

Health-Care Utilization and Outcomes with 10 kHz Spinal Cord Stimulation for Chronic Refractory Pain

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Background: Chronic pain is a common condition associated with decreased quality of life and increased health-care costs. Opioid analgesics are routinely used to treat chronic pain despite limited evidence of long-term efficacy. Spinal cord stimulation at a frequency of 10 kilohertz (10kHz-SCS) has been shown to be effective for treating chronic pain.

Objective: This study was conducted to evaluate the effects of 10kHz-SCS on patients' pain intensity, volume of pain interventions, and opioid intake in a real-world setting.

Study Design: This study was a retrospective review of patient data.

Setting: The study was conducted at a single, community-based clinic.

Methods: Outcomes including pain relief, quality of life, opioid intake, and rate of health-care usage were evaluated using data from patients who were implanted with a 10kHz-SCS device to treat chronic pain. These outcomes were then compared for the pre- and post-implant periods.

Results: A total of 47 patients with a mean follow-up duration of 15.6 ± 6.2 months were included in this analysis. Mean pain relief was $73 \pm 22\%$ and 89% were responders at the final follow-up visit. The rate of medical interventions fell from 3.48 ± 3.05 per year before starting 10kHz-SCS to 0.49 ± 1.16 per year afterward ($P < 0.001$). Of 30 patients with available opioid consumption data, 89% maintained or decreased their intake after implant.

Conclusion: Retrospective data from a single center, with minimal exclusion criteria shows clinically significant pain relief with 10kHz-SCS, accompanied by significant indirect benefits including stable or reduced opioid use and reduced interventional procedures.

Keywords: chronic pain, pain management, spinal cord stimulation, health care costs, opioid analgesics

Introduction

Chronic pain is a common condition estimated to affect 50 million people in the US in 2016, or over 1 in 5 adults, and 19.6 million had pain that frequently limited work and life activities.¹ Chronic pain is also associated with substantial health-care costs and decreased productivity, which were valued at up to \$635 billion in 2011 or about \$2000 per American.² Non-steroidal anti-inflammatory drugs (NSAIDs) are most common first-line treatment for chronic pain, but if the pain cannot be managed with NSAIDs alone, opioid analgesics are often prescribed.³ However, there is little evidence supporting the efficacy of these drugs for treating chronic pain,^{4,5} and their long-term use can result in side effects and substance abuse disorders.⁶ Pain treatments including epidural steroid injections and nerve blocks

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have been used for chronic pain, including low back pain, but studies have shown these procedures to be ineffective over periods of a year or longer in a majority of patients.^{7–9}

To avoid increased opioid utilization in patients who are refractory to conventional medical management, physicians are beginning to focus on minimally invasive, reversible interventional treatments such as spinal cord stimulation (SCS) for certain chronic pain populations.^{10–14} High-frequency SCS delivered at a frequency of 10 kilohertz (10kHz-SCS) has also proven to be effective for treating chronic pain with multiple etiologies,^{11,15–19} and this modality possesses the added benefit of producing paresthesia-independent pain relief.²⁰ Previous research has also indicated 10kHz-SCS in patients with chronic pain is associated with maintenance, or even reductions, in opioid consumption over time.^{21,22} Many patients with chronic pain are already being treated with opioids by the time SCS is considered, so a treatment that addresses pain and simultaneously reduces or stabilizes patient risk from opioids would be doubly beneficial in this population.²³

Several reviews have been published that analyze real-world outcomes in patients with chronic pain who receive 10kHz-SCS,^{24–26} however, more data is needed to evaluate not only the direct effects of high-frequency SCS on pain but also its indirect effects on health-care utilization and opioid consumption. The objective of this retrospective review is to determine if 10kHz-SCS is effective in minimizing the requirement for opioids and reducing health-care contacts and interventions.

