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Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain

The SENZA-RCT Randomized Controlled Trial

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ABSTRACT

Background: Current treatments for chronic pain have limited effectiveness and commonly known side effects. Given the prevalence and burden of intractable pain, additional therapeutic approaches are desired. Spinal cord stimulation (SCS) delivered at 10 kHz (as in HF10 therapy) may provide pain relief without the paresthesias typical of traditional low-frequency SCS. The objective of this randomized, parallel-arm, noninferiority study was to compare long-term safety and efficacy of SCS therapies in patients with back and leg pain.

Methods: A total of 198 subjects with both back and leg pain were randomized in a 1:1 ratio to a treatment group across 10 comprehensive pain treatment centers. Of these, 171 passed a temporary trial and were implanted with an SCS system. Responders (the primary outcome) were defined as having 50% or greater back pain reduction with no stimulation-related neurological deficit.

Results: At 3 months, 84.5% of implanted HF10 therapy subjects were responders for back pain and 83.1% for leg pain, and 43.8% of traditional SCS subjects were responders for back pain and 55.5% for leg pain ($P < 0.001$ for both back and leg pain comparisons). The relative ratio for responders was 1.9 (95% CI, 1.4 to 2.5) for back pain and 1.5 (95% CI, 1.2 to 1.9) for leg pain. The superiority of HF10 therapy over traditional SCS for leg and back pain was sustained through 12 months ($P < 0.001$). HF10 therapy subjects did not experience paresthesias.

Conclusion: HF10 therapy promises to substantially impact the management of back and leg pain with broad applicability to patients, physicians, and payers. (ANESTHESIOLOGY 2015; 123:00-00)

WE present a multicenter, randomized, controlled trial evaluating the safety and efficacy of 10-kHz high-frequency (HF10) therapy, which is an innovative spinal cord stimulation (SCS) system for the management of chronic back and leg pain. This system delivers electrical stimulation pulses at high frequency (10,000 Hz) as compared with traditional low-frequency SCS systems (typically around 50 Hz). Previous work suggests that the higher-frequency system may treat back and leg pain to a greater degree. Moreover, it may be able to do so without producing paresthesias associated with low-frequency SCS, which some patients find uncomfortable.¹⁻³

What We Already Know about This Topic

- Spinal cord stimulation (SCS) often relieves radicular pain but is relatively poorly effective for the treatment of back pain
- High-frequency SCS may improve the efficacy of SCS for the treatment of low back pain

What This Article Tells Us That Is New

- This randomized trial involving 198 participants demonstrated that high-frequency spinal cord stimulation (SCS) was superior to conventional SCS for the treatment of back pain and leg pain
- The effects of high-frequency stimulation relative to conventional stimulation persisted for 12 months

This article is featured in "This Month in Anesthesiology," page 1A. Full protocol available at: gliner@nevro.com. Raw data available at: gliner@nevro.com.

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