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NEWSLETTER #113 MARCH 2023

Et Tu, Cochrane?

A Cochrane review on spinal cord stimulation (SCS) for low back pain was published on March 7, 2023 ([Traeger et al.](#)). Based on an analysis of 13 studies described as "randomised controlled trials (RCTs) and cross-over trials comparing SCS with placebo or no treatment for low back pain" and limited further to subsets of each of these categories, the authors drew the broad conclusion that "SCS probably does not have sustained clinical benefits that would outweigh the costs and risks."

There are 3,082 reports of SCS primary data and relevant study protocols in WIKISTIM, and one might reasonably ask whether a subset of only 13 could be representative and whether analysis of this subset could justify such a conclusion in an influential publication. In fact, a subset of only 6 is relevant to the clinical decision to perform an SCS trial or implant because 7 of the 13 studies analyzed "required participants to already be implanted with an SCS [sic] and have achieved stable pain control." (see page 15).

Notably excluded from the Cochrane review were RCTs comparing SCS with alternative active treatments for low back pain in widespread use, with their attendant expense and risks. Among these alternatives is surgery; thus, [our 2005 RCT of SCS vs. reoperation](#), which has been widely cited, was excluded because of its "ineligible comparator." Our finding, namely that, at 2.9-year mean followup, SCS had significantly better outcomes and, in the great majority of patients, obviated the need for reoperation, was dismissed. Also dismissed was [our companion cost-effectiveness study](#) that showed SCS to be dominant (more effective and at the same time less expensive).

WIKISTIM lists many SCS studies reporting favorable results with follow-up of several years and a few with two decades or more. One might think this would inform the definition of "long term," but on page 1 in the Traeger review, the authors note, "Our primary time point was long-term follow-up (≥ 12 months)," and then, on page 2, go on to say, "None of our included studies evaluated the impact of SCS on mean LBP

intensity in the long term." In the context of prior literature with much longer followup, albeit of lower quality (typically case series), how can a conclusion about "sustained clinical benefits" be drawn from the current review?

Curiously, the Traeger review included the study by [Hara et al. in JAMA](#), a negative SCS trial published on October 18 more than four months after the review search end date of June 10 (see page 9). The Hara paper was the subject of our [November newsletter](#) and led us to ask "Cui bono?" Inclusion of this study allowed Traeger et al. to claim (on page 20), "Only the Hara 2022 study assessed the benefits of SCS versus placebo using a treatment period of longer than three weeks," and it appears that this inclusion altered the conclusion of the Cochrane review. Should we question this as confirmation bias, perhaps with a Latin phrase?

Traeger et al. (see page 8) say, "We excluded studies that only compared different forms of SCS." SCS trials have been reported for 66 years, but paresthesia-free waveforms enabling blinded RCTs have been in use for no more than 10 years. To date such studies have generally compared one waveform with another, and while this might be useful in showing noninferiority and securing regulatory approval for market, it is not particularly relevant to the clinical decision to perform an SCS trial or implant or to judging the overall benefits of SCS. Waveform comparisons should not have been dismissed outright, however, as this eliminated widely cited studies ([Senza](#), [Sunburst](#), [DTM](#), [Evoke](#)) in which the superiority of the study waveform presumably represented real net benefit. We may hope that future Cochrane reviews will include such studies, that future SCS studies will use a relevant clinical comparator, and that SCS can be represented by multiple waveforms available from the same device.

"Low back pain" (LBP), of course, is not a diagnosis but rather a symptom attributable to a variety of conditions (degenerative, traumatic, post-surgical, etc.) and mechanisms (nociceptive, neuropathic, etc.) with different clinical presentations (viz., mechanical or not). Historically, paresthesia-based SCS had limited technical success in achieving overlap by paresthesia of axial LBP (as opposed to radiating leg pain) and correspondingly limited clinical results. Only in recent years, with the development of novel waveforms, have claims been made supporting broader use of SCS for axial LBP. The new Cochrane review makes none of the above distinctions, and by excluding so many recent studies, it fails to represent its subject faithfully.

