Spinal Cord Stimulation (SCS): Using a Digital Health Platform to Characterize the Patient Journey

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INTRODUCTION

Chronic pain is estimated to occur in 20.4% of US adults (50 million), with 8% of US adults (19.6million) with high impact chronic pain[1] and higher prevalence associated with advancing age. Further, chronic pain contributes to an estimated $560billion each year in direct medical costs, lost productivity and disability programs.[2] Spinal Cord Stimulation (SCS) is a proven therapy option for these patients refractory to conventional medical management. Patients may assess the benefits of SCS therapy using a temporary SCS device during a device trial evaluation (SCStrialEval) prior to permanent SCS implant.

Patients' pain management experiences are complex, personal and every patient is unique. Digital Health platforms (Medtronic CareGuidePro™ (CGP)) are well suited to enable individualized care coordination during the trial evaluation period by providing patients access to educational resources and connecting them to their care team. The ability to receive real time data and feedback from patients can provide care-teams opportunities to adjust therapies more efficiently and effectively when necessary. This is an important step forward in the pursuit of further improving and optimizing patient care with SCS.

Our objective was to characterize the patient journey from SCStrialEval to permanent SCS implant.

We present the following real-world clinical outcomes in chronic pain patients undergoing SCStrialEval under guidance of a digital health platform (CareGuidePro/CGP):

- Successful SCStrialEval
- Permanent SCS implant rate after successful SCStrialEval
- Outcomes across sites of service

MATERIALS & METHODS

We retrospectively analyzed a random selection of 2500 SCStrialEval patients that downloaded and used the Digital Health app (CGP) between August 2021 to April 2022.

Data Collection:

- Digital health platform (CGP) based care coordination during the trial evaluation period
- Manufacturer records of SCStrialEval and permanent implant

SCStrialEval Success designation

- For each patient, the SCStrialEval success or failure was documented in the records based on clinical judgement at conclusion of the 3- to 10-day trial

Permanent Implant rate

- After a successful SCStrialEval, quantification of permanent SCS rate was possible with a minimum 2-month follow-up period. Cumulative implant rate assessed over the follow-up period
- Hazard rate (p/day) derived to illustrate implant rate trends over time. Calculated to evaluate the change in probability of receiving a permanent SCS implant conditional on lack of implant until that date(using bin length of 7 days)

Outcomes stratified by site of service

- Ambulatory Surgery Center (ASC), Hospital, and Office
- Comparison across site of service (ASC vs. Hospital, Hospital vs. Office and ASC vs. Office): p-value adjusted for multiple comparisons using FDR (false discovery rate) correction

RESULTS

Patients Demographics

Among 2500 patients who underwent SCStrialEval enabled by the CGP digital health platform, subjects were aged 58.9±12.9yrs [IQR 50 - 69], primarily Female (55.4% F, 36.6% M and 8.0% unknown). The site of service for the SCStrialEval was distributed as: ASC (n=949, 38.0%), Hospital (n=770, 30.8%), Office (n=781, 31.2%).

SCS Trial Success Rate

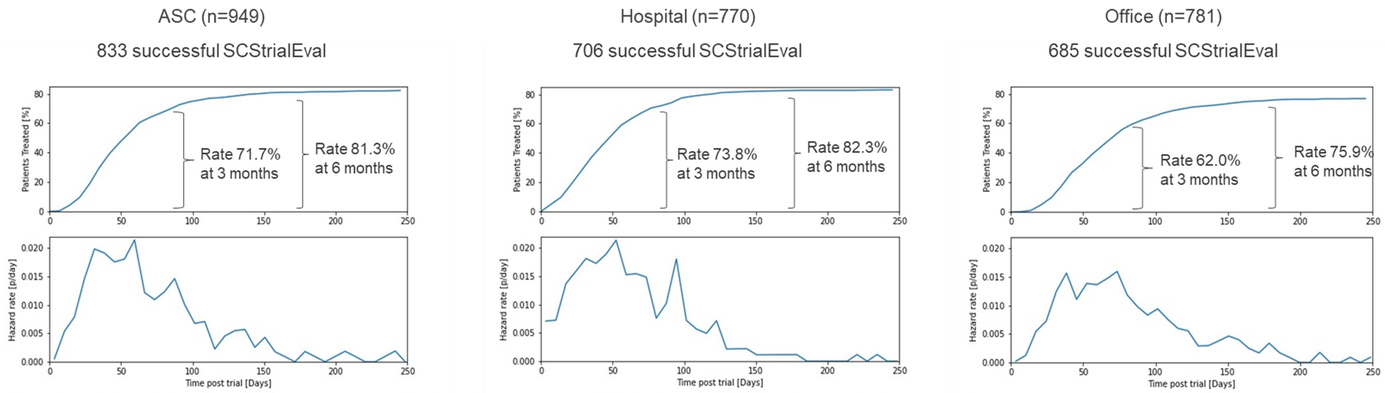
The SCStrialEval success rate differed across the three types of service sites: ASC (87.8%), Hospital (91.7%) and Office (87.7%), with inter-site comparison p-value of ASC vs Hospital (p=0.019), Hospital vs. Office (p=0.019) and ASC vs. Office (p=1.0).

Implant Rate after successful SCS Trial

Within 6 months of a successful SCStrialEval, 80.1% of the full cohort received a permanent SCS implant. Cumulative implant rate stratified by the site of service (Figure 1) revealed a 6-month implant rate of 81.3% (ASC), 82.3% (Hospital) and 75.9% (Office)

The hazard rate peaked within 60 days and thereafter declined. The in-Office site of service had the lowest implant rate over the 6-month time period and hit a declining hazard rate after 90days

Figure 1. Permanent SCS Implant Rate after successful SCSTrial stratified by Site of Service: Cumulative Implant Rate (%) and daily Hazard Rate (p/day)



Hazard rate (p/day) derived to evaluate change in probability of receiving a permanent SCS implant conditional on absence of an implant until that date

DISCUSSION

After a successful SCS trial, various factors may impede conversion to permanent implantation. It is imperative that patients successfully trialed receive access to permanent implantation avoiding time delays which could lead to patient's frustration and reduced overall benefit from the therapy.

A Digital health platform enables feedback from patients to their care-teams irrespective of site of service of the SCStrialEval enabling oversight during the trial period.

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DISCLOSURE

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