Health care resource utilization and costs in patients with painful diabetic neuropathy treated with 10 kHz spinal cord stimulation therapy

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Plain language summary

This study evaluates the effect of high-frequency 10 kHz spinal cord stimulation (SCS) on health care resource use and costs in patients with painful diabetic neuropathy (PDN). Study participants were randomly assigned to SCS treatment or conventional medical management (CMM), with outcomes measured at 6 months. The results demonstrated that there were fewer hospitalizations and lower total health care costs in the SCS treatment group compared with the CCM group.

Implications for managed care pharmacy

Up to 25% of people with diabetes develop PDN. The standard-of-care pharmacotherapies for PDN have limited efficacy with a considerable side-effect profile. Patients who are with PDN that is refractory to CCM have high health care resource utilization and associated costs. Managed care organizations would see health economic benefits by adding 10 kHz SCS, proven as a safe and efficacious treatment option, for patients with refractory PDN.

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ABSTRACT

BACKGROUND: Diabetic peripheral neuropathy, a common comorbidity of diabetes, is a neurodegenerative disorder that targets sensory, autonomic, and motor nerves frequently associated with painful diabetic neuropathy (PDN). PDN carries an economic burden as the result of reduced work and productivity. A recent multicenter randomized controlled trial, SENZA-PDN (NCT03228420), assessed the impact of high-frequency (10 kHz) spinal cord stimulation (SCS) on pain relief. The effects of high-frequency SCS on health care resource utilization and medical costs are not known.

OBJECTIVE: To evaluate the effect of high-frequency (10 kHz) SCS on health care resource utilization (HRU) and medical costs in patients with PDN using data from the SENZA-PDN trial.

METHODS: Participants with PDN were randomly assigned 1:1 to receive either 10 kHz SCS plus conventional medical management (CMM) (SCS treatment group) or CMM alone (CMM treatment group). Patient outcomes

and HRU up to the 6-month follow-up are reported here. Costs (2020 USD) for each service was estimated based on publicly available Medicare fee schedules, Medicare claims data, and literature. HRU metrics of inpatient and outpatient contacts and costs are reported as means and SDs. Univariate and bivariate analyses were used to compare SCS and CMM treatment groups at 6 months.

RESULTS: At 6-month follow up, the SCS arm experienced approximately half the mean rate of hospitalizations per patient compared with the CMM treatment group (0.08 vs 0.15; $P = 0.066$). The CMM treatment group's total health care costs per patient were approximately 51% higher compared with the SCS treatment group (equivalent to mean annual cost per patient of $9,532 vs $6,300).

CONCLUSIONS: Our analysis of the SENZA-PDN trial indicates that the addition of 10 kHz SCS therapy results in lower rates of hospitalization and consequently lower health care costs among patients with PDN compared with those receiving conventional management alone.

In the United States, 37 million people have diabetes and an additional 96 million people with prediabetes are at risk for developing the disease.[1] Diabetic peripheral neuropathy, a common comorbidity, is a neurodegenerative disorder of the peripheral nervous system that targets sensory, autonomic, and motor nerves.[1] Diabetic peripheral neuropathy is frequently associated with neuropathic pain, referred to as painful diabetic neuropathy (PDN).[2,3] An estimated 15%-25% of patients with diabetes have PDN.[4] PDN symptoms are described as burning, sharp, aching, electric, and evoked pains, in addition to feelings of numbness, tingling, and pins and needles.[4] PDN often results in a poor health-related quality of life, depression, anxiety, and impaired sleep.[4]

PDN also carries an economic burden, including increased health care resource use, direct medical costs, and indirect costs as the result of reduced work and productivity.[2] A retrospective study reported medical costs 4.2-fold higher in patients with PDN compared with control patients with diabetes ($27,931 vs $6,632; $P < 0.0001$), with even higher costs among patients with severe disease ($30,755; $P < 0.001$).[2,3] Another longitudinal study found that diabetes patients with PDN were hospitalized 2.5 times more frequently than those without PDN and that lost productivity time was 18% higher.[5]

