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Cost-effectiveness of 10-kHz spinal cord stimulation therapy compared with conventional medical management over the first 12 months of therapy for patients with nonsurgical back pain: randomized controlled trial

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OBJECTIVE This analysis evaluated if spinal cord stimulation (SCS) at 10 kHz plus conventional medical management (CMM) is cost-effective compared with CMM alone for the treatment of nonsurgical refractory back pain (NSRBP).

METHODS NSRBP subjects were randomized 1:1 into the 10-kHz SCS (n = 83) or CMM (n = 76) group. Outcomes assessed at 6 months included EQ-5D 5-level (EQ-5D-5L), medication usage, and healthcare utilization (HCU). There was an optional crossover at 6 months and follow-up to 12 months. The incremental cost-effectiveness ratio (ICER) was calculated with cost including all HCU and medications except for the initial device and implant procedure, and cost-effectiveness was analyzed based on a willingness-to-pay threshold of < $50,000 per quality-adjusted life-year.

RESULTS Treatment with 10-kHz SCS resulted in a significant improvement in quality of life (QOL) over CMM (EQ-5D-5L index score change of 0.201 vs −0.042, $p < 0.001$) at a lower cost, based on reduced frequency of HCU resulting in an ICER of −$4964 at 12 months. The ICER was −$8620 comparing the 6 months on CMM with postcrossover on 10-kHz SCS.

CONCLUSIONS Treatment with 10-kHz SCS provides higher QOL at a lower average cost per patient compared with CMM. Assuming an average reimbursement for device and procedure, 10-kHz SCS therapy is predicted to be cost-effective for the treatment of NSRBP compared with CMM within 2.1 years.

Clinical trial registration no.: NCT03680846 (ClinicalTrials.gov)

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KEYWORDS low-back pain; cost benefit; spinal cord stimulation

Low-back pain is a leading cause of disability.[1] Patients with chronic low-back pain have more comorbidities and higher healthcare costs than those without.[2] Current nonsurgical treatments for chronic low-back pain include pharmacological treatments, physical therapy, and injections. However, these treatments may have limited efficacy, without providing lasting relief.[1,3]

Spinal cord stimulation (SCS) is electrical stimulation of the spinal cord primarily used to provide relief of chronic pain.[4] Since its introduction in 1967,[5] SCS has gained widespread acceptance for the treatment of many chronic pain conditions.[6] One such condition is chronic low-back pain. The traditional stimulation parameters for SCS include frequencies between 30 and 120 Hz, but there is a growing body of evidence that high-frequency (10-kHz) SCS may produce greater pain reduction without the adverse side effect of paresthesia.[7] Most of the high-level evidence for SCS has supported treating chronic low-back

ABBREVIATIONS CMM = conventional medical management; CPT = Current Procedural Terminology; EQ-5D-5L = EQ-5D 5-level; FDB = First Databank; HCU = healthcare utilization; ICER = incremental cost-effectiveness ratio; IPG = implantable pulse generator; NSRBP = nonsurgical refractory back pain; ODI = Oswestry Disability Index; PGIC = Patient Global Impression of Change; PRO = patient-reported outcome; QALY = quality-adjusted life-year; QOL = quality of life; SCS = spinal cord stimulation; VAS = visual analog scale; WAAMP = Weighted Average of Average Manufacturer prices.

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pain that is postsurgical,[5] while limited evidence had supported SCS therapy for refractory back pain in patients who have not had previous spine surgery.[8,9] Nonsurgical refractory back pain (NSRBP) refers to chronic neuropathic pain that is refractory to conventional medical management (CMM) among surgically naive patients who are not spine surgery candidates.[10] The recently published 12-month results from a multicenter randomized controlled trial demonstrated improved outcomes for pain relief, function, and quality of life (QOL) with 10-kHz SCS therapy compared with CMM alone.[11]

With increasing healthcare costs, it is important to determine the cost benefit of treatments for chronic low-back pain. Low-frequency and 10-kHz SCS have been found to significantly reduce costs when compared with CMM for chronic low-back pain, specifically in postsurgical low-back pain.[12–15] However, there are few analyses of prospectively collected healthcare utilization (HCU) data with 10-kHz SCS, and there has been no analysis specifically in the NSRBP population.

Methods

The design of the NSRBP randomized controlled trial was previously reported by Patel et al.[10] Enrollment began in September 2018 for the multicenter, prospective, randomized study examining clinical efficacy, safety, and cost-effectiveness of 10-kHz SCS in addition to CMM versus CMM alone in subjects with NSRBP. The primary inclusion criteria were having chronic, refractory back pain, not being an acceptable surgical candidate as assessed by a surgeon, and no previous spine surgery (complete listing in Supplementary Table 1). The "refractory" criterion means that all patients had undergone nonoperative treatment and did not achieve therapeutic goals prior to randomization.