Methods

Study Design

This single center retrospective analysis included patients who received 10kHz-SCS therapy between January 2, 2017 and December 29, 2019 at the Neuroscience Research Center in Overland Park, Kansas. The Midlands Investigational Review Board (Lenexa, Kansas) determined that the study met the criteria for an IRB exemption under the United States Code of Federal Regulations Title 45 Part 46 and a waiver of the informed consent requirement was given for the retrospective data collection, given that extracted data was deidentified protecting patient health information. The study was in compliance with the Declaration of Helsinki. Electronic medical record (EMR) data from Kansas Pain Management's Prognosis (San Jose, California) EMR database were searched to identify patients with a diagnosis of chronic pain

who were implanted with a 10kHz SCS device (Nevro, Redwood City, California) and whose EHR included data for at least 1 month after implant and an equivalent period of time before implant. Patients were excluded if their implant was removed for any reason or if they were involved with Workman's Compensation cases.

Patient-Reported Outcomes

Self-reported data on pain intensity and quality, patient satisfaction, and quality of life were collected at baseline and at the final follow-up. Pain intensity and quality were assessed using an 11-point NRS scale with five custom items that included commonly reported neuropathic pain symptoms. Responders were defined as patients who reported $\geq 50\%$ pain relief after implant, which is a threshold used in previous studies of 10kHz-SCS.^{11,16,24,27} Patient-reported quality of life was assessed using the Quality of Life Scale published by the American Chronic Pain Association,²⁸ satisfaction was assessed on a 11-point scale, and percentage of pain relief reported using a visual analog scale. These items were collected per standard of care in our clinic to assess patient's pain and response to SCS therapy, the questionnaire is available in Supplement 1.

Healthcare Utilization

Changes in health-care utilization following implant were assessed using the number of interventional pain procedures that were recorded in patients' EHR including clinic visits, medical procedures, emergency room admissions, and surgeries. Types of medical procedures included radio-frequency ablation, medial branch block, transforaminal epidural steroid injection, and lumbar epidural steroid injection. The pre-implant procedure rate was calculated by the total pre-implant procedures recorded in the EMR divided by the months between the first clinic visit and the implant date. The post-implant procedure rate was similarly the total post-implant procedures recorded in the EMR divided by the months between the implant procedure and the database review. Finally, the total number of interventional pain procedures during the analyzed time periods was used to calculate a rate of contacts per year.

The average cost of medical procedures including radio-frequency ablation, medial branch block, transforaminal epidural steroid injection, and intralaminar epidural steroid injection was calculated using the national mean 2020 Medicare reimbursement levels. First, the mean reimbursement for ASCs, hospitals, and physicians was determined

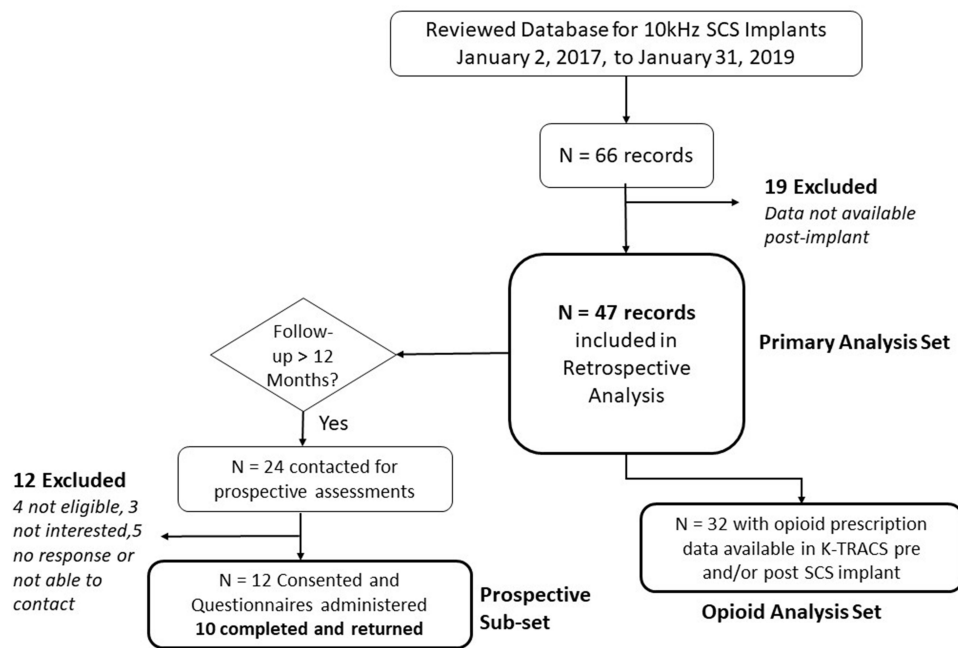


Figure 1 The selection of patient records for use in the retrospective analysis and prospective follow-up are shown in this flow chart.

