SPINAL CORD STIMULATION IN PATIENTS WITH PAINFUL DIABETIC PERIPHERAL NEUROPATHY: A SUB-ANALYSIS FROM THE SENSE SCS STUDY

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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) has been shown to be an effective treatment for painful DPN in multiple randomized controlled trials.[2-3]
- The SENSE SCS Study – Study to Evaluate Neuromodulation Subject Experience with Contemporary Spinal Cord Stimulation Modalities for Chronic Pain – is a prospective clinical study that is currently ongoing.
  - Employs a hybrid decentralized model of execution.
  - Uses a digital health platform to collect patient reported outcomes (PROs) from subjects undergoing SCS treatment for indicated chronic intractable pain.
- **OBJECTIVE: A sub-analysis of PROs collected from subjects with painful DPN enrolled in the SENSE SCS study was conducted to assess "real-world" SCS efficacy for painful DPN.**

MATERIALS & METHODS

- Design: Prospective, post-market, non-randomized, observational US-based study.
- This study was IRB approved and is registered on clinicaltrials.gov (NCT05775510).
- Enrollment is currently ongoing at 9 sites.
- Subjects are electronically consented using a mobile application that serves as a digital health tool.
- Subjects were trialed with commercially available SCS systems with a variety of programming types.
- PROs collected electronically using the mobile application at baseline, and end of SCS trial include PROMIS-29 (Patient-Reported Outcomes Measurement Information System®).
- **A sub-analysis of SCS trial data collected to-date from enrolled subjects with a primary or secondary painful DPN indication is shown here.**
- Analysis of all subjects enrolled in the SENSE SCS Pilot phase to-date are presented elsewhere[4].

Table 1. Key Inclusion / Exclusion Criteria

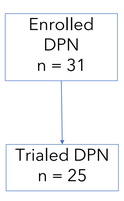
Pilot Phase Key Inclusion Criteria
• Candidate with an on-label SCS indication prior to enrollment in the study for a commercially available Medtronic SCS system. • Willing and able to use a personal smart phone for study surveys.
Pilot Phase Key Exclusion Criteria
• Any active implantable neuromodulation device or system.

RESULTS

Table 2. Baseline demographics in enrolled subjects with primary or secondary DPN indication

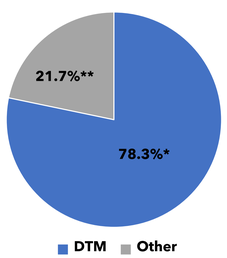
	Enrolled DPN Subjects (N=31)
Mean age (SD)	62 (11)
Sex, n (%)	20 (64.5%) M
DPN Primary Indication, n (%)	19 (61.3%)
Mean BMI, kg/m2 (SD)	34.8 (8.3)
% Type II Diabetes, n (%)	21 (67.7%)
Mean years since pain onset (SD)	10 (9.4)
Pain Intensity, 0 – 10 (SD)	7.3 (1.7)
Pain Medication Usage, n (%)	23 (85.2%)

Figure 1. Subject disposition chart for DPN sub-analysis



92% (23/25) DPN trial success

Figure 2. Successful SCS Programming at Trial (n=23)



* DTM includes therapy with a low-rate (<200 Hz) and high-rate (200 – 1200 Hz) waveform applied at 2 targets with and without cycling
** other programming types include high dose (HD) or low dose (LD) / tonic

Figure 3. Percent of patients reporting normal, mild, moderate, and severe PROMIS-29 domain scores at baseline (BL) and end of SCS trial (EOT) (n = 21)

° Defined as: Normal (≥45), Mild (40-45), Moderate (30-40) and Severe (<30)
* Defined as: Normal (<55), Mild (55-60), Moderate (60-70) and Severe (≥70)

DISCUSSION AND CONCLUSIONS

- This sub-analysis of subjects with DPN who underwent SCS trial for their painful symptoms demonstrates that SCS can provide improvement in pain-related symptoms.
  - 78.3% of subjects had a successful SCS trial with DTM SCS programming.
  - SCS therapy resulted in observed improvements from baseline in all 7 PROMIS-29 health domains at end of SCS trial, including sleep and physical function.
- Additionally, this study supports the use of digital health technology to allow for rapid and robust collection of electronic PROs.
- SENSE SCS is an ongoing clinical study. Data presented here are preliminary.
- **CONCLUSION: Preliminary findings from the ongoing SENSE SCS study suggest SCS may be an effective therapy for painful DPN that should be considered when treating this patient population.**

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ins International Neuromodulation Society

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