SCS for Painful Diabetic Peripheral Neuropathy: 3-Month Clinical Outcomes Collected Using a Digital Health Platform

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INTRODUCTION

- Diabetic peripheral neuropathy (DPN) is a common neuropathic syndrome seen in 30% of patients with diabetes[1].
- DPN can present with painful symptoms including bilateral stabbing or burning pain, in addition to numbness in the feet and lower legs[1].
- Spinal cord stimulation (SCS) is a non-opioid therapy that has been shown to be an effective treatment for painful DPN[2-3].
- An analysis of 3-month real-world data collected from DPN patients treated with SCS was conducted utilizing a digital health platform.

MATERIALS & METHODS

- CareGuidePro™ (CGP) is a mobile application that serves as a digital health platform for patient education, feedback, and patient reported outcomes throughout the course of their SCS journey.
- We conducted a retrospective sub-analysis of real-world clinical data from DPN patients being treated with SCS in the United States utilizing CGP.
- We analyzed preoperative patient demographics and characterized patient pain profiles using PROMIS-29 (Patient-Reported Outcomes Measurement Information System®) surveys at baseline and at 3-month follow-up.
- The PROMIS-29 profile measure assesses 7 domains (pain interference, ability to participate in social roles and activities, sleep disturbance, fatigue, depression, anxiety and physical function) and pain intensity.
- Higher PROMIS symptom scores reflect worse symptom burden, and higher PROMIS function scores reflect better functioning.

RESULTS

- Between 2022-October-01 and 2023-July-28, 295 patients with a DPN indication were implanted with SCS devices while utilizing the digital health platform (Table 1), with 204 of them (69.2%) converting to a permanent implant.
- PROMIS-29 surveys were completed by 42 patients at baseline (pre-implant) and 26 patients at 3-months. P-values were computed considering only the cohort of patients with paired answers at baseline and 3-months using a paired T-test (n=20).
- Average pain intensity scores (± standard deviation) improved from 7.1 (± 1.67) at baseline to 4.4 (± 2.13) at 3-months ($p < 0.001$).
- All but one of the functional domains report significant improvement between baseline and 3 months (Table 1). The mental domain of depression showed no change ($p = 0.81$).
- Of patients with paired baseline and 3 months PROMIS-29 surveys (n=20), 95.0% reported an improvement of at least 5 points in any PROMIS domain.

Table 1. Demographics of CGP enrolled patients with DPN indication (n = 295)

Age (years)	60.5 ± 15.9 [IQR 53 - 71]
% Pts with Age ≥ 65yrs	44.1%
Gender Female N (%)	111 (37.6%)
Gender Male N (%)	119 (40.3%)
Gender Unknown N (%)	65 (22.1%)
Known SCS Trial Type N (%), total	**211 (71.5%)**
Differental Target Multiplexed (DTM™)[4]	165 (78.2%)
DTM™ SCS Endurance[5]	21 (10.0%)
Evolve℠ Workflow[6]	25 (11.8%)

Table 2. PROMIS-29 domain T-scores at baseline and 3-month follow-up. Data reported as T-score ± standard deviation. P-values are reported for the change from baseline to 3-month follow-up for each domain.

PROMIS-29 domain	Baseline	3-months	P-value
Ability to Participate in Social Roles and Activities	41.3 ± 8.5	46.7 ± 9.2	0.010
Anxiety	52.8 ± 9.4	49.3 ± 8.7	0.022
Depression	49.7 ± 9.3	49.5 ± 9.9	0.808
Fatigue	57.1 ± 7.6	52.3 ± 7.9	0.023
Pain Intensity	7.0 ± 1.7	4.3 ± 2.1	< 0.001
Pain Interference	65.4 ± 5.2	59.9 ± 7	0.003
Physical Function	33.8 ± 5.6	40.0 ± 7.4	< 0.001
Sleep Disturbance	56.0 ± 6	50.6 ± 6	< 0.001

CONCLUSIONS

- This analysis demonstrates that SCS can provide significant improvement in pain-related symptoms for patients with DPN.
- Findings from this analysis suggest SCS can be an effective therapy for painful DPN that should be considered when treating this patient population.
- Additionally, this study supports the use of digital health technology to allow for robust patient-reported outcomes collection.

REFERENCES

1. Sloan G, et al. The treatment of painful diabetic neuropathy. Current Diabetes Reviews. 2022;18(5):e070721194556.
2. de Vos CC, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial. Pain. 2014;155(11):2426-31.
3. Slangen R, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. Diabetes Care. 2014;37(11):3016-24.
4. Fishman M, et al. 12-Month Results from Multicenter, Open-Label, Randomized Controlled Clinical Trial Comparing Differential Target Multiplexed Spinal Cord Stimulation and Traditional Spinal Cord Stimulation in Subjects with Chronic Intractable Back Pain and Leg Pain. Pain Pract. 2021. Aug 7. doi: 10.1111/papr.13066.
5. Provenzano D, et al. A Prospective Multi-Center Study of a Reduced-Energy DTM™ Stimulation Derivative: Long-Term Outcomes in Therapy Naïve Patients. Poster presented at American Society of Regional Anesthesia and Pain Medicine (ASRA) Annual Pain Medicine Meeting; Nov. 17-19, 2022; Orlando, FL, USA.
6. Hatheway J, et al. Long-Term Efficacy of a Novel Spinal Cord Stimulation Clinical Workflow Using Kilohertz Stimulation: Twelve-Month Results From the Vectors Study. Neuromodulation. 2020. Oct 28. doi: 10.1111/ner.13324.

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