both doctors and patients. Until I see better evidence of efficacy, spinal stimulation is one treatment I am unlikely to recommend to my patients.

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