High-frequency spinal cord stimulation

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 a randomized, parallel-arm, noninferiority study was to compare long-term safety and efficacy of SCS therapies in patients with back pain and leg pain. HF10 therapy promises to substantially impact the management of back and leg pain with broad applicability to patients, physicians, and payers [1)].

HF10 SCS uses a charge-balanced stimulation waveform that has been shown to be safe in both animal and human studies. Data from a multicenter, prospective clinical trial shows that the therapy provides substantial back and leg pain relief. Numerous additional reports suggest improved pain relief in other body areas and for complex pain patterns, even for patients who have previously failed other neuromodulation therapies.

The clinical experience supports the efficacy and pain relief provided by HF10 SCS therapy. Clinical studies have also concluded that HF10 SCS does not generate paresthesia nor was it necessary to provide adequate coverage for pain relief. As clinical evidence accumulates and technological innovation improves patient outcomes, neuromodulatory techniques will be sought earlier in the treatment continuum to reduce the suffering for the many with otherwise intractable chronic pain [2)]

A analysis of the cost effectiveness of HF10 SCS suggests that it is more cost effective and provides a greater number of QALYs than both TNR-SCS and TR-SCS [3)].

Case series

This study aims to evaluate the efficacy of 10-kHz high-frequency (HF10) devices as a rescue treatment in patients with failure of conventional spinal cord stimulation (SCS) for chronic pain treatment without the need to change the spinal hardware.

Methods: In this real-world prospective study, patients with neuropathic pain treated with conventional tonic SCS in whom the therapy had failed, either during the trial phase or after a period of optimal functioning, were recruited throughout 2 years for HF10-SCS therapy. Data on analgesia, functionality, analgesics use and treatment safety were collected 12 months after treatment.

Results: Eleven of the 18 (61%) patients included in the study were successfully rescued with HF10-SCS. Of them, 5 out of 12 (45%) were in the trial phase and 6 out of 6 (100%) had previously functioning implants. A significant improvement in low-back and limb pain was obtained ($p = .003$ and $p = .0001$, respectively). Treatment success was significantly associated with gender ($p = .037$), weight ($p = .014$), body mass index (BMI) ($p = .007$) and time of rescue ($p = .015$). A linear regression test confirmed a significant association between treatment failure and BMI and gender ($p = .004$).

Conclusions: Our results suggest that analgesic rescue with HF10-SCS is an effective therapeutic option for non-responders to conventional SCS, although obesity might be a limiting factor for treatment success. Nevertheless, more comprehensive studies are needed to corroborate our findings.

Significance: This study shows that high-frequency stimulation may be useful in patients with failure of conventional tonic stimulation for chronic pain, both in the trial phase and in previously implanted

subjects. The novelty of this study lies in the use of the implanted epidural electrodes, which avoids the need for further surgery. The results in terms of pain control and recovery of functionality are satisfactory. In addition, variables such as male gender and high body mass index could be predictors of therapy failure [4)].

2016

In a study, 198 subjects were randomized (101 HF10 therapy, 97 traditional SCS). One hundred seventy-one subjects (90 HF10 therapy, 81 traditional SCS) successfully completed a short-term trial and were implanted. Subjects averaged 54.9 ± 12.9 years old, 13.6 ± 11.3 years since diagnosis, 86.6% had back surgery, 88.3% were taking opioid analgesics. 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 ($P < .001$ for both back and leg pain comparisons, non-inferiority and superiority). At 24 months, more subjects were responders to HF10 therapy than traditional SCS (back pain: 76.5% vs 49.3%; 27.2% difference, 95% CI, 10.1%-41.8%; $P < .001$ for non-inferiority and superiority; leg pain: 72.9% vs 49.3%; 23.6% difference, 95% CI, 5.9%-38.6%; $P < .001$ for non-inferiority and $P = .003$ for superiority). Also at 24 months, back pain decreased to a greater degree with HF10 therapy (66.9% ± 31.8%) than traditional SCS (41.1% ± 36.8%, $P < .001$ for non-inferiority and superiority). Leg pain also decreased to a greater degree with HF10 therapy (65.1% ± 36.0%) than traditional SCS (46.0% ± 40.4%, $P < .001$ for non-inferiority and $P = .002$ for superiority).

This study demonstrates long-term superiority of HF10 therapy compared with traditional SCS in treating both back and leg pain. The advantages of HF10 therapy are anticipated to impact the management of chronic pain patients substantially [5)].

