Research Article

Measuring pain phenomena after spinal cord injury: Development and psychometric properties of the SCI-QOL Pain Interference and Pain Behavior assessment tools

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Objective: To develop modern patient-reported outcome measures that assess pain interference and pain behavior after spinal cord injury (SCI).
Design: Grounded-theory based qualitative item development; large-scale item calibration field-testing; confirmatory factor analyses; graded response model item response theory analyses; statistical linking techniques to transform scores to the Patient Reported Outcome Measurement Information System (PROMIS) metric.
Setting: Five SCI Model Systems centers and one Department of Veterans Affairs medical center in the United States.
Participants: Adults with traumatic SCI.
Interventions: N/A.
Outcome Measures: Spinal Cord Injury - Quality of Life (SCI-QOL) Pain Interference item bank, SCI-QOL Pain Interference short form, and SCI-QOL Pain Behavior scale.
Results: Seven hundred fifty-seven individuals with traumatic SCI completed 58 items addressing various aspects of pain. Items were then separated by whether they assessed pain interference or pain behavior, and poorly functioning items were removed. Confirmatory factor analyses confirmed that each set of items was unidimensional, and item response theory analyses were used to estimate slopes and thresholds for the items. Ultimately, 7 items (4 from PROMIS) comprised the Pain Behavior scale and 25 items (18 from PROMIS) comprised the Pain Interference item bank. Ten of these 25 items were selected to form the Pain Interference short form.
Conclusions: The SCI-QOL Pain Interference item bank and the SCI-QOL Pain Behavior scale demonstrated robust psychometric properties. The Pain Interference item bank is available as a computer adaptive test or short form for research and clinical applications, and scores are transformed to the PROMIS metric.

Keywords: Outcome assessment (health care), Psychometrics, Rehabilitation, Spinal cord injuries

Introduction

Pain after spinal cord injury (SCI) is common, and is often complex, chronic, and severe.[1] The reported prevalence of pain after SCI is extremely variable, from 26–96%,[2] depending on definition, type, and measurement of pain, as well as other factors.[3,4] Among individuals with SCI, pain is associated with worse physical functioning,[5] reduced self-efficacy,[6] depression[7] and other forms of psychological distress,[8,9] poor sleep,[7] unemployment,[10] higher healthcare utilization and expenditures,[11] and more difficult delivery of rehabilitation services.[12] For many individuals with SCI, pain is chronic and resistant to treatment.[1,13] However, individuals vary in the degree to which pain

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affects their behavior (e.g. displays of anger or sadness) and in the degree to which pain interferes with activities. *Pain interference* or *pain impact* describes how pain may limit or interfere with individuals' physical, mental, and social activities, and may be modifiable when pain itself is not. For example, individuals may develop coping strategies to limit the impact that pain has on their life[14] or may learn these skills in psychotherapy.[15,16]

Pain is a multidimensional construct, and there are many measures that exist to assess each aspect of the pain experience, its correlates, and its consequences. Bryce *et al.*[17] reported on the 2006 National Institute on Disability and Rehabilitation Research (NIDRR) SCI Measures Meeting, which produced a consensus on the best available measures to assess pain phenomena after SCI. As noted by these authors and others,[18] assessing pain after SCI is unique because patients' motor and sensory impairments need to be taken into consideration. For example, many measures developed for non-SCI populations ask about pain interference with walking, which is not likely to be useful and may actually be insulting for a person who uses a wheelchair on a regular basis. Bryce *et al.*[19] recommended using the single pain interference item from the SF-36 as well as pain interference items from the Multidimensional Pain Inventory (MPI) and/or the Brief Pain Inventory (BPI).[20] The MPI and BPI have been tailored to better fit an SCI population[18,21] than their original versions, but these measures still have limitations. For example, the MPI-SCI version may confound interference from pain with interference from physical impairment.[22] Equally problematic as unnecessary or inappropriate material is that measures that were adapted to SCI post-hoc may omit or underemphasize content that is important to pain interference in persons with SCI. Another limitation of existing measures is that they are static instruments, meaning that they require respondents to complete every item regardless of whether the item confers additional information about the respondent's pain interference. Many static instruments are consequently clumsy, inaccurate, and inefficient. In turn, this obscures researchers' and clinicians' understanding of SCI-related pain interference and behavior and their responses to interventions.

Recently, a wave of modern patient reported outcomes (PRO) tools that are founded in item response theory (IRT)[23,24] have been developed that permit computerized adaptive testing (CAT)—an alternative to static testing.[25–27] These tools include the Patient Reported Outcome Measurement Information System (PROMIS),[28] the Quality of Life in Neurological Disorders (Neuro-QOL) measurement system,[29,30] and the Spinal Cord Injury Quality of Life (SCI-QOL) measurement system.[31,32] These are multidimensional sets of item banks that assess health-related quality of life in the domains of physical, mental, and social functioning. This paper is to describe the development and initial validation of two pain assessment tools that are part of the SCI-QOL. An item bank is a comprehensive set of items (i.e. questions) that capture all levels of the trait or dimension being studied (e.g. pain interference). A CAT administration of an item bank strategically selects next items to administer based on the participant's earlier responses. In this way, IRT and CAT permit precise, individually-tailored measurement of a trait or dimension with only a few items. Resulting scores are directly comparable across participants and time, despite the likelihood that participants have completed different items within the bank.[26] One particular strength of the PROMIS is that it is has sophisticated normative data that match the demographic makeup of the 2000 U.S. Census.

The PROMIS Pain Interference item bank comprises 41 items that were calibrated with 14,848 people, including 531 individuals with SCI.[33] However, even though this measure included individuals with SCI in the calibration sample, it is designed for use with the general population, contains inappropriate items for individuals with SCI (e.g. *"how often did pain prevent you from walking more than 1 mile?"*), and may omit content that is important to pain interference after SCI specifically.

