

SCS Candidates with Painful Diabetic Peripheral Neuropathy: Patient Demographics and Pain Presentation from the SENSE SCS Study

Melissa Murphy¹, Andrew Will², Jugal Dalal³, Velimir Micovic⁴, Thomas White⁵, David Provenzano⁶, Xiaoxi Sun⁷, Grace Santa Cruz Chavez⁷, Cory Goracke⁷



¹North Texas Orthopedics & Spine Center, Dallas-Fort Worth, TX, United States, ²Twin Cities Pain Clinic, Minneapolis, MN, United States, ³Novant Health Spine Specialists, Winston-Salem, NC, United States, ⁴Pain Management Consultants of Southwest Florida, Fort Myers, FL, United States, ⁵Procura Pain and Spine PLLC, Houston, TX, United States, ⁶Pain Diagnostics and Interventional Care, Sewickley, PA, ⁷Medtronic Neuromodulation, Minneapolis, MN, United States.

OBJECTIVE

- The use of spinal cord stimulation (SCS) has been shown to be a successful treatment for painful Diabetic Peripheral Neuropathy (DPN) in multiple randomized clinical trials (RCTs) ¹⁻².
- However, strict inclusion and exclusion criteria used in RCTs may not translate to actual patient populations in the real world³.
- Painful DPN can be a complex condition due to patients often having multiple pain indications and presentation types. Therefore, a better understanding how this patient population presents in the real world may aid in optimizing SCS treatment outcomes for patients.
- This poster presents real-world patient-reported baseline characteristics from subjects with painful DPN enrolled in the SENSE SCS study to further our understanding of who these patients are and the complexities with which they present in clinic.**

RESULTS

Table 2. Baseline Demographics of Enrolled DPN Subjects (N=40, Unless Otherwise Noted)

Subject Characteristics	Enrolled Mean (SD) or n (%)
Age (Years)	63 (10)
Male	25 (62.5%)
White	35 (87.5%)
BMI (kg/m ² , N=34)	35.7 (8.8)
Type II Diabetes	30 (75.0%)
Year Since Onset of Chronic, Intractable Pain (N=33)	12 (11)

Figure 1a. DPN Indication Breakdown by N (N=40)

