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Long-term evaluation of SCS in painful DPN: an eight-ten-year prospective cohort study

***Aims*:** The longitudinal efficacy of spinal cord stimulation (SCS) was evaluated for the treatment of painful diabetic polyneuropathy (DPN).
***Methods*:** This prospective cohort study evaluated the longitudinal effects of SCS for refractory painful DPN. The cohort consisted of N=19 former participants of two combined prior trials evaluating SCS for painful DPN who were still using SCS after at least 8 years. The inclusion criteria for the original two studies (Pluijms WA et al *Br J Anaesth 2012;109:623-629* and Slangen R et al *Diabetes Care 2014;37:3016-3024*) were: DPN based on the Michigan Diabetic Neuropathy Score, inadequate pain relief or intolerable side effects from medical therapy for painful DPN, and pain in the lower extremities for >12 months with a mean numeric rating pain scale (NRS) score ≥5. The primary outcome for longitudinal cohort study was pain intensity scores as measured by a 4-day average NRS score compared to the baseline scores prior to SCS implantation. Secondary outcomes included patient-reported outcomes such as quality-of-life (QoL), sleep, and depression scores compared to baseline.
***Results*:** Of the initial 40 participants from the original two SCS implantation studies for painful PDN, 12 had their SCS devices removed due to treatment failure (n=10) or complications (n=2), typically within five years of implantation, and 9 were not included due to lack of follow-up data, informed consent, or long-term data. A total of 19 participants were included. The mean age at follow-up was 56 years, 74% were men, and most participants (90%) had type 2 diabetes (T2D) with mean duration of 9.6 years and mean painful neuropathic symptoms duration of 4.5 years. Mean NRS scores decreased by 2.3 ± 2.5 points during the day and by 2.2 ± 2.4 points at night. More than half of participants achieved ≥30% reduction in pain scores. There were no differences in the secondary outcomes of QoL, sleep quality or depression symptoms at long-term follow-up Vs. baseline. Eighty-two percent of participants needed up to 8 setting adjustments per year. Over half of participants (53%) needed replacements of their implantable pulse generator and 19 complications occurred due to hardware failure (n=8) or pain at the device site (n=6).
***Conclusions*:** SCS had a persistent pain reduction at eight years in a subset of participants with T2D and refractory painful DPN. However, there are no changes in QoL, sleep quality, or mood symptoms. Device complications are relatively common and frequent follow-up for these devices is needed.

Comments. Painful DPN remains a treatment challenge due to the lack of disease-modifying therapies, limited efficacy, or safety of currently available treatment modalities (Pop-Busui R et al *Diabetes Care 2016;40:136-154*). SCS has emerged a potentially promising therapy for refractory painful DPN symptoms. However, the long-term efficacy of SCS is unknown. This is the longest prospective cohort study addressing the longitudinal follow-up of participants of two RCTs receiving low-frequency SCS for painful DPN. The strengths of this study include the longitudinal follow-up of SCS therapy, which addresses pain reduction at up to eight years. The primary limitation is the lack of a true sham-control arm (either in the original two SCS trials or the longitudinal follow-up). While more than half of the participants had clinically meaningful pain reduction at 8 years, there were no improvements in QoL, sleep or mood though the study was likely underpowered to evaluate these domains. Additionally, participants required frequent follow-up and the burden of this follow-up was not evaluated. Complications due to SCS were also common. SCS remains an option for treatment of refractory painful DPN symptoms though, based on this study, it remains unclear for whom this treatment modality benefits the most. Additionally, prior to SCS implantation, the need for frequent follow-up and high risk for complications are important points for discussion with patients considering this therapy.
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Reference. Zuidema X, van Daal E, van Geel I, de Geus TJ, van Kuijk SMJ, de Galan BE, de Meij N, Van Zundert J. Long-Term Evaluation of Spinal Cord Stimulation in Patients With Painful Diabetic Polyneuropathy: An Eight-to-Ten-Year Prospective Cohort Study. Neuromodulation. 2023 Jul;26(5):1074-1080. doi: 10.1016/j.neurom.2022.12.003. Epub 2022 Dec 31. PMID: 36587999.
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