The Senza SCS system (Nevro Corp.) is an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with intractable low-back pain and leg pain,[16] with specific labeling for management of NSRBP. The system was programmed to high-frequency (10-kHz) electrical stimulation of the spinal cord via two implantable percutaneous leads and an implantable pulse generator (IPG).[17]

The choice of appropriate CMM was made by the investigator to be the best standard of care for each individual patient. These conservative measures could include medications, physical therapy, and interventional procedures such as radiofrequency ablation, steroid injections, and nerve blocks. Appropriate interventional procedures were tried prior to enrollment in the study, and ongoing beneficial treatments were continued as needed.

A total of 15 study centers in the US participated. Enrollment began in September 2018 and was completed in January 2020, with patients being followed for a 12-month period after baseline assessment. The protocol was amended to include an observational study extension to 24 months after baseline assessment or crossover, which required additional patient consent and is ongoing. Patients were randomized 1:1 to one of two study treatment groups: 10-kHz SCS therapy plus CMM (referred to as 10-kHz SCS) or CMM alone. Patients in either treatment group were given the option to cross over to the other treatment arm at the 6-month visit if they met all the following criteria: < 50% back pain relief from baseline, documented dissatisfaction with the treatment, and investigator agreement. For subset analyses, crossover patients were identified as "crossovers."

The sample size was determined as previously described,[10] and 211 patients were enrolled in the study (for complete patient disposition, see Fig. 1 in the study by Kapural et al.[11]). Fifty-two patients did not meet inclusion criteria; 159 patients were randomized 1:1 to either the CMM (n = 76) or 10-kHz SCS (n = 83) treatment group. Assignment of interventions was as previously described.[10] Of 83 patients randomized to the 10-kHz SCS group, 83.1% (69/83) underwent implantation of the permanent SCS system. None of the patients in the 10-kHz SCS group elected to cross over to the CMM group, whereas 86.6% (65/75) elected to cross over from the CMM group to the 10-kHz SCS group at 6 months. Study retention was high, with 121 of 125 patients (96.8%) remaining in the study through the 12-month follow-up (Fig. 1).[11] Safety outcomes were previously reported.[11]

The trial protocol[10] and data reporting followed Consolidated Standards of Reporting Trials (CONSORT) guidelines.[18] The included outcomes were in line with the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) guidelines.[19] The trial was registered at ClinicalTrials.gov (registration no. NCT03680846) prior to patient enrollment. Both the protocol and informed consent were approved by the Western Institutional Review Board and local site IRBs as appropriate.

Patient-reported outcomes (PROs) that made up the primary and secondary endpoints were back pain as reported on a visual analog scale (VAS), Oswestry Disability Index (ODI), EQ-5D 5-level (EQ-5D-5L) instrument, Patient Global Impression of Change (PGIC), and daily opioid diary were assessed as previously described.[11]

HCU and Medication Usage Costs

Along with recording PROs, health economic outcome measures since last visit were recorded for each patient at 1-, 3-, 6-, 9-, and 12-month visits. The economic outcome measures consisted of two categories of utilization: HCU and medication usage.

Healthcare Utilization

HCU included office visits, emergency department visits, hospital admissions, medical tests, and surgical procedures related to the condition being treated with 10-kHz SCS or CMM therapy. Current Procedural Terminology (CPT) codes[20] for each of the HCUs were approximated as listed in Supplementary Table 2. HCU did not include utilization unrelated to the condition being treated with 10-kHz SCS or CMM therapy (e.g., podiatrist visits, anterior cruciate ligament repair, and COVID-19 tests) or any costs associated with the SCS trial procedure or the permanent SCS device implant procedure. The average costs associated with the CPT codes (Supplementary Table 2) were subsequently determined from the commercially