The Spinal Cord Injury – Quality of Life (SCI-QOL) measurement system is a comprehensive set of instruments to assess health-related quality of life after SCI.[31,32] This endeavor began with focus groups and individual interviews with individuals with SCI and clinicians who specialize in SCI to identify important content areas.[34] When an existing item bank from PROMIS or Neuro-QOL addressed an important content area (e.g. depression), it was optimized for use with individuals with SCI. This involved removing inappropriate items, writing new items to address missed content, recalibrating the items with an SCI-only sample, and transforming resulting scores to a PROMIS metric for use with the PROMIS normative data. When no existing PROMIS or Neuro-QOL item bank assessed focus group generated content, a new item bank was created. The SCI-QOL consists of 19 calibrated item banks and 3 fixed-length scales in total. Three item banks and one scale were derived from the PROMIS and contain mostly PROMIS items (Depression, Anxiety, Pain Interference, and Pain Behavior). Four item banks were derived from the

Neuro-QOL measurement system (Positive Affect and Well-Being, Stigma, Ability to Participate in Social Roles and Activities, and Satisfaction with Social Roles and Activities) and contain mostly Neuro-QOL items. The remaining 12 item banks and 2 fixed-length scales did not derive from PROMIS or Neuro-QOL and assess constructs advanced by SCI stakeholders. These include domains of physical functioning[35–38] (basic mobility, ambulation, fine motor functioning, self-care, and wheelchair mobility), physical-medical health (pressure ulcers,[39] bladder management difficulties,[40] bladder complications, bowel management difficulties), and emotional health (resilience,[41] grief/loss,[42] self-esteem,[43] and psychological trauma[44]) and Independence. Here, we present the development and psychometric properties of the SCI-QOL Pain Interference item bank and short form, and the SCI-QOL Pain Behavior scale. These were adapted from the PROMIS Pain Interference and Pain Behavior item banks and optimized for individuals with SCI.

Methods

Development of a pain item pool

To learn about the factors that influence health-related quality of life after SCI we conducted semi-structured interviews and focus groups with individuals with SCI and clinicians who specialize in SCI. The details and results of these groups are reported elsewhere.[34] Rigorous qualitative analysis[45] of the resulting data revealed important content areas. During the focus groups, pain was mentioned in 16% of patient comments and 14% of clinician comments, making pain the most frequently mentioned secondary medical complication of SCI.[34] Participants described subtopics of pain such as type of pain (e.g. neurogenic pain, musculoskeletal pain), frequency of pain (e.g. chronic pain), location of pain (e.g. arm/shoulder pain, pain from urinary tract infections), pain interference (e.g. inability to work or socialize due to pain), and pain behavior (e.g. wincing). Eighty-one new items were written based on specific phrases or concepts from the interviews and focus groups. We also identified 34 existing items from the PROMIS Pain Interference item bank and 18 items from the PROMIS Pain Behavior item bank for inclusion in the preliminary item pool. We excluded 6 of the 40 PROMIS Pain Interference items and 21 of the PROMIS Pain Behavior items because they potentially confounded physical functioning with pain. For example, we excluded the PROMIS Pain Interference items "*How often did pain prevent you from walking more than one mile*" and "*How often did pain prevent you from standing for more than 1 hour?*", as well as the PROMIS Pain Behavior item, "*Pain caused me to bend over while walking*." In cases where newly written items were redundant with existing PROMIS items, the new items were dropped in favor of the existing items. At this stage of instrument development, it was not yet determined if the different aspects of pain (e.g. pain interference, pain behavior) constituted a unidimensional construct (a requirement of IRT) in individuals with SCI or not. Thus, during the item development phase all items were included in a single item pool related to all aspects of pain.

The preliminary item pool consisted of 133 items—52 PROMIS items and 81 newly written items. These items were then subjected to the same process as PROMIS and Neuro-QOL items.[46] Expert Item Review[47] was a process whereby project investigators considered items' relevance and clarity, and suggested revisions and deletions. This winnowed the item pool down to 58 items; including 29 PROMIS items and 29 new items. Given the extensive reviews involved in the PROMIS item development process,[48] the 29 PROMIS items did not undergo any further review at this time. The 29 new items, however, then underwent a series of cognitive debriefing interviews[49,50] whereby we asked 5 individuals with SCI to answer each item and describe out loud their process of receiving, considering, and answering the question. This was conducted in order to flag items that were unclear, offensive, or otherwise inappropriate. No items were modified or deleted based on the cognitive interviewing. Next, the 29 new items were reviewed for ease of translatability,[51] and 6 items were modified to ensure amenability to future translation. For example, the item Pain_15, "I experienced constant pain" was modified to "I had constant pain" due to the difficulty of translating the word "experienced" in this context. Finally, the Lexile framework[52] was used to ensure that all items were written at or below a 5th grade reading level.

Calibration sample and analyses

The 58 items in the item pool were presented to persons with SCI at six collaborating sites: Kessler Foundation/Kessler Institute for Rehabilitation, University of Michigan, Rehabilitation Institute of Chicago, University of Washington, Craig Hospital, and the James J. Peters/Bronx Department of Veterans Affairs Medical Center. The pain items were completed along with other preliminary pools of items related to physical/medical health and secondary complications that would become the other domains of the SCI-QOL.[31,32,53] All participants provided informed consent according to protocols approved by the

institutional review boards of the participating center at which they enrolled. All participants were at least 18 years old, able to read and understand English, and had medically documented traumatic SCI. Participants were stratified by level of injury (paraplegia or tetraplegia), completeness of injury (complete or incomplete), and time since injury (<1 year, 1–3 years, >3 years). We confirmed diagnoses by medical record review; level and completeness was documented by the most recent International Standards for the Neurological Classification of SCI exam.[54] To achieve the statistical requirements for graded response model IRT analyses, at least 500 participants were desired to ensure at least 5 participants needed to select each of the 5 response options for each item. Successful stratification was achieved by careful monitoring of enrollment and targeted recruitment of each subgroup (e.g. paraplegia, complete, <1 year). Trained interviewers administered items using a standardized protocol either in person or by telephone, as described elsewhere.[31]

