NEWSLETTER #131 September 2024 See ABOUT WIKISTIM

SCS Misrepresented in the News

On September 14th, *The New York Times* published an article by Paula Span that described "Three Medical Practices that Older Patients Should Question." Only two of these were "practices" (thickening liquids for patients with difficulty swallowing and stopping blood pressure medication before a surgical procedure). The third topic was spinal cord stimulation (aka "spine implant for back pain").

The author began her discussion of SCS by referencing the US Food and Drug Administration's 2020 review of SCS implantations over four years that led to "108,000 [the FDA reported 107,728] reports of "patient injuries, including 497 deaths, and malfunctioning stimulators." Readers of *The Times* who are not health care practitioners might be alarmed by this. It is worth copying the FDA mortality finding verbatim:

"The 497 reports coded as a patient death represent 428 unique events [emphasis added] which were reported to the FDA between July 27, 2016 and July 27, 2020 and associated with devices implanted between November 2005 and July 2020 [emphasis added]. The average age of the patient in these reports was 69 years, and reports noted the presence of comorbidities including malignancy, chronic diseases (including Parkinson's Disease, diabetes, dementia, and heart disease), and acute illness or injury (including influenza, infection, suicide, and substance abuse). In approximately 30 percent of the cases where times to event were available, the death occurred within 30 days of implantation. However, none of the reports provide enough information to conclude that the device caused or contributed to the death."

The FDA estimated that 50,000 devices were implanted annually. Thus, 200,000 implants over the four-year-period led to 77,937 "injuries" and 29,294 device malfunctions. As for deaths? In order to determine a percentage to consider risk properly, we would have to know how many stimulators were implanted in the more than 15-year-period (*The New York Times* doesn't state that the deaths were associated with a 15-year implantation period) as well as the causes of the deaths. In other words, we need better data. Furthermore, *The Times* fails to note that a certain number of deaths is to be expected among 200,000 (really many thousands more, considering the 15-year-time period) patients averaging 69 years of age, even after placebo treatment, even after no treatment, or that correlation does not mean causation.

The article then gives a lot of space to comments by Dr. Rita Redberg, who repeated claims from a study she co-authored that opioid use did not decline among SCS patients. (This is the very study that we debunked in this newsletter in January 2023, noting the authors' failure to acknowledge reported findings that contradict the study's conclusions; furthermore, investigators continue to report reduced opioid consumption after implantation--see Jacobs et al. in this month's list of SCS citatons for an example.) *The New York Times* article tries to appear balanced: it quotes Dr. Konstatin Slavin, one of our section editors and a Neuromodulation Foundation board member as well as President of the International Neuromodulation Society, and Dr. Lawrence Poree, President of the Institute of Neuromodulation. Both make excellent points: Dr. Slavin notes that SCS is not meant to reduce pain to zero and the amount of pain medication a patient consumes is not a good indication of the amount of pain that patient experiences, and Dr. Poree pointed out that SCS is not meant to treat every type of pain and emphasized the importance of the SCS screening trial. Nonetheless, Dr. Redberg was given the last word: "We all want to help patients with pain. . . This is not the way to do it." *Sic transit gloria*.

People to Thank This Month

This month, we are deeply thankful to Boston Scientific for its grant in support of our work. We are grateful for all donations, large and small: small because they indicate that WIKISTIM has widespread support and large because they reinforce that sentiment and play a big part in keeping us solvent. We have applied to the three big neurostimulation companies and hope to have more good news to share next month. If you work for or with Boston Scientific, please add your thanks to ours!

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We only list correction citations if the error was substantial. For small changes, such as a missing initial in an author's name, we simply update the WIKISTIM database.

Deep Brain Stimulation (now 8530 citations)

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