Retrospective Study

10 kHz High-Frequency Spinal Cord Stimulation for Chronic Thoracic Pain: A Multicenter Case Series and a Guide for Optimal Anatomic Lead Placement

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Background: Surgical options for thoracic pain are limited and carry significant risk and morbidity. Spinal cord stimulation has the potential to be used for treatment of thoracic pain, as it has been useful for treating multiple types of chronic pain. Conventional tonic stimulation is limited in the treatment of thoracic pain, as it can produce paresthesia that is difficult to localize. Conversely, high-frequency spinal cord stimulation (HF-SCS) does not activate dorsal column Aβ fibers and does not produce paresthesia, and thus may be more beneficial in treating thoracic back pain not manageable with tonic stimulation.

Objectives: To evaluate (1) the efficacy of 10 kHz HF-SCS for patients with chronic thoracic pain; and (2) appropriate paresthesia-free lead placement and programming targets for 10 kHz HF-SCS for patients with chronic thoracic pain.

Study Design: Retrospective case series.

Setting: Multisite academic medical center or pain clinic.

Methods: A retrospective chart review was performed on 19 patients with thoracic back pain who underwent HF-SCS implantation. These patients had lead placement and stimulation between the T1-T6 vertebral levels. Outcome measures collected include location of device implant, stimulation settings, and pain scores at baseline, end of trial, and 1, 6, and 12 months postimplant. Follow-up phone calls collected information on if the patient reported functional improvement, improved sleep, or decreased pain medication usage. A Wilcoxon signed-rank test compared differences in mean pain scores across time points.

Results: Significantly decreased Visual Analog Scale scores were observed with 17/19 (89.5%) patients demonstrating response to therapy (> 50% reduction in pain scores). These results were sustained relative to baseline at 1, 6, and 12 months postimplant, depending on length of follow-up. Many patients also reported functional improvement (17/19), improved sleep (14/19), and reduction in use of pain medications after implantation (9/19). A total of 15/19 patients reported best relief when contacts over T1 or T2 vertebrae were used for stimulation.

Limitations: This study is limited by its retrospective design. Additionally, including documentation from multiple sites may be prone to selection and abstraction bias. Data were also not available for all patients at all time points.

Conclusions: HF-SCS may be a viable option for significant, long-lasting pain relief for thoracic back pain. There may also be evidence for anatomically based lead placement and programming for thoracic back pain. Randomized, controlled trials with extended follow-up are needed to further evaluate this therapy.

Key words: Thoracic pain, back pain, spinal cord stimulation, high frequency, 10 kHz

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Chronic thoracic pain in the general population has a lifetime prevalence of 13% with etiologies including disc herniation, disc degeneration, facet diseases, and spinal stenosis (1,2). In interventional pain medicine practices, the incidence of thoracic pain has ranged from 3% to 33% (3-6). With such a significant portion of the pain patient population living with this chronic problem, it is imperative that the pain medicine field address the issue. It has been shown that facetogenic pain makes up 34% to 48% of chronic thoracic pain (7). In treatment of facetogenic thoracic pain, repeated thoracic medial branch blocks can offer some therapeutic effects (8), however, radiofrequency neurotomy shows limited benefit (7,8). For chronic thoracic pain of nonfacet origin, repeated thoracic epidural injections are an effective option for conservative management (2). However, alternative therapies used in conservative management can be costly to the health care system (9) and bring additional risk to patients by means of repeated exposure. Surgical options for thoracic pain are limited and carry significant risk and morbidity. Therefore there is of great interest in developing alternative methods of thoracic pain management. Spinal cord stimulation (SCS), which has proven to be a more cost-effective option than conservative management in patients with low back pain due to failed back surgery syndrome (FBSS) (9,10), has the potential to be used for treatment of thoracic pain.

