

To the Editor We believe that there are multiple issues that limit the generalizability of the recent randomized clinical trial of spinal cord burst stimulation vs placebo stimulation in patients with chronic radicular pain after lumbar spine surgery.¹

First, by definition, a pragmatic trial should resemble routine clinical practice, and the results need to be applicable in multiple settings in addition to the setting in which the trial was conducted.²

Second, the placebo design in this study¹ was quite unusual. A placebo, more typically referred to as a sham in this context, should be an inactive substance (ie, no pharmacological activity). Studies have shown that injection of a sodium chloride solution into the epidural space provides relief patterns similar to steroids.³

Third, the inclusion criteria were not consistent with common clinical practice and insurance coverage policies in the US. For spinal cord stimulation to be covered by insurance in the US, a patient must be experiencing neuropathic pain rather than radicular pain, and a trial stimulation must produce a minimum of 50% relief. Most clinicians look for 60% to 70% relief, which translates to a 3- to 6-point reduction on an 11-point scale. Furthermore, minimum pain scores must be 6 and are usually 8 or 9. As a result, the criteria used in this study¹ were a 33% reduction of pain at best and a 20% reduction of pain at worst.

Fourth, the study¹ used a 16-contact lead for unilateral leg pain and two 8-contact leads for bilateral leg pain, which are not equivalent and would be expected to produce significant differences. Furthermore, the leads were placed at T9/T10 for all patients, which provided nonspecific placement.

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1. Hara S, Andresen H, Solheim O, et al. Effect of spinal cord burst stimulation vs placebo stimulation on disability in patients with chronic radicular pain after lumbar spine surgery: a randomized clinical trial. *JAMA*. 2022;328(15):1506-1514. doi:10.1001/jama.2022.18231

2. Dal-Ré R, Janiaud P, Ioannidis JPA. Real-world evidence: how pragmatic are randomized controlled trials labeled as pragmatic? *BMC Med*. 2018;16(1):49. doi:10.1186/s12916-018-1038-2

3. Manchikanti L, Knezevic NN, Sanapati J, Kaye AD, Sanapati MR, Hirsch JA. Is epidural injection of sodium chloride solution a true placebo or an active control agent? a systematic review and meta-analysis. *Pain Physician*. 2021;24(1):41-59.