Data analyses began with a confirmatory factor analysis (CFA) to confirm construct unidimensionality, a psychometric requirement for IRT. *Acceptable* model fit was defined as Comparative Fit Index (CFI) > 0.90 and Root Mean Square Error of Approximation (RMSEA) < 0.08. *Good* model fit was defined as CFI > 0.90 and RMSEA < 0.08. *Excellent* fit was defined as CFI > 0.95 and RMSEA < 0.06. A graded responses IRT model was then used to iteratively identify poorly fitting items, items that displayed differential item functioning (DIF), local item dependence (LID), and significant loadings on the single factor (values > 0.30). DIF occurs when participant responses to a particular item are unduly influenced by characteristics other than the trait of interest.[55] In other words, DIF represents "bias" against subsamples of participants, for example, based on age, sex, level of injury, etc. Statistical criteria for possible DIF were a significant χ^2 test ($P < 0.01$) and effect sizes (McFadden's pseudo R^2) greater than 0.02—a small but non-negligible effect. A core assumption of IRT is that the items are independent after accounting for the trait being measured.[55] LID means that two items are inappropriately correlated, implying that they are redundant and that the inclusion of both would unduly influence the score. Here, LID was defined by residual correlations > |0.20|. Items that were identified as poorly fitting or as displaying DIF were removed from the item pool and the steps were repeated. Items that remained comprised the final item bank. The preliminary IRT parameters that resulted from these analyses were SCI-specific, in that a mean of 50 referenced the calibration sample mean.

Transformation to PROMIS metric

To ensure that the final SCI-QOL Pain items were directly comparable to PROMIS pain scores, a linear transformation was conducted so that SCI-QOL scores reference the PROMIS metric—that is, a sample that represents all United States citizens who completed the 2010 census. Therefore, a T score of 60 (1 standard deviation above the mean) on this measure means that the individual reported more/stronger symptoms than 84% of the general population. This transformation is accomplished by the Stocking-Lord method,[31] which uses "anchor items" that are common to both the PROMIS and the SCI-QOL Pain Interference item banks. We examined item-response plots and scatter plots of item parameters, estimated transformation constants, and modified the initial item parameters accordingly. The final calibrations for these items were used to program a CAT on the Assessment Center™ website (www.assessmentcenter.net). A brief, fixed-length form ("short form") was also assembled from these final items.

Reliability sample and analyses

As also reported elsewhere,[31] test-retest reliability was assessed with a separate sample of 244 individuals with SCI at 4 SCI Model Systems centers: University of Michigan, Kessler Foundation/Kessler Institute for Rehabilitation, Rehabilitation Institute of Chicago, and Craig Hospital. Participants were community dwelling individuals with SCI who were more than 4 months post-injury at the time of study enrollment. Participants completed the Pain Interference CAT, as well as item pools related to other domains of functioning, 1–2 weeks apart. Test-retest reliability was assessed with a Pearson's *r* coefficient and an intraclass correlation coefficient (ICC) between the two assessments.

Results

Participant characteristics

Table 1 summarizes the demographic and injury characteristics of the calibration sample.

Separation of 'pain interference' and 'pain behavior'

Analyses began with data from the pool of 58 items related to multiple aspects of pain–pain interference, pain behavior, and general aspects of pain; however, as anticipated, the first round of CFA indicated that these three types of items did not measure a single, unidimensional construct. As a consequence, 12 general pain items were removed and the remaining items were split into Pain Interference (28 items) and Pain

Table 1 Calibration sample characteristics.

Variable	Calibration Sample (*n* = 757)
Age (mean ± SD)	42.9±15.5 years
Sex	
Male	79.1%
Female	20.9%
Ethnicity	
Hispanic	10.6%
Non-Hispanic	87.8%
Not Reported	1.6%
Race	
Caucasian	71.1%
Black or African-American	17.2%
Asian	1.5%
American Indian/Alaska Native/Native Hawaiian/Pacific Islander	0.9%
More than one race	1.5%
Other	6.8%
Not Reported	1.1%
Time Since Injury (mean±SD)	6.7±9.9 years
< 1 year post injury	28.9%
1–3 years post injury	27.6%
> 3 years post injury	43.5%
Diagnosis	
Paraplegia Complete	23.9%
Paraplegia Incomplete	18.5%
Tetraplegia Complete	23.1%
Tetraplegia Incomplete	34.4%
Education Level	
High school or less	38.4%
Some college	33.5%
Bachelor's degree or more	28.1%
Cause of Injury	
Motor Vehicle Accident	32.4%
Fall	22.3%
Gunshot Wound/Violence	11.8%
Diving	6.6%
Other sports	7.4%
Medical/Surgical accident	3.7%
Motorcycle/dirt bike/ ATV accident	3.9%
Other or Not Reported	11.9%
Method(s) of Mobility (not mutually exclusive)	
Manual Wheelchair	54.4%
Power Wheelchair	44.1%
Ambulation	32.7%

Behavior (18 items) based on psychometric fit. These items became separate measures and are described below.

Data analysis for pain interference items

Preliminary analysis & item removal

After items targeting pain interference were removed from the overall pool of pain items, CFA was performed and 3 items were removed: 1) rPain42: "*Neck pain interfered with my ability to do things*" was removed due to LID, a low item-total correlation, and DIF for diagnosis; 2) PAININ24: "*How often was pain distressing to you?*" was removed for misfit (significant χ^2 test); and 3) PAININ10, "*How much did pain interfere with your enjoyment of recreational activities?*" was removed due to LID. For the remaining 25 items, $\alpha = 0.968$ and item-total correlations ranged from 0.47 to 0.86. All of the items had more than 35% of the sample selecting category 1 ("Never" or "Not at all"), and no items had sparse data (i.e. fewer than 5 responses for each level of each item). No additional items were removed at this stage.

Confirmatory factor analysis

CFA results supported good fit to a unidimensional model (CFI = 0.983; RMSEA = 0.063), suggesting that a single dimension underlies the item content. R^2 values were greater than 0.400 for 23 of 25 items. The R^2 values for the remaining items were rPain24 = 0.390 rPain27 = 0.307. No item pairs exhibited LID. The first to second eigenvalue ratio was 19.1, indicating that the main factor accounted for a very large proportion of the variance. Collectively, these fit statistics support a unidimensional construct of pain interference.