based on the above-mentioned procedure types performed and were then averaged to calculate a mean procedure cost.

Opioid Consumption

Data from the EHR for each patient were combined with data from the Kansas Tracking and Reporting of Controlled Substances (K-TRACS) database to determine whether individual patients used opioid analgesics and calculate their mean daily intake.²⁹

Prospective Long-Term Follow-Up

Prospective surveys were sent to patients in the retrospective analysis who had been implanted for longer than 12 months. IRB approval was obtained to contact these patients both to get their consent to be included in the prospective analysis and to ask them to complete a questionnaire about their current pain. Individual pain scores determined by averaging the “best” and “worst” pain reported. They were also asked to complete a self-assessment with open text responses regarding activities they were not able to do before therapy versus after therapy. The prospective survey is included as Supplement 2.

Statistical Analysis

Data are presented throughout as means $\pm$ standard deviation (SD), or as a median and range, when test for normality was not met based on the Anderson-Darling test.

Significance in differences between pre- and post-implant values were calculated using a paired *t*-test for data with normal distribution and the One-Way ANOVA test when normality criteria was not met. Significant differences were defined as those with *p*-values ≤ 0.05 .

Results

Subject Demographics and Disposition

A search of the institution’s database identified EHRs for 66 patients who were implanted with 10kHz-SCS to treat a diagnosis of chronic pain from January 2, 2017, through January 31, 2019, and met all eligibility criteria. Of these, the EHRs for 47 patients included all necessary information and were included in the retrospective analysis, as shown in Figure 1. In addition, prospective surveys were sent to patients with more than 1 year since implant, and 10 patients were ultimately eligible, consented, and completed these surveys.

The demographics and baseline clinical characteristics of the 47 patients included in the analysis are summarized in Table 1. Patients ranged in age from 39 to 86 years old with a mean age of 65 years, and 27 (58%) were men. The most common areas associated with patients’ diagnoses of chronic pain were lower back (85%) and lower extremities (60%). The included patients had a mean follow-up interval of 15.6 ± 6.2 months and ranged from 2 to 28 months.

Table 1 Patient Demographics and Baseline Clinical Characteristics

Characteristics	Subjects (N=47)
Gender - n (%)	
Female	20 (42.6)
Male	27 (57.4)
Age (years) at enrollment	
Mean $\pm$ SD	64.7 (14.1)
Range	39–86
Surgery Naïve n (%)	34 (72.3)
Baseline Opioid Daily Dose (MME) (n = 32)	12.6 (9.2)
Anatomic Region of Pain^a - n (%)	
Lower back	41 (85.4%)
Lower extremities	29 (60.4%)
Upper extremities	8 (16.7%)
Buttocks/hip	8 (16.7%)
Thoracic	2 (4.2%)
Abdominal	2 (4.2%)
Head/neck	4 (8.3%)

Note: ^aSubjects may have multiple diagnosis.

Abbreviations: SD, standard deviation; VAS, Visual Analog Scale.

