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PATIENT-REPORTED SATISFACTION WITH USING A RECHARGEABLE 10 KHZ SPINAL CORD STIMULATION DEVICE

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Introduction

In 2021, an estimated 20.9% of US adults experienced chronic pain lasting 3 or more months, including 6.9% of whom with pain that substantially restricted their daily activities.¹ Chronic pain is frequently treated with pharmacotherapies, including opioid analgesics, which often have low efficacy and negative side-effects.^{1,2} High-frequency spinal cord stimulation delivered at 10 kilohertz (10 kHz SCS) is a non-pharmacological approach demonstrated to be safe with substantial and durable relief of trunk and limb pain.³ High-frequency SCS works by delivering paresthesia-free currents via leads powered by implanted pulse generators (IPGs), which are recharged using an external charger placed next to the skin. Rechargeable devices eliminate the clinical risks and costs associated with periodic surgeries to replace non-rechargeable IPGs used in some conventional SCS devices. However, required recharging may pose a burden to patients, though few studies have evaluated this issue. The current study evaluated whether rechargeable technology is practical and convenient for patients receiving 10 kHz SCS therapy for management of chronic pain.

Materials and Methods

Using real-world, de-identified data from an industry-maintained registry, we retrospectively evaluated patient-reported outcomes (PROs) in patients implanted with a 10 kHz SCS system for treatment of chronic refractory pain of the trunk and/or limbs. No exclusion criteria were applied. Implantation, which entailed surgical insertion of octapolar leads in the epidural space at locations determined by the patient's pain, was conducted only in patients who experienced a $\geq 50\%$ reduction in pain during a pre-implant trial period. The study included PRO data collected from October 2, 2016, through January 29, 2020, via telephone contacts at 3, 6, 12, and 24 months after implant. In patients with data from multiple time points, data from the most recent time point was included. Study data were analyzed descriptively; median values and percentages were reported. The study did not require Ethics Board review or approval as per United States 45 Code of Federal Regulations (CFR).

Results/Case Report

The study included data from 10,391 patients (56.1% women; median age, 67 years), among whom 65.5% had

previous spine surgery and 16.2% had previous neuromodulation therapy. The median follow-up after implantation was 361 days (range, 180-1550 days).

Most patients reported that after initiating 10 kHz SCS treatment, activity limitations, symptoms, emotions, and overall quality of life were a great deal or moderately better (83%; n= 10,390; Figure 1). Most patients also reported being “likely” or “very likely” to repeat the procedure to achieve the same results (71%; n=10,369) and to recommend 10 kHz SCS to others with a similar pain experience (77%; n=10,035). Almost all patients reported using the device while sleeping (96%; n=10,388) and driving (96%; n=10,035). Among patients with prior SCS treatment (N = 1205), 75% rated 10 kHz SCS as “great deal better” or “moderately better” than conventional SCS.

Most patients did not individually adjust the therapy settings of their 10 kHz SCS device; 49% of patients reported never doing so, and 38% reported doing so once per week or less (n=10,387; Figure 2). Overall, 66% of patients reported recharging their device daily, and 34% reported recharging every other day or 2 to 3 times per week (n=10,385). Recharging took 60 minutes or less in 84% of patients (n=10,386). Seventy percent of patients were “satisfied” or “very satisfied”, 19% were “neutral”, and 11% “dissatisfied” or “very dissatisfied” with the convenience of recharging their 10 kHz SCS device (n=10,387). Notably, most patients who reported being “dissatisfied” or “very dissatisfied” with the device’s recharging requirements, nevertheless reported experiencing “a great deal better” or “moderately better” overall quality of life since initiating 10 kHz SCS (64%) and over half stated they would recommend the same therapy to others with similar pain.

Discussion

The efficacy of 10 kHz SCS for relieving chronic pain has been documented in many clinical trials, but there is a paucity of data assessing patient perceptions and benefits of RC IPGs. This study of over 10,000 patients demonstrates high satisfaction rates amongst patients that use 10 kHz SCS for chronic pain, in addition to other benefits including patients’ functioning and quality of life. A large majority of patients in our sample indicated that their activity, limitations, symptoms, emotions, and overall quality of life was “better” or “a great deal better” than before beginning 10 kHz SCS, would be willing to undergo the same process again to achieve the same result, and would recommend it to friends or family members with similar pain.

In this sample of over 10,000 patients, a large majority reported being either “very satisfied”, “satisfied”, or “neutral” with the convenience of the recharging process, which is reflective of results in patients with RC devices for low-frequency SCS. The frequency of recharging and length of individual recharge sessions can impact the convenience of the recharging process as well as the amount of time the device is available to provide pain relief. Our results showed that two-thirds of respondents charged their device daily and that the majority spent 30 to 60 minutes in each charging session, and nearly one-quarter of respondents charged for less than 30 minutes at each recharge session. These data suggest that although daily charging is often needed for 10 kHz SCS, the aggregate time spent in charging is comparable to those for low-frequency stimulation.