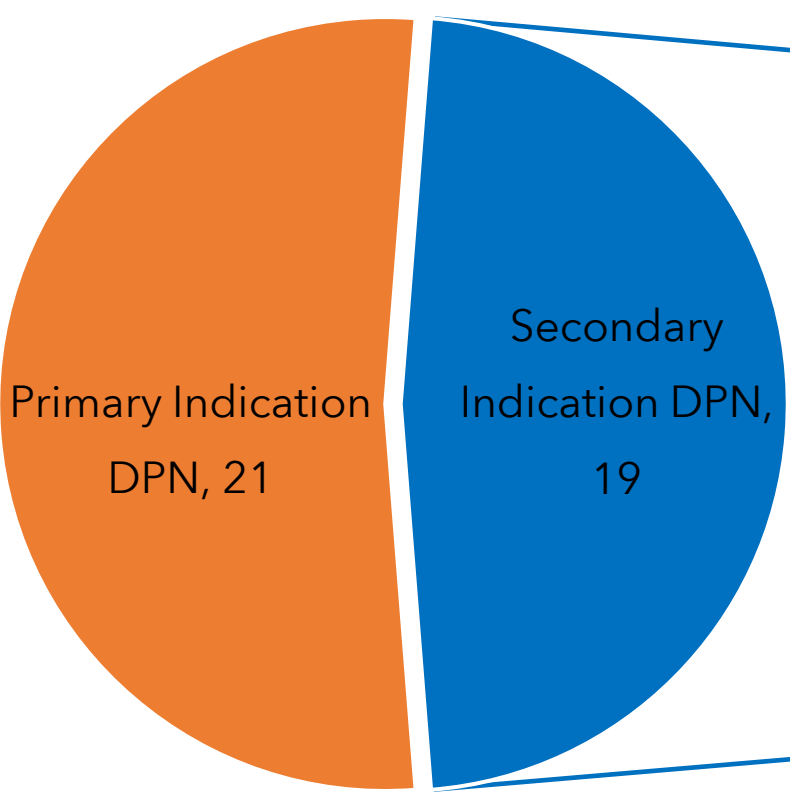
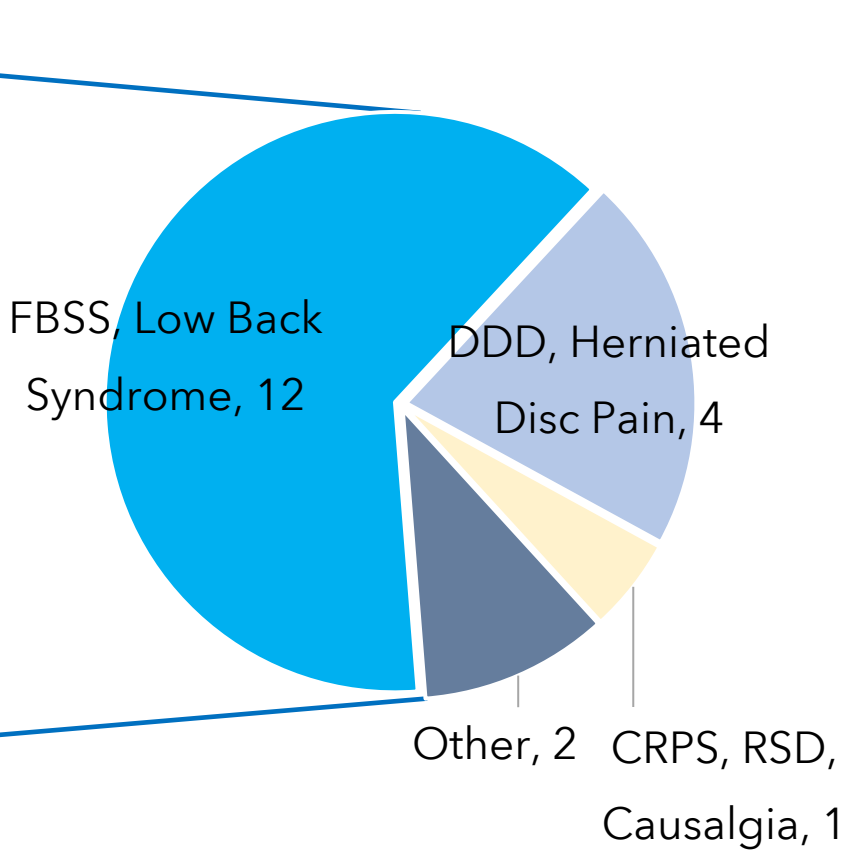


Figure 1b. Primary Indications Other Than DPN by N (N=19)



Abbreviations: FBSS = Failed Back Surgery Syndrome, DDD = Degenerative Disc Disease, CRPS = Complex Regional Pain Syndrome, RSD = Reflex Sympathetic Dystrophy