SCS has been shown to be effective at treating multiple types of chronic pain. Evidence supports the use of SCS for treatment of FBSS (11-14), complex regional pain syndrome types 1 and 2 (15), ischemic coronary and limb pain (16,17), multiple sclerosis (18), chronic painful peripheral neuropathy (19), postherpetic neuralgia (20), postthoracotomy pain, intercostal neuralgia, and axial low back and leg pain (21). Traditional, low-frequency SCS can be an effective treatment for low back and leg pain, but its study and use has been limited in treating some thoracic pain secondary to difficulty in localizing paresthesia sensation and experienced discomfort in the anterior chest wall (22,23). Although the landmark work of Barolat et al (22) was instrumental in mapping paresthesias for many parts of the body, identification of proper placement of leads for the corresponding dermatomal distributions of thoracic pain remains unstudied.

The use of high-frequency spinal cord stimulation (HF-SCS) has shown efficacy in treatment of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with FBSS, intractable low back pain, and leg pain (24,25). In patients with low back and leg pain, the randomized, controlled study referred to as the SENZA-RCT trial showed HF-SCS produced higher responder rates and greater reduction in pain scores than conventional SCS (24,26,27); the authors of a retrospective review of over 1,600 patients with chronic back and/or leg pain reported a similar response rate of over 70% in patients receiving HF-SCS for 12 months (28). Several retrospective studies have also found HF-SCS to be effective in other types of chronic, refractory thoracic and limb pain, including nonsurgical back pain, complex regional pain syndrome, and chronic widespread pain (29-32). In addition to adequate pain relief, there is a growing body of evidence showing that opioid analgesic use is also reduced in patients with chronic pain who receive HF-SCS, further improving patient outcomes (33,34).

In contrast to conventional low-frequency stimulation, the pain relieving effects of HF-SCS are paresthesia-independent (24,35); therefore HF-SCS may be effective in treating thoracic pain that would not be manageable with traditional SCS. Although the mechanism of action of HF-SCS is not entirely understood, it appears to be independent of the mechanism of action of conventional SCS, and preclinical research in rats has shown differential effects of HF-SCS and conventional SCS on neurons in the dorsal horn (DH) (36). Recent work has suggested HF-SCS can activate inhibitory neurons in the DH at low intensities and reduce the activity of pain projecting circuits in the superficial DH without activating dorsal column neurons. SCS at conventional low frequencies is not able to produce this effect, which may be key to the ability of HF-SCS to produce pain relief without paresthesia (36,37). In addition, HF-SCS has been shown to be more cost-effective than both conservative medical management and traditional SCS (38).

Despite this evidence, the application and efficacy of HF-SCS for treatment of chronic thoracic pain is relatively unknown. To date, no published work has specifically examined HF-SCS therapy in treatment of thoracic pain. In this case series, we examine the application and efficacy of HF-SCS therapy in treatment of 19 patients with chronic thoracic pain. The objective of this case series was to evaluate (1) efficacy of HF-SCS therapy for patients with chronic, refractory thoracic pain; and (2) appropriate lead placement and programming for HF-SCS therapy in the management of thoracic distributions of pain.

Methods

Patient Selection

A multicenter, retrospective review was conducted and included patients with thoracic pain treated with HF-SCS implantation with lead placement between T1-T6 vertebral levels. Patients were implanted with the Senza System (Nevro Corp., Redwood City, CA), a rechargeable implantable pulse generator that is capable of delivery of HF-SCS. Patients were identified from device manufacturer records of device implantation and a chart query for patients. All patients to receive an HF-SCS trial and implant had previously trialed and failed appropriate conservative treatments, including physical therapy, medication management, and minimally invasive injections. This study was approved by our institutional review board.

Device Placement and Programming

All patients underwent a 5 to 10 day HF-SCS trial prior to implant, in which either 1 or 2 percutaneous 8-contact leads were placed. Specific lead placement was based on dermatome mapping and provider discretion, but all patients had at least one lead placed between T1-T6 per inclusion criteria. The patients were given 3 different programs for stimulation contact locations. Optimal stimulation level was noted for best patient reported pain relief. Following successful trial, defined as ≥50% pain relief over the course of the trial, permanent implantation was accomplished.

