

Longitudinal Patient-Reported Outcomes in Spinal Cord Stimulation implanted chronic pain patients

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INTRODUCTION

- Spinal cord stimulation (SCS) is a proven non-opioid therapy for chronic-pain patients.
- Post-implant management is often contingent on scheduled and unscheduled clinic visits.
- Digital health platforms are helpful in the settings of patient education, care-coordination, and collection of patient-reported outcomes throughout their SCS journey.
- We present here longitudinal real-world outcomes and transitions of pain phenotypes over a 6-month period after permanent SCS implant.

MATERIALS & METHODS

- This was a retrospective observational cohort study from 1049 chronic pain patients followed for six months between July 2022 to July 2023.
- Chronic-pain patients received SCS implants in the US while using a mobile digital health platform for education, feedback and patient reported outcome (PRO) data collection.
- PROMIS-29 (Patient-Reported Outcomes Measurement Information System[®]) surveys¹⁻³ were sent before implant (baseline) and then at 4wk, 6wk, 8wk, 3mo and 6mo post-implant.
- This survey assesses seven domains (pain interference, ability to participate in social roles and activities, sleep disturbance, fatigue, depression, anxiety and physical function) and pain intensity.
- PROMIS scores⁴⁻⁵ and pain intensity were compared at baseline and post-implant, and durability of responses over follow-up period was assessed using Kruskal-Wallis analysis of variance.
- Utilizing previously reported phenotypes of chronic-pain⁶, we further assessed distribution of chronic pain states severity over follow-up period using proportions at each time-point.

