Impact of psychosocial factors on the success of neuromodulation treatment for patients with persistent pain

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ABSTRACT
Introduction Significant interindividual variability in spinal cord stimulation (SCS) outcomes exists. Due to its high cost and risks of complications, criteria to guide patient selection for SCS trials and their outcomes would be helpful. With increased focus on the use of patient-reported outcomes to improve care, we aim to evaluate the National Institute of Health Patient Reported Outcome Measurement Information System measures for an association with successful SCS trials in patients with persistent pain.

Methods Our prospective, observational study enrolled 60 patients with persistent pain who underwent an SCS trial. Patients completed demographic and Patient Reported Outcome Measurement Information System computer adaptive test (PROMIS CAT) assessments to measure self-reported pain interference, depression, anxiety, physical functioning, and sleep disturbance at the time they presented for placement of their trial device.

Results Of the 58 patients who underwent successful electrode placement, 11 had an unsuccessful trial. There were no differences in patient demographics between patients with a successful and an unsuccessful trial. Patients who had a successful SCS trial reported lower pre-trial levels of anxiety, depression, and sleep disturbance and decreased post-trial levels of depression, sleep disturbance, and pain interference.

Conclusions We found that patients with high levels of depression, anxiety, and sleep disturbance using the PROMIS CAT were predictive of unsuccessful trials. In addition, we found that patients with successful SCS trials reported lower levels of these domains on PROMIS CAT administered at the end of the trial.

INTRODUCTION
Neuromodulation has emerged as an effective means of treatment for refractory neuropathic pain conditions. It is currently approved to treat a number of conditions such as chronic neuropathic pain of the trunk and limbs, complex regional pain syndrome (CRPS), and diabetic peripheral neuropathy, and is indicated for selected patients with persistent pain who have not responded to or tolerated conventional medical management. The first patient is implanted with temporary percutaneous electrodes that connect to an external pulse generator for determination of spinal cord stimulation (SCS) effectiveness and tolerability. If this trial is successful, permanent electrodes are later placed and connected to an implantable pulse generator for long-term analgesic therapy.

WHAT IS ALREADY KNOWN ON THIS TOPIC
⇒ Pre-trial assessments of psychosocial variables are associated with spinal cord stimulation (SCS) outcomes.
⇒ An easy-to-implement assessment is needed to guide patient selection for SCS trials and to monitor their outcomes.

WHAT THIS STUDY ADDS
⇒ We performed a prospective observational study of patients undergoing a neuromodulation trial for persistent pain and found that those patients who had an unsuccessful trial had higher depression, anxiety, and sleep disturbance.
⇒ Repeated Patient Reported Outcome Measurement Information System computer adaptive test (PROMIS CAT) assessments were used to monitor SCS trial success.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY
⇒ PROMIS CAT provides another assessment of patient-reported outcomes that clinicians can use to guide treatment decisions.
important implications for patient education regarding available treatment options.

Despite the use of varying outcome measures, studies to date have not incorporated standardized patient-reported outcomes (PROs). The National Institute of Health (NIH) Patient Reported Outcome Measurement Information System (PROMIS) standardizes the measurement of individual domains of well-being and disease burden.\(^8\)\(^9\) The PROMIS computer adaptive test (CAT) format uses item response theory to sequentially select the most appropriate questions based on the patient’s response to prior questions. This format reduces patient burden by requiring fewer responses while maintaining strong content validity and favorable psychometric properties compared with the standard PROMIS forms.\(^8\)\(^9\) PROMIS CAT versions allow for an efficient and comprehensive individualized assessment of multiple health domains for each patient during a clinic visit.\(^10\)\(^11\) All scales are scored in a standardized format, integrated with the Epic electronic medical record, and have been translated into multiple languages.