Conventional medical management (CMM) for PDN includes pharmacological agents, psychological treatment (eg, cognitive behavioral therapy), physical or restorative therapy, noninvasive or minimally invasive spinal procedures, nerve blocks, and others.[6,10] Pharmaceutical treatments, however, provide limited relief for PDN. Because of side effects or lack of efficacy, 77% of patients with PDN who are prescribed the common anticonvulsant pregabalin discontinue its use within 1 year.[7] When a treatment is discontinued, most patients with PDN do not switch to an alternative treatment, leaving their condition untreated.[7]

Spinal cord stimulation (SCS) is a form of electrical neurostimulation that modulates neural function via stimulation electrodes implanted into the spinal epidural space.[8] Although low-frequency SCS (typically 40-60 Hz) has been shown to be potentially effective for treating pain associated with neuropathies, it masks pain perception by inducing paresthesia. The success of low-frequency SCS depends on a patient's tolerance of the induced paresthesia, limiting patient acceptability.[9,10] Compared with low-frequency SCS, high-frequency (10 kHz) SCS delivers paresthesia-free therapy, and as was shown in a randomized controlled trial (RCT), 10 kHz SCS is safe, effective, and superior to low-frequency SCS for treating back and leg pain.[9,11] The 10 kHz SCS therapy is now an FDA-approved treatment for lower limb pain associated with PDN.[12] A recent multicenter RCT, SENZA-PDN (NCT03228420), assessed whether 10 kHz SCS therapy combined with CMM provided meaningful pain relief compared with CMM alone for patients with refractory PDN symptoms.[10] Although 5% of the CMM treatment group met the study's primary endpoint of having 50% or more pain relief without observed deterioration on neurological examination, 79% of the 10 kHz SCS plus CMM treatment group met the same endpoint (95% CI = 64.2-83.0; $P < 0.001$).[13]

The SENZA-PDN clinical trial also collected information about health care resource utilization (HRU) for all patients. The results presented here are from the secondary analysis of data collected during this trial. The aim of this analysis was to compare the health care utilization and medical costs of 10 kHz SCS plus CMM vs CMM alone in patients with PDN over a 6-month duration using the SENZA-PDN trial data.

