SCS Trial Evaluation in Diabetic Peripheral Neuropathy Patients: Real-World Evidence 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].
- Prior to implantation of an SCS device, patients are required to trial the therapy using an external neurostimulator (SCSeval procedure).
- A retrospective sub-analysis of real-world data collected from patients with painful DPN who underwent SCSeval procedures 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 patients with DPN who underwent SCSeval procedures while utilizing CGP in the United States.
- We analyzed preoperative patient demographics and characterized patient pain profiles using PROMIS-29 (Patient-Reported Outcomes Measurement Information System®) surveys at baseline and at the end of the SCSeval procedure (EOT).
- The PROMIS-29 profile measure assesses seven 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.

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Results

- Between 2022-October-01 and 2023-July-28, 295 patients with a painful DPN indication underwent SCSeval procedures while utilizing CGP (Table 1).
- PROMIS-29 surveys were completed by 132 patients at baseline and 93 patients at EOT. P-values were computed considering only the cohort of patients with paired answers at baseline and EOT using a paired T-test (n=69).
- Average pain intensity scores (±standard deviation) improved from 7.5 (±1.4) at baseline to 3.9 (±2.0) at EOT ($p < 0.001$).
- Evaluation of SCS was associated with significant improvements ($p < 0.001$) in all PROMIS-29 domains (Figure 1), with 91.3% of patients reporting an improvement of at least 5 points and 94.3% of patients reporting an improvement of at least 3 points in any PROMIS domain.

Figure 1. Percent of patients reporting normal, mild, moderate, and severe PROMIS-29 domain T-scores at baseline and end of SCS eval procedure (n = 69)

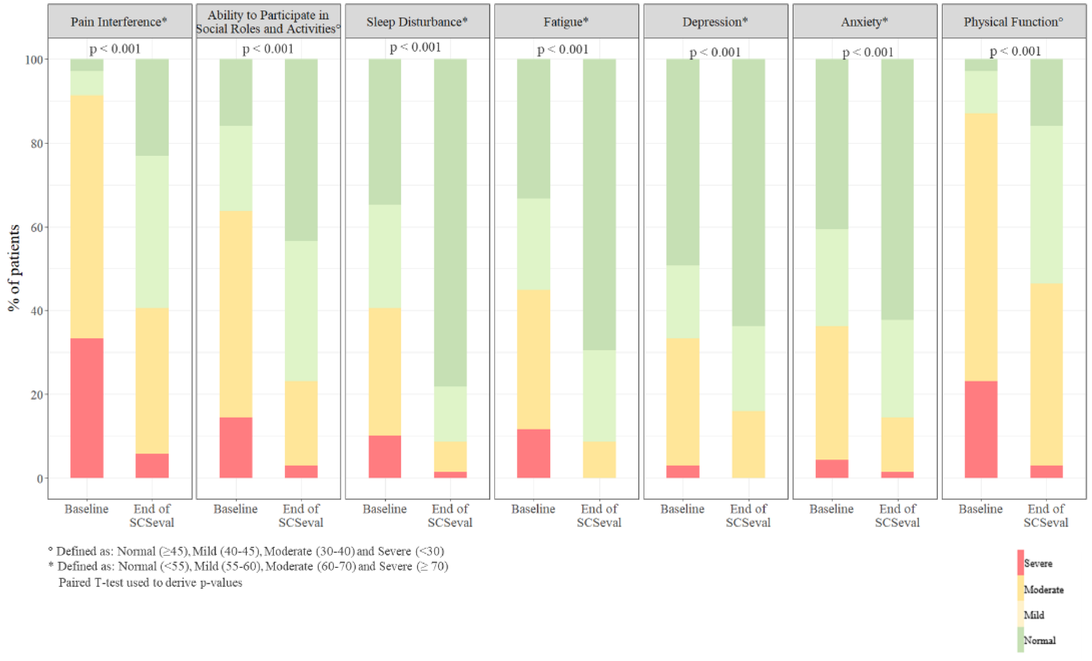

Table 1. Demographics of CGP enrolled patients with DPN indication (n = 295)

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%)

Conclusions

- This retrospective sub-analysis of patients with DPN who underwent SCSeval procedures while utilizing CGP demonstrates that SCS therapy can provide significant improvement in pain-related symptoms.
- 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

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