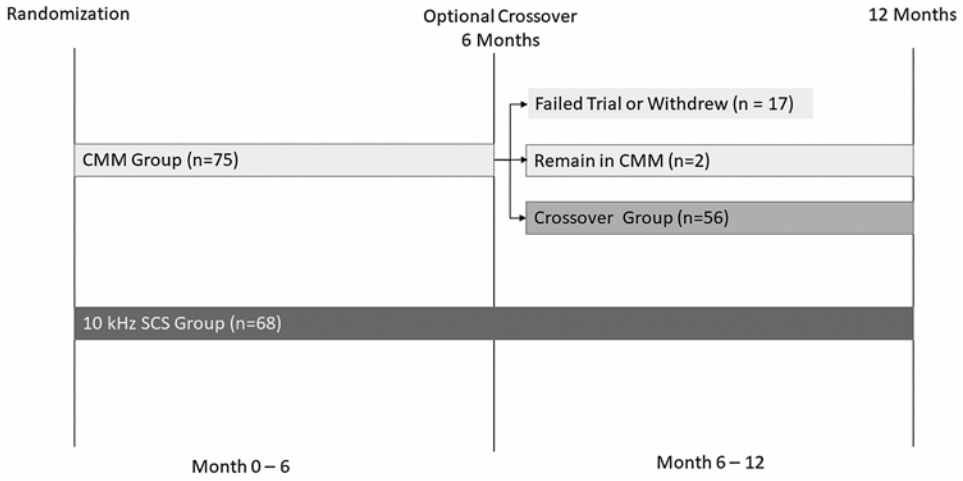

FIG. 1. Schematic of treatment groups. The numbers shown are the patients in each group who were part of the per-protocol primary endpoint analysis at 3 months (75 patients in the CMM group and 68 of the 69 patients in the 10-kHz SCS group). All 56 patients who underwent implantation as part of the crossover group and 65 patients in the 10-kHz SCS group remained in the study at 12 months. At 12 months, 64 patients were included in the per-protocol analysis in the 10-kHz SCS group because of 1 missed visit.

available PearlDiver database (PearlDiver Technologies). PearlDiver derived the average HCU costs using 5 sources of payer data (commercial, Medicare, Medicaid, government, and cash pay) for healthcare claims within the period from January 1, 2010, to October 31, 2020. Using the HCU-determined costs, the average HCU cost per patient was thus determined for 0–6 months (CMM, 10-kHz SCS, and crossover groups) and 6–12 months (10-kHz SCS and crossover groups). Standard deviation and group sizes were also reported.

Medication Usage

Medication usage included medications taken by each patient directly related to the condition or symptoms treated with 10-kHz SCS or CMM therapy and was recorded in two ways. 1) For patients taking opioids, patients recorded their exact daily opioid usage (opioid name, dose, and consumed units) in an opioid diary during participation in the study. Opioid-using patients who were put on a regimen of buprenorphine or buprenorphine derivatives had their opioid usage removed from the analysis, as buprenorphine is used for opioid addiction. Thus, the costs associated with opioid usage for these specific patients could falsely skew the average medication usage. 2) For patients not taking opioids, patients' nonopioid mediation usage (medication name, dose, consumed units, and start/end date of consumption) was recorded at each visit in a medication log covering the period from their last visit to the current visit.

Medication costs were derived as Weighted Average of Average Manufacturer prices (WAAMP) using the commercially available First Databank (FDB) database (First Databank, Inc.). The FDB database is continuously updated, and thus the medication cost estimates were derived from the database as of November 30, 2021. To remove potential bias across prescribers, an average WAAMP was taken of generic and brand name medications. The average medication usage cost per patient was determined for 0–6 months (CMM, 10-kHz SCS, and crossover groups), and 6–12 months (10-kHz SCS and crossover groups). Standard deviation and group sizes were also reported.

Total Costs

The total average cost per patient for 0–6 months and 6–12 months was derived by adding the average HCU cost and the average medication usage cost. The total average cost was determined for the following groups and time periods: 1) the CMM group at 0–6 months; 2) the 10-kHz SCS group at 0–6 and 6–12 months; 3) the crossover group at 0–6 months (precrossover) and 6–12 months (postcrossover); and 4) the 10-kHz SCS group (at 0–6 months) plus the crossover group (at 6–12 months postcrossover). Note that the latter group is similar to the 10-kHz SCS group at 0–6 months, as the patient is experiencing their first 6 months of 10-kHz SCS treatment.

The primary analysis excluded the cost of the device and the initial SCS trial and implant procedure from the overall HCU cost. This analysis only examined the initial and short-term cost benefit based on immediate HCU and medication usage. Because of variability in the device cost, the cost-effectiveness would be distorted in the short-term, concealing the cost effects of medication and general HCU after SCS treatment start. The values are reported that allow the reader to evaluate the incremental cost-effectiveness ratio (ICER) and therefore time to cost-effectiveness for any device, initial trial, and implant procedure cost.

Incremental Cost-Effectiveness Ratio

Using the EQ-5D-5L QOL index scores and the derived total average HCU/medication cost per patient, the ICER will be determined between the 10-kHz SCS and CMM therapies.

Specifically, the ICER was calculated as follows: ICER = (total average cost #1 − total average cost #2)/(QOL #1