The purpose of this study was to evaluate patient demographics, preprocedural clinical characteristics, and psychosocial factors that are associated with successful neuromodulation trials for patients with persistent pain. We implemented the NIH PROMIS CAT to measure self-reported outcomes (PROs) including pain interference, depression, anxiety, physical functioning, and sleep disturbance, embedded in our electronic medical record system (EMR). Patients were asked to complete the PRO questionnaires electronically using a tablet computer on arrival for their clinical visits. PRO scores are immediately calculated and available through the patient’s EMR along with vital signs, medications, and other clinical information. Further, we aimed to determine the responsiveness in multiple PROMIS CAT domains during the 7-day neuromodulation trial period.

**METHODS**

**Participants and setting**

This prospective, observational study followed patients with persistent pain who underwent a neuromodulation trial at the University of Arkansas for Medical Sciences Interventional Spine and Pain Center between June 2020 and July 2023. All adult patients who met the clinical criteria for implantation of a neuromodulation device and were able to speak, write, and understand English were invited to participate. Patients were excluded if (1) there was evidence of monetary gain related to the outcome of their procedure (eg, worker’s compensation, ongoing litigation, pending disability claim) and/or (2) the patient had pain >4/10 at a bodily site not being treated by the SCS.

Patients who met the inclusion/exclusion criteria were approached at the time they presented for placement of their trial device by a research nurse (figure 1). Of the 71 patients approached, 60 (84.5%) completed demographic and symptom-related questionnaires. Medical records were later reviewed for pain history and treatment-related data. Eleven patients were not interested in participating. All participants gave written,
informed consent to participate and completed all study-related procedures prior to their procedure.

**SCS trial procedure**
The SCS trial was conducted according to UAMS pain clinic protocols. Each patient underwent preoperative imaging and neuropsychological assessments. Anticoagulants were held in concordance with the American Society of Regional Anesthesia and Pain Medicine guidelines for Interventional Spine and Pain Procedures in Patients with Anticoagulant Medications. Preprocedural labs were done to ensure proper coagulation status and intravenous antibiotics were administered. Patients were placed under live sedation in order to facilitate comfort but allow for conversation and on-table testing if needed. Temporary leads were percutaneously placed via a 14G Touhy needle into the epidural space of the thoracic or cervical spine under live fluoroscopic guidance. After the procedure, the percutaneous leads were stably secured. Patients were monitored during the 7-day trial for coverage area, pain reduction, lead migration, and complications, after which patients returned to the clinic to have the leads removed. At this visit, patients were asked to provide the percentage of their usual pain relief and functional benefits during the trial and their satisfaction with the SCS.

**Data collection**
**Patient demographics**
Each patient was asked to provide their demographic information which included gender, race, ethnicity, marital status, educational level, work status, smoking history, and income.

Pain intensity
Each patient was asked to report their current level of pain on the Numeric Pain Rating Scale (NRS). The NRS is a well-established and validated assessment of pain using an 11-point scale, where ‘0’ represents no pain and ‘10’ represents the most intense pain imaginable.¹³

**PROMIS CAT**
In September 2020, the UAMS Interventional Spine and Pain Center implemented routine administration of the NIH PROMIS CAT for all patients. PROMIS assessments are available within EPIC, our medical record system. We custom-built the CAT functionality and the integration of each assessment with MyChart and each of the tablets we used for data acquisition. Additional details can be shared on reasonable request to the corresponding author. On arrival, patients were given a tablet computer through which they completed their assessments. Each patient was asked to complete assessments for five health domains: anxiety (CAT V.1.0), depression (CAT V.1.0), pain interference (CAT V.1.1), physical function (CAT V.2.0), and sleep disturbance (CAT V.1.0). This set of assessments was selected by the clinic providers as these PROs are clinically relevant in patients with complex persistent pain for monitoring changes in these domains during treatment. Responses to each item were captured in their EMR and available to the health providers at the time of their visit. Each PROMIS scale score is calculated according to the distribution of gender-matched and age-matched normative data using the T-score algorithm.¹⁴ The mean T-score for each instrument is 50 and an SD of ±10 units. For the symptom-oriented domains (anxiety, depression, sleep disturbance, and pain interference), higher scores indicate worse symptomatology for the domain being assessed. Higher scores on the physical function domain indicate better functioning.

