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Global, Multicenter Registry of Prospectively-Enrolled Patients Utilizing SCS for Chronic Pain: Long-Term Outcomes from a Sub-Cohort Diagnosed with Diabetic Peripheral Neuropathy

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Introduction

With the global rise in scale of the incidence of type-2 diabetes mellitus, there exists a growing population of those that will experience Diabetic Peripheral Neuropathy (DPN). Of those that experience DPN, a substantial will experience chronic pain (thought to occur in up to ~26%) (1). Patients diagnosed with DPN who suffer from associated chronic pain often display a complex array of clinical manifestations often requiring an extensive calibration of treatment regimen according to specific needs of the patient (2). Additionally, clinical outcomes using 1st and 2nd line therapies (e.g., drugs, lifestyle modification, physical therapy) are often suboptimal mainly due to occurrence of side effects and/or patient noncompliance (3,4). With the burgeoning advances in neuromodulatory-based systems, interest has grown in reassessing this patient population when treated with implanted Spinal Cord Stimulation (SCS) devices. Moreover, the American Diabetes Association now recommends referring DPN patients to interventional pain management care when pharmacological therapies have no meaningful effect.5 Here, we sought to assess real-world outcomes from a subset of those diagnosed with DPN as derived from a global, multicenter SCS patient registry.

Materials and Methods

RELIEF (NCT01719055) is a global, multicenter, prospective, single-arm, observational registry that collects real-w orld data derived from the use of neurostimulation systems for chronic pain by patients w ithin routine clinical practice. A sub-set of patients with a diagnosis of painful DPN were assessed for pain relief (e.g., Responder Rate [(% of patients reporting ≥50% targeted pain relief], Quality-of-Life [EQ-5D]), and Treatment Satisfaction [Patient Global Impression of Change, PGIC] and other relevant clinical measures, per standard of care. Participants in the registry were required to provide a signed Institutional Review Board/Ethics Committee-approved consent form.

Results/Case Report

Forty-three patients enrolled in the registry for this sub-analysis w ere permanently implanted. In those patients who reached their 12-, 24- and 36-month timepoint, a leg pain responder rate (percent of patients w ith ≥50% pain relief)

of 73%, 74%, and 85%, respectively, was observed. Correspondingly, the responder rates for targeted pain (i.e., area of pain intended to be treated by SCS) was 78%, 81%, and 73% at 12-months (n=28), 24-months (n=21), and 36-months (n=15), respectively. Furthermore, ODI score decreased by -11.48 and -15.81 points (baseline score 47.3 with respective decrease to 37.7 and 32.8), at 24- and 36-months after implant, in accordance with reported minimal clinically important difference (-5 to -10-points or -11 %).6 At 36-months after implant, EQ5D scores improved by over 33% compared to baseline.

Discussion

These preliminary results demonstrate long-term, sustained clinically significant improvement among patients receiving SCS for treatment of pain associated with Diabetic Peripheral Neuropathy (DPN). As such, these data help demonstrate the potential of contemporary neuromodulation systems that have been designed to provide for more advanced and highly customized therapy, as an important treatment option for DPN-related chronic pain.

References

1. Schreiber AK, Nones CF, Reis RC, Chichorro JG, Cunha JM. Diabetic neuropathic pain: Physiopathology and treatment. World J Diabetes. 2015 Apr 15;6(3):432-44.
2. Yang H, Sloan G, Ye Y, Wang S, Duan B, Tesfaye S, Gao L. New Perspective in Diabetic Neuropathy: From the Periphery to the Brain, a Call for Early Detection, and Precision Medicine. Front Endocrinol (Lausanne). 2020 Jan 17;10:929.
3. Finnerup NB, Attal N, Haroutounian S, McNicol E, Baron R, Dworkin RH, et al. Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. Lancet Neurol. (2015)14:162–73.
4. Yang M, Qian C, Liu Y. Suboptimal Treatment of Diabetic Peripheral Neuropathic Pain in the United States. Pain Med. 2015;16(11):2075–83.
5. Pop-Busui R, Boulton AJM, Feldman EL, et al. Diabetic Neuropathy: A position statement by American Diabetes Association. Diabetes Care. 2017; 40(1): 136-154.
6. McClure NS, Sayah FA, Ohinmaa A, Johnson JA. Minimally Important Difference of the EQ-5D-5L Index Score in Adults with Type 2 Diabetes. Value Health. 2018 Sep;21(9):1090-1097.

Disclosures

Yes

Tables / Images