IRT parameter estimation and model fit

Slopes ranged from 1.26 to 4.44 and thresholds ranged from –0.46 to 2.10. Measurement precision in the theta range between –0.8 and 2.2 is roughly equivalent to a classical reliability of 0.95 or better. Figure 1 shows the Pain Interference bank's test information and precision. We calculated the S-χ^2 model fit statistics using the IRTFIT[56] macro program. All but 4 items (rPain27, PAININ20, PAININ18, PAININ48) had adequate or better model fit statistics ($P > 0.05$) with marginal reliability equal to 0.933.

Data analysis for pain behavior items

Preliminary analysis & item removal

After the 18 items related to pain behavior were isolated, preliminary analyses with CFA resulted in the removal of 11 items for the following reasons (not mutually exclusive): bimodal distribution (6 items), LID (3 items), misfit (significant χ^2 test; 1 item), DIF for sex (1 item, "*I had pain so bad it made me cry.*"), and DIF for time since injury (1 item, "*When I was in pain I called out for someone to help me*"). For the 7 retained items, $\alpha = 0.899$ and item-total correlations ranged from 0.59 to 0.81. All of the 5-point items had more than 50% of the sample selecting category 1 (*Never* or *Not at all*) and all of the 6-point items (i.e. those PROMIS items that included the option, *Had no pain*) had more than 30% of the sample selecting category 2 (*Never*). No items had sparse data and no additional items were removed at this stage. The following summary is based on the final 7-item set. Due to the small number of retained items, the Pain Behavior

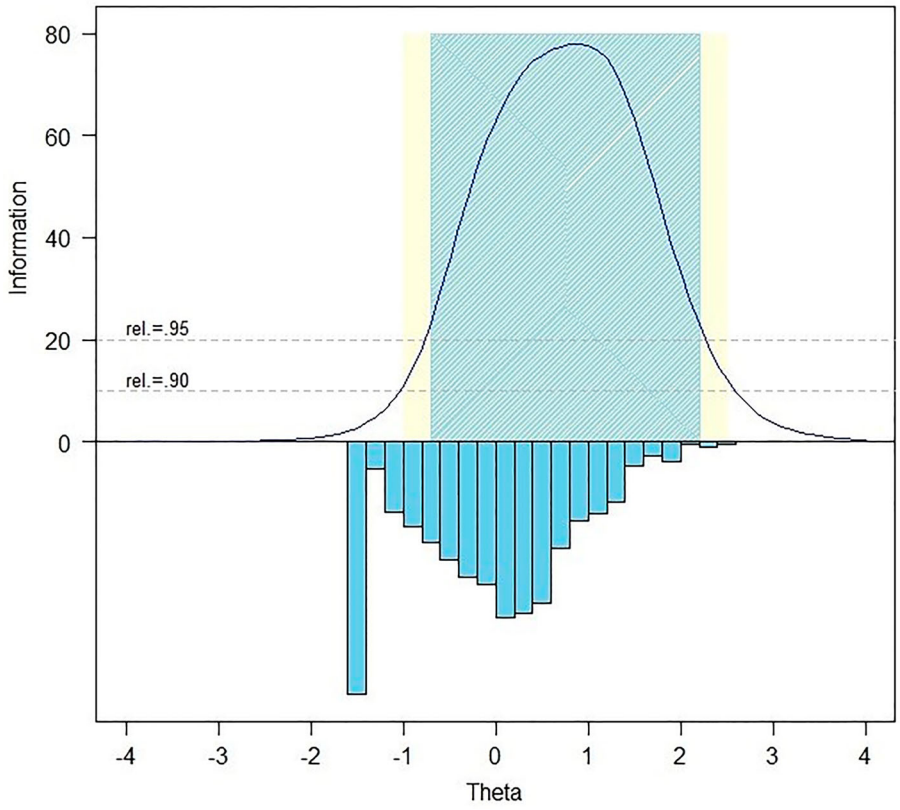

Figure 1 Information and Precision of the SCI-QOL Pain Interference Item Bank. The blue and yellow shaded regions show at what levels of the trait the item bank is highly reliable (.95 and.90, respectively). The inverted columns show the distribution of participant scores at each level of the trait.

items are referred to as fixed-length *scale* rather than an *item bank*.

Confirmatory factor analysis

CFA results confirmed fit to a unidimensional model, with CFI = 0.996 and RMSEA = 0.076. R^2 values for all 7 items were greater than 0.40. No item pairs were identified for LID and the eigenvalue ratio (first to second) was 9.0.

IRT parameter estimation & model fit

For the 7 items, slopes ranged from 2.08 to 4.97 and thresholds ranged from –1.09 to 2.08. Measurement precision in the theta range of –1.2 to 1.9 was roughly equivalent to a classical reliability of 0.95 or better. Figure 2 shows the Pain Behavior scale's test information and precision. The IRTFIT macro program confirmed that all but 3 items (rPain46, PAINBE23, PAINBE32) had adequate or better fit ($P > 0.05$) to the S-χ^2 model, with marginal reliability equal to 0.920.

Differential item functioning

We examined DIF using *lordif*[57] for six characteristics: age (≤49 vs. ≥50), sex (male vs. female), education (some college or less vs. college degree or more), injury level (tetraplegia vs. paraplegia), injury severity (incomplete vs. complete), and time since injury (<1 year vs. >1 year). Eleven remaining Pain Interference items and 3 retained Pain Behavior items produced significant χ^2 tests for at least one characteristic. However, the effect sizes associated with these items indicated that the potential DIF was negligible. Descriptive statistics for the final items are presented in Table 2.

