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Study Finds High-Frequency SCS Effective In Reducing Opioid Dose for Managing Pain

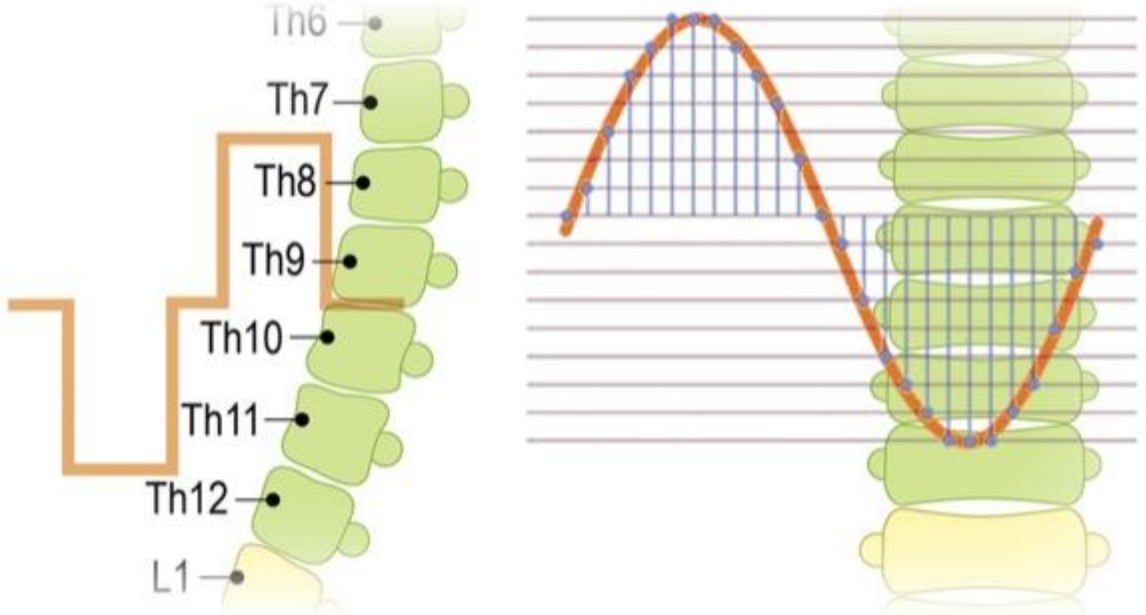
A retrospective study comparing high-frequency (10-kHz) spinal cord stimulation with conventional medical management for treating low back and lower extremity pain concluded that reductions in opioid dose were dramatically greater in the active study group.

In total, 32 patients underwent 10-kHz spinal cord stimulation (SCS) implantation and 64 patients received conventional medical management.

“Patients treated with 10-kHz SCS [Senza, Nevro] experienced significant reductions in pain scores for both low back and lower extremity, opioid dosing and self-reported disability 12 months after undergoing permanent implantation,” said principal investigator David DiBenedetto, MD, the medical director of Boston PainCare in Waltham, Mass. “The volume of interventional procedures performed in the SCS-treated subjects was also significantly reduced in the 12 months following implant as compared to the preceding 12 months.”

The SCS group achieved a 26.2-mg morphine equivalent dose reduction, representing a 28% reduction from baseline, versus no meaningful change in dose in the conventional medical management group.

Moreover, 71.4% of patients in the SCS group decreased their dose at 12 months post-implantation.



Combined, the SCS and conventional medical management groups attained significant reductions in numerical pain rating scale scores for low back and lower extremity pain: 46.2% and 50.9% decreases, respectively, from baseline.

“Treatment options for chronic back pain were frustratingly limited prior to the introduction of high-frequency neuromodulation to the U.S. market in 2015,” Dr. DiBenedetto said of his study (*J Pain Res* 2018;11:2929-2941). “Furthermore, the results from these treatments were often disappointing, and in part contributed to an overreliance on opioid medications.”

The investigators’ initial intention to collect outcome data stemmed from a need to determine the clinical circumstances and patient characteristics for which 10-kHz SCS treatment would offer notable value within the contexts of their interdisciplinary, biopsychosocial model of care.

Dr. DiBenedetto said the study results support those reported in the SENZA-RCT study (*Anesthesiology* 2015;123[4]:851-860), a randomized controlled trial comparing high-frequency with traditional low-frequency SCS for treating chronic back and leg pain. “We provide evidence that 10-kHz SCS treatment can be an effective treatment option when employed in an interdisciplinary practice setting,” he said.

Although the improvement in self-reported disability in patients receiving high-frequency SCS treatment was not unexpected, “similar results were also observed in subjects receiving only CMM [conventional medical management],” Dr. DiBenedetto said. “These results may reflect the effectiveness of the interdisciplinary treatment model, which has been associated with improved clinical outcomes in published literature.”

Overall, the findings of the current study suggest that in properly selected patients, “the use of 10-kHz SCS may not only provide pain relief and improved functioning but also reduce the overall cost of treatment, given the reductions in both interventional procedures and opioid dosing observed,” said Dr. DiBenedetto, an adjunct faculty in the Department of Diagnostic Sciences at Tufts University School of Medicine, in Boston.

Dr. DiBenedetto noted that clinicians typically perform comprehensive medical screenings before SCS treatment to identify pathology amenable to neuromodulation. “However, standardized, robust psychological assessments and evaluation of the patient’s realistic expectations or goals related to pain and functional outcomes with the therapy is often lacking,” he said.

Achieving optimal outcomes with SCS treatment depends on patient selection, according to Dr. DiBenedetto, “and the performance of comprehensive behavioral assessments is crucial to this process,” he said. “Regularly scheduled follow-up postimplantation visits are also critical to long-term success with all treatment goals related to SCS therapy, such as improved physical activity and reduction in medication dosages. If patients are to attain meaningful outcomes with SCS, it requires an active process post-implantation by both the patients and clinicians.”

Timothy Deer, MD, the president and CEO of the Spine and Nerve Center of the Virginias, in Charleston, W.Va., said although the study was performed by a highly qualified group of physicians who produce excellent work, “there are several limitations of the data that greatly diminish the value of the study. The data is limited by the retrospective design and by the method of choosing the control group.”

The selection of matched groups cannot be adequately determined because the study was conducted retrospectively with no prescreening, according to Dr. Deer, who is a member of the *Pain Medicine News* editorial advisory board. “This could lead to a dramatically heterogeneous group of patients who were poor candidates for implantable devices, and therefore were maintained on opioids with little reason to show a reduction.”

There was also no difference in functional pain scores between the two groups, thus showing no significant improvement in pain difference between high-frequency SCS and conventional medical management. “This would suggest a failed therapy, based on defined parameters of pain reduction with comparative efficacy studies in neurostimulation research protocols,” Dr. Deer said.

Furthermore, the study did not include data from those patients who were explanted in a 12-month period after implantation, and the investigators excluded patients who failed a screening trial. “It would be important to know the comparison in the two groups, had they

included all patients receiving high-frequency SCS therapy," Dr. Deer said. "The current design could lead to bias towards a more successful outcome in the stimulation group."

Despite his reservations about the study, Dr. Deer is impressed by the opioid reduction and improved function achieved with SCS.

"I applaud the researchers for using neurostimulation to reduce the need for opioid burden and requirements," he said. "Considering the death of 72,000 people from opioids in the United States in the past year, it is important that we seek alternatives to improve pain that can be used in the algorithm prior to initiating opioid treatment."

—Bob Kronemyer

Dr. DiBenedetto reported no relevant financial disclosures. Dr. Deer is a consultant to Abbott, Axonics, Nalu and Saluda.