TABLE 1. Patient and baseline clinical characteristics

	10-kHz SCS (n = 83)	CMM (n = 76)
Female sex, n (%)	50 (60.2)	40 (52.6)
Age in yrs, mean (SD)	54.5 (12.1)	56.2 (11.6)
BMI in kg/m^2, mean (SD)	31.9 (6.6)	30.8 (6.5)
Race, n (%)*		
White	75 (90.4)	73 (96.1)
Black or African American	4 (4.8)	2 (2.6)
American Indian or Alaska Native	2 (2.4)	1 (1.3)
Asian	2 (2.4)	0 (0)
Native Hawaiian or other Pacific Islander	1 (1.2)	0 (0)
Other	1 (1.2)	0 (0)
Pain etiology, n (%)*		
Degenerative disc disease	60 (72.3)	52 (68.4)
Internal disc disruption/annular tear	8 (9.6)	6 (7.9)
Spondylosis	55 (66.3)	49 (64.5)
Lumbar facet–mediated pain	24 (28.9)	25 (32.9)
Radiculopathy	34 (41.0)	35 (46.1)
Mild/moderate spinal stenosis	23 (27.7)	24 (31.6)
Spondylolisthesis	7 (8.4)	9 (11.8)
Sacroiliac dysfunction	3 (3.6)	5 (6.6)
PROs, mean (SD)		
VAS	7.40 (1.15)	7.23 (1.02)
ODI	47.2 (10.9)	47.4 (10.8)
EQ-5D-5L	0.579 (0.121)	0.558 (0.130)
Opioid daily dose, mean MME (SD)	45.4 (47.5)	32.0 (29.2)

MME = morphine milligram equivalents.
* Patients may have more than one race and more than one pain etiology.

× duration − QOL #2 × duration), where #1 is group 1, and #2 is group 2, as indicated in the subsequent ICER comparison table.

The following comparisons were done: 1) 10-kHz SCS vs CMM (time frame: first 6 months); 2) 10-kHz SCS versus CMM (time frame: 12 months; the latter group was projected to maintain 0- to 6-month QOL and average HCU/medication costs out to 12 months); 3) crossovers (6–12 months) versus crossovers (0–6 months) (time frame: 6 months; note that the first group used 10-kHz SCS, while the latter did not [i.e., the patients were part of the CMM group before crossing over to 10-kHz SCS therapy]); and 4) 10-kHz SCS (0–6 months) plus crossovers (6–12 months) versus CMM (time frame: first 6 months; note that the former group consisted of two subgroups as the crossover subgroup at 6–12 months) was equivalent to the 10-kHz SCS subgroup at 0–6 months, as the patients experienced their first 6 months of 10-kHz SCS treatment).

The derived ICER for each comparison was then compared with the cost-effectiveness threshold (willingness to pay), which has been determined to be for ICER < $50,000 per quality-adjusted life-year (QALY).[21,22] Additionally, the ICER was compared with scenarios (Supplementary Table 3) within the cost-effectiveness plane.[23,24] An analysis that includes cost of the device and implant procedures using the average Medicare payment for an SCS permanent implant at a hospital[25] is also reported. This cost-effectiveness calculation uses scenario 1 (Supplementary Table 3), with group 1 being "10-kHz SCS total average costs in months 0–6," and group 2 being "CMM total average costs in months 0–6." The QOL change from baseline through 6 months is assumed to stay stable.

Results

Of 211 enrolled patients, 159 were randomized into either the 10-kHz SCS group (n = 83) or the CMM group (n = 76), as shown in Table 1. At baseline, the two treatment groups were similar in terms of age, sex, race, mean pain scores (VAS), ODI, EQ-5D-5L, and time since diagnosis. The top three reasons for screening failure after enrollment were failing the psychological evaluation, back pain below 5 cm on the VAS, and evaluation by a spine surgeon resulting in a recommendation for spine surgery.

The primary endpoint was met with a superior responder rate in the 10-kHz SCS group at 3 months (Supplementary Table 4),[11] and the secondary endpoints related to ODI, pain relief, PGIC, QOL, and opioid reduction were all met at 6 months (Supplementary Table 5).[11] Importantly, the responder rate was 80.0% (52/65) in the 10-kHz SCS group compared with 2.7% (2/75) in the CMM group at 6 months. Responder rates were accompanied by a significant QOL improvement in the 10-kHz SCS group, while no change occurred in the CMM group (0.201 ± 0.126 vs −0.042 ± 0.144, $p < 0.001$). Treatment with 10-kHz SCS also significantly improved disability scores (ODI), percentage relief of back pain, PGIC, and QOL, and significantly reduced opioid daily use by the 6-month follow-up (Supplementary Table 5).[11] All improvements were stable through 12 months (Fig. 2). Reported PGIC was "Better" or "A great deal better" for 46 (72%) of the 64 patients in the 10-kHz SCS group with follow-up at 12 months. The outcomes in the 10-kHz SCS group were not different between the first and second 6 months of follow-up (Supplementary Table 6).

CMM patients who crossed over to 10-kHz SCS therapy also saw significant improvements in pain, disability, and QOL scores at 3 and 6 months postcrossover (Fig. 2 and Supplementary Table 7). Of the 19 CMM patients who did not cross over, 17 failed the trial or withdrew consent, and only 2 remained in the study, providing insufficient data to use for comparisons to the 10-kHz SCS group (Fig. 1).