Transformation to PROMIS metric

Stocking-Lord[58] techniques were used to calculate the constants, slopes, and intercepts for 17 anchor items (items common to PROMIS and the SCI-QOL). These comprised a linear algebraic formula that transformed the SCI-QOL Pain Interference parameters to the PROMIS Pain Interference metric and the SCI-QOL Pain Behavior parameters to the PROMIS Pain Behavior metric. Final parameters are shown in Table 3. The SCI-QOL Pain Interference calibration sample mean and standard deviation were 48.7 (9.3) before transformation and 53.1 (9.9) after transformation. The calibration sample's mean on the Pain

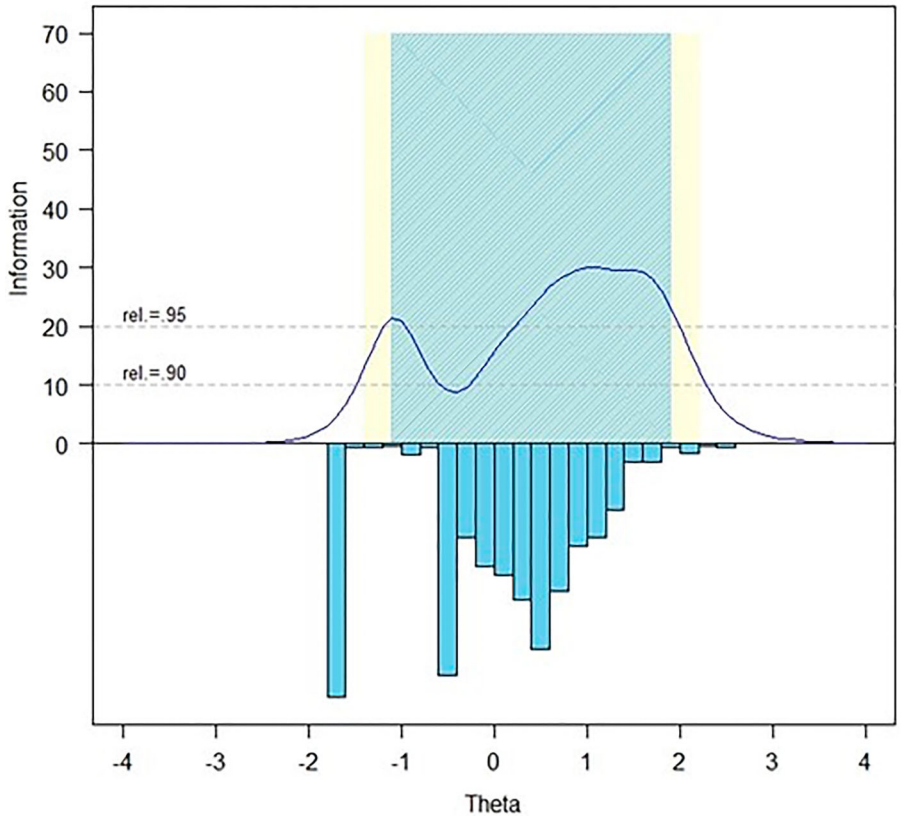

Figure 2 Information and Precision of the SCI-QOL Pain Behavior Scale. The blue and yellow shaded regions show at what levels of the trait the item bank is highly reliable (.95 and.90, respectively). The inverted columns show the distribution of participant scores at each level of the trait.

Behavior scale was 49.9 (9.6) before transformation and 53.5 (9.3) after transformation. Because higher scores indicate more pain interference and pain behavior, these results not surprisingly indicate that our SCI sample experienced more pain interference and pain behavior than the general population.

Administration modes

Pain interference

Once the final Pain Interference item parameters were transformed to the PROMIS metric, all items and parameters were programmed into the Assessment Center platform.[59] The item bank may be administered as a CAT or as a 10-item fixed-length short form. This form, the *SCI-QOL Pain Interference SF10a*, may be administered electronically through Assessment Center, by traditional paper-and-pencil or interview methods, or may be administered through alternate data collection platforms such as REDCap.[60] Raw scores generated from the SCI-QOL Pain Interference SF10a can be converted to IRT-based T scores using with a lookup table (described below). Participants must complete all 10 items on the short form in order to produce a valid score.

When administering the Pain Interference bank as a CAT, Assessment Center provides the user with options for customized CAT administration. By default, the CAT will administer a minimum of 4 items and a maximum of 12 items and will discontinue when the standard error falls below 0.3. However, in some cases the user may want to maximize reliability by increasing the minimum number of items or reduce respondent burden by decreasing the maximum number of items to be administered. A comparison of the measurement precision of the 25-item bank, 10-item short form, variable length CAT with a minimum of 4 items, and variable length CAT with a minimum of 8 items is presented in Figure 3. Table 4 presents the number of items that were typically administered, as well as their correlation with the total item bank score. Table 5 presents the means and standard errors for the full item bank, CATs, and short form.

Pain behavior

Due to the small number of initial and retained items, the SCI-QOL Pain Behavior items are only available as a 7-item fixed-length scale. The scale is available either through Assessment Center or as a standalone form.

Table 2 Descriptive item statistics.

