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NEWSLETTER #116 JUNE 2023

Hara Redux

On Tuesday June 13th, JAMA published a letter to the editor (LTE) by Hara et al. ([Hara et al., 2023](#)) presenting additional, longer-term followup data from their randomized controlled trial that compared a novel spinal cord stimulation (SCS) burst waveform with sham SCS for persistent low back pain. As reported in JAMA on October 18, 2022 ([Hara et al., 2022](#)), the study had shown “no significant difference in . . . the self-reported Oswestry Disability Index” (ODI). A litany of criticisms followed, beginning with the November edition of this newsletter and continuing with multiple LTEs and editorials, too voluminous and, in some cases, too nuanced to detail here (see, for example [Abd-Elssayed et al., 2023](#); [Eldabe et al., 2023](#); [Goel et al., 2023](#); [Hunter et al., 2023](#); [Hussain et al., 2023](#); [Manchikanti et al., 2023](#); [Thomson et al., 2023](#) as well as our [Discussion section](#)).

In their LTE, Hara et al. state, “The main limitation of the trial was that blinding of treatment allocation prohibited repeated fine-tuning of stimulation parameters (i.e., amplitude, pulse width, and frequency) in open dialogue with patients and the use of paresthesia-inducing tonic stimulation.” This implies that the limitation has been addressed in this unblinded follow-up study, but all we learn under Methods is that “After the final randomization period, all trial participants received a programmer that allowed adjustment of stimulation amplitude and switching between burst and tonic stimulation and had follow-up appointments after 3 and 6 months.” This falls short of “repeated fine tuning,” which is standard care in SCS patients, typically requiring multiple face-to-face sessions. Patients do not just “receive a programmer.”

We recall of course that tonic stimulation was used in the trial phase of the study to identify candidates for generator implantation. The 2022 JAMA paper told us only that a 2-point improvement on a 0-10 point Numeric Rating Scale (NRS) was required for success, but we subsequently learned from an LTE by the authors published March 14th ([Gulati et al., 2023](#)) that “the mean improvement was 63% (median, 5 points) in Numerical Rating Scale score for leg pain before entering the trial.” We might therefore

have reasonably expected substantial improvements in NRS, not only for leg pain but also for back pain, but these data have not been provided. Were they collected?

Only 30 patients of the original 50 remained in the “complete case set” in this “Six-Month Follow-up.” This rate of attrition is unusually high for SCS, and it is especially remarkable given the provisions for open-label treatment with new waveforms, offering substantial potential benefits and requiring no additional procedures. Were study subjects adequately informed? Were the limited data from the remaining 30 representative of the full study population? Are the Results (“no significant between-group differences for ODI change”) representative, and can any conclusions be justified? At issue is not just the adequacy of sample size, which has arisen before in extended followup of SCS study patients ([Kemler et al., 2006](#)). Even the largest sample cannot correct for bias, which can be conveyed to subjects and staff and can influence study results despite the efforts of investigators to avoid it.

The LTE format in which Hara et al. have reported these results, with its limits on word count, references, etc., constrains full reporting, and the Supplements and Supplemental Content have not redressed this limitation. We encourage the authors to report their methods and results more fully, and we look forward to further comments in our [Discussion section](#) (which has an unlimited word count allowance) and in other publications.

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What's In a Name?

The name "failed back surgery syndrome" (FBSS) is being replaced with "persistent spinal pain syndrome" (PSPS). This change is happening between the time a paper appears as an e-publication and the time it appears in print. Thus, our quarterly update of epubs this month required more than the usual number of changes in titles. (We sometimes encounter small changes--an added or deleted hyphen or abbreviation, for example.)

This change is a welcome improvement even though we wish that publishers would remain consistent with initially released titles for papers. We caution authors, however, to continue to include "failed back surgery syndrome" as a keyword when appropriate in order for their papers to appear in a PUBMED search when they have used "persistent spinal pain syndrome" in their title. We checked PUBMED, and no clinical papers on FBSS appear with a search of the new term. We plan to add appropriate keywords to the back-end of WIKISTIM so that both FBSS and PSPS papers will appear with a search of either term.

We Are Grateful to Dr. Cedeno and Dr. Mejia

This month, we thank Dr. David Cedeno and Dr. Pilar Mejia for their generous donation to WIKISTIM. When he contacted us about this donation, Dr. Cedeno noted that he "appreciates the compilation of evidence in WIKISTIM" and our "efforts towards highlighting the benefits of neuromodulation." Dr. Cedeno also joins us in looking forward to WIKISTIM becoming an important forum for researchers and leaders in the field.

Please consider joining those who have made an individual donation to acknowledge the value of WIKISTIM to your practice and/or your research. Please also encourage your employer to look favorably on grant requests from The Neuromodulation Foundation. At this point, WIKISTIM continues on a shoestring budget (we will advise when we are out of the woods and can stop mixing our metaphors).

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Deep Brain Stimulation (now 7644 citations)

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Gastric Electrical Stimulation (still 520 citations)

Peripheral Nerve Stimulation (now 705 citations)

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Contact

The Neuromodulation Foundation, Inc.

117 East 25th Street

Baltimore, MD 21218

wikistim@gmail.com