

Characterization of Spinal Cord Stimulation Trial Evaluation subjects: Digital Health Platform Experience

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INTRODUCTION

Digital health platforms can facilitate patient engagement and unique clinical insights. In the patient's journey from temporary Spinal Cord Stimulation (SCS) therapy trial evaluation (SCStrialEval) to final implanted device, the Medtronic CareGuidePro™ (CGP) digital-health platform enables care-coordination, and app-based survey responses specific to pain-history and Patient Reported Outcomes (PROs). This further enables detailed pain characterization and quantification of the multi-dimensional impact of chronic pain.

The present study summarizes the demographics and chronic pain history survey responses in chronic pain patients undergoing SCStrialEval. We further highlight the inter-relationships between those characteristics.

METHODS

Prior to an SCStrialEval, patients may download the CareGuidePro™ app (CGP) on their smartphones. This digital health platform gives a patient access to educational resources and connects them to their care team; it also allows patients to complete standardized and customized surveys from the comfort of their own home. CGP provides secure/encrypted sharing of Patient Reported Outcomes with a patient's physician and care-team to keep them informed and connected.

Before beginning the SCStrialEval, the patient receives baseline pain history and PROMIS-29 surveys to complete through the app. A tabulation of patient characteristics at baseline (i.e. before exposure to SCS therapy) allows us to quantify their chronic pain in terms of pain location, pain description, duration of chronic pain diagnosis, treatments attempted, impact of pain on life, and opioid usage.

Given that a single patient may exhibit chronic pain in unique ways, we sought to quantify dominant etiology of pain in these patients, while understanding the interrelationships between the chronic pain features. This was done using Jaccard dissimilarity scores and visually representing these via heatmap.

Aiming to find groups of pain characteristics Hierarchical Clustering was applied over the characteristics. Distance matrix (pairwise matrix, where each cell (i, j) denotes the distance of the corresponding pain characteristic c_i and c_j). Each characteristic was represented by the group of patients that included it in their survey. The distance between pair of characteristics was defined as the Jaccard Distance between these groups. Intuitively – two characteristics are close if the number of times they appear together at the same survey is greater than the number of times they appear separately

Jaccard Index

$$J(A, B) = \frac{|A \cap B|}{|A \cup B|}$$

RESULTS

In a nationally representative US cohort of 2000 patients who received an SCStrialEval between Aug 2021 to July 2022, we retrospectively analyzed SCStrialEval patients that enrolled in CGP, providing insights into their demographics, history of pain and inter-relationship between the history features.

Patients were aged 57.6 ± 13.0 yrs [IQR 48 - 68], primarily Female (54.0% F, 35.2% M and 10.8% unknown), primary trial type was Differential Target Multiplexed (DTMTM) 67.4%, primary indication of impant was lower-back with coexisting pain in other locations.

Table 1. Chronic Pain Characteristics

Survey response regarding history of pain highlighted the multi-dimensional nature of the chronic pain

Pain Location	n	%
Upper Limb (arms/hands)	275	13.75 %
Other location	524	26.2 %
Lower Limb (feet/ankles)	603	30.15 %
Right Leg	1047	52.35 %
Left Leg	1111	55.55 %
Lower Back	1711	85.55 %
Pain Description		
Other pain	163	8.15 %
Prickly	406	20.3 %
Difficult to describe	424	21.2 %
Burning	1090	54.5 %
Stabbing	1102	55.1 %
Shooting	1121	56.05 %
Tingling/numbness/pins and needles	1200	60.0 %
Sharp	1404	70.2 %
Aching	1505	75.25 %
Pain Duration		
Less than 6 months	20	1.0 %
6-12 months	172	8.6 %
1-3 years	475	23.75 %
3 years or longer	1334	66.7 %
Treatments Tried		
Chiropractic Care	96	4.8 %
Other treatment	441	22.05 %
Therapy, acupuncture, massage	1404	70.2 %
Topical pain relievers	1438	71.9 %
Over the counter medication	1476	73.8 %
Targeted injections	1695	84.75 %
Prescription medications (opioids, etc.)	1736	86.8 %
Heat/Ice Pads	1755	87.75 %
Impact of Pain on life		
Other impact	277	13.85 %
Ability to socialize	1426	71.3 %
Ability to work	1496	74.8 %
Mood	1556	77.8 %
Ability to sleep	1652	82.6 %
Ability to exercise	1820	91.0 %
Other impact	277	13.85 %
Opioid Usage		
Goal of Reducing Opioid usage	1416	70.8 %
	1605	80.25 %

Table 2. Patients Demographics and SCS Trial characteristics

	SCStrialEval patients N = 2000	p-value****
Age (years)	57.6 ± 13.0 [IQR 48 68]	
% Pts with Age ≥ 65yrs	33.2%	
Gender Female N (%)	1079 (54.0%)	
Gender Male N (%)	704 (35.2%)	
Gender Unknown N (%)	217 (10.8%)	
SCS Trial indication N (%)		
Back*	643 (32.2%)	
Complex Regional Pain Syndrome	41 (2.0%)	
Herniated Disc**	52 (2.6%)	
Radiculopathy	182 (9.1%)	
Other/Unknown***	1082 (54.1%)	
SCS Trial Type N (%)		
DTM	1347 (67.4%)	p < 0.001
DTM Endurance	168 (8.4%)	
Evolve	133 (6.6%)	
Other/Unknown^	352 (17.6%)	
SCS Trial Location N (%)		
Ambulatory Surgery Center	653 (32.6%)	p < 0.001
Office	530 (26.5%)	
Hospital	549 (27.5%)	
Unknown	268 (13.4%)	