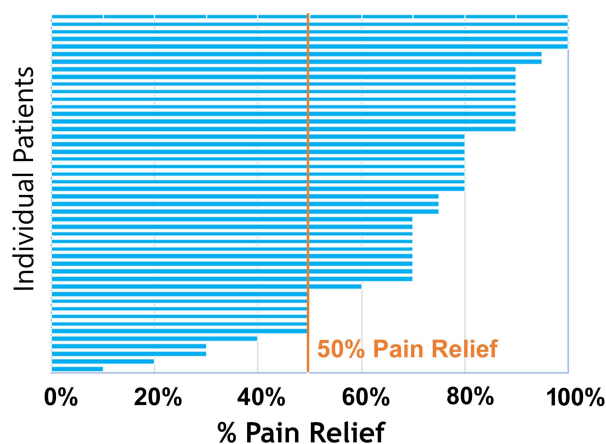
Pain

Post-implant pain relief was calculated using patient-reported pain intensity scores at last follow-up relative to baseline scores and is shown in Figure 2A. In total, 42 subjects (89%) were responders at last follow-up, and mean pain relief was $73\% \pm 22\%$, including 23 patients who reported $>80\%$ pain relief. Self-reporting by patients at the last follow-up visit also revealed significant reductions in multiple domains of pain relative to baseline, as shown in Figure 2B.

Healthcare Utilization

Data on all interventional pain procedures were analyzed for each patient and included procedures such as radio-frequency ablation, medial branch block, transforaminal epidural steroid injection, and lumbar interlaminar epidural steroid injection. The mean rate of medical interventions in this patient sample declined from a mean rate of 3.48 ± 3.05 interventions per year before implantation to 0.49 ± 1.16 interventions per year after implantation (One-way ANOVA, $p < 0.001$), a decline of 86% (Figure 3). The estimated cost savings for medical procedures only was calculated using 2020 Medicare reimbursement levels, and calculating a weight mean procedure cost for before and after SCS implant based on the proportion of different

A



B

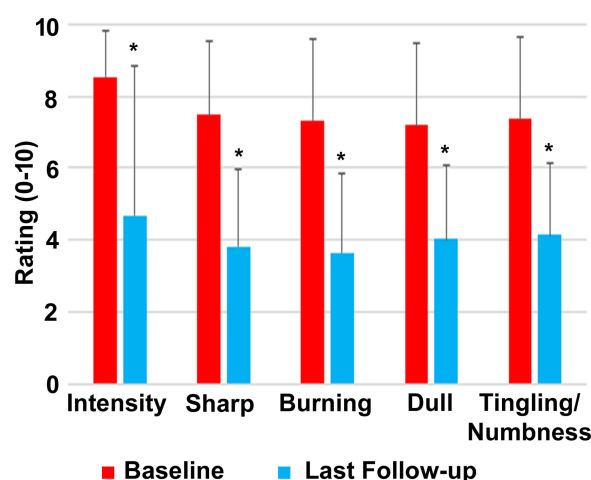


Figure 2 The pain relief associated with 10 kHz SCS was calculated from patient-reported pain scores collected before implant and at the last follow-up. **(A)** The tornado plot shows the individual scores for each patient, relative to the 50% threshold that defined responders and non-responders. **(B)** Mean ($\pm$ SD) pre- and post-implant scores in multiple pain domains. As indicated by the (*), all domains were significantly different pre and post implant using the One-Way ANOVA test to compare means.

procedures that were performed. This resulted in a weighted mean procedure cost of \$838.00 pre-implant and \$790.83 post-implant due to a reduction in the frequency of use of the more expensive RFA procedure post-implant (Supplemental Table 1), which translates to approximate savings of \$2528.74 per year per patient.

Opioid Consumption

Data on opioid use was obtained from the K-TRACS registry, which was available for 32 patient records. Among these patients, 28 (88%) decreased their daily opioid dose or remained on a stable dose of opioids from the pre- to the post-implant period, while daily opioid dose increased in 4 patients (13%) as shown in Figure 4A. None of the patients