Outcome Measures

Patient records were reviewed for the primary outcome variables of location of device implant (i.e., lead placement at vertebral level T1-6), pain patterns, stimulation settings, baseline pain scores, and pain scores at end of trial and 1, 6, and 12 months postimplant. Pain scores were reported using a Numeric Rating Scale (NRS-11), with 0 indicating no pain and 10 indicating worst pain imaginable. Pain scores were also recorded and evaluated at the patients' most recent follow-up, regardless of duration of therapy. Secondary outcome variables included whether or not patients experienced (1) functional improvement, (2) improved sleep, or (3) decreased pain medication usage following implantation. These were recorded as binary (yes/no) variables collected via follow-up patient telephone calls. Data were collected using a RedCap database. A paired, 2-tailed Wilcoxon signed-rank test was conducted to assess differences in mean pain scores across time points. All statistical analyses were conducted in MATLAB r2017b (The MathWorks, Natick, MA) with a significance level of 0.05.

Results

The study included 19 patients with chronic, treatment-refractory pain with multiple pain patterns. All patients had a chief complaint of thoracic back pain, with additional pain patterns including cervical, abdominal, and lumbar. In all cases, the pain was chronic and refractory to previous interventional treatments. In the subset of 12 patients for whom such data were available, the median duration of pain before the HF-SCS trial was 60 months, ranging from 8 to 265 months, and these patients reported a median of 4 previous failed treatments. Frequently reported previous failed treatments included transcutaneous electrical nerve stimulation, nerve blocks, and radiofrequency ablation, among others. Pain score, with 0 indicating no pain and 10 indicating the worst pain imaginable, was collected at baseline (n = 19), at the end of trial (n= 12), and 1 month (n = 17), 6 months (n = 13), and 1 year (n = 9) postimplant. Some data points were not available due to inconsistent follow-up and chart documentation across patients at multiple institutions.

Changes in pain score are displayed in Fig. 1. The mean reported pain score at baseline was 8.7 (n = 19, standard deviation = 1.3). Mean pain score was 2.3 (12, 1.4) at the end of trial, 3.5 (17, 1.5), 3.5 (13, 1.5), and 2.7 (9, 1.5) at 1, 6, and 12 months postimplant, respectively. Compared with baseline, HF-SCS therapy significantly reduced pain scores at the end of trial stimulation ($P < 0.001$, n = 12; paired, 2-tailed Wilcoxon signed-rank test), and at 1 month ($P < 0.001$, n = 17), 6 months ($P < 0.001$, n = 13), and 12 months postimplant ($P = 0.004$, n = 9). Compared with baseline, pain scores were also significantly decreased across all patients at the patients' last follow-up visit, regardless of duration of therapy (NRS-11 = 3.3, $P < 0.001$, n = 19). There was across all patients a mean decrease in reported pain score between baseline and 1 month postimplant of 58.6% (n = 17; 95% confidence interval [CI], 50.5%–66.7%; $P < 0.001$). From baseline, patients had a mean decrease of 58.9% at 6 months (n = 13; 95% CI, 50.3%–67.5%; $P < 0.001$) and 70.4% at 12 months (n = 9; 95% CI, 59.9%–90.0%; $P = 0.004$).

