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NEWSLETTER #114 APRIL 2023

Lessons in SCS Study Design

The October JAMA paper we critiqued in our November newsletter has been the subject of growing commentary, and at long last on March 14, five months after publication of the original paper, JAMA itself published several letters to the editor that augment and amplify our concerns (Goel et al., 2023; Hunter et al., 2023; Hussain et al., 2023; Manchikanti et al., 2023; Thomson et al. 2023) as well as a response (Gulati et al., 2023). Summary presentations are beginning to appear on professional meeting programs, and we look forward to a publication that will pull all of the critiques together.

On the heels of the Cochrane review that we critiqued in our March newsletter, a new systematic review and meta-analysis of spinal cord stimulation (SCS) by Fatima et al. (Fatima et al. 2023) offers conclusions favorable to SCS: “SCS is a more effective treatment option than CMM and reoperation for patients with chronic neuropathic pain.” This reinforces our criticism of the Cochrane review, which used unreasonably stringent inclusion criteria. Even the criteria used by Fatima et al., along with the Medline search syntax, are subject to criticism for excluding some important SCS studies and focusing unduly on paresthesia-free SCS, which allows blinded trials but is not representative of SCS as a whole and has yet to accumulate decades of followup.

We agree with Fatima et al. that “More studies with longer follow-up times are needed.” Such studies, however, face important practical and ethical constraints; SCS study patients randomized to a control or comparator treatment cannot be expected to wait indefinitely if their randomized treatment is unsatisfactory. Crossover designs are commonly used to address this reality. For an invasive procedure such as SCS, however, unless all patients receive an implant (as is often the case for waveform comparisons), crossover must be optional, and as such it reflects patient dissatisfaction with the initial treatment assignment and can be considered an outcome measure.

In our 2005 randomized controlled trial (RCT) comparing SCS with repeat lumbosacral spine surgery (North et al., 2005), we defined a "successful" outcome a priori as at least 50% pain relief by the initial randomized treatment assignment combined with patient satisfaction; thus, the request for crossover represented failure. Using this practical measure of real-world outcomes, we observed a significant advantage for SCS with a sample of only 50 patients. Our companion cost-effectiveness analysis (North et al., 2007) demonstrated that SCS was "dominant," i.e., less costly and more effective; among the obvious reasons was that crossover, which was much more common after reoperation than after SCS, incurred the expense of both procedures.

This month's SCS publications list (below) includes a protocol for an RCT comparing SCS with reoperation (Krause et al., 2023). Like our study, it offers patients the option of crossover to SCS after 6 months, but when this occurs patients are censored and, it appears, not counted as failures of surgery. Not only would this be unfair, it misses an opportunity to follow patients after crossover and collect additional data.

The design of clinical trials for pain in general, and SCS in particular, has received attention in recent years (Duarte et al., 2022; Katz et al., 2021; Pilitzis et al., 2021), and we hope that new studies with longer followup will lead to more meaningful conclusions to guide clinical practice.

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On Another Front

Last month, we noted that PubMed has started listing “Preprints,” and we decided to cite them in WIKISTIM. This practice is growing: five merited WIKISTIM inclusion this month versus only one last month. Such papers, which report research funded by the U.S. National Institutes of Health, would be best described as “online ahead of peer review” (to mirror PubMed’s description of epubs as “online ahead of print”). To stay close to PubMed terminology, however, we are flagging each of such entries as a “preprint before peer review,” and we advise caution when quoting, citing, or relying upon them.

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WIKISTIM now has 1735 subscribers. Thank you for spreading the word!

Citations Added From Search on April 8, 2023

Whenever possible, we provide free full-text links. For journals where a full-text PDF downloads immediately when a page is opened or has a “watermark,” we link to the link rather than to the PDF. (If necessary, please click “View Entire Message" to see all of the citation lists in this newsletter.)

Deep Brain Stimulation (now 7527 citations)

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