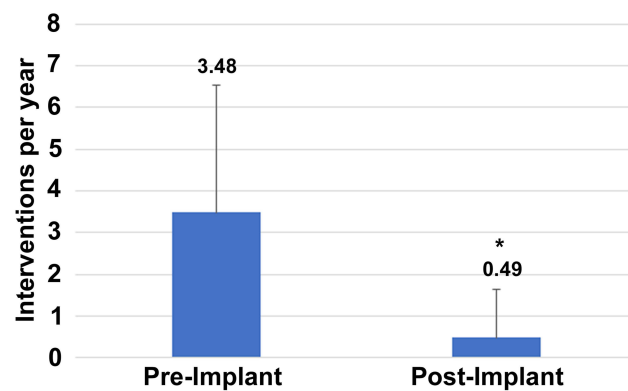


Figure 3 Patients' mean rate of medical interventions per year ($\pm$ SD) is shown before and after implant of the 10 kHz SCS device, with (*) indicating statistically different (One-way ANOVA, $p < 0.001$).

whose opioid consumption increased was taking more than 20 milligrams morphine equivalent (MME) by the last follow-up, and of 5 patients taking opioid doses of ≥ 20 MME daily before implant, 4 reduced their daily consumption under 20 MME by the last follow-up. The distribution of opioid doses among these 32 patients is shown in Figure 4B. The mean opioid dose was not significantly reduced following SCS implant with a change from an average of 9.6 ± 13.4 to 7.0 ± 9.3 MME ($p = 0.310$).

Quality of Life and Patient Satisfaction

Patients' quality of life was assessed at the most recent visit using the Quality of Life Scale,²⁸ a descriptive scale with responses reported in whole numbers from completely non-functioning (0) to a normal quality of life (10). Among this patient population, the median response was 8, and responses ranged from 3 to 10. The results are summarized in Figure 5A and show that 34 patients (74%) reported quality of life scores of ≥ 7 , which indicates they were able to participate

in work, home, and social activities. Patient satisfaction was reported using a scale with a minimum score of 1, meaning not satisfied at all, and a maximum of 10, meaning extremely satisfied. The distribution of responses from patients in this sample is shown in Figure 5B, including 23 patients (49%) who reported satisfaction scores of 9 or 10, more than double the proportion who reported satisfaction scores of ≤ 6 .

Prospective Assessments Regarding Long-Term Pain Relief

A total of 10 eligible patients had follow-up intervals of at least 12 months and responded to a prospective follow-up survey (Figure 1). The mean follow-up interval among this group was 20.8 ± 2.3 months, and their mean pain relief was 62%. All 10 were responders ($\geq 50\%$ pain relief), and 4 reported decreases in pain of 80% or more. Six out of 10 reported sustained improvement in function with at least one activity they can do now that they could not do prior to therapy. Results are shown in Supplemental Table 2.

Discussion

There is currently an unmet need for safe and effective treatment options for chronic pain. Multiple prospective clinical studies have been published demonstrating the efficacy of 10 kHz SCS,^{30–34} and observational data from community pain centers can add useful information on how this intervention affects real-world patient outcomes. However, previous observational, retrospective studies of patients treated with 10kHz-SCS for chronic pain have included limited sample sizes and shorter follow-up intervals than the prospective studies.^{24,25,35}

Patients eligible for this retrospective review included all those at our institution who were treated with 10kHz-SCS for chronic pain, regardless of the cause, and we found significant

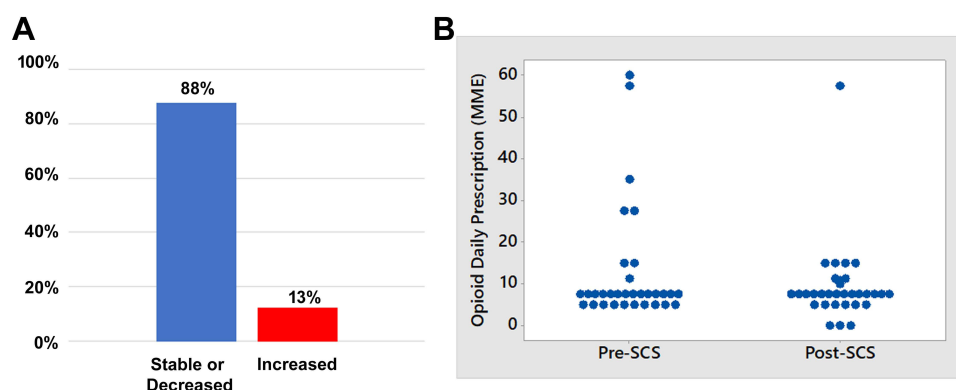


Figure 4 The changes in patient opioid consumption after implant is shown in (A). (B) Shows, the pre- and post-implant distributions of opioid consumption in the patient sample.