Item ID		Item Stem	Mean	SD	% at Min.	% at Max.
Pain Interference						
PAININ1	P	How difficult was it for you to take in new information because of pain?	1.52	0.96	71.3	1.8
PAININ12	P,S	How much did pain interfere with the things you usually do for fun?	2.08	1.31	48.0	8.4
PAININ13	P,S	How much did pain interfere with your family life?	1.67	1.09	64.9	4.0
PAININ16	P	How often did pain make you feel depressed?	1.87	1.18	56.3	5.2
PAININ18	P,S	How much did pain interfere with your ability to work (include work at home)?	1.98	1.33	55.2	8.7
PAININ19	P	How much did pain make it difficult to fall asleep?	2.18	1.29	44.4	7.5
PAININ20	P	How much did pain feel like a burden to you?	2.53	1.47	36.6	14.7
PAININ29	P,S	How often was your pain so severe you could think of nothing else?	1.87	1.16	55.4	3.7
PAININ3	P,S	How much did pain interfere with your enjoyment of life?	2.31	1.40	40.8	12.0
PAININ35	P	How much did pain interfere with your ability to make trips from home that kept you gone for more than 2 hours?	1.63	1.14	70.7	4.6
PAININ37	P	How often did pain make you feel anxious?	2.03	1.20	49.0	4.0
PAININ39	P,S	How often did pain make simple tasks hard to complete?	2.24	1.30	41.9	7.3
PAININ48	P	How much did pain interfere with your ability to do household chores?	1.90	1.25	56.2	7.1
PAININ49	P,S	How much did pain interfere with your ability to remember things?	1.44	0.92	76.5	2.2
PAININ53	P,S	PROMIS How often did pain restrict your social life to your home?	1.83	1.16	58.0	3.7
PAININ56	P	How irritable did you feel because of pain?	2.24	1.32	39.1	9.6
PAININ6	P,S	How much did pain interfere with your close personal relationships?	1.74	1.17	63.7	4.8
PAININ9	P,S	How much did pain interfere with your day-to-day activities?	2.18	1.29	42.5	7.8
rPain24		Numbness interfered with my ability to do things.	2.03	1.40	56.1	11.4
rPain25		I was not able to accomplish as much as I'd like because of pain.	2.19	1.40	48.0	11.0
rPain27		Shoulder pain interfered with my ability to do things.	2.13	1.34	48.5	9.5
rPain39		Pain interfered with my ability to care for family members.	1.50	1.05	77.1	4.2
rPain41		Muscle pain interfered with my daily activities.	2.10	1.28	46.2	7.9
rPain43		Back pain interfered with my ability to do things.	2.00	1.35	55.6	8.9
rPain_Com16		Pain interfered with my sex life.	1.54	1.17	77.6	6.7
Pain Behavior						
PAINBE16	P	When I was in pain I appeared upset or sad.	2.83	1.350	16.2	3.7
PAINBE23	P	When I was in pain I asked one or more people to leave me alone.	2.36	1.133	16.6	2.4
PAINBE32	P	When I was in pain I became quiet and withdrawn.	2.85	1.393	16.2	4.5
PAINBE9	P	When I was in pain I became angry.	1.87	1.184	57.7	4.5
rPain22		I was more sensitive to pain than usual.	1.78	1.159	61.8	4.5
rPain46		My pain was so bad that I wanted to give up on everything.	2.23	1.015	16.0	1.7
rPain8		I experienced excruciating pain.	2.10	1.390	52.7	9.5

P = PROMIS Item; S = Short form 10a item.
Context for all items was: "In the past 7 days…".
Response sets for Pain Interference were: Not at all/A little bit/Somewhat/Quite a bit/Very much - or - Never/Rarely/Sometimes/Often/Always.
Response Sets for Pain Behavior were: Had No Pain/Never/Rarely/Sometimes/Often/Always or Never/Rarely/Sometimes/Often/Always.

Scoring

All SCI-QOL scores are reported on the standardized T metric, with a mean of 50 and a standard deviation of 10. Since both the Pain Interference and Pain Behavior scores have been transformed to the PROMIS metric, a score of 50 on either measure reflects the mean of the U.S. population. Also, for both Pain Interference and Pain Behavior, higher scores indicate more severe symptoms, so a T-score of 60 indicates that a participant has 1 standard deviation more pain interference (i.e. their pain interference is worse than) than the general population average. The Pain Interference CAT and Pain Behavior scale are automatically scored by Assessment Center, whereas the Pain Interference SF10a (Table 6) and any paper-and-pencil or other alternate administrations of the Pain Behavior scale must be manually scored and then converted to the T-metric using the lookup tables provided here (Table 7).

Test-retest reliability

For the community-dwelling reliability sample (n = 244), the default stopping rules for the CAT were used (minimum items = 4; maximum items = 12; maximum SE = 0.3). For Pain Interference, the CAT administration averaged 5.8 items (SD = 3.1). Pearson's r between the CAT scores at the baseline and 1–2 week test-retest assessments, respectively, was 0.84 ($P < 0.01$) and the intraclass correlation coefficient (ICC)

Table 3 Item response parameters.

Item ID	Slope	Threshold				
		1	2	3	4	5
PAININ1	2.94326	1.00559	1.52197	2.02297	2.65759	--
PAININ12	4.27213	0.33938	0.89954	1.36190	1.77462	--
PAININ13	3.62569	0.78475	1.26382	1.77684	2.18978	--
PAININ16	2.90874	0.56811	1.07869	1.72344	2.15765	--
PAININ18	3.68169	0.51610	0.93308	1.39410	1.78204	--
PAININ19	2.33926	0.19421	0.74308	1.52047	2.08077	--
PAININ20	3.27609	0.00225	0.55721	1.01577	1.52601	--
PAININ29	2.57886	0.54852	1.08582	1.77248	2.43486	--
PAININ3	3.97897	0.15205	0.75989	1.16018	1.58710	--
PAININ35	2.98811	0.97986	1.32606	1.74088	2.20347	--
PAININ37	2.62955	0.35119	0.83253	1.59122	2.35825	--
PAININ39	3.34840	0.16589	0.68735	1.35501	1.91976	--
PAININ48	3.35782	0.54239	1.03126	1.54620	1.93442	--
PAININ49	2.70208	1.19292	1.60108	2.23708	2.63660	--
PAININ53	3.67835	0.60834	1.08480	1.62202	2.23641	--
PAININ56	2.98482	0.06140	0.84405	1.32017	1.79485	--
PAININ6	3.66788	0.75353	1.16351	1.64355	2.09424	--
PAININ9	4.14230	0.20249	0.79462	1.32543	1.81593	--
rPain24	1.42125	0.60165	1.13721	1.84156	2.24170	--
rPain25	3.42346	0.33929	0.76319	1.29945	1.69083	--
rPain27	1.21526	0.26183	0.98245	1.91654	2.55865	--
rPain39	2.80722	1.19823	1.52511	1.93774	2.28070	--
rPain41	2.33326	0.24769	0.90039	1.55052	2.04096	--
rPain43	1.89948	0.53006	1.02339	1.56041	2.10892	--
rPain_Com16	2.56961	1.23043	1.53021	1.80644	2.08712	--
PAINBE16	5.25766	-0.60079	0.48878	0.90366	1.41087	1.89856
PAINBE23	4.54702	-0.59437	1.00348	1.28393	1.74683	2.09456
PAINBE32	4.54279	-0.61151	0.52981	0.89017	1.39514	1.86752
PAINBE9	3.27800	0.68343	1.01218	1.60042	2.03276	
rPain22	2.25605	0.80181	1.20271	1.84087	2.31204	
rPain46	5.39075	-0.61851	1.16311	1.41920	1.80285	2.15595
rPain8	2.41280	0.56297	0.94877	1.37143	1.84961	

Note: Item stem can be found in Table 2. Only a few items had 5 thresholds. This reflects the fact that only a few items had 6 response choices (See Table 2).

