SCS for Painful Diabetic Peripheral Neuropathy: Consistent Outcomes from Multiple RCTs and Prospective Registry Data

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INTRODUCTION

- Pain associated with diabetic peripheral neuropathy (DPN) is treated medically with antineuralgics, tricyclic antidepressants, and serotonin-norepinephrine reuptake inhibitors which are often not satisfactory long-term[1].
- Spinal Cord Stimulation (SCS) is an effective treatment alternative per 3 randomized controlled trials (RCTs)[2,3,4] which consistently demonstrate that SCS is more effective than conventional medical management (CMM) for the treatment of painful DPN.
- The difference in treatment success between SCS and control in the RCTs ranged 52 – 58% for the primary endpoint in the intention-to-treat populations[2-5], and subjects reported improvements in EQ-5D quality of life (QoL) index scores of 0.12 – 0.38 at 6-months[2-7].
- We qualitatively looked for consistency in outcomes between published RCT results for SCS and registry data to assess "real-world" therapy efficacy for painful DPN.

MATERIALS & METHODS

- Registry data was obtained from the Medtronic Product Surveillance Registry.
- An analysis of outcomes including leg pain, QoL, disability, and medication usage was conducted using paired data at baseline and 1st follow-up (6- or 12-months) collected between November 2012 and October 2023 from subjects with either a primary or secondary DPN indication.
- Not all subjects in the registry had data at both baseline and 1st follow-up. Only subjects with paired data at baseline and 1st follow-up were included in the analysis. Sample size noted is indicative of data availability.

RESULTS

- There were 84 subjects enrolled in the registry indicated for DPN, and 69 implanted at the time of data cutoff (Table 1).
- Subjects experienced a mean (standard deviation, SD) reduction in leg pain at 1st follow-up of 2.6 (3.6) on 0 - 10 pain scale from 6.8 (2.5) at baseline (n=16) [Figure 1].
- QoL measured by the EQ-5D index was improved at 1st follow-up by a mean (SD) of 0.17 (0.26) from 0.40 (0.26) at baseline (n = 30), with 60.0% of subjects experiencing a minimally clinically important difference[8] [Figure 2].
- Subjects reported decreased disability with 30% of subjects improving to a better disability category and 45% remaining in the same disability category as determined by the Oswestry Disability Index (ODI) (n=20) [Figure 3]. ODI categories include minimal disability, moderate disability, severe disability, crippled, and bed-bound.
- Baseline medications were recorded in 58 subjects with decreased usage or no change in usage of baseline medications reported by 62.0% of subjects (36/58), with 37.9% of subjects (22/58) decreasing dosage in at least 1 baseline medication.

Table 1. Baseline characteristics in DPN subjects. Data presented indicate the number of subjects (%), unless noted otherwise.

Baseline Characteristics	Registry Subjects with a Primary or Secondary DPN Indication (n=84)
Race	
White	51 (60.7%)
Other	2 (2.4%)
Not reportable per local laws or regulations	31 (36.9%)
Ethnicity	
Non-Hispanic or -Latino	43 (51.2%)
Hispanic or Latino	2 (2.4%)
Unknown	7 (8.3%)
Not reportable per local laws or regulations	32 (38.1%)
Sex	
Male	55 (65.5%)
Female	29 (34.5%)
Age (years)	
Mean (SD)	61.2 (12.72)
Median	63.0
Min to Max	27 to 85

Figure 1. Leg pain measured by VAS in DPN subjects from baseline to first follow-up (n=16).

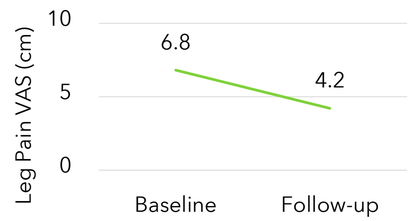


Figure 2. EQ-5D index Scores in DPN subjects at baseline and first follow-up (n=30)

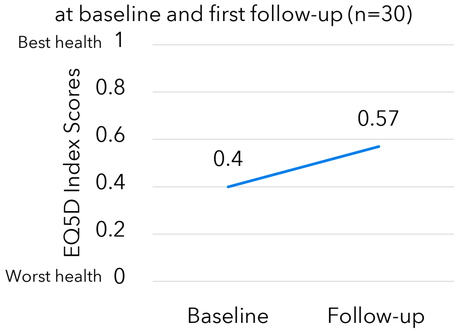
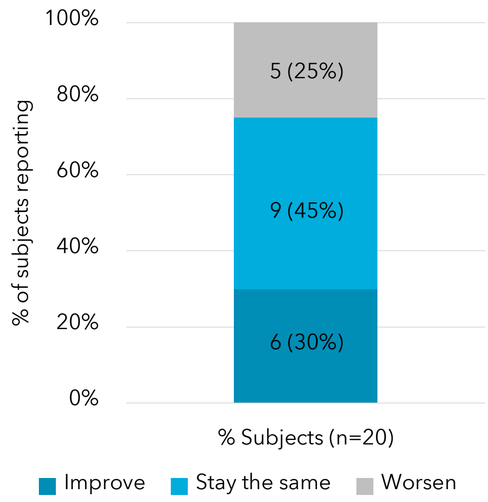


Figure 3. Change in Oswestry Disability (ODI) disability categories in DPN subjects from baseline to first follow-up. Data presented as n (% of total).



CONCLUSIONS

- An analysis of data from a clinical registry suggests that SCS provides pain relief, and improvements in quality of life and disability for patients with painful DPN.
- As a newer indication, the volume of registry subjects with DPN is relatively low. More data is needed.
- Collectively, robust published outcomes from 3 RCTs in combination with preliminary data from a clinical registry support the efficacy of SCS for painful DPN for the lower extremities that should be considered when CMM is unsatisfactory.
- Registry data on SCS for painful DPN will continue to be collected as more DPN patients gain access to SCS therapy.

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This study was sponsored by Medtronic UC202408765EN