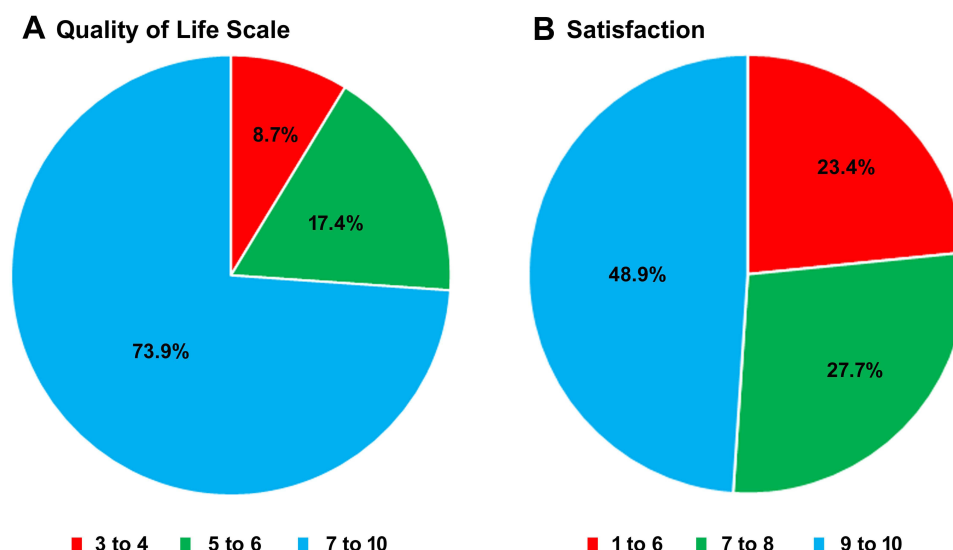


Figure 5 Patient-reported scores for quality of life and satisfaction. **(A)** Quality of life as assessed at the last follow-up using the “Quality of Life Score” (American Chronic Pain Institute). Ranges from 0: “stay in bed all day. Feel hopeless and helpless about life”, to 10: “Go to work/volunteer each day. Normal daily activities each day. Have a social life outside of work. Take an active part in family life.” **(B)** Reported satisfaction with the therapy (scale of 1 to 10), 1 = Not Satisfied at all, to 10 = Extremely Satisfied.

and long-lasting reductions in patient-reported pain intensity after the initiation of stimulation. The mean pain relief of 73% and responder rate of 89% after a mean stimulation time of over 15 months compare favorably with results from previous clinical and real-world studies of 10 kHz SCS for treating chronic, refractory pain. The pivotal SENZA-RCT study and the prospective SENZA-EU study both reported pain relief in the back and legs ranging from 63% to 70% after 12 months of stimulation and responder rates from 65% to 79%.^{11,27} Other prospective studies reported similar results after 1 year of stimulation, including 72% pain relief and a responder rate of 90% in subjects with inoperable back pain¹⁵ and 82% pain relief and a 88% responder rate in patients with chronic post-surgical pain.¹⁶ In similar real-world studies, the much larger review by Stauss et al reported 63% pain relief and a responder rate of 74% after a mean treatment interval of less than 9 months,²⁴ while another single-center review reported pain relief of 46% to 51% after 12 months of stimulation.²⁵

It is important to consider cost as part of evaluating any new treatment for chronic pain, particularly in light of the expensive nature of chronic pain, which has been estimated to cost the US economy from \$560 billion to \$635 billion every year in direct health-care expenditures as well as lost productivity and reduced time at work.² Recent reviews have concluded that SCS is a cost-effective option for treating patients with chronic, neuropathic low back pain,^{36,37} and although such a cost analysis was beyond the scope of this retrospective study, the estimated savings for each patient in this study due to reduced medical procedures alone was

approximately \$2500 per patient per year conservatively based on Medicare reimbursement.