Based on the HCU reported at each visit, the most frequent HCUs were doctor visits for pain management (130%; i.e., more than one visit per patient within the examined periods), general primary care physician visits (30%), or injections (31%; including epidural, sacroiliac joint, lumbar nerve blocks, caudal, lumbar epidural steroid, trigger point, and caudal/bursa) (Table 2). Injection frequency was favorable for the 10-kHz SCS group compared with the CMM group (8% vs 24% within the first 6 months, $p = 0.0083$). This pattern was repeated for the crossover group when 10-kHz SCS commenced (23% before SCS vs 9% after SCS start, $p = 0.0394$). The frequencies of lead and IPG revisions in the combined 10-kHz SCS and crossover groups was 5% and 3%, respectively, overall (Table 2).

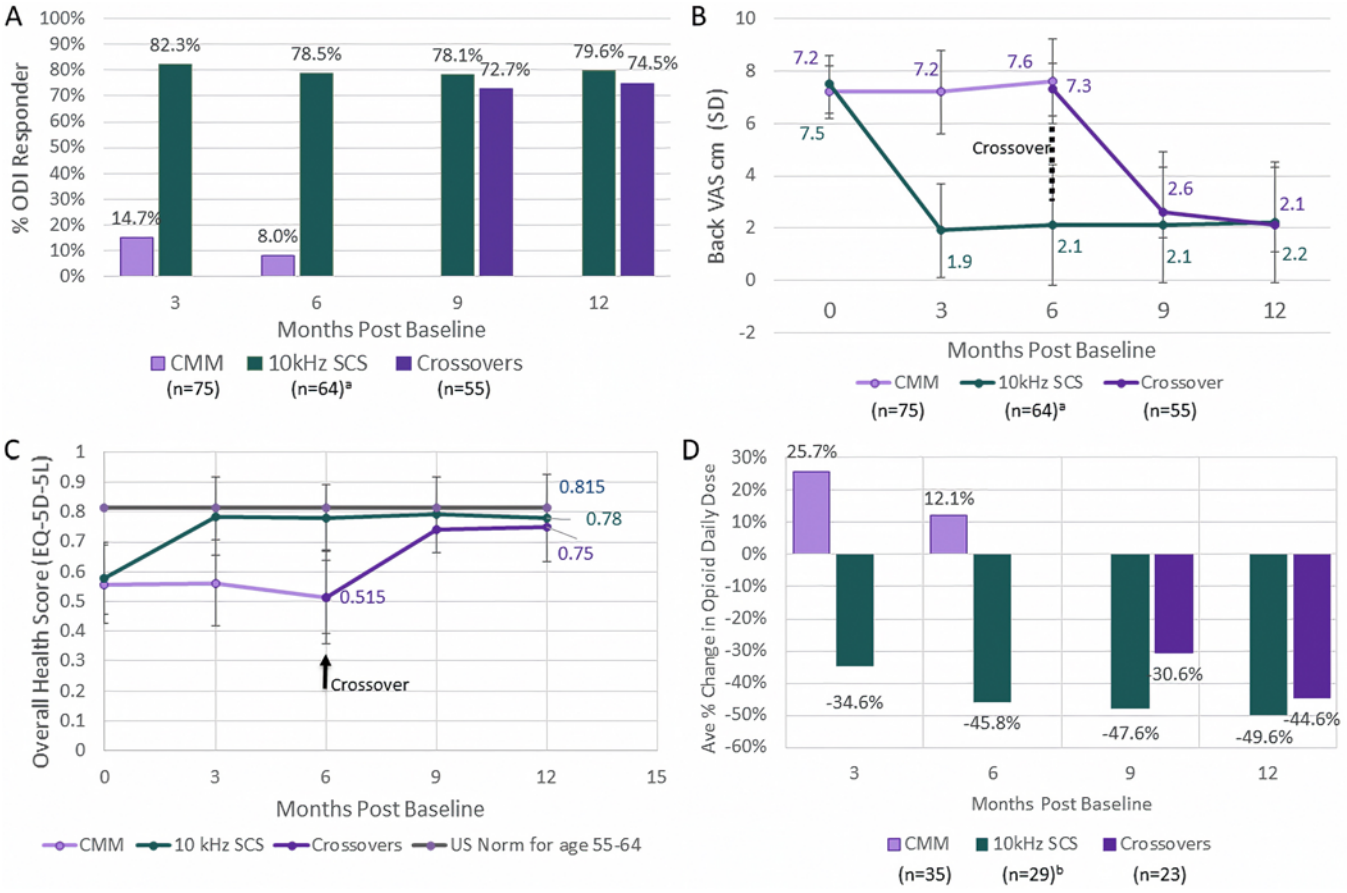

FIG. 2. The 10-kHz SCS arm outcomes are shown to 12 months and the crossover arm to 6 months postcrossover, including functional improvement based on ODI responder (at least 10-point reduction or score ≤ 20) (**A**), back pain (**B**), QOL from the reported EQ-5D-5L index score (**C**), and opioid use (**D**). [a]Sample size shown is 12 months per protocol; at 3 months, n = 68; at 6 months, n = 65; and at 9 months, n = 64. [b]Sample size shown is 12 months per protocol; at 3 months, n = 31; at 6 months, n = 30; and at 9 months, n = 30. Ave = average. Figure is available in color online only.