**Medical records**
Medical records were reviewed to obtain disease and treatment information which included diagnoses, pain etiology, pain-related medical and surgical treatment, medications, relevant coexisting medical conditions, and outcome of spinal cord stimulation trial.

**Statistical analyses**
The primary outcome of this secondary data analysis was the success of the SCS trial. The SCS trial was successful if the patient reports (1) at least a 50% reduction in pain, (2) satisfaction with SCS during the trial, and (3) a desire to proceed with a permanent implant at the time of their follow-up visit. For univariate analyses of patients’ demographics, clinical characteristics, and responses to each questionnaire, we applied the t-test for continuous variables and the Fisher’s exact test for categorical variables to evaluate for statistical differences between patients with a successful or unsuccessful SCS trial. The Wilcoxon matched-pair signed-rank test was used to evaluate PROMIS CAT responses for patients with successful trials.

To determine the responsiveness of PROMIS CAT in patients with a successful trial, we calculated the effect size (ES) and standardized response mean (SRM) for each assessment at the post-trial time point compared with the pre-trial time point. The ES was calculated as the mean change in T-scores divided by the SD of the pre-trial score. The SRM was calculated by dividing the mean change in T-scores by the SD of the mean change in T-scores. The ES and SRM were interpreted as small (0–0.3), moderate (0.31–0.6), or large (>0.61).¹⁵ Higher values indicate greater responsiveness of the PROMIS CAT assessment to pain relief during the SCS trial.

Data management and statistical analyses were done using R, V.4.2.2, and GraphPad Prism, V.10.0 for macOS. A p value <0.05 was considered statistically significant for each test. All values are presented as mean±SD deviation, unless otherwise noted.

**RESULTS**
**Patient characteristics**
Between June 1, 2020 and July 1, 2023, 60 patients completed all questionnaires and 58 (96.7%) underwent successful placement of trial electrodes. The procedures for two patients were aborted due to the inability to safely place stimulating electrodes at the ideal spinal location. Of the 58 patients who had successful placement of trial electrodes, 11 (19.0%) had an unsuccessful trial. There were no statistically significant differences in the patient demographic between the patients who had successful or unsuccessful trials (table 1). Patients with CRPS were less likely to have a successful trial than patients with radiculopathy and/or post-laminectomy syndrome (61.1% vs 88.2%; p=0.03).

**SCS trial outcomes**
During the trial period, patients with a successful trial reported an average of 75.4±14.2% reduction in their usual pain, while patients with an unsuccessful trial reported an average pain reduction of just 15.0±20.1%. There were no differences in pre-trial pain scores between the two groups (table 1).