(2,1) was 0.83 ($P < 0.01$). The test-retest reliability of the Pain Behavior scale was not assessed.

Discussion

Pain after SCI is common and often refractory to treatment; however, individuals vary in the degree to which pain influences behavior and interferes with physical, mental, and social activities. Individuals can learn skills to modify the influence of pain[15,16] when pain itself is not modifiable. Existing assessment measures of pain behavior or interference are not optimal for individuals with SCI because they omit important information, confound pain symptoms with physical limitations, contain inappropriate information, and/or are static instruments.

Here, we report that the SCI-QOL Pain Interference measure is a psychometrically sound instrument that has been optimized for individuals with SCI. The item bank and scale capitalize on all of the innovations of PROMIS; they are founded in IRT, can be administered by CAT, and reference high quality normative data from a sample that matches the general U.S. population. The Pain Behavior Scale is a 7-item fixed length scale that contains mostly PROMIS items and references the PROMIS metric. Some other PROMIS Pain Behavior items, when tested in this SCI sample, showed poor psychometric fit (bimodal distributions, local dependence, poor item fit, or differential item functioning) and were removed, resulting in a smaller, fixed length scale.

The advantages of modern patient reported outcome instruments (e.g. PROMIS) have been demonstrated with other instruments and populations.[61–65] Instruments that use IRT and CAT are less burdensome to administer, score, and interpret, and can be interpreted alongside other modern patient-reported outcome instruments (e.g. that are also reported on a T metric that reference the general U.S. population).[66,67] Furthermore, CAT parameters are highly customizable so administration can be easily tailored for different purposes, for example, in situations where low test burden is more important than precision (e.g. clinical screening), or in the opposite scenario (e.g. studying patient

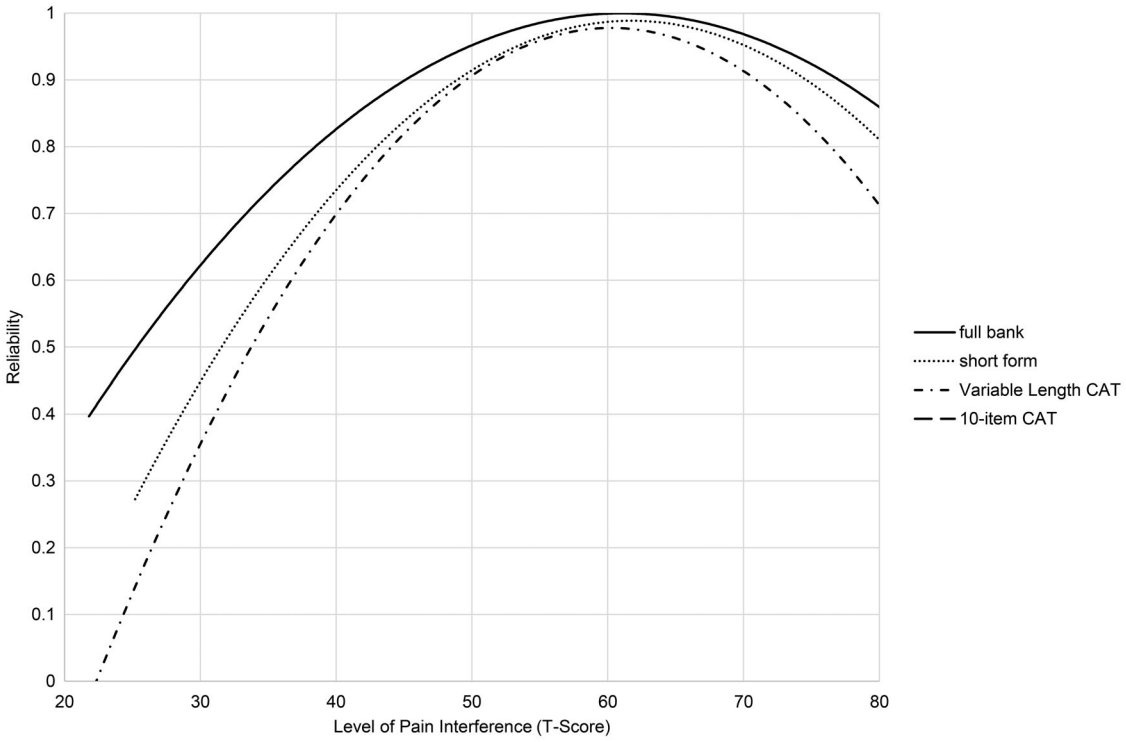

Figure 3 Reliability by Assessment Method and Level of the Pain Interference. This graph shows how reliable is the measurement at each level of the trait and with different assessment methods. CAT = computerized adaptive test.

responses to pain intervention). A short form can be administered when internet access is unavailable or respondents have difficulty using a computer. The results presented here demonstrate that all administration modes produce reliable scores and that a 10-item CAT demonstrates precision that is nearly equal to that achieved with administration of the full item bank.

The use of IRT and CAT and optimization of item content and selection algorithms specifically for individuals with SCI likely make the SCI-QOL Pain Interference and Pain Behavior measures more sensitive

Table 4 Modes of administration: Descriptive information and correlations with full-bank score.

