



Self-rated measure of pain frequency, intensity, and burden: Psychometric properties of a new instrument for the assessment of pain



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ABSTRACT

Background: A brief, self-administered measurement of pain frequency, intensity, and burden is desirable in both research and clinical settings. We describe the development and initial psychometric properties of a new instrument, the Pain Frequency, Intensity, and Burden Scale (P-FIBS).

Methods: The P-FIBS was administered to all participants ($N = 302$) with psychostimulant use disorders in the National Institute on Drug Abuse Clinical Trials Network's STRIDE (Stimulant Reduction Intervention using Dose Exercise) multisite trial.

Results: The four items on the P-FIBS demonstrate high item–total correlations (range 0.70–0.85) with a high Cronbach's alpha (0.90). The P-FIBS demonstrated a strong negative correlation with the bodily pain sub-score of the Short Form Health Survey ($r = -0.76, p < 0.0001$) and did not correlate with a measure of cocaine ($r = 0.09, p = 0.12$) or methamphetamine ($r = -0.06, p = 0.33$) craving.

Conclusions: The P-FIBS demonstrates good psychometric properties. This brief measure can be used to assess pain in research settings or as a screen in clinical settings. Further research is needed to assess the measure's sensitivity to change with treatment.

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1. Background and objectives

The measurement of pain is important in both clinical and research samples. The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) introduced new standards for the screening and management of pain in 2001, leading to the consideration of pain as the “fifth vital sign” (Joint Commission, 2013). A 2011 report by the Institute of Medicine revealed that 100 million Americans are affected by pain with an annual economic burden of approximately \$600 billion (Institute of Medicine (IOM), 2011). These numbers demonstrate that pain is a common and serious problem that requires more thorough understanding and treatment. Additionally, the rising epidemic of opioid prescription misuse (Substance Abuse and Mental Health Services Administration (SAMHSA), 2011) also highlights the need

for easy-to-use, brief assessment tools to monitor progress of pain symptoms in the general population.

Although several tools have been developed to aid in the measurement of pain, no gold standard brief pain assessment is universally utilized. Commonly used scales include numeric rating scales (NRS) and visual analogue scale (VAS). The numeric rating scale is more straightforward to administer than the VAS in that the NRS requires a patient to verbally state a number corresponding to the current level of pain (most commonly 0–10, with 0 = no pain and 10 = worst pain imaginable), while the VAS requires patients to make a mark on a line corresponding to their pain level (Breivik et al., 2008). The VAS can be presented horizontally or vertically, and orientation can affect the level of pain reported (Peters et al., 2007). Other single response pain scales include the visual numeric scale (Ritter et al., 2006) and the verbal descriptor scale (Peters et al., 2007). These scales have the advantages of being very brief and easy to administer, and they are useful for rapid screening in clinical settings but may lack precision necessary to monitor progress. They are less useful in research settings and in many clinical settings in which measurement of more than one aspect of pain is desired. Additionally, there is concern that these single item

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measures, though similar, are not interchangeable (Lund et al., 2005) and may function differently in different populations (Peters et al., 2007). Longer scales that explore more aspects of pain have been developed, although these longer scales tend to focus on a particular type of pain such as cancer (Hjermstad et al., 2008) or back (Longo et al., 2010) pain. The specific focus of these scales makes them inappropriate to use in a clinical trial in which assessment of pain in a heterogeneous sample is needed or in clinical settings as brief screening tools.

Several pain assessments have been previously developed; however, each of these scales has limits on its utility. The Brief Pain Inventory (BPI; Cleeland and Ryan, 1994; Daut et al., 1983; Tan et al., 2004) was originally developed to assess chronic pain in patients with cancer. This self-report questionnaire includes questions on severity of pain at worst, least, and on average. Several questions ask patients to rate the extent to which pain interferes with a variety of daily activities; one question asks patients to mark on a drawing the location of their pain and two additional questions ask about relief of pain by medications (and current pain medications). The psychometric properties of the BPI have been assessed in English and non-English speaking populations, and this instrument has been used in a variety of conditions, including psychiatric samples (Brannan et al., 2005; Tan et al., 2004). Disadvantages of the BPI include different scoring methods (Cleeland, 2009) and the length of this scale. A second instrument, the Pain Disability Questionnaire (Anagnostis et al., 2004) has been validated on both a normal population and groups of patients with different types of pain. This scale is rapidly administered but potentially time-consuming to score, as it contains fifteen items rated on a visual analogue scale. The NIH-sponsored Patient Reported Outcomes Measurement Information System (PROMIS; www.nihpromis.org) has also generated several versions of a brief pain interference scale (4–8 items) as well as a 29-item scale (PROMIS-29 Profile) that assesses functioning across seven domains that includes 4 items that assess pain interference and a single item to measure pain intensity. The PROMIS scales have benefitted from an extensive development and validation process (Ammann et al., 2010). As implied by the name, these scales assess the degree to which pain interferes with several aspects of daily living, but they do not assess frequency of pain or the use of medications for pain. Our goal was to create a brief, easily scored instrument for the assessment of pain in research trials with the potential for use as a screen in clinical settings. Additionally, we sought to create an instrument that assessed multiple aspects of pain. Here, we present the initial validation of the Pain Frequency, Intensity, and Burden Scale (P-FIBS) in a sample of 302 adults seeking treatment for psychostimulant (cocaine, amphetamine, and methamphetamine) use disorders. Analyses were performed on baseline data collected in the National Institute on Drug Abuse Clinical Trials Network's STRIDE (Stimulant Reduction Intervention using Dose Exercise) multisite trial (Trivedi et al., 2011), which was designed to test the efficacy of aerobic exercise compared to health education as augmentation to treatment as usual for psychostimulant use disorders.

2. Materials and methods

Methods for the STRIDE trial have been fully described elsewhere (Trivedi et al., 2011). Pertinent information is given below. Data for the present study were collected at baseline, prior to randomization into treatment groups.

2.1. Participants

Participants in STRIDE ($N = 302$) were men and women aged 18–65 admitted to one of nine participating residential substance

abuse treatment programs with use of a psychostimulant (cocaine, methamphetamine, amphetamine, or other stimulant excluding caffeine and nicotine) in the 30 days prior to admission and meeting DSM-IV-TR diagnosis of substance abuse or dependence for a psychostimulant in the past 12 months. Exclusion criteria for the STRIDE trial were as follows: unable to pass medical clearance for exercise, general medical condition that prevented exercise, opioid dependence, psychosis or other psychiatric issues that posed a safety risk, pregnancy, or concomitant therapy with beta blockers or