The highest ranked medications in terms of dollars spent per patient (Supplementary Table 8) indicated that nonnarcotic neuromodulating pain medications (duloxetine, pregabalin, and gabapentin) and narcotics (oxycodone/acetaminophen and hydrocodone/acetaminophen) were the primary drivers for medication costs, with an average expenditure per patient ranging from $131 to $519.

For the cost-benefit analysis, it was noted that 1 patient (in the crossover group) had significantly increased opioid usage for cancer-related pain following crossover. Because

TABLE 2. Highest frequency HCU among patients

	Subgroup					
	CO (0–6 mos)	CO (6–12 mos)	CMM (0–6 mos)	10-kHz SCS (0–6 mos)	10-kHz SCS (6–12 mos)	10-kHz SCS (0–6 mos) + CO (6–12 mos)
Doctor's visit, pain management	64%	57%	67%	64%	41%	61%
Injections*	23%	9%	24%	8%	7%	9%
Doctor's visit, PCP	20%	7%	18%	13%	8%	11%
Lead revision/reposition	0%	4%	0%	6%	0%	5%
IPG revision/reposition	0%	7%	0%	0%	0%	3%
IPG explant	0%	2%	0%	2%	0%	2%
Lead explant	0%	0%	0%	0%	0%	0%

CO = crossover; PCP = primary care physician.
* Injections included epidural injection, sacroiliac joint injection, lumbar nerve block, caudal injection, lumbar epidural steroid injection, trigger point injection, and caudal/bursa injection.

TABLE 3. Cost summary

	0–6 Mos			6–12 Mos		
	Mean	SD	No. of Pts	Mean	SD	No. of Pts
HCU costs						
CMM	$984	$1,576	76	NA	NA	NA
CO	$1,231	$1,759	56	$843	$2,112	56
10-kHz SCS	$656	$1,575	83	$511	$1,624	83
Medication costs						
CMM	$2,820	$3,271	74	NA	NA	NA
CO	$2,836*	$3,526	54	$2,421*	$3,348	54
10-kHz SCS	$2,851	$3,588	61	$2,275	$3,332	61
		Mean			Mean	
Total costs†						
CMM		$3,804			NA	
CO		$4,067			$3,264	
10-kHz SCS		$3,507			$2,785	
10-kHz SCS + COs (post-SCS)		$3,386			NA	

NA = not applicable; pt = patient.
* Significant difference between groups indicated (p = 0.03).
† HCU + medication.

of the potential for skewing medication usage data, opioid usage for this patient was excluded.

The direct cost analysis (Table 3) shows that total average cost (HCU plus medication costs), while numerically lower for the 10-kHz SCS plus crossover group compared with the CMM group, did not statistically differ between groups. This is attributed to the large standard deviations within each group. The majority of the total average cost was driven by medication costs, as major HCU expenses (interventional pain management or surgical SCS revisions) were infrequent. Despite this, it should be noted that the HCU costs for months 0–6 trended lower for the 10-kHz SCS group compared with the CMM group (p = 0.19) (Supplementary Fig. 1). This was likely driven by interventional pain medicine, such as injections. Overall medication costs for the 10-kHz SCS group at 0–6 months and at 6–12 months did not differ from the CMM group (Supplementary Fig. 2), despite the significant opioid reduction in the 10-kHz SCS group. This may be partially due to a higher average opioid daily dose (mean morphine milligram equivalents) at baseline for the 10-kHz SCS group compared with the CMM group (45.4 [SD 47.5] vs 32.0 [SD 29.2], p = 0.14).

When comparing HCU and medication cost before and after implant for the crossover patients, we found significant reductions in medication costs (p = 0.03; Supplementary Fig. 3), while HCU costs were trending lower (p = 0.32; Supplementary Fig. 4) following the start of 10-kHz SCS treatment. Once the crossover group initiated 10-kHz SCS treatment, the average HCU cost was reduced by 32% (Supplementary Fig. 4).

Using QOL (Table 4) and total average cost (Table 3), the ICER (Table 5) shows that over the first 6 and 12 months of therapy, 10-kHz SCS therapy is a highly cost-effective and/or the dominant therapy compared with CMM. The ICER for 10-kHz SCS therapy is significantly below the willingness-to-pay threshold because 10-kHz SCS therapy provides a combination of clinically significant improvement in QOL at a lower average cost per patient over 12 months. A within-group comparison between the 6 months before and after 10-kHz SCS treatment for the crossover group also found that 10-kHz SCS therapy was a dominant therapy compared with CMM. Additional subset analyses showed that over the first 6 months of 10-kHz SCS therapy, it is a dominant therapy compared with CMM.