We used the volume of interventional pain procedures as a proxy for health-care usage to indirectly examine the issue of cost. The number of procedures we observed during the post-implant period in this real-world patient population was substantially reduced from pre-implant levels, and are broadly similar to findings in previous real-world, single-site studies of 10 kHz SCS, which have found reductions of 39% to 84% in medical pain interventions such as epidural steroid injections, facet joint injections, radiofrequency ablations, and major joint injections following implant.^{25,38,39} EMR review allowed us to examine the type of procedures that were provided pre and post SCS implant, and showed the proportion of the more expensive RFA procedure decreased from 14.0% to 9.6%, while the frequency of the less expensive trigger point injection increased from 1.7% to 38.7%, which also contributes to cost reduction. Our results further support the conclusion that 10kHz-SCS can help to reduce health-care costs despite a larger initial investment by reducing follow-up care necessary for treating chronic, refractory pain with various etiologies.

It is also important to consider the effect of new, non-pharmacologic treatments for chronic pain on opioid consumption. The long-term use of opioids to treat chronic pain is associated with many risks, and guidelines from the Centers for Disease Control and Prevention recommend minimizing their use to the extent possible to reduce the danger to patients.^{40,41} Previous studies with 10 kHz SCS have shown

stimulation is associated with stable or decreasing opioid consumption in patients with chronic pain,^{15,21,25,42–45} and our results likewise revealed stable or decreasing daily opioid doses in 89% of patients. Nearly a quarter decreased their opioid use, despite the lack of an active protocol of opioid reduction, supporting evidence that 10 kHz SCS could be an important tool in reducing opioid use in chronic pain patients. It is important to note that the risks presented by opioids increase in a dose-dependent manner,⁴¹ and 4 of the 5 patients in our study taking doses of more than 20 MME per day before implant reduced their intake below this threshold in response to 10kHz-SCS, which has been shown to reduce the risk of overdose and opioid-related mortality.^{46–48} Conversely, the 4 patients who increased their opioid intake during the study period were already at relatively low doses, and none increased their intake above 20 MME. The low average daily opioid prescription for our patients may be due to the fact that we attempt to wean them from high doses of opioids before considering SCS.

Limitations

This study was limited by its retrospective design and lack of randomization or control group, which could introduce bias into patients selected for treatment. The possibility of bias is partially mitigated by the use of broad eligibility criteria that included all patients who were implanted with a 10kHz-SCS device at the institution during the time period of interest, regardless of the cause of their chronic pain. Although there was no control group, the chronic nature of the patients' pain means spontaneous recovery is unlikely and increases confidence that the observed, durable pain relief is associated with treatment. The study was also limited by its small size, and that the HCU data was collected through a retrospective EMR review, therefore patient recall was therefore not a factor. ER visits were included that were recorded in EMR which were generally pain-related visits. There was no attempt to determine if additional ER visits occurred that were not in the patient's EMR. Office visits for healthcare outside of the clinical practice (such as physical therapy) were not analyzed. The patient's interventional pain management was exclusively at Kansas Pain Management. Pain meds may have been prescribed by other care providers but the information for opioid use was extracted from KTRACS which is practice independent since it is based on state gathered prescription records. Another limitation is the small number of patients who we were able to contact and obtain consent to participate in prospective surveys makes those reported outcomes difficult to interpret except qualitatively. Finally, we produced an estimate

of cost savings associated with reduced rates of interventional pain procedures in patients following initiation of 10kHz-SCS; however, a detailed cost analysis was beyond the scope of this review.

Conclusions

This retrospective review included data from patients at a single center who had chronic pain and were treated with 10kHz-SCS. Patients were selected using expansive eligibility criteria to include patients with pain in a variety of body regions and without regard to the etiology of the pain. The results show clinically significant and durable pain relief after the implant of the 10kHz-SCS device. In addition, we observed significant indirect benefits of treatment with 10kHz-SCS, including fewer interventional pain procedures as well as stable or reduced opioid use.

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