The principles of evidence-based medicine confer priority but not exclusivity on high-quality studies, recognizing the importance of prior art and clinical experience ([Sackett et al., 1996](#)). In fact, [Concato et al. reported in 2000](#) that "meta-analyses of observational studies produce results that are similar to meta-analyses of randomized trials." Evidence that is judged as weak by new standards should not be treated as if it were nonexistent (see [Guyatt et al., 2000](#)). Furthermore, as [Petticrew noted in 2003](#), meta-analyses of studies of high technical quality but limited relevance can yield misleading results, as appears to be the case in the Traeger study.

Cochrane reviews have been an important part of evidence-based medicine. Like systematic reviews in general they can be at the mercy of their selection processes vis-à-vis the available evidence at the time(s) chosen. On occasion, Cochrane has acknowledged the validity of criticisms: “selection of studies for inclusion was faulty . . . choice of outcomes was faulty” and has [published corrections](#). SCS researchers, for their part, are addressing methodological deficiencies that once were common, as guidelines specifically for neuromodulation are published and adopted by journals (see, for example, [Katz et al., 2021](#); [Duarte et al., 2022](#)). We look forward to reviews that are more representative of the benefits, risks, and costs of SCS and thus useful for guiding practice and policy.

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Long COVID and WIKISTIM

Most of the longtime industry supporters who have issued grants to support WIKISTIM in years past have disappointed us this year. Many tell us that the economic downturn coinciding with COVID and continuing afterwards is to blame. As we approach our 10th anniversary, we are dangerously close to becoming a casualty.

We have 150 subscribers who use the corporate email addresses of the four largest neurostimulation companies and presumably are their employees; an unknown additional number of employees, consultants, etc. use personal addresses. WIKISTIM's benefit to these companies can be measured in employee time savings and efficiency, and thus in full-time equivalents or dollars. We believe that by serving all of you at scale, we contribute to the field of neuromodulation very cost-effectively.

We urge all our subscribers whose employers and businesses benefit from their use of WIKISTIM to request that they support us with a grant or donation.

Likewise, we urge those who appreciate the benefits of neurostimulation to donate to WIKISTIM so that we can continue to provide this free service.

Thank You

We thank the Terry Daglow and Todd Sitzman for their donations, which were greatly appreciated.

Discuss Freely

Letters to the Editor are a slow process; not until this week (after 5 months) did JAMA publish the letters responding to its October paper by Hara. Our comments appeared in this newsletter after only 5 weeks. This month's comments on the Cochrane report, which by the way does not support or allow letters to the editor, are appearing after only 10 days.

Please consider adding your thoughts on this and other subjects to our Discussion section. Unlike letters to the editor, it has no deadlines or limitations on number of authors, word count, or citations

Increase in the Number of Subscribers

WIKISTIM now has 1713 subscribers. Thank you for spreading the word!

Citations Added From Search on March 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 to see all of the lists, please click "View Entire Message.") Please note, The National Library of Medicine is now including what it refers to as "preprints" in PubMed. By "preprint," the NLM means an article that has not yet been peer reviewed. Such articles report research funded by the U.S. National Institutes of Health. PubMed also includes links to peer-reviewed full text articles before they appear in print (referred to here as "epubs") and full-text links to accepted articles before they have been formatted for print. One might well call these "preprints." In the full-text links in WIKISTIM, we don't distinguish between versions of accepted articles. We do, however, note when an article appears in PubMed in advance of peer review (see Gao in the DBS section below).

Deep Brain Stimulation (now 7459 citations)

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Dorsal Root Ganglion Stimulation (now 242 citations)

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Gastric Electrical Stimulation (still 519 citations)

Peripheral Nerve Stimulation (now 686 citations)

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