RESULTS

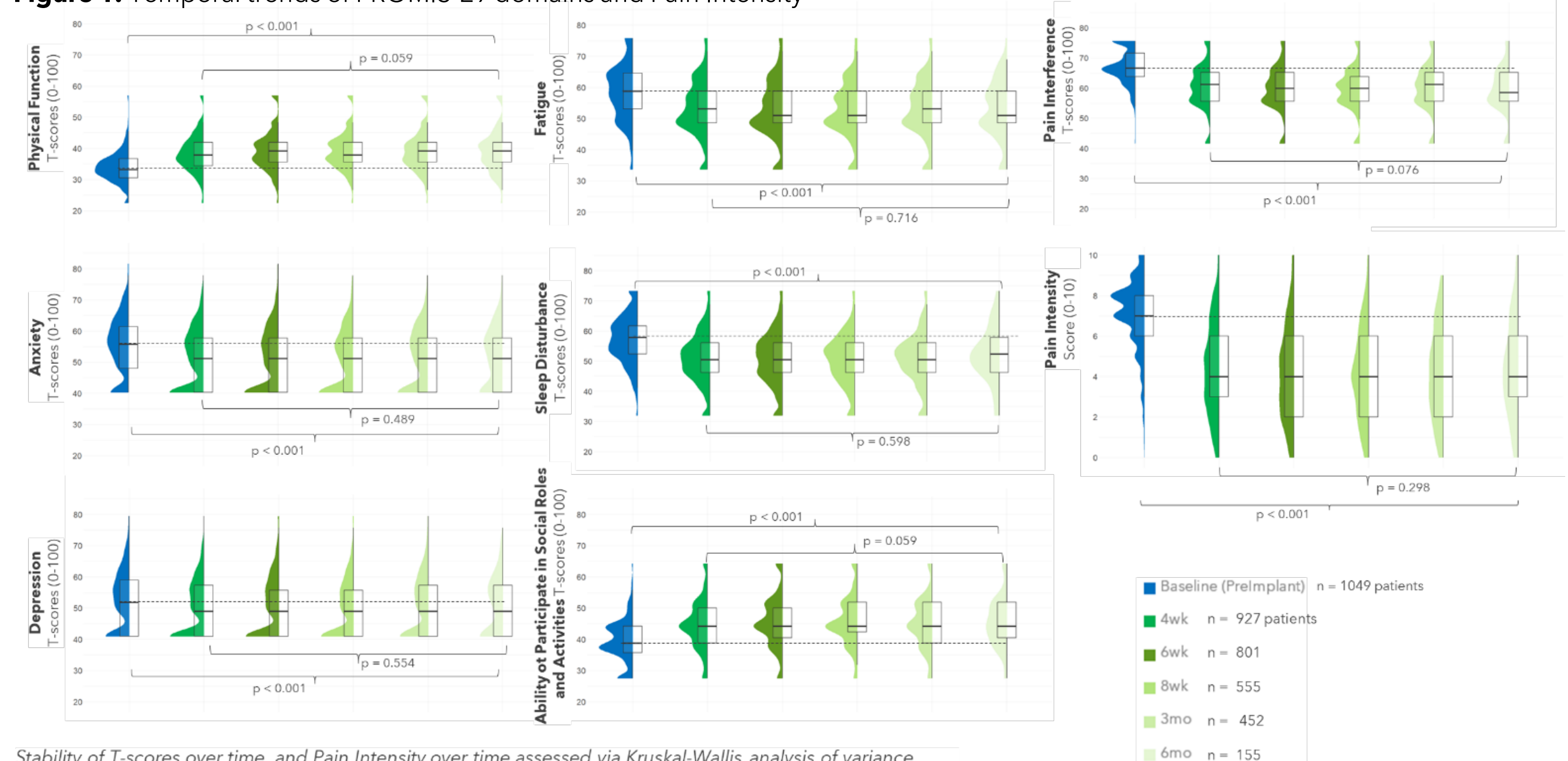
DEMOGRAPHICS & PAIN ETIOLOGY

- Patients were aged 59.9±15.0yrs [IQR 50 - 70] and 50.1% were Female (33.9% Male and 16.0% unknown).
- The pain location in majority of the patients was lower back (86.0%), patients had long-standing pain (66.1% with over 3 years, 25.3% with 1-3 year pain).
- Patients commonly experienced aching (78.2%), sharp (70.6%), stabbing (55.8%), tingling, numbness (62.8%), and burning (55.8%) pain. Patients had tried multiple prior therapies and one objective was to reduce their use of opioids and pain.

PROMIS-29 SCORES

- The baseline PROMIS scores for all seven domains were reduced significantly in the follow-up period ($p < 0.001$).
- The temporal trends showed no difference in outcomes for the population ($p > 0.05$) for each PRO over the 4wk, 6wk, 3mo and 6mo follow-up period (**Figure 1**).
- Chronic-pain phenotypes derived from PROMIS-29 responses highlighted a significant improvement in state from baseline and confirmed stability over the follow-up period.

Figure 1. Temporal trends of PROMIS-29 domains and Pain Intensity



CONCLUSIONS

- Real-world data from this digital-health platform enabled a robust quantification of long-term improvement in chronic-pain, highlighting stability and durability of SCS therapy after SCS implant.

REFERENCES

- Hays RD, Spritzer KL, Schalet BD, Cella D. PROMIS[®]-29 v2.0 profile physical and mental health summary scores. Qual Life Res. 2018 Jul;27(7):1885-1891. doi: 10.1007/s11136-018-1842-3. Epub 2018 Mar 22. PMID: 29569016; PMCID: PMC599556.
- Dunbar MS, Rodriguez A, Edelen MO, Hays RD, Coulter ID, Siconolfi D, Herman PM. Longitudinal Associations of PROMIS-29 Anxiety and Depression Symptoms With Low Back Pain Impact in a Sample of U.S. Military Service Members. Mil Med. 2023 Mar 20;188(3-4):e630-e636. doi: 10.1093/milmed/usab339. PMID: 34417805; PMCID: PMC10226420.
- Cella D, Choi SW, Condon DM, Schalet B, Hays RD, Rothrock NE, Yount S, Cook KF, Gershon RC, Amtmann D, DeWalt DA, Pilkonis PA, Stone AA, Weinfurt K, Reeve BB. PROMIS[®] Adult Health Profiles: Efficient Short-Form Measures of Seven Health Domains. Value Health. 2019 May;22(5):537-544. doi: 10.1016/j.jval.2019.02.004. PMID: 31104731; PMCID: PMC7201383.
- HealthMeasures. HealthMeasures Scoring Service - Scoring PROMIS Global, Profiles, and Psychosocial Illness Impact. <https://www.youtube.com/watch?v=KM2FqYoS--A>. Published 2016.
- Cella D, Gershon R, Bass M, Rothrock N. WHAT IS ASSESSMENT CENTER. Published 2007. <https://www.assessmentcenter.net>.
- Lad SP, Lempel N, Amit R, Coletti F, Venkatraman V, Sharan AD, Bharmi R, Reeve BB. Health-Related Quality of Life Phenotypes Among Chronic Pain Patients Receiving Spinal Cord Stimulation <https://asnpain.com/wp-content/uploads/2023/06/Top-Abstracts-2023.pdf>

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