*Back = Chronic Low Back Pain, Failed Back Surgery Syndrome (FBSS), FBSS Leg/Back

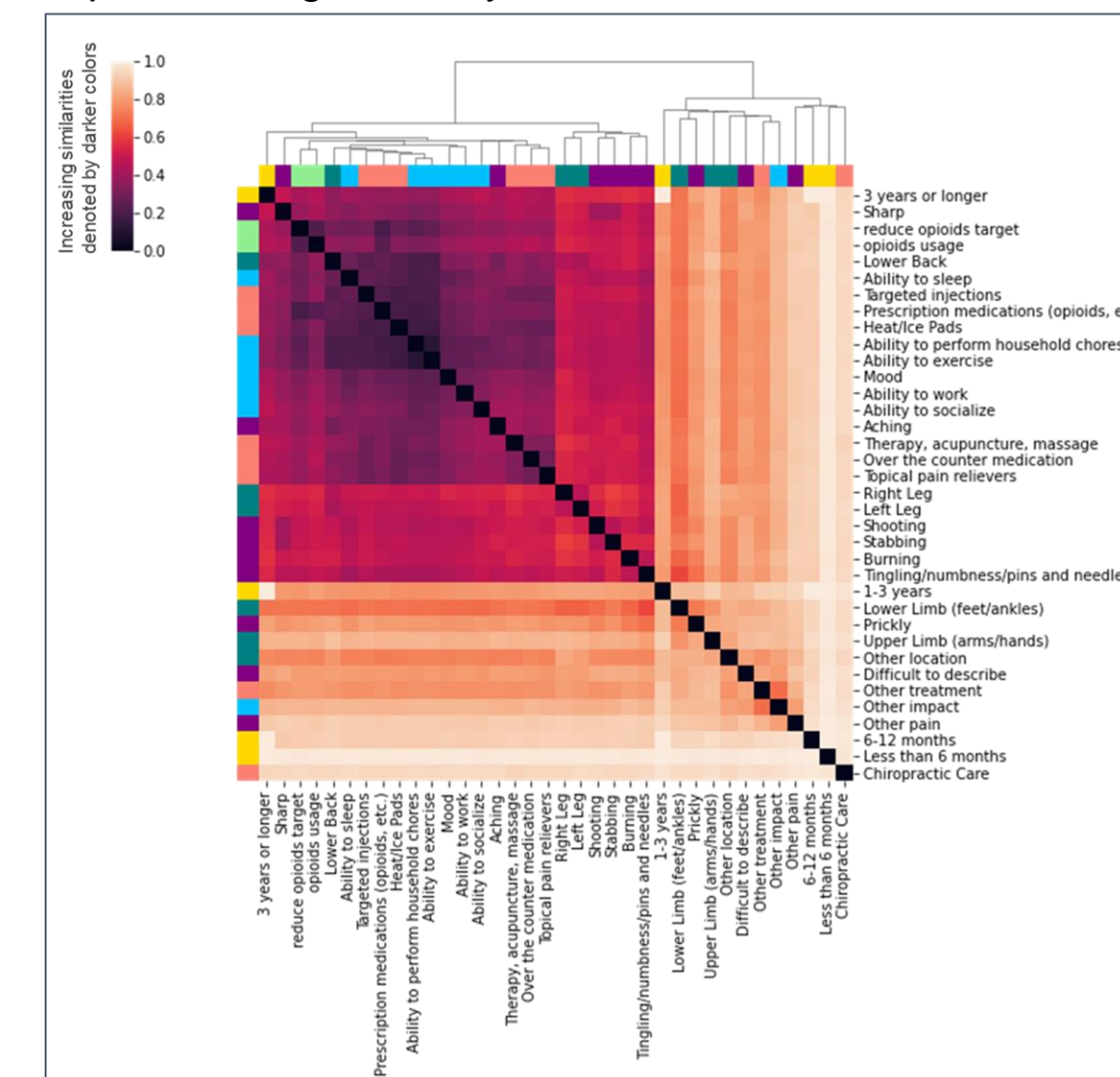
**Herniated Disc = Degen Disc Disease / Herniated Disc Pain

*** Other/Unknown = Empty, FBSS Upper Limb, Other, Diabetic Peripheral Neuropathy, Peripheral Neuropathy (Other)

**** p-values from Chi-square test determined after removing Unknown cases

^ Other/Unknown = Trial, Other

Figure 1. Inter-relationships between Chronic Pain characteristics
Heatmap illustrating similarity levels



DISCUSSION

Insights

The Jaccard similarity index-based evaluation of these characteristics revealed four main clusters of pain etiology in SCStrialEval patients, with the dominant being: Lower back pain with sharp, aching sensation among patients symptomatic for 3-years or more. These were rarely seen concomitant with lower-limb, upper-limb pain that had a history of 6-12months and was described as prickly pain.

The hierarchical clustering based on Jaccard distance revealed four main clusters of pain etiology in SCStrialEval patients, with the dominant being: Lower back pain which is treated with targeted injections, heat/ice pads and prescription medications, accompanied with sleep difficulties and limited ability to perform household chores.

REFERENCES

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DISCLOSURE

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