2014

After a trial period, 88% (72 of 82) of patients reported a significant improvement in pain scores and underwent the permanent implantation of the system. Ninety percent (65 of 72) of patients attended a 24-month follow-up visit. Mean back pain was reduced from 8.4 ± 0.1 at baseline to 3.3 ± 0.3 at 24 months ($P < 0.001$), and mean leg pain from 5.4 ± 0.4 to 2.3 ± 0.3 ($P < 0.001$). Concomitantly to the pain relief, there were significant decreases in opioid use, Oswestry Disability Index score, and sleep disturbances. Patients' satisfaction and recommendation ratings were high. Adverse Events were similar in type and frequency to those observed with traditional SCS systems.

In patients with chronic low back pain, HF10 SCS resulted in clinically significant and sustained back and leg pain relief, functional and sleep improvements, opioid use reduction, and high patient satisfaction. These results support the long-term safety and sustained efficacy of HF10 SCS [6)].

2013

Eighty-three patients, with significant back pain, were recruited for a trial of high-frequency stimulation through two percutaneous eight-contact epidural leads. Patients' pain ratings, disability, sleep disturbances, and satisfaction, as well as complication rates, were assessed for up to six

months.

After a trial period, 88% (72 out of 82) of patients reported a significant improvement in visual analog scale (VAS) scores and underwent permanent implantation of the high-frequency SCS system. Mean back pain VAS of 8.4 was reduced to 2.7 at six months ($p< 0.001$). Mean leg pain VAS of 5.4 was reduced to 1.4 at six months ($p< 0.001$). Seventy-four percent of patients had greater than 50% back pain relief at six months. There were significant improvements in Oswestry disability score and sleep, and reductions in pain medication use. Adverse events observed were those seen with conventional SCS therapy–lead migration, wound infection, and pain around implant site.

In a cohort of patients with difficult-to-treat chronic back pain, high-frequency SCS provided significant and sustained low back pain and leg pain relief to more than 70% of treated subjects. Notably, this was achieved without paresthesia. Patients also experienced significant improvement in disability and sleep. Overall, the results confirm a favorable safety and efficacy profile of the high-frequency SCS system [7].

1)
Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Brown LL, Yearwood TL, Bundschu R, Burton AW, Yang T, Benyamin R, Burgher AH. 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. Anesthesiology. 2015 Oct;123(4):851-60. doi: 10.1097/ALN.0000000000000774. PubMed PMID: 26218762.
2)
Russo M, Van Buyten JP. 10-kHz High-Frequency SCS Therapy: A Clinical Summary. Pain Med. 2015 May;16(5):934-42. doi: 10.1111/pme.12617. Epub 2014 Nov 7. PubMed PMID: 25377278.
3)
Annemans L, Van Buyten JP, Smith T, Al-Kaisy A. Cost effectiveness of a novel 10 kHz high-frequency spinal cord stimulation system in patients with failed back surgery syndrome (FBSS). J Long Term Eff Med Implants. 2014;24(2-3):173-83. PubMed PMID: 25272216.
4)
Cordero Tous N, Sánchez Corral C, Ortiz García IM, Jover Vidal A, Gálvez Mateos R, Olivares Granados G. High-frequency spinal cord stimulation as rescue therapy for chronic pain patients with failure of conventional spinal cord stimulation. Eur J Pain. 2021 Apr 7. doi: 10.1002/ejp.1776. Epub ahead of print. PMID: 33829605.
5)
Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Yearwood TL, Bundschu R, Yang T, Benyamin R, Burgher AH. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial. Neurosurgery. 2016 Nov;79(5):667-677. PubMed PMID: 27584814; PubMed Central PMCID: PMC5058646.
6)
Al-Kaisy A, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. Pain Med. 2014 Mar;15(3):347-54. doi: 10.1111/pme.12294. Epub 2013 Dec 5. PubMed PMID: 24308759; PubMed Central PMCID: PMC4282782.
7)
Van Buyten JP, Al-Kaisy A, Smet I, Palmisani S, Smith T. High-frequency spinal cord stimulation for the treatment of chronic back pain patients: results of a prospective multicenter European clinical study. Neuromodulation. 2013 Jan-Feb;16(1):59-65; discussion 65-6. doi: 10.1111/ner.12006. Epub 2012 Nov 30. PubMed PMID: 23199157.

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