Of the 47 patients who had a successful trial, 41 (87.2%) proceeded with permanent implantation. There were no statistically significant differences in demographic or clinical characteristics between patients who had a successful trial and those who...
Table 1  Patient demographic and clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>Failed trial (n=11)</th>
<th>Successful trial (n=47)</th>
<th>Total sample (n=58)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>5 (45.5)</td>
<td>33 (70.2)</td>
<td>38 (65.5)</td>
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<tr>
<td>Age</td>
<td>55.1±15.3</td>
<td>63.5±13.3</td>
<td>62.2±13.8</td>
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<tr>
<td>Education*†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>1 (9.1)</td>
<td>2 (4.3)</td>
<td>2 (3.5)</td>
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<tr>
<td>High school</td>
<td>3 (27.3)</td>
<td>16 (34.8)</td>
<td>19 (33.3)</td>
</tr>
<tr>
<td>Some college</td>
<td>4 (36.3)</td>
<td>13 (28.3)</td>
<td>17 (29.8)</td>
</tr>
<tr>
<td>≥4 year college degree</td>
<td>3 (27.3)</td>
<td>15 (32.6)</td>
<td>18 (31.6)</td>
</tr>
<tr>
<td>Income*†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;$50,000</td>
<td>2 (18.2)</td>
<td>3 (6.5)</td>
<td>5 (8.8)</td>
</tr>
<tr>
<td>$15,001–$40,000</td>
<td>6 (54.5)</td>
<td>23 (50.0)</td>
<td>29 (50.9)</td>
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<td>$40,000–$75,000</td>
<td>2 (18.2)</td>
<td>12 (26.1)</td>
<td>14 (24.5)</td>
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<tr>
<td>&gt;$75,000</td>
<td>1 (9.1)</td>
<td>8 (17.4)</td>
<td>9 (15.8)</td>
</tr>
<tr>
<td>Employment status</td>
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<td></td>
</tr>
<tr>
<td>Currently employed</td>
<td>3 (27.3)</td>
<td>12 (25.5)</td>
<td>15 (25.9)</td>
</tr>
<tr>
<td>Disabled</td>
<td>4 (36.3)</td>
<td>8 (17.0)</td>
<td>12 (20.7)</td>
</tr>
<tr>
<td>Retired</td>
<td>2 (18.2)</td>
<td>25 (53.2)</td>
<td>27 (46.5)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (18.2)</td>
<td>2 (4.3)</td>
<td>4 (6.9)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/cohabitating</td>
<td>4 (36.4)</td>
<td>30 (63.8)</td>
<td>34 (58.6)</td>
</tr>
<tr>
<td>Divorced</td>
<td>4 (36.4)</td>
<td>11 (23.4)</td>
<td>15 (25.9)</td>
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<tr>
<td>Widowed</td>
<td>1 (9.1)</td>
<td>4 (8.5)</td>
<td>5 (8.6)</td>
</tr>
<tr>
<td>Single/never married</td>
<td>2 (18.2)</td>
<td>2 (4.3)</td>
<td>4 (6.9)</td>
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<tr>
<td>Smoking status</td>
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<tr>
<td>Never smoked</td>
<td>5 (45.5)</td>
<td>23 (50.0)</td>
<td>28 (48.3)</td>
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<td>Former smoker</td>
<td>5 (45.5)</td>
<td>20 (42.6)</td>
<td>25 (43.1)</td>
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<tr>
<td>Current smoker</td>
<td>1 (9.1)</td>
<td>4 (8.5)</td>
<td>5 (8.6)</td>
</tr>
<tr>
<td>Mean body mass index in kg/m²</td>
<td>30.7±6.1</td>
<td>30.7±6.8</td>
<td>30.7±6.6</td>
</tr>
<tr>
<td>Indication for trial†</td>
<td>Radiculopathy/post-laminectomy Syndrome</td>
<td>4 (36.4)</td>
<td>30 (63.8)</td>
</tr>
<tr>
<td>Complex regional pain syndrome</td>
<td>7 (63.6)</td>
<td>11 (23.5)</td>
<td>18 (31.0)</td>
</tr>
<tr>
<td>Other§</td>
<td>0</td>
<td>6 (12.7)</td>
<td>6 (10.4)</td>
</tr>
<tr>
<td>Placement of lead tips</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervical</td>
<td>2 (18.2)</td>
<td>7 (14.9)</td>
<td>9 (15.5)</td>
</tr>
<tr>
<td>Thoracic</td>
<td>3 (27.3)</td>
<td>27 (57.5)</td>
<td>30 (51.2)</td>
</tr>
<tr>
<td>Thoracic/lumbar</td>
<td>1 (9.1)</td>
<td>1 (2.1)</td>
<td>2 (3.4)</td>
</tr>
<tr>
<td>Thoracic/sacral</td>
<td>0</td>
<td>1 (2.1)</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Lumbar¶</td>
<td>0</td>
<td>2 (1.2)</td>
<td>2 (3.4)</td>
</tr>
<tr>
<td>Lumbar/sacral¶</td>
<td>3 (27.3)</td>
<td>10 (21.3)</td>
<td>13 (23.1)</td>
</tr>
<tr>
<td>Sacral¶</td>
<td>2 (18.2)</td>
<td>2 (4.3)</td>
<td>4 (6.9)</td>
</tr>
<tr>
<td>Opioid use at time of trial</td>
<td>7 (63.6)</td>
<td>29 (61.7)</td>
<td>36 (62.1)</td>
</tr>
<tr>
<td>Mean pain rating at time of trial</td>
<td>7.3±0.9</td>
<td>7.0±1.8</td>
<td>7.1±1.6</td>
</tr>
</tbody>
</table>