The epidural leads were implanted in each patient based on the most cephalad dermatome of pain presentation. Three different programs were tested to determine which vertebral areas were associated with

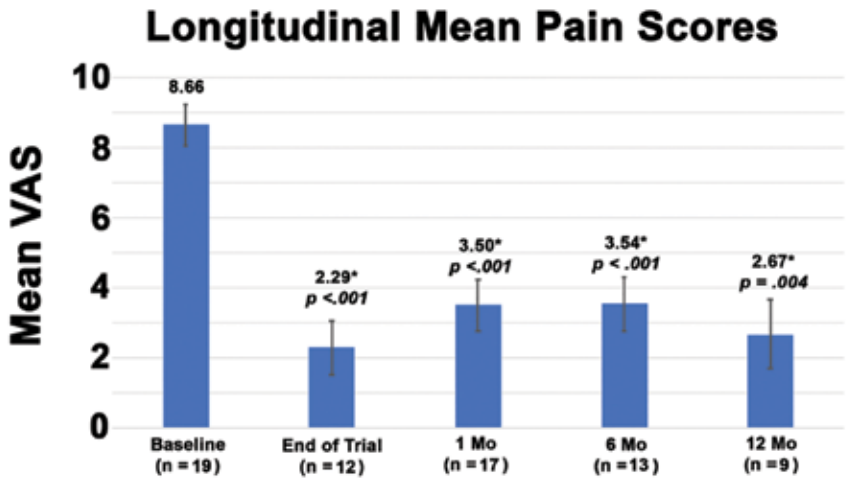

Fig. 1. Mean Visual Analog Scale (VAS) pain scores at baseline, end of trial, 1, 6, and 12 months postimplantation. Mean VAS pain scores across all patients at baseline, and across each cohort of reporting patients at each time point postimplantation. Error bars represent 95% CIs and * indicates significant difference from baseline for the respective cohort (paired, 2-tailed Wilcoxon signed-rank test).

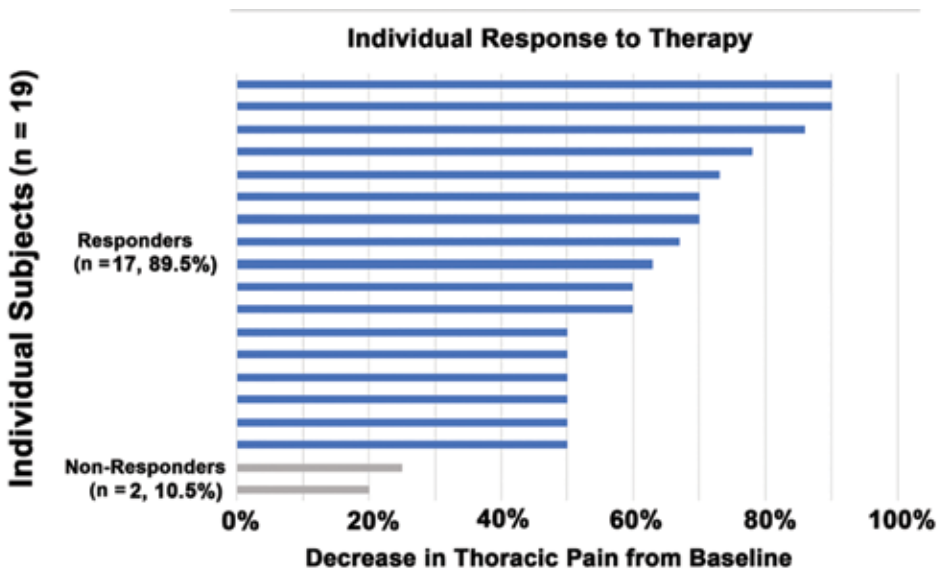

Fig. 2. *Individual responders to therapy.*

the greatest pain relief. The results are displayed in Fig. 2. Interestingly, stimulation of the mid-T2 area was observed to produce pain relief in the greatest number of patients (7/19, 36.8%), followed by low-T1 (3/19, 15.8%). In total, 10 patients achieved greatest pain relief with T2 (upper, mid, or lower) stimulation, and 5 patients achieved greatest pain relief with T1 stimulation (Fig. 3).