Figure 2. Pain Location at Baseline (N=36)*

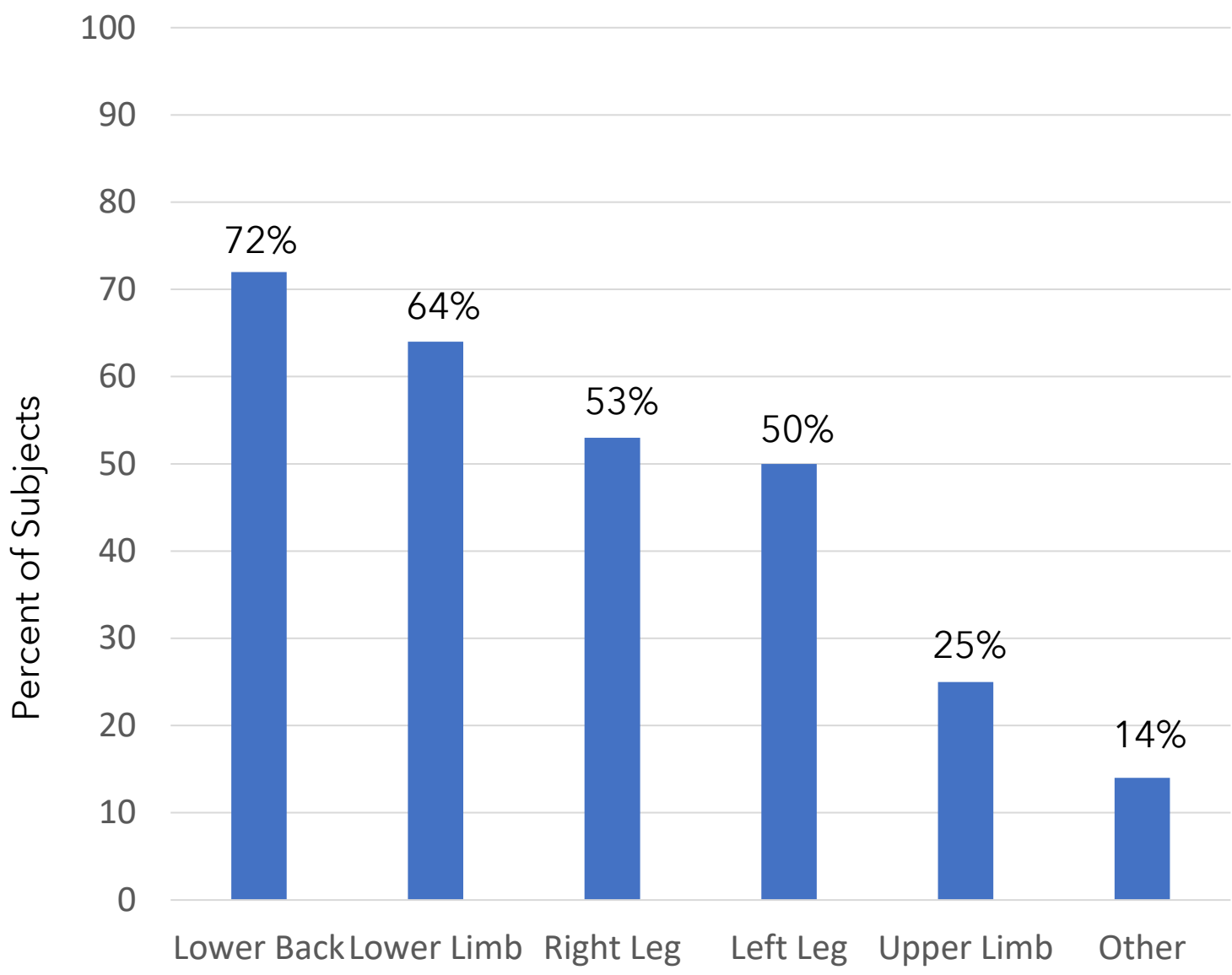


Figure 3. Pain Description at Baseline (N=36)*