*One patient did not report their education and income levels.
†Missing data omitted from analyses.
§Other pain conditions were neuralgia (n=3), neuropathy (n=1), chronic pelvic pain (n=1), and chronic migraine (n=1).
¶Includes dorsal root ganglion placements.

Table 2  Health domain scores from PROMIS CAT for 58 SCS trial patients

<table>
<thead>
<tr>
<th></th>
<th>Anxiety</th>
<th>Depression</th>
<th>Pain interference</th>
<th>Physical functioning</th>
<th>Sleep disturbance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size, n</td>
<td>56</td>
<td>55</td>
<td>54</td>
<td>54</td>
<td>46</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>55.1±10.1</td>
<td>51.1±10.1</td>
<td>68.0±5.6</td>
<td>32.0±5.5</td>
<td>55.8±9.9</td>
</tr>
<tr>
<td>95% CI</td>
<td>52.4, 57.8</td>
<td>48.3, 53.8</td>
<td>66.5, 69.5</td>
<td>30.5, 33.5</td>
<td>52.9, 58.8</td>
</tr>
</tbody>
</table>

Opioid use at time of trial 7 (63.6) 11 (23.5) 18 (31.0)

received a permanent implant (data not shown). The 6 patients who did not receive a permanent implant after a successful trial needed to receive treatment for other pain conditions (n=3), decided not to undergo an implant to treat their pain (n=2), or were unable to have permanent leads placed (n=1).

Patient-reported outcomes

Patients in our study reported higher levels of anxiety, sleep disturbance, pain interference, and lower levels of physical functioning than the general population which has mean T-score of 50 for each assessment (table 2). On average, these patients reported levels of depression/sadness near the population mean.

When compared with patients with unsuccessful trials, the patients who had a successful SCS trial reported significantly lower levels of anxiety (52.4±8.9 vs 65.7±7.9; p<0.001), depression (49.0±8.9 vs 60.2±10.5; p=0.001), and sleep disturbance (54.2±9.5 vs 62.4±9.7; p=0.024) (figure 2). No significant differences in pain interference and physical functioning were found between these groups (figure 2).

To determine whether PROMIS CAT T-scores correlated with pain relief during the 7-day trial, we analyzed pre-trial and post-trial responses to each assessment and calculated the SRM to determine whether any differences we found were clinically significant. Out of the 47 patients with a successful trial, 20 had PROMIS CAT data at the end of the 7-day trial period. As a group, these patients reported significantly decreased levels of depression (53.2±8.7 to 47.9±10.6; p=0.0054), sleep disturbance (58.1±7.8 to 51.3±8.7; p=0.0024), and pain interference (69.1±3.3 to 63.2±8.0; p=0.0039) on their assessment at the end of their trial (figure 3). The responsiveness of the PROMIS CAT for patients with a successful trial was found to be large for depression, sleep disturbance, and pain interference, and moderate for anxiety (table 3).

DISCUSSION

While patients with successful trials did not differ from patients with unsuccessful trials by their demographic characteristics, patients with CRPS were less likely than those with radiculopathy or post-laminectomy syndrome to have a successful trial. Our study found that our patients had higher levels of anxiety, sleep disturbance, pain interference, and lower levels of physical functioning than the general population, and patients with a successful trial had lower levels of anxiety, depression, and sleep disturbance than patients with failed trials. Further, PROMIS CAT assessments provided a feasible means of monitoring clinical response to treatment. We find that PROMIS CATs are responsive to the 7-day neuromodulation trials in patients with persistent pain.