Methods

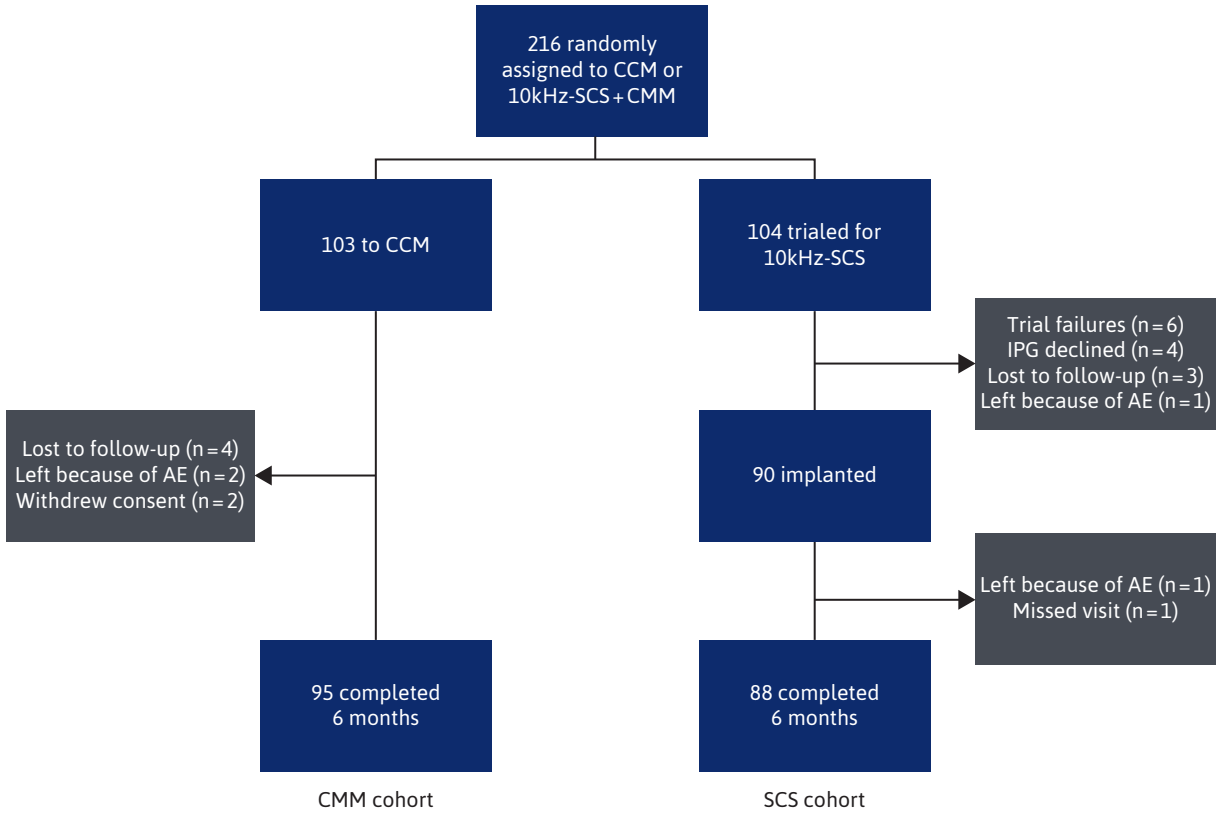
DATA SOURCE

The SENZA-PDN RCT enrolled 216 participants from 18 sites in the United States, representative of academic and community institutions, from August 28, 2017, to August 23, 2019 (Figure 1). This study was exempt from institutional review board approval, as it involved a secondary data analysis of deidentified data.

STUDY DESIGN

Participants were randomly assigned to 2 groups, 10 kHz SCS plus CMM (SCS treatment group) and CMM alone (CMM treatment group). Patients in the SCS treatment group underwent temporary trial stimulation; those who reported

FIGURE 1 Study Design: Patient Disposition



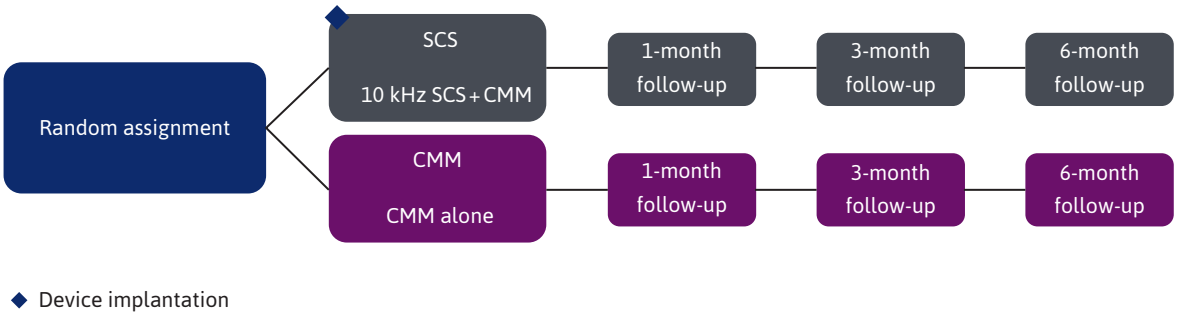
Patient disposition is shown by study arm assignment. Reasons for exiting the study or for missing data are described in the horizontal branches.
AE = adverse event; CMM = conventional medical management; IPG = implantable pulse generator; SCS = spinal cord stimulation.