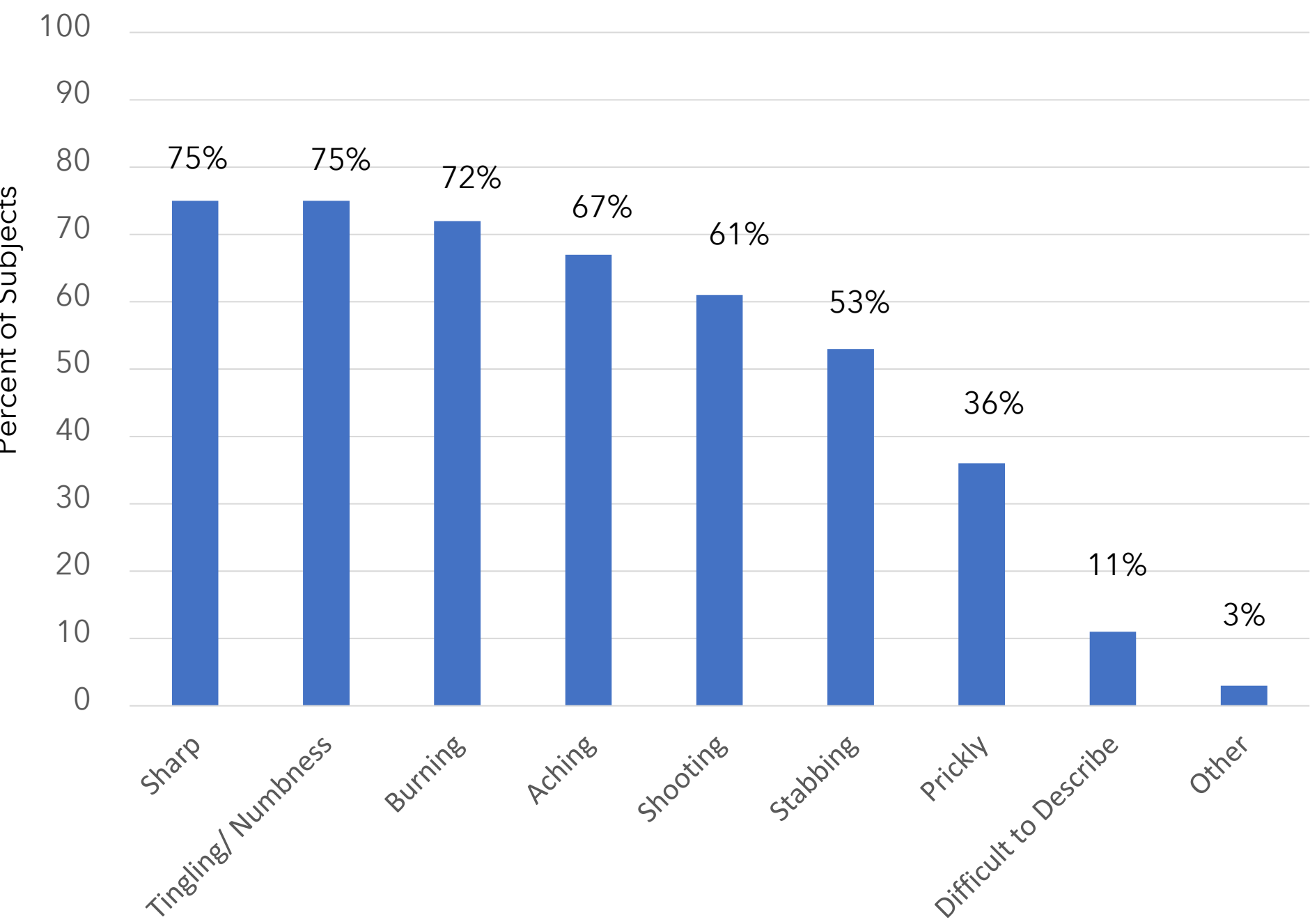