The association between persistent pain and increased levels of anxiety, depression, and sleep disturbance is well established. Further, the presence of one or more of these symptoms has an impact on a patient’s response to treatment. In the present study, we found that patients undergoing a neuromodulation trial had higher levels of depression, anxiety, sleep disturbance,
Figure 2  PROMIS CAT (Patient Reported Outcome Measurement Information System computer adaptive test) scores by trial success. Box and whisker plots with individual patient T-scores for the preprocedure PROMIS CAT for anxiety (A), depression (B), sleep disturbance (C), pain interference (D), and physical functioning (E). Individual scores are normalized to a T-score of 50 (dashed line) with an SD of 10 (shaded region). Higher scores indicated increased levels of the outcome assessed.

Figure 3  Change in PROMIS CAT (Patient Reported Outcome Measurement Information System computer adaptive test) scores in patients with a successful trial. Matched pre-trial and post-trial PROMIS CAT scores of patients with successful SCS trials for anxiety (A), depression (B), sleep disturbance (C), pain interference (D), and physical functioning (E). Individual scores are normalized to a T-score of 50 (dashed line) with an SD of 10 (shaded region). Higher scores indicated increased levels of the outcome assessed.
and pain interference, and lower levels of physical functioning than the general population.

Our findings support an association between lower levels of preprocedural PROMIS CAT depression, anxiety, and sleep disturbance and successful SCS trials. Not surprisingly, prior work has demonstrated a significant association between psychosocial variables and the success of SCS trials, implantation, and long-term SCS treatment.\textsuperscript{17–21} Depression is linked to poorer outcomes of SCS, as assessed by the Minnesota Multiphasic Personality Inventory\textsuperscript{22} and patients who reported over 50\% pain relief during their trial also exhibited lower depression scores on this instrument.\textsuperscript{23} Similarly, lower anxiety scores on the Derogatis Affects Balance Scale are associated with successful SCS trials and better long-term results.\textsuperscript{20}

To create a clinic-friendly assessment to aid in standardized patient selection for SCS, Thomson \textit{et al.}\textsuperscript{24} created an e-health tool that considers various psychosocial factors. Patients with moderate or severe levels of psychosocial problems were less likely to experience pain reduction during the SCS trial compared with those with absent or low levels, despite clinical recommendations. The psychosocial factors assessed through this tool include lack of engagement, dysfunctional coping, unrealistic expectations, inadequate daily activity level, problematic social support, secondary gain, psychological distress/mental health problems, and unwillingness to reduce high-dose opioids.\textsuperscript{23}

Here, we chose to implement NIH PROMIS CAT instruments in our clinic as they provide important advantages over the previously mentioned instruments for the assessment of PROs. Many of the PROMIS instruments can be used in the CAT format which maintains high precision of the assessment, but with reduced response burden especially when multiple tests are administered.\textsuperscript{10} In addition, PROMIS was developed with the goal of standardizing the measurement of PROs and enabling comparisons among patients which differ in the degree of disease burden and the impact of treatment across a variety of chronic diseases.\textsuperscript{25} Like any psychosocial assessment tool, the PROMIS CAT requires engagement from clinic staff and providers as well as informatic and electronic resources to ease the collection and tracking of responses.

Importantly, those patients who had unsuccessful trials had higher PROMIS CAT scores for depression and anxiety with their scores reaching levels consistent with the Diagnostic and Statistical Manual of Mental Disorders-5 diagnostic criteria.\textsuperscript{27} Of note, the majority of these patients had no prior documented history of a depressive or anxiety disorder in our health system. The neuropsychiatric evaluation each patient receives is used to identify contraindications for neuromodulation therapy and not to determine the position of a patient’s symptoms on the spectrum of depression or anxiety. Therefore, assessing psychosocial factors using PROMIS CAT may provide value in identifying untreated and undiagnosed psychosocial comorbidities. We did not explore whether depression-related and/or anxiety-related symptoms were pre-morbid or post-morbid to the onset of the persistent pain condition. If depression/anxiety develops because of persistent pain, SCS outcomes and adjunctive treatment may be different than if the depression/anxiety were pre-existing.

