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Durability of high-frequency 10-kHz spinal cord stimulation for painful diabetic neuropathy refractory to conventional treatments: 12-month results from a randomized controlled trial

Aim: In this study, Petersen et al report on the durability of 10-kHz spinal cord stimulation (SCS) for the treatment of pharmacotherapy refractory painful diabetic neuropathy (pDN) over a 12-month period.

Methods: This is a follow-up publication of the multicentre SENZA-PDN trial which randomised 216 patients to either conventional medical management (CMM) or CMM+SCS. Inclusion criteria were pDN for 1 year or more refractory to pharmacotherapy, lower limb pain intensity ≥ 5 cm on a 10-cm visual analogue scale (VAS), HbA1c $\leq 10\%$ and BMI ≤ 45 kg/m².

Results and Conclusions: The earlier publication (Petersen EA et al *JAMA Neurol.* 2021;78: 687-698) reported that a significantly higher proportion receiving SCS achieved the primary end point of the study, which was 50% improvement in VAS at 3 months (73.6% difference, $p < 0.001$). At 6 months, the VAS score in the CMM group was 6.9 cm (baseline 7.0 cm) while in CMM+SCS group it was 0.7 cm (baseline 7.6 cm). In the current report, the improvement in pain noted at 6 months in the CMM+SCS arm was maintained at 12 months with a mean VAS score of 1.7 cm. Participants were allowed to crossover at 6 months - none from the intervention arm opted for conventional therapy; however, 81% of those who underwent CMM only crossed over to SCS with the same improvement in pain as the CMM+SCS group. Overall, for the 154 permanent implants, there were 8 (5.2%) procedure related infections, of which 5 (3.2%) required device explantation. One participant experienced lead migration.

Comments. The lack of disease modifying treatments for pDN has meant that we are current heavily reliant on drugs to provide symptomatic control. The use of neuropathic pain medications such as gabapentinoids, serotonin-norepinephrine reuptake inhibitors, tricyclic antidepressants, and opioids is widespread but durable effect is inconsistent. The numerous side-effects associated with these therapies can ultimately impact on adherence levels. The use of SCS, a type of neuromodulation has been an option in a select few individuals for the management of pDN - however, all guidelines on pDN continue to approach the technology with caution. Reasons for this are multiple: it is invasive, requiring epidural implantation with attendant risks of infection and the older low-frequency technology often provided uncomfortable 'stimulations' and could add to the pain milieu, especially in people with paraesthesia. The two studies by Petersen EA et al go some way to bridge the gap in evidence and stimulate guidance development organisations to actively consider the technology. However, the lack of blinding is a significant limitation. Long-term follow-up is also required (26-60 months) to assess if the early efficacy is sustained and to measure the true, clinical and cost-effectiveness. Many pain units providing SCS already offer these 10-kHz high-frequency devices as their default option, however, until now quality supportive evidence has not been available.

Prash Vas

Reference. Petersen EA, Stauss TG, Scowcroft JA, Brooks ES, White JL, Sills SM, Amirdelfan K, Guirguis MN, Xu J, Yu C, Nairizi A, Patterson DG, Tsoufas KC, Creamer MJ, Galan V, Bundschu RH, Mehta ND, Sayed D, Lad SP, DiBenedetto DJ, Sethi KA, Goree JH, Bennett MT, Harrison NJ, Israel AF, Chang P, Wu PW, Argoff CE, Nasr CE, Taylor RS, Caraway DL, Mekhail NA. Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial. *Diabetes Care.* 2022 Jan 1;45(1):e3-e6. doi: 10.2337/dc21-1813.

<https://diabetesjournals.org/care/article/45/1/e3/139017/Durability-of-High-Frequency-10-kHz-Spinal-Cord>