		# Items Admin						
Mode of Administration	N	Mean	SD	Min	Max	%Min	%Max	Corr. w/ Full Bank
Variable-Length CAT (min 4)	757	6.38	3.45	4	12	61.16	25.10	0.98
Variable-Length CAT (min 8)	757	9.06	1.74	8	12	72.26	25.10	0.99
10-Item Fixed-Length CAT	757	10	0	10	10	n/a	n/a	0.99
10-Item Short Form	757	10	0	10	10	n/a	n/a	0.97

* "Corr" = correlation.

Table 5 Modes of administration: Breadth of coverage.

		T Score				Standard Error	
Mode of Administration	N	Mean ± SD	Range	% Ceiling	% Floor	Mean ± SD	Range
Variable-Length CAT (min 4)	757	52.93±9.70	37.23–82.16	0.13	14.51	0.31±0.13	0.20–0.58
Variable-Length CAT (min 8)	757	53.09±9.71	38.49–80.99	0.13	19.42	0.28±0.16	0.15–0.58
10-Item Fixed-Length CAT	757	53.05±9.79	37.79–81.51	0.13	16.51	0.26±0.16	0.13–0.58
10-Item Short Form	757	53.10±9.47	40.20–79.60	0.26	21.93	0.31±0.18	0.14–0.62
Full Bank	757	53.10±9.89	36.80–81.40	0.13	12.68	0.23±0.16	0.10–0.58

Table 6 T-Score lookup table for SCI-QOL Pain Interference Short Form 10a.

Raw Score	Scaled Score	Standard Error
10	40.2	6.0
11	47.1	3.3
12	49.1	2.9
13	50.7	2.5
14	52.0	2.3
15	53.0	2.1
16	53.9	2.0
17	54.7	1.9
18	55.5	1.8
19	56.2	1.8
20	56.8	1.8
21	57.5	1.7
22	58.1	1.7
23	58.7	1.7
24	59.2	1.7
25	59.8	1.7
26	60.3	1.7
27	60.9	1.7
28	61.4	1.7
29	61.9	1.7
30	62.5	1.7
31	63.0	1.7
32	63.5	1.7
33	64.1	1.7
34	64.6	1.7
35	65.1	1.7
36	65.7	1.7
37	66.2	1.7
38	66.8	1.7
39	67.4	1.7
40	68.0	1.8
41	68.7	1.8
42	69.3	1.9
43	70.1	1.9
44	70.9	2.0
45	71.7	2.1
46	72.7	2.3
47	73.8	2.4
48	75.1	2.7
49	76.6	2.9
50	79.7	3.9

Table 7 T-score lookup table for SCI-QOL Pain Behavior Scale.

Raw Score	Scaled Score	Standard Error
7	38.2	4.0
8	40.8	2.7
9	42.8	2.5
10	44.7	2.4
11	49.1	2.3
12	52.1	2.3
13	53.1	2.2
14	54.1	2.2
15	55.7	2.1
16	56.9	2.0
17	56.9	1.9
18	58.5	1.9
19	59.1	1.9
20	59.6	1.8
21	60.1	1.8
22	60.9	1.8
23	61.7	1.7
24	62.7	1.7
25	63.5	1.7
26	63.7	1.7
27	64.5	1.6
28	64.9	1.6
29	65.8	1.6
30	66.4	1.6
31	67.6	1.7
32	68.2	1.7
33	68.8	1.8
34	69.4	1.8
35	70.1	1.9
36	70.8	1.9
37	73.3	2.0
38	73.4	2.2
39	76.1	3.3

than traditional measures, although this remains to be studied. Research using traditional measures of pain interference reported that individuals with pain from SCI may experience interference at lower levels of pain, compared to individuals with pain from other causes.[68] However, the literature on pain interference after SCI may be obscured because traditional measures may confound interference from pain with interference from physical disability.[22] Because the SCI-QOL Pain Interference and Behavior measures were developed specifically for individuals with SCI, we anticipate that they are better able to assess the unique influence of pain, although this remains to be formally studied.

More accurate assessment of these constructs may improve researchers' and clinicians' understanding of SCI-related pain interference and behavior and their responses to intervention. For example, future studies may investigate what kind of psychotherapy optimally improves pain interference and behavior in this population, for example, cognitive and behavioral therapy or acceptance and commitment therapy (ACT).[69] Among a non-SCI sample at high risk for pain-related disability, four 1-hour sessions of ACT significantly reduced the number of sick days from work and less healthcare utilization than a treatment-as-usual control group for up to the maximum follow-up time point (6 months).[70] Future studies may also investigate the interference and behavior caused by different locations and kinds of pain, for example, neuropathic versus nociceptive pain.

Pain is a multidimensional construct and one limitation of this study is that not all dimensions were assessed (e.g. pain intensity). An additional limitation is that types of pain (e.g. musculoskeletal versus neuropathic) were not differentiated. Many of the PROMIS Pain Behavior items did not psychometrically fit our SCI population and were rejected from the final scale. We supplemented the retained PROMIS Pain Behavior items with psychometrically fitting items that

were generated from our SCI-specific focus groups, some of which assessed affect. The final SCI-QOL Pain Behavior items fit a unidimensional model in our SCI population, but includes some content that the PROMIS Pain Behavior item bank does not. Finally, although the sample is large and heterogeneous, it was recruited from 5 SCI Model System sites and one VA medical center, and may not be representative of all individuals living with SCI in the United States.

Conclusions

The SCI-QOL Pain Interference item bank and short form and the SCI-QOL Pain Behavior scale are versions of the PROMIS Pain Interference and Pain Behavior item banks, respectively, that have been optimized for individuals with SCI. The research presented here shows these measures to reliably capture pain behavior and interference across a wide range of severity, and with different administration modalities. Because these instruments were developed with modern measurement approaches and designed specifically for individuals with SCI, we anticipate that they will provide more sensitive, valid, and reliable assessment of pain interference and behavior after SCI than traditional measures.

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Conflict of interest None.

Ethics approval None.

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