These results also raise the question of whether treatment for anxiety or depression prior to trial/implant would improve post-trial outcomes and improve the cost/benefit analysis for treating persistent pain with SCS. To date, this has not been directly studied, but with the validation of PROMIS-29 and PROMIS-CAT as a tool to assess these variables in chronic pain patients, we believe this is something that should be pursued.

Using repeated PROMIS CAT assessments from the patients who had a successful trial, we sought to determine how responsive our PROs were to SCS treatment. Prior work has demonstrated that patients report changes in mood, anxiety, and suffering with a successful trial.\textsuperscript{26} However, these findings were obtained using a diary which each patient completed during the 7-day trial. We found statistically significant longitudinal reductions in PROMIS CAT Depression, Sleep disturbance, and Pain interference scores in patients with a successful 7-day SCS trial using PROMIS CAT which was administered prior to their scheduled clinic appointment. The moderate to large absolute value of SRM and effect sizes of our data indicate the strength of these measures to guide neuromodulation treatment in patients with persistent pain. Interestingly, while these groups showed an overall improvement in their symptoms, we observed individual variability in which approximately half of the patients experienced large reductions in their T-scores, and the remaining had very mild reductions if their T-scores reduced at all. Future studies with larger sample sizes will allow us to identify differences in these groups which may aid in treatment decision-making. Nonetheless, because the success of the trial SCS is significantly determined by the patient reports of pain relief, gain-of-function, and overall satisfaction, the use of PROMIS CAT provides another assessment of patient-reported outcomes which clinicians can use to guide treatment decisions prior to SCS trial, but also after.

It is important to note that our data were collected throughout the COVID-19 pandemic. During the COVID-19 pandemic, levels of depression and anxiety were increased in patients with persistent pain\textsuperscript{29} which may have affected patients’ responses in our study and the contribution of psychological distress to their pain.

In conclusion, our findings support the adoption of PROMIS CAT for consideration of patient selection for SCS and underscore the importance of assessment of psychosocial factors in patients with complex chronic pain.

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\textbf{Contributors} Conceptualization: JHG, NP, KS. Methodology: JHG, NP, LB, JS, GS, KS. Formal analysis: KS. Writing—original draft: JHG, NP, KS. Writing—review and editing: JHG, NP, LB, JS, GS. KS. Funding acquisition: KS. Guarantor: KS.

\begin{table}
\centering
\caption{Responsiveness of PROMIS CAT for patients with successful trials}
\begin{tabular}{|cccccc|}
\hline
 & Anxiety & Depression & Pain interference & Physical functioning & Sleep disturbance \\
\hline
Average difference between pre-trial and post-trial assessments (T-score) & −3.1 ± 7.4 & −5.2 ± 7.1 & −5.8 ± 8.8 & +0.6 ± 3.3 & −6.8 ± 9.5 \\
SRM & −0.42 & −0.73 & −0.67 & +0.17 & −0.72 \\
Effect size & −0.36 & −0.60 & −1.79 & +0.14 & −0.88 \\
\hline
\end{tabular}
\end{table}
Funding This study was funded by the National Institutes of Health grants: P20GM121293 (KES), UL1TR003107 (KES), KL2 TR003108 (KES), the Arkansas Children’s Research Institute (KES), the Horace C. Cabe Distinguished Chair in Infectious Disease (KES).

Competing interests LB, GLS, JS, and KS have no conflicts to disclose. JHG is a consultant for Saluda Medical, Abbott, and Stratus Medical and the recipient of research support paid to the institution by SPR Therapeutics and Mainstay Medical. NP is an employee of Eli Lilly and Company.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the University of Arkansas for Medical Sciences (protocol number 260886). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request as permitted by the UAMS Institutional Review Board for data that involve human subjects.

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