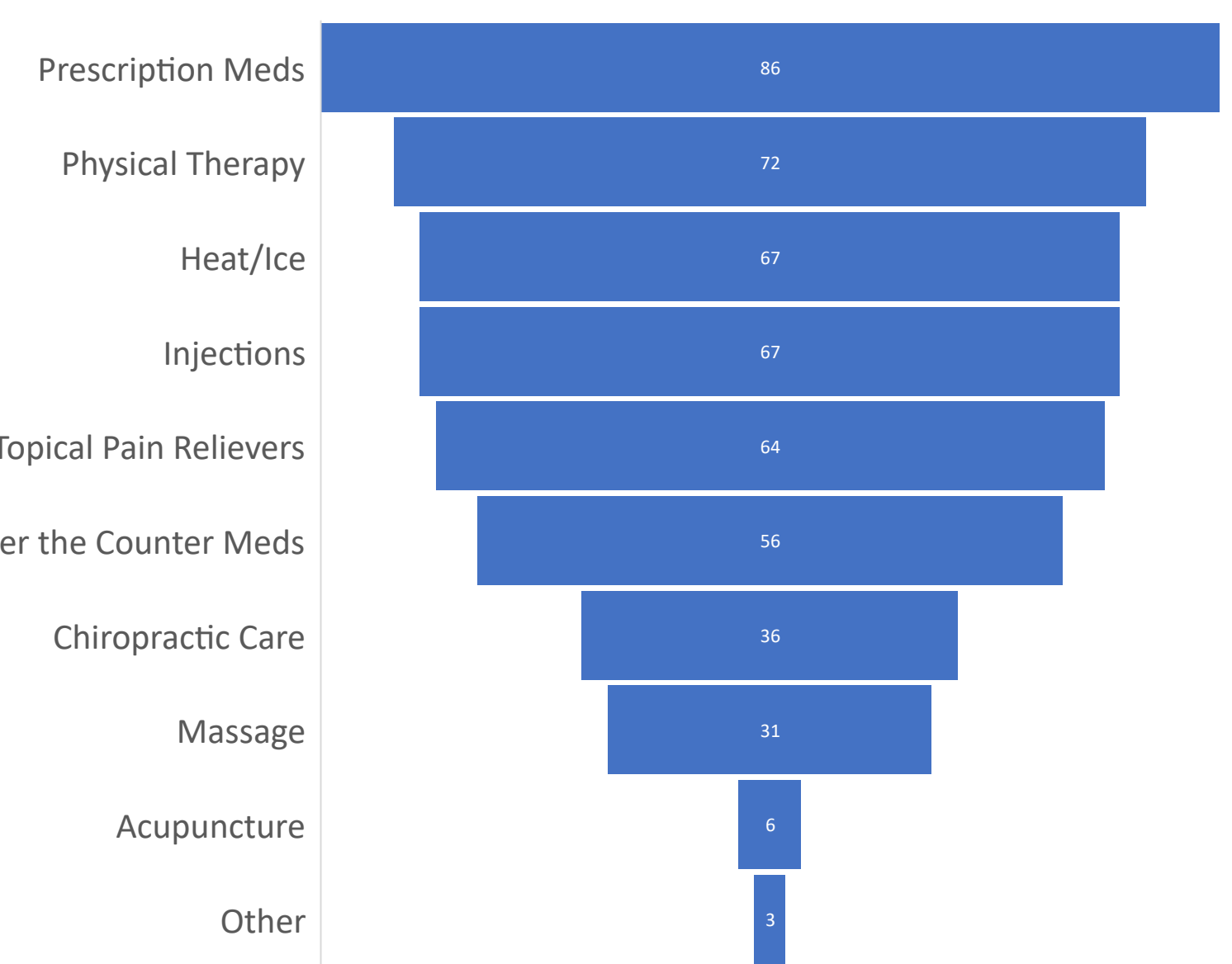
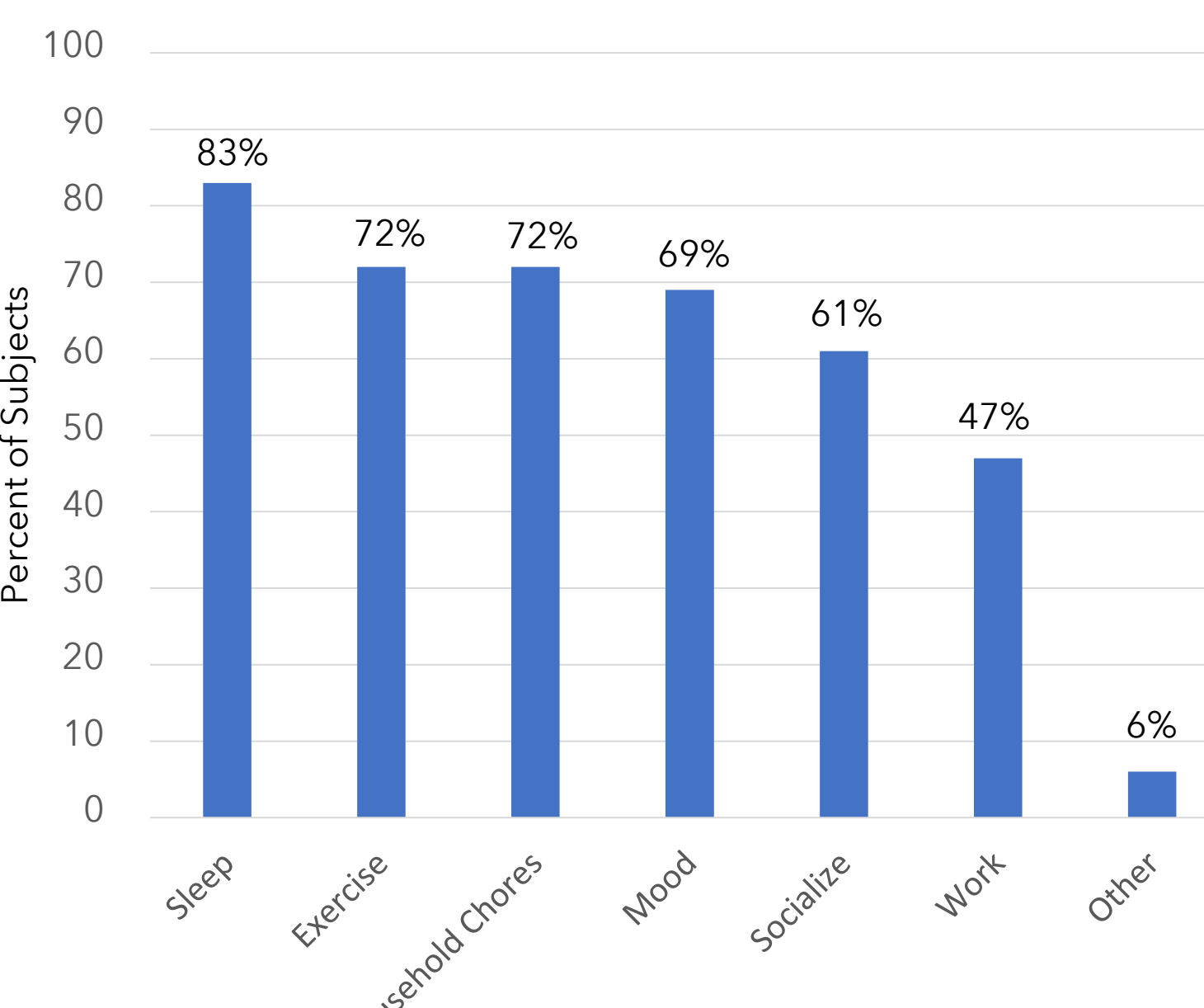