at least 50% pain relief were eligible for permanent 10 kHz SCS device implant.[13] At the 6-month study visit, patients were given the option to switch treatment arms if they had insufficient pain relief, were dissatisfied with treatment, and were appropriate to proceed as determined by their physician.[13] Study patients randomly assigned to 10 kHz SCS plus CMM were followed up to 24 months after random assignment and study patients randomly assigned to CMM alone were followed up to 24 months after crossing over to 10 kHz SCS plus CMM. Outcomes, including patient-reported HRU and quality of life data, were collected at the baseline and at routine 1-, 3-, 6-, 9-, 12-, 18-, and 24-month follow-up visits. Patient-reported HRU was recorded at each study visit as the number of office visits, emergency department (ED) visits, and tests/procedures since the previous visit. The clinical trial sites also recorded hospitalizations when they occurred, which were documented as serious adverse events.[10] Detailed clinical trial inclusion criteria are described elsewhere.[10,13] To evaluate the effects of 10 kHz SCS on HRU, the study compared inpatient and outpatient HRU in patients assigned to 10 kHz SCS plus CMM against those assigned to CMM alone. To focus on comparative data during the random assignment phase of the study, the HRU and cost results up to the 6-month follow-up are reported and compared here (Figure 2).

STUDY MEASURES

Study measures included patient demographics (age, sex, race) and patient clinical characteristics (diabetes type, duration of diabetes, lower limb pain score [10-cm visual analog scale (VAS)], hemoglobin A1c, body mass index), which were measured at clinical trial enrollment (baseline); inpatient HRU that required hospitalization and length of stay; outpatient HRU that were patient-reported office visits, ED visits, and tests/procedures. All hospitalizations (ie, both diabetes- and nondiabetes-related hospitalizations)

FIGURE 2 Study Design: Health Care Resource Utilization Study Visits



The study design included a baseline and 3 follow-up visits during the first 6 months of the trial (the time period over which the health care resource utilization and costs were evaluated).

CMM = conventional medical management; HRU = health care resource utilization; SCS = spinal cord stimulation.

and their severity were recorded in the serious adverse event file and were reported as the total number of hospitalizations and the mean number of hospitalizations per patient per 6 months. Patient-reported office visits detailed all visits, with the exception of the clinical trial's routine follow-up visits for 10 kHz SCS, which were excluded. HRU were evaluated for each treatment group and reported as observed means (SD), defined as the average number of each type of health care encounter per patient per 6 months. The proportion of patients with at least 1 encounter was also calculated for each treatment group. When reporting events that were recorded at specific study follow-up visits for CMM, the 1-month period reported events that occurred between baseline and the 1-month follow-up visit; the 3-month period reported events that occurred between the 1-month follow-up visit and the 3-month follow-up visit; and the 6-month period reported events that occurred between the 3-month follow-up visit and the 6-month follow-up visit. When reporting events that were recorded at specific study follow-up visits for SCS, the 1-month period reported events that occurred between implantation and the 1-month follow-up visit; the 3-month period reported events that occurred between the 1-month follow-up visit and the 3-month follow-up visit; and the 6-month period reported events that occurred between the 3-month follow-up visit and the 6-month follow-up visit.

COST ESTIMATION

Costs for inpatient and outpatient HRU were estimated using publicly available Medicare fee schedules, Medicare claims data, and literature that reported costs associated with PDN.[14,15] Office visit cost estimates were based on Medicare fee schedules and hospitalization costs on average reported payments by Centers for Medicare and Medicaid Services (CMS) to providers. ED visit costs were estimated using payments by commercial insurers. All cost estimates were based on payments by public (CMS) and private (commercial) insurers to providers and did not include patient cost-sharing responsibilities. To ensure that cost estimates were consistent across service types, office visit and hospitalization costs were adjusted to reflect differences in payments by CMS, which are lower than those by commercial insurers.[13] Tests/procedures (which included procedures such as radiological scans, routine blood work, routine and screening examinations, cardiovascular assessments [eg, EKG], and orthopedic surgery and follow-up visits) were not included in total costs because of the variability of the procedures received by patients. Costs associated with the initial implantation were not included because of variability in the device and surgical procedure costs by site of care and location, which could lead to inconsistency between patients in the short-term, taking away from the longer-term HRU and cost implications of each therapy. Costs associated with any hospitalization in the 6 months of follow-up were captured in the cost estimation. All cost estimates were adjusted to 2020 US dollars, using the Medical Care Component of the Consumer Price Index. Finally, costs estimated from the 6-month period were annualized, as much of the comparable research and HRU results report annualized outcomes and the random assignment period of this study was only for the first 6 months. To estimate costs over a full year, we assumed that costs in each group over the first 6 months of the trial were consistent with costs in the following 6 months, for which data were not included in this study. As such, the 6-month study period estimated costs were doubled to estimate annual costs.