HF-SCS therapy also resulted in several improvements reported by patients, which are summarized in Fig. 4. Relative to baseline, 16 of 19 patients (84.2%) reported functional improvement, and 14 of 19 patients

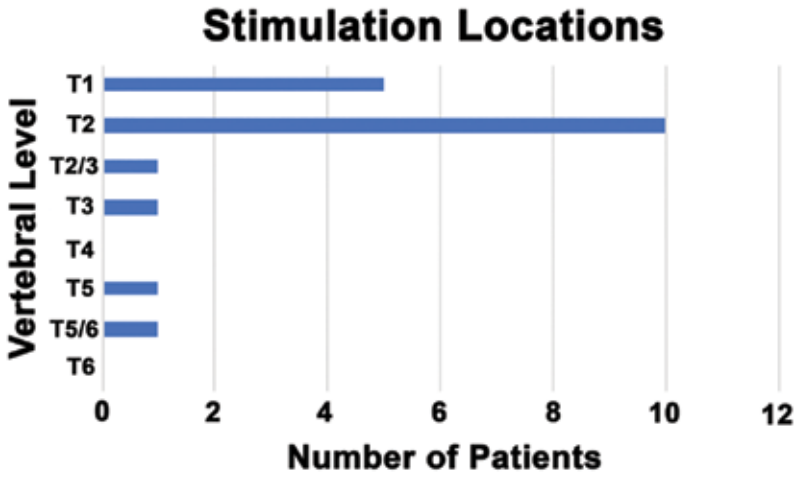

Fig. 3. *Anatomic stimulation location for individual patients.*

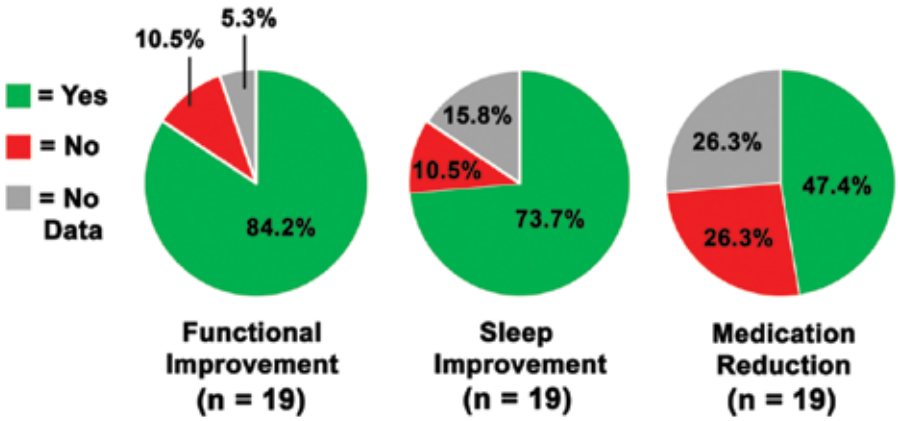

Fig. 4. *Qualitative outcomes of HF-SCS therapy.*

(73.7%) reported improvements in sleep. Additionally, 9 of 19 patients (47.4%) were reportedly able to reduce the amount of pain medications used after implantation. Of note, these data were not available for all patients.

Discussion

Historically, chronic thoracic back pain has been difficult to treat. Conservative measures and spinal interventions have been only modestly successful as treatments (2,7,8). Paresthesia mapping and stimulation of the chest wall has proven difficult, which has halted the advancement of study for traditional low-frequency SCS (22). This may be partially because of the limitations of paresthesia-based systems in addition to the difficulty in eliciting therapeutic paresthesias (22). To this point, there is a paucity of literature studying SCS for thoracic pain. With the introduction of HF-SCS therapy, some of the barriers to treatment of thoracic pain that existed with paresthesia-dependent SCS may be removed. This multicenter, retrospective case series shows that HF-SCS therapy for thoracic back pain may

reliably and sustainably reduce pain scores, improve function, improve sleep, and decrease opioid requirements. It also serves as a guide for lead placement and stimulation for HF-SCS for thoracic pain.

