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## NEWSLETTER #109 NOVEMBER 2022

## SCS, JAMA, and EBM

Between 1992 (Guyatt et al., 1992) and 2000 (Guyatt et al., 2000), the “Evidence-Based Medicine (EBM) Working Group" published 31 papers in the Journal of the American Medical Association (JAMA) to address the critical question, “What is the best evidence for making clinical decisions?” and JAMA has continued to publish important papers in the field of EBM. Until this month, however, as a search of WIKSTIM's list of SCS citations sorted by journal will readily confirm, JAMA (the parent journal) had never published a paper reporting primary spinal cord stimulation (SCS) data and neither had any of the 17 co-authors of a new paper by Hara et al. As detailed in its WIKISTIM abstract, Hara’s paper follows many of the important principles of EBM, but it follows them in such a way that we and our colleagues have begun a dialogue questioning the study’s validity, its ethics, and JAMA’s decision to publish it.

Until about 10 years ago, the stimulation parameters used for SCS elicited paresthesia, which made blinded controlled trials and, thus, achieving the highest levels of EBM impossible. Today, however, various frequencies and pulse sequences can lead to pain relief at amplitudes below the paresthesia threshold. Among these are frequencies as high as 10 kHz and "burst" waveforms. Of course, none of these is effective if the amplitude is so low that they are effectively sham stimulation. Indeed, although not mentioned as a limitation in this paper, Hara’s choice of amplitude between 50 and 70% of the paresthesia threshold might be too low. Even more significant, however, this burst waveform has been studied at only 10% below paresthesia threshold in a 3-way sham-controlled trial reported by Eldabe et al. in 2021 (but not cited in the Hara paper), in which burst was no more effective than placebo/sham, whereas a 500Hz waveform was significantly more effective. This prior art makes the Hara results neither surprising nor newsworthy, even as they receive undue attention.

Like many therapies, SCS was an established treatment before the principles of EBM were devised and applied to SCS research reports. As we summarized a decade ago (North, Shipley, 2012), SCS studies not only have to describe patient selection, patient

selection must be appropriate; implanting clinicians not only have to be identified, they must be sufficiently experienced; the interventions not only have to be listed, they must follow best practices, including accepted screening and treatment protocols to ensure patient safety and efficacy; outcome measures not only have to be clearly defined, they must be generally accepted. In the Hara study, however (to mention only a few of our concerns), patients underwent an SCS trial with traditional paresthesia-based settings, not the burst waveform to be studied, and the trial was deemed successful if only 2 points of improvement were achieved on a 0-10 rating scale, rather than the usual 50%. This is not representative of usual care and standard practice for SCS.

When journals venture beyond their familiar topics, their peer reviewers might not identify problems that predispose a study to failure or to a false negative result. Were the JAMA peer reviewers sufficiently familiar with SCS technology to recognize whether or not it was delivered correctly and whether or not patient safety was protected? Did they consider, for example, whether using blinding as an excuse for not optimizing the therapy by fine-tuning stimulation parameters for an entire year might be outside the standard of care? Likewise, did they consider whether patients should be screened with a trial of the burst waveform under study rather than with tonic stimulation? Did they consider whether use of a non-rechargeable battery in the implanted generator was in the patients' best interests? Was the "Southeast Norway Committee for Research Ethics" sufficiently knowledgeable to judge these issues and the adequacy of patient informed consent? Might another review board have rejected the protocol?

Preparation of the WIKISTIM abstract for this paper revealed that the authors, reviewers, and editors certainly did not pay attention to details (the pain scale for inclusion was described as 1 to 10 on one line and as 0 to 10 on the next [p 1507]; 7 of the 112 initially included patients "with chronic radicular pain" were eliminated because they had no radicular pain). These are small errors, but small errors signal the possible existence of larger errors—after all, many sets of eyes missed these errors (17 authors, at least 3 peer reviewers, at least one copy editor). The use of WIKISTIM abstract templates not only by authors but also by reviewers would help to address such errors before publication and might even prompt reviewers to ask important questions (e.g., what were the reasons that 10% of the randomized sample withdrew from the trial?).

Publications in JAMA are influential, and this new paper on SCS already is being cited by payors as reason to deny treatment. This is of course absurd, not only because of the above issues, but also because the waveform that was studied here, a new form of burst for which no claims have been made and which has been reported to be ineffective (Eldabe et al., 2021), is not representative of SCS. With all the new waveforms introduced over the past decade, SCS is no longer a single entity, and its overall efficacy should not be called into question by a lone, foreseeably negative study. The champions of EBM (Guyatt et al., 2000) surely would frown upon this. As is often the case, we are left wondering *cui bono*—the authors? the journal? certainly not the study participants who didn't receive optimal therapy and certainly not other patients in pain seeking relief through SCS.

We will end by reminding our readers that WIKISTIM includes a discussion section (https://www.wikistim.org/discuss/) where we can continue this dialogue with no word or time limit.

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We thank our GES Editor, Dr. Thomas Abell for bringing WIKISTIM to Enterra's attention. This resulted in a much needed donation for which we are most grateful. We also thank Dr. North for enhancing all of his volunteer work on behalf of the Foundation with a monetary gift.

## Increase in the Number of Subscribers

WIKISTIM now has 1659 subscribers. Thank you for spreading the word!

## Citations Added From Search on November 11, 2022

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.”)

**Deep Brain Stimulation (now 7249 citations)**

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**Peripheral Nerve Stimulation (now 656 citations)**

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