Although it is possible that costs for SCS patients were increasingly lower as patients responded to decreases in pain over time, our method of calculating estimated annual costs was a more conservative estimate.

DATA ANALYSES

Data analyses were limited to patients in SCS and CMM treatment groups who provided complete HRU data over the 6-month follow-up period. Univariate analyses and bivariate analyses (Mann-Whitney for continuous variables and Fisher exact/chi-squared tests for discrete variables) were used to describe patients' demographic and clinical characteristics at random assignment. The same univariate analyses and bivariate analyses were used to compare patients in the SCS and CMM treatment groups over the first 6 months of the study. In all analyses, continuous variables were summarized using means and SDs, and discrete variables were summarized using frequency counts and percentages. As hospitalizations are rare events and HRU encounters were self-reported by patients, unadjusted bivariate analyses were conducted to assess differences in the proportion of patients with at least 1 encounter by setting between treatment groups. Nonparametric analyses were used to account for outcomes that did not meet assumptions of normality and conducted using statistical software, version 9.4 (SAS Institute Inc.).

TABLE 1 Baseline Demographic and Clinical Characteristics for All Randomly Assigned Participants

	SCS treatment group (n = 113)	CMM treatment group (n = 103)
Age in years, mean (SD)	60.72 (11.40)	60.83 (9.90)
Sex, n (%)		
Male	70 (61.95)	66 (64.08)
Female	43 (38.05)	37 (35.92)
Race, n (%)		
White	87 (76.99)	85 (82.52)
Black	18 (15.93)	13 (12.62)
Native Hawaiian or Pacific Islander	3 (2.65)	1 (0.97)
American Indian or Alaska Native	2 (1.77)	0 (0.00)
Asian	1 (0.88)	1 (0.97)
Other	2 (1.77)	3 (2.9)
Diabetes, n (%)		
Type 1	8 (7.08)	3 (2.91)
Type 2	105 (92.90)	100 (97.09)
Duration of diabetes (in years), mean (SD)		
Diabetes	12.99 (8.55)	12.28 (8.50)
Peripheral neuropathy	7.43 (5.70)	7.12 (5.12)
Lower limb pain VAS, mean (SD)	7.45 (1.58)	7.10 (1.57)
<7.5 cm, n (%)	54 (47.79)	57 (55.34)
≥7.5 cm, n (%)	59 (52.21)	46 (44.66)
HbA1c, mean (SD)	7.31 (1.16)	7.45 (1.20)
<7.0%, n (%)	46 (40.71)	40 (38.83)
≥7.0%, n (%)	67 (59.29)	63 (61.17)
BMI, mean (SD)	33.58 (5.37)	33.90 (5.25)

BMI = body mass index; CMM = conventional medical management; HbA1C = hemoglobin A1c; SCS = spinal cord stimulation; VAS = visual analogue scale.

Results

STUDY PATIENTS

Among 216 patients randomly assigned at baseline (CMM: n = 103, SCS: n = 113) (Table 1), a total of 183 completed the 6-month follow-up visit (CMM: n = 95, SCS: n = 88) (Supplementary Table 1, available in online article). In both treatment groups, the majority of patients were White (CMM: 85, 82.52%; SCS: 87, 76.99%; P = 0.398) and most were male (CMM: 66, 64.08%; SCS: 70, 61.95%; P = 0.779). Nearly all were individuals with type 2 diabetes (and the remaining participants were individuals with type 1 diabetes), but the CMM treatment group had a slightly greater percentage of patients with type 2 diabetes (CMM: 100, 97.09%; SCS: 105, 92.90%; P = 0.220). At baseline, the CMM treatment group had a slightly lower average value of lower limb pain (10-cm VAS) compared with the 10 kHz SCS treatment group (CMM: 7.10 ± 1.57 cm; SCS: 7.45 ± 1.58 cm; P = 0.088). The remaining clinical characteristics did not differ significantly between the 2 study treatment groups with the significance level set at 0.05 (Table 1).