TABLE 4. EQ-5D QOL summary

	Mos 0–6			Mos 6–12		
	Mean	SD	No. of Pts	Mean	SD	No. of Pts
CMM	0.515	0.155	75	NA	NA	NA
CO	0.563	0.125	56	0.750*†	0.124	55
10-kHz SCS	0.781*†	0.111	65	0.780*†	0.147	64
10-kHz SCS + CO (post-SCS)	0.767*†	NA	120	NA	NA	NA

* Significant difference between the CMM group (months 0–6) and the other groups (p < 0.01).
† Significant difference between the crossover group (months 0–6) and the other groups (p < 0.01).

TABLE 5. Incremental cost-effectiveness ratio

Group 1	Group 2	Time Frame	ICER, $/QALY	Conclusion for Group 1
10-kHz SCS	CMM	1st 6 mos	–$2,236	Dominant
10-kHz SCS	CMM	12 mos (projected CMM alone to 12 mos)	–$4,964	Dominant
CMM (CO), post-SCS	CMM (CO), pre-SCS	6 mos	–$8,620	Dominant
10-kHz SCS + CO post-SCS	CMM	6 mos	–$3,330	Dominant

A cost-effectiveness analysis that included the cost of the SCS system and implantation procedures was also performed, assuming a mean medical bundle reimbursement for the initial SCS system and procedure cost of $30,000. Assuming that HCU and medication costs stay constant and QOL is maintained, cost-effectiveness can be achieved within 2.1 years (Fig. 3).

Discussion

The purpose of this study was to determine if 10-kHz SCS in addition to CMM provided significant clinical improvement for NSRBP patients compared with CMM alone and to establish whether 10-kHz SCS therapy is cost beneficial.

Prior studies have demonstrated that SCS in general has pain relief outcomes that are superior to those of CMM.[26,27] Specifically, in patients with intractable spine pain, SCS was associated with greater pain reduction.[28] In addition, studies have suggested that considering SCS earlier in the care continuum for chronic low-back pain may improve patient outcomes, with reductions in hospitalizations, clinic visits, and opioid usage.[29] Furthermore, evidence supports the use of high-frequency SCS, demonstrating statistically and clinically significant superiority of 10-kHz SCS therapy for relief of persistent back pain when compared with low-frequency SCS.[7,8,30]

Parallel to these findings, the current study shows that 10-kHz SCS provides improvements for patients with NSRBP. Assessments for all primary and secondary endpoints verified that the addition of 10-kHz SCS to CMM results in profound improvements in pain relief, function, and QOL, as well as reduction in daily opioid use. Importantly, the QOL improvement was more than double the minimum clinically important difference[31] in the 10-kHz SCS group at 6 and 12 months.

The HCU data that were prospectively collected in both groups showed that the frequency of injections in the first 6 months was significantly lower in the 10-kHz SCS group than in the CMM group, leading to an overall HCU cost that was 33% lower on average per patient.

Both HCU and medication costs decreased during the 6- to 12-month postimplantion follow-up. The calculated ICER was negative for all comparisons, meaning that significant QOL improvement was achieved at lower cost. The greatest cost savings was achieved for crossovers when comparing the 6 months preimplantation with the 6 months postimplantion, resulting in an ICER of –$8620/QALY. Given the calculated ICER in this analysis, 10-kHz SCS plus CMM therapy is cost-effective when compared with CMM alone. Because of the large standard deviations in total average cost, statistically significant direct cost differences were not found between groups, except for medication costs pre- and postcrossover. Hence, the 10-kHz SCS cost-effectiveness relative to CMM is predominantly attributed to the significant increase in QOL.

This positive result in cost benefit for 10-kHz SCS is supported by other studies that have shown that the total costs for patients who underwent SCS implantation consistently decreased over time[32] and at 9 years postimplantation were less than half of the annualized costs for the non-SCS group.[33] Additionally, there is an economic case for favoring 10-kHz SCS over low-frequency SCS. SCS treatment at 10 kHz has clinical advantages, including shorter and more predictable procedure times.[14] Other studies have suggested favorable cost-effectiveness of 10-kHz SCS in comparison with CMM or reoperation in patients with failed back surgery syndrome (FBSS).[13,34] The use of 10-kHz SCS for the management of patients with FBSS can be considered cost-effective, especially when considering long-term time horizons.[15] While 10-kHz SCS is more effective and less costly in the long term, there is an initial high cost associated with device implantation and early revision procedures.[35] Accordingly, this analysis shows that in the 10-kHz SCS group, the revision and explantation rate was lower in the 6- to 12-month time frame compared with 0–6 months, which contributed to a lower HCU cost in the second 6 months (i.e., 6–12 months). Published analysis has supported that 10-kHz SCS systems, although associated with a high upfront cost, are cost-effective in the long term using traditional willingness-to-pay thresholds.[36] The economically favorable results for NSRBP patients pre-