Figure 4. Treatments Tried Before SCS to Manage Pain (Percent of Subjects, N=36)*



*These metrics represent all pain etiologies in medical history and may not be exclusive to their DPN diagnosis.

Figure 5. Impacted by Pain (N=36)*



DESIGN

SENSE SCS - Study to Evaluate Neuromodulation Subject Experience with Contemporary Spinal Cord Stimulation Modalities for Chronic Pain

Design: Prospective, post-market, non-randomized, observational study, enrolling in the US only

- IRB approved study, registered on clinicaltrials.gov (NCT05775510)
- Hybrid decentralized model of execution
- Subjects with an on-label SCS indication eligible to enroll
- Ongoing enrollment and follow-up; currently in a pilot phase with 9 active sites

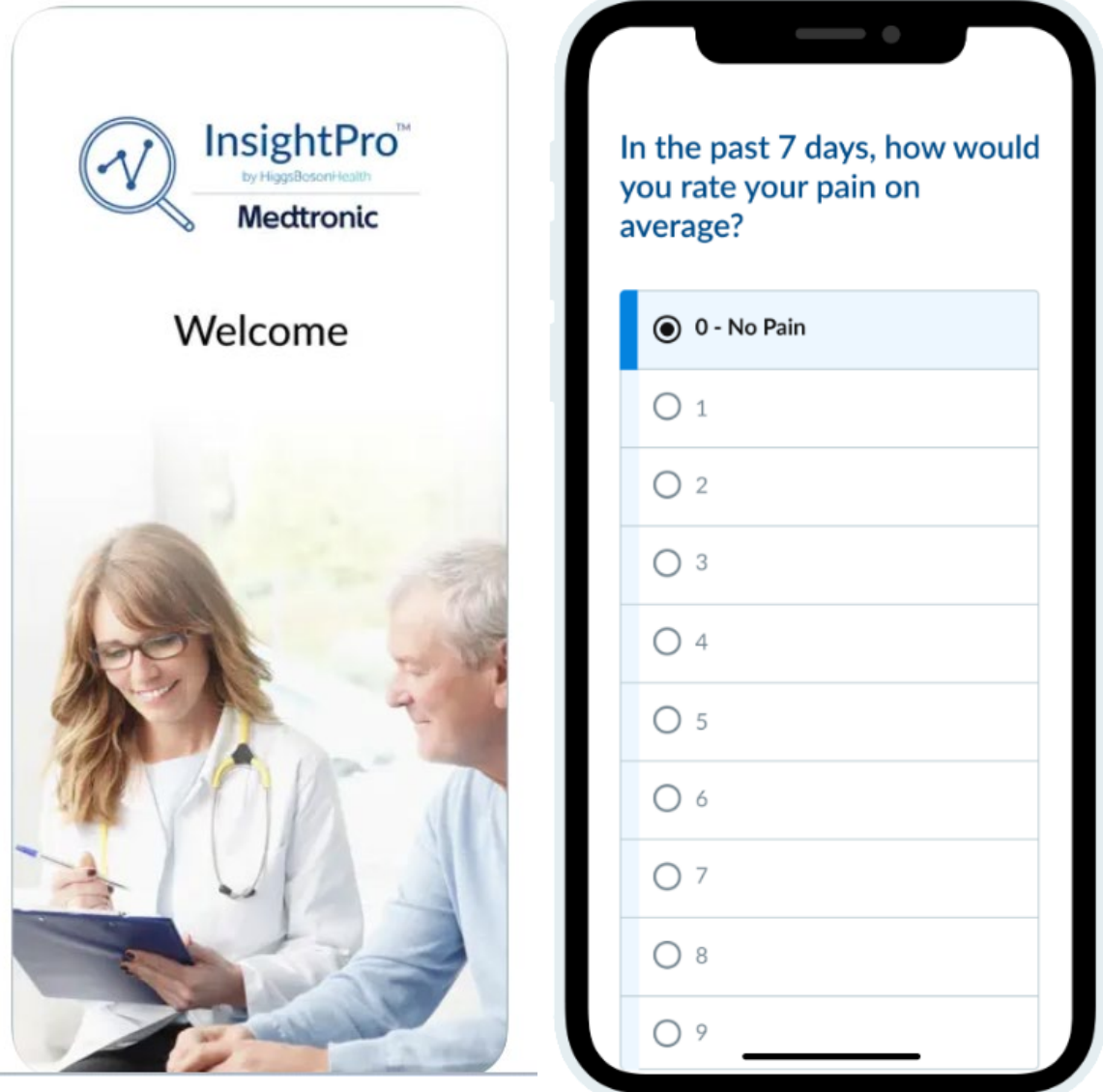
Purpose: Evaluate workflow of a mobile clinical trial application for collection of patient reported outcomes and to characterize outcomes on patient experience with commercially available Medtronic SCS devices

- Subjects electronically consented using a custom-made mobile application, InsightPro™ clinical trial app
- Subjects were trialed and implanted with commercially available SCS systems with a variety of programming types, including eCAP sensing-capable neurostimulators.
- PROs collected electronically using InsightPro™ at baseline, SCS trial, and after permanent SCS implantation through 12 months.

- EQ-5D-5L
- Satisfaction
- Pain Intensity Surveys
- Activity Goals
- PGIC
- PROMIS-29 (Patient-Reported Outcomes Measurement Information System®)⁴

Table 1. Key Inclusion / Exclusion Criteria

Pilot Phase Key Inclusion Criteria
- Candidate with an on-label SCS indication for a commercially available Medtronic SCS system. - Willing and able to use a personal smart phone for study surveys.
Pilot Phase Key Exclusion Criteria
Any active implantable neuromodulation device



RESULTS AND CONCLUSIONS

- These results demonstrate that DPN patients in this study present with multiple pain types, locations, and sensations.
- Many different pain etiologies present with DPN in this cohort, including FBSS and DDD.
- Lower back and lower limb pain were the most common pain locations indicated.
- Subjects described numerous pain sensations, with individuals experiencing many different kinds of pain sensations.
- These subjects have unsuccessfully tried a multitude of treatments to help manage their DPN pain, with 86% of subjects utilizing prescription medication.
- Multiple areas of subjects' lives are impacted by their pain, with the ability to sleep impacting the most subjects.
- Outcome measures from this study will be reported as the study continues.

CONCLUSION: The findings from this dataset illustrate the complexity of DPN pain presentation and underscore the importance of continuing to study this population to understand how these complexities may impact clinical outcomes.

References
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