HRU

INPATIENT

Over 6 months of follow-up, the CMM treatment group experienced consistently higher mean hospitalization

TABLE 2 Comparison of SCS and CMM Treatment Groups' 6-Month Results for Office Visits, ED Visits, Test/Procedures, Hospitalizations, LOS, and Health Care Costs

Follow-up visit: 6-month total		SCS treatment group (n = 88)	CMM treatment group (n = 95)	SCS vs CMM	
	Encounter type	Patients with 1+ visit, mean ± SD; visits per patient, n (%)	Patients with 1+ visit, mean ± SD; visits per patient, n (%)	Difference (mean ± SD); % difference in proportion of patients with 1+ visit	*P* value[a]
	Office visits	4.43 ± 3.54; 84 (95.46)	3.92 ± 2.84; 87 (91.58)	+0.51 ± 0.48; +4.15	0.376
	ED visits	0.38 ± 0.79; 23 (26.14)	0.35 ± 0.70; 23 (24.21)	+0.03 ± 0.11; +7.67	0.865
	Tests/procedures	2.06 ± 2.26; 62 (70.46)	1.28 ± 2.00; 54 (56.84)	+0.78 ± 0.32; +21.40	0.066
	Hospitalization admissions	0.08 ± 0.27; 7 (7.95)	0.15 ± 0.46; 11 (11.58)	–0.07 ± 0.06; –37.17	0.464
	LOS (days per admission)	4.14 ± 2.61	5.21 ± 5.31	–1.07 ± 1.88	—
	Estimated health care costs (USD)	3,149.82 ± 7,283.20	4,765.97 ± 12,534.07	–1,616.15 ± 1,502.16	—

LOS and estimated health care costs are displayed as mean ± SD.

[a]*Comparing the proportion of patients with 1+ visit between the 10 kHz SCS treatment group and the CMM. treatment group.*

CMM = conventional medical management; ED = emergency department; LOS = length of stay; SCS = spinal cord stimulation; USD = US dollars; — = not applicable.

rates per patient (0.15 ± 0.46) compared with the SCS treatment group (CMM: 0.08 ± 0.27). Overall, the CMM treatment group had a total of 14 hospitalizations in contrast to the 7 hospitalizations for the 10 kHz SCS treatment group. Likewise, the CMM treatment group had more patients who were hospitalized (CMM: 11, 11.58% compared with the SCS treatment group (SCS: 7, 7.95%; P = 0.464). The mean length of stay for hospital admissions was slightly higher for the CMM treatment group (CMM: 5.21 ± 5.31 days per admission) compared with the SCS treatment group (SCS: 4.14 ± 2.61 days per admission) (Table 2). There was also an observable difference in the hospitalization rate over time between the 2 groups. From month 1 to month 6, patients in the SCS treatment group had a smaller rate of increase of hospitalizations compared with those in the CMM treatment group only (Figure S2).