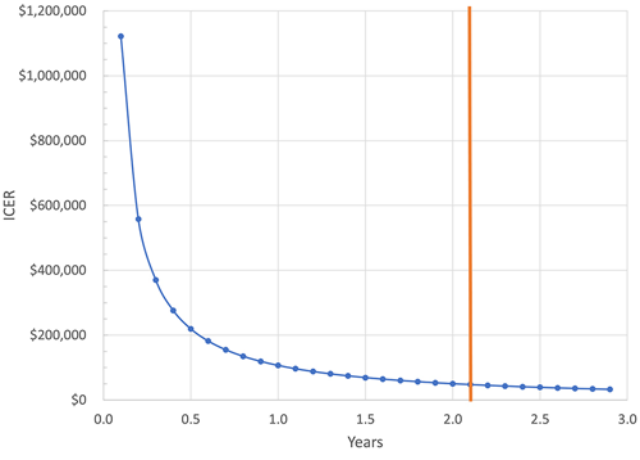

FIG. 3. Time to cost-effectiveness. Assuming that HCU and medication costs stay constant and QOL is maintained, cost-effectiveness can be achieved within 2.1 years (*orange line*). Figure is available in color online only.

sented in this study over 6–12 months may therefore also be anticipated to become even more favorable in the long term. In support of this, if long-term projections are made with the presented data, cost-effectiveness can be achieved within 2.1 years if using a mean medical bundle reimbursement for the initial SCS system and procedure of $30,000. This would be assuming that HCU and medication utilization remains constant and QOL is maintained beyond 12 months (using CMM at 6 months and 10-kHz SCS at 12 months to project future costs and QOL). However, long-term HCU including medication use could be anticipated to continue to decrease over time for those on 10-kHz SCS therapy, which would reduce the time to cost-effectiveness. More studies are needed to clarify specific timelines.

Limitations

There were limitations to this study. There is a potential source of bias from relationships that some authors have with the manufacturer of the spinal cord stimulator. Independent consultants were contracted to perform the data analysis to mitigate as much bias as possible. In terms of data collection, one limitation was the analog capturing of the HCU for each patient in the HCU clinical research forms. While each patient recorded their provider visits, the specific CPT codes for each visit were not recorded. Hence the correlation between the estimated CPT codes and the identified HCU within the patient-reported form may differ. However, care was taken to encompass the most prevalent CPTs associated with the identified HCUs and thus provide a reasonable estimation of the average HCU cost. Another limitation was excluding the cost of the implant and the cost of the trial SCS procedure from the overall HCU cost. The reasoning for this is due to the presented analysis examining only the initial/short-term cost benefit based on immediate HCU and medication usage. As there is great variability in the high initial device cost, the cost-effectiveness would be skewed in the short term, thereby obfuscating the cost effects of changes in medication and general HCU subsequent to starting SCS. However, in the long term, and similar to the study mentioned above,[36] the cost-effectiveness of 10-kHz therapy is expected to become greater, even with the initial device cost included, as the QOL will be increased over a longer period, thereby providing support for long-term economic benefit, although this may not be apparent in the short-term data. Continued clinical studies through 2 years are ongoing and are needed to provide data to verify this assumption. There is evidence of some loss of efficacy for SCS in the 2-year time frame, but a recent paper reported that only 5.2% of a large real-world cohort had the device explanted for loss of efficacy after an average of 793 days of follow-up.[37] Another study reported that if the implant is effective past 6 months, it is unlikely to be explanted prior to 24 months with a median time to explant for inefficacy of 33 months.[38] Reports from two large prospective studies support consistent effectiveness of 10-kHz SCS out to 24 months,[39,40] and a small feasibility study showed strong outcomes to 36 months.[41]

Conclusions

Treatment with 10-kHz SCS provides a concurrence of significantly improved QOL at a lower average cost per patient. Based on this cost analysis and the National Institute for Health and Care Excellence $50,000/QALY willingness-to-pay threshold, 10-kHz SCS therapy is likely a cost-effective treatment, relative to CMM alone, for NSRBP patients within the first 2 years of treatment.

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Disclosures

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Conception and design: Wu, Kapural. Acquisition of data: Patel, Wu, Lad, Jameson, Kosek, Sayed, Azalde, Kapural. Analysis and interpretation of data: Patel, Kosek, Waldorff, Shum, Azalde, Kapural. Drafting the article: Waldorff, Shum. Critically revising the article: Patel, Wu, Lad, Waldorff, Shum, Azalde, Kapural. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Patel. Statistical analysis: Waldorff, Shum.

Supplemental Information

Online-Only Content

Supplemental material is available with the online version of the article.

Supplementary Tables and Figures. https://thejns.org/doi/suppl/10.3171/2022.9.SPINE22416.

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