Of the 19 patients who underwent thoracic implantation with HF-SCS, 17 patients (89.5%) showed > 50% pain relief, as demonstrated in Fig. 2. This responder rate is not only comparable, but higher than those seen for the same therapy applied for low back pain (24). This increased responder rate may be attributable to appropriate patient selection, therapy efficacy, or a number of biases. For example, there may be many patients who underwent thoracic trial and failed to achieve > 50% pain relief, but these results would not be discovered in this case series. However, the responder rate of 89.5% for implanted patients suggests that significant pain relief from thoracic back pain can be achieved with implanted HF-SCS therapy. This reduction in pain is comparable to that previously found for HF-SCS therapy in low back pain (24,25). Despite being prone to certain biases, these findings may signify a substantial advancement in SCS application. Previously, uncomfortable paresthesias prohibited low-frequency SCS from being a legitimate option for patients with thoracic pain. With HF-SCS, paresthesia-free pain management is possible for this difficult-to-treat population. In this series, it was also significant that 9 of 9 patients reporting at the 12-month mark demonstrated lasting pain relief (> 50% reduction from baseline). This may further expand the findings of both Al-Kaisy et al (25) and Kapural et al (24) that HF-SCS therapy provides durable pain relief for chronic low back pain. Further study, including randomized, controlled trials, should be pursued to examine these findings.

Another interesting finding was that 10 out of 19 patients reported their greatest pain relief with stimulation over the T2 vertebral body (upper, mid, or lower portion). The next highest proportion of patients (5 of 19) reported their greatest pain relief with stimulation over the T1 vertebral body. Together, 15/19 (79%) had their greatest relief with stimulation over either the T1 or T2 vertebral bodies. These findings suggest it is plausible that an anatomic approach to placement and programming of stimulation can be identified and reproduced for successful treatment of thoracic back pain with HF-SCS, similar to how the anatomic placement of stimulation in HF-SCS therapy has been successfully applied to low back pain. However, more testing in larger numbers of patients will be required to determine the reliability of these results and the feasibility of such an approach.

In addition to these findings, our results suggest that HF-SCS therapy for thoracic back pain may also improve functionality, improve sleep, and decrease medication use. These qualitative outcomes, although positive, require further investigation. Standardization and measurement of these outcomes would make the findings more substantial. Measuring Oswestry Disability Index and morphine milligram equivalents would be possible areas of study.

This series is limited by its retrospective design. Data were gathered from physician documentation at multiple centers, which inconsistently included all of the parameters of interest. In this manner, a retrospective chart review may be subject to significant selection bias. A multicenter chart review is also prone to abstraction bias. Likewise, there were 10 patients for whom data were not available at all time points. Evidence of trial nonresponders and completed follow-up visits may alter the implications seen here. These results show that patients with chronic refractory thoracic back pain may benefit from HF-SCS; however, effectiveness in this patient population cannot be generalized to other types of pain, and further studies are needed. Previously, Al-Kaisy et al (25) showed that HF-SCS therapy provided sustained relief of low back pain for at least 24 months. Further study may be beneficial to follow the longevity of the efficacy of the therapy for thoracic pain. This study did not examine safety or adverse effects as outcome measures. Although, anecdotally, no significant adverse events were reported, a higher-powered prospective study should include examining the safety of HF-SCS for thoracic pain. The groundwork of this case series will assist in guiding such future studies.

Conclusions

In this case series, patients with chronic thoracic pain have shown significant pain relief with HF-SCS. Patient functionality, sleep, and opioid use were all improved, although studies utilizing appropriate validated measures should further investigate these outcomes. Additionally, many patients sustained pain relief to at least 12 months after implantation. In addition to these positive outcomes, this case series suggests that an anatomically based approach to HF-SCS contact stimulation for thoracic pain is beneficial. The encouraging results of this retrospective case series should inspire further study of the role of HF-SCS in the treatment of chronic thoracic pain.

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