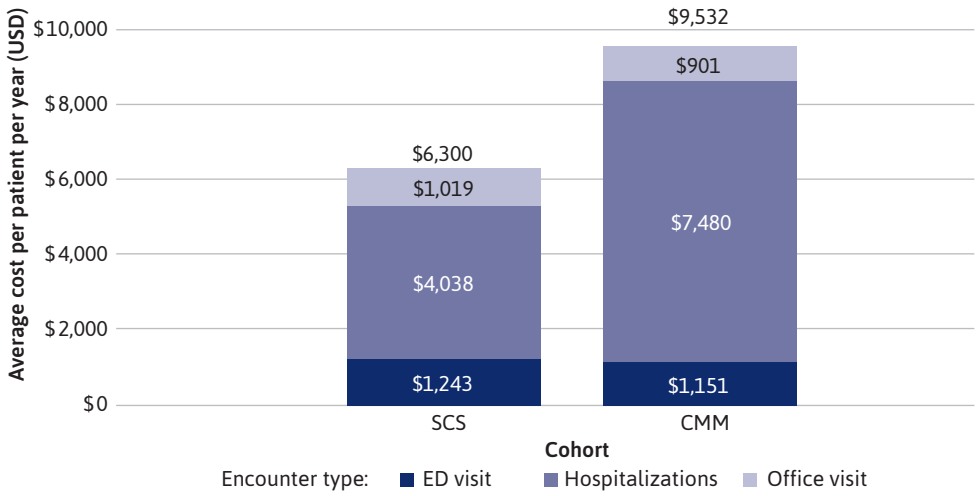
OUTPATIENT

The CMM treatment group and SCS treatment group had a similar number of office visits (CMM: 3.92 ± 2.84 office visits, SCS: 4.43 ± 3.54 office visits) as well as the proportion of patients who used the service (CMM: 84, 95.46%; SCS: 87, 91.58%; P = 0.376) (Table 2). Overall, the proportion of patients with ED visits was consistent on average for CMM patients (CMM: 23, 24.21%) in comparison with the SCS treatment group (SCS: 23, 26.14%; P = 0.865), as were the utilization rates (CMM: 0.35 ± 0.70 ED visits per patient, SCS: 0.38 ± 0.79 ED visits per patient). Yet CMM patients had slightly more ED visits at the 6-month follow-up visit (CMM: 0.26 ± 0.57 ED visits per patient) vs the SCS treatment group (SCS: 0.18 ± 0.42 ED visits per patient) (Table S2). The CMM treatment group had a lower utilization rate of tests/procedures (CMM: 1.28 ± 2.00 tests/procedures per patient) when compared with the SCS treatment group (2.06 ± 2.26 tests/procedures per patient); however, a larger percentage of the CMM treatment group used them, compared with the SCS treatment group (CMM: 70.46%, SCS: 56.84%; P = 0.066) (Table S2).

ANNUALIZED RATES OF HOSPITALIZATION AND SELF-REPORTED HRU

Annualized rates of hospitalizations and annualized rates of HRU were calculated from the 6-month period for CMM and 10 kHz SCS patients. Extrapolating 6-month results to 12 months, CMM patients would be expected to have 0.29 hospitalizations per patient per year (29 hospitalizations per 100 patients per year) if rates were consistent after continuing with only CMM. Patients treated with 10 kHz SCS are expected to have lower rates of hospitalizations in comparison (0.16 hospitalizations per patient per year or 16 hospitalizations per 100 patients per year). Annualized rates of self-reported health care services were not significantly different across the treatment groups. Annualized rates for office visits and ED visits for CMM patients were consistent compared with the annualized rates of 10 kHz SCS patients. The observed rates for the CMM patients may reflect the higher rate of hospitalization, as hospitalized patients have fewer opportunities for office and ED visits (Figure S1).

FIGURE 3 Estimated Annualized Average Costs per Patient by Encounter and Study Cohort



CMM = conventional medical management; ED = emergency department; SCS = spinal cord stimulation; USD = US dollars.

ESTIMATES OF ANNUAL COSTS FOR HOSPITALIZATIONS, OFFICE VISITS, AND ED VISITS

CMM patients had estimated annual costs for hospitalizations of $7,480 per patient per year. The estimated annual hospitalization costs for 10 kHz SCS patients were $4,038 per patient per year. Estimated annual costs for outpatient HRU were not considerably different between CMM patients and 10 kHz SCS patients. When costs for hospitalizations, ED visits, and office visits were combined, total costs for 10 kHz patients were 34% lower compared with costs for CMM patients projected over a 12-month study period ($6,300 vs $9,532 per patient per year). These cost differences largely reflect higher hospitalization rates, as hospitalizations are costly and key drivers of patient costs (Figure 3).

Discussion

Based on the SENZA-PDN trial, we conducted an analysis of the effects of 10 kHz SCS on HRU and costs for patients with PDN. Patients treated with 10 kHz SCS had considerably fewer hospitalizations, compared with those treated with CMM only. This difference was evident when 10 kHz SCS patients (7 hospitalizations; 0.08 hospitalizations per patient per 6 months) were compared with CMM patients (14 hospitalizations; 0.15 hospitalizations per patient per 6 months) in the first 6 months of the study. Although not statistically significant, patients who received 10 kHz SCS consistently had lower rates of hospitalizations across study visits compared with those who received CMM only, with values trending toward significance (Figure S2). Across study visits, there were observable differences in the utilization rates for office visits and ED visits between 10 kHz SCS patients and CMM patients. The absolute rate difference per 10 kHz SCS patient vs CMM-only patient for office visits for the 1-, 3-, and 6-month study visits were +0.47, +0.08, and -0.03, respectively (Table S2). Additionally, the absolute rate differences per 10 kHz SCS patient vs CMM-only patient for ED visits for the 1-, 3-, and 6-month study visits were +0.08, +0.03, and -0.08, respectively (Table S2). This study was powered for the primary effectiveness endpoint (pain relief responder rate), so we would expect to observe statistical differences in HRU metrics with a larger sample size and additional time to capture the magnitude of the effect of 10 kHz SCS on patients treated with the therapy. Nonetheless, the lower hospitalization rate and lower estimated health care costs demonstrate the benefits of 10 kHz SCS for decreasing HRU in the PDN patient population.

Hospitalizations are key drivers of costs, and exploratory analyses suggest that the lower rates of hospitalization among patients treated with 10 kHz SCS would be associated with overall lower patient costs. In exploratory analyses of costs, we estimated that total costs per patient

per year for hospitalizations and office and ED visits were approximately 34% lower for patients treated with 10 kHz SCS over a 1-year period. This study's findings are consistent with previous studies that suggest PDN adds to the economic burden of diabetes by increasing HRU and cost with increasing disease severity and decreasing pain management.[2,3,5,14]

PAIN MANAGEMENT, DIABETES MANAGEMENT, AND HOSPITALIZATIONS

At the 6-month study visit of the SENZA-PDN trial, 79% (95% CI = 64.2-83.0) of those treated with 10 kHz SCS experienced at least 50% pain relief and had an average pain reduction of 76.3% (95% CI = 70.8-81.8).[13] Successful management of pain from PDN could lead to the successful management of diabetes while also decreasing the risk of developing other diseases.[16] Previous pain studies have shown that increased pain severity caused a significant increase in HRU, particularly ED visits and hospitalizations, and that the increase in utilizations could be explained by inadequate pain control.[17-19]

LIMITATIONS

This study had several potential limitations. First, existing PDN guidelines show inconsistencies regarding recommended therapies; consequently, the treatments selected for the study's CMM therapy may not be representative of treatments administered to all patients.[20] Next, when considering data, the study analyzed and reported data from the first 6-month period of an ongoing randomized trial in which comparative data were available. Individuals included had at least 6 months of follow-up within their randomized treatment arm, and it is possible that these findings are not representative of the final results, as PDN is a chronic disease and we only evaluated results for a relatively short period in a controlled study. These follow-up data will be evaluated when the study is completed. As with all clinical studies, the data collected may not be representative of "real-world" outcomes. Additionally, patient-reported data were used for outpatient HRU, which are at an increased risk for bias.[21,22] Future analysis could also look at HRU costs both before and after implantation to assess reductions in HRU associated with the SCS therapy. Of note, the SENZA-PDN RCT was powered to assess the primary outcome of pain relief due to 10 kHz SCS therapy rather than to assess HRU—the primary outcome for this study. Therefore, the factors that were used to power the clinical trial should be taken into consideration when interpreting results from this HRU evaluation.

Lastly, cost estimations reported in the study may not reflect true total costs.[23,24] PDN costs do not necessarily progress linearly, as disease progression is associated with increasingly higher costs over time. Moreover, the study did not include indirect costs, such as loss of work productivity or travel costs, costs for medications, costs for tests/procedures, and the actual costs of the 10 kHz SCS implant, implantation procedures, and possible complication management.

Conclusions

PDN is a condition with a high negative health and economic burden. This analysis of the SENZA-PDN RCT indicates that, compared with CMM alone, the addition of 10 kHz SCS therapy results in lower rates of hospitalization and lower medical costs for patients with PDN over a 6-month follow-up period. Longer-term data are needed to assess if these economic benefits of 10 kHz SCS at 6 months continue over time for the patient with PDN.

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