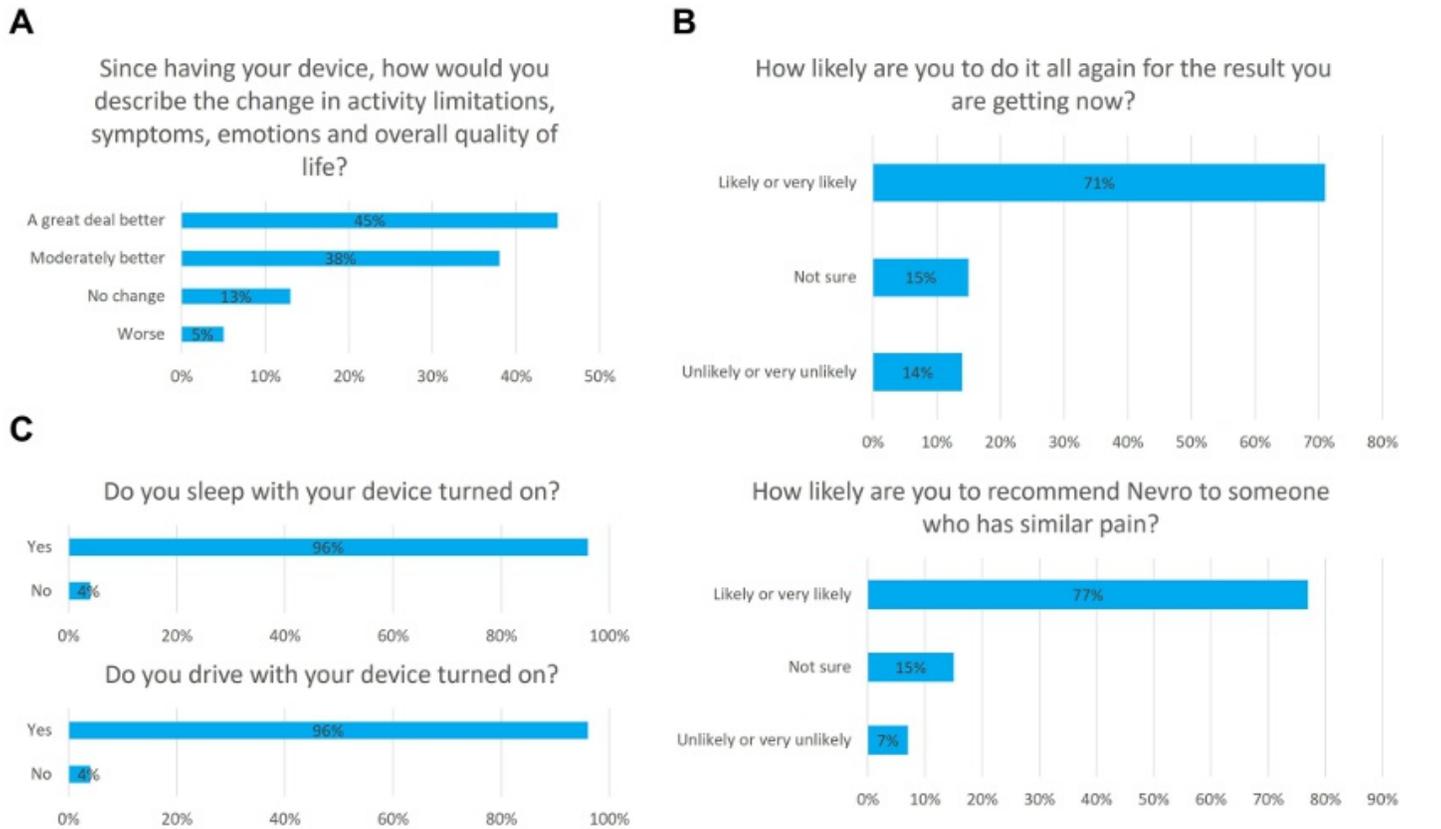
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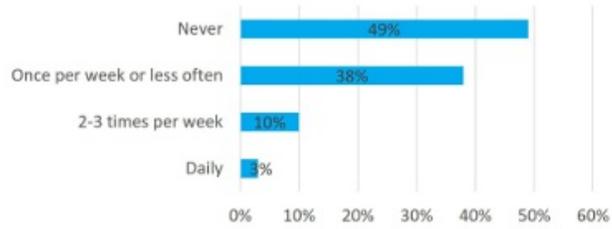
Disclosures

No

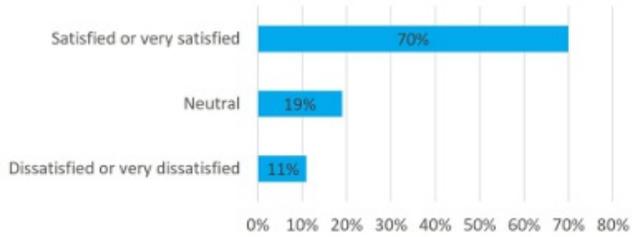
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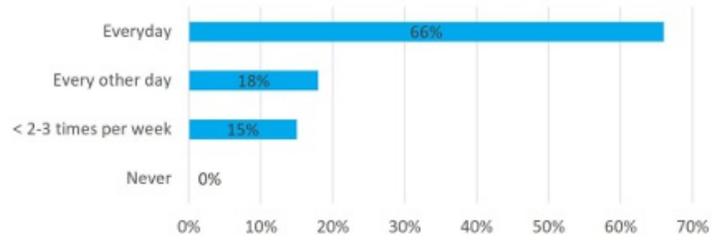
A How often do you use your remote control to adjust your therapy settings?



B How satisfied are you with the convenience of charging your device?



C How often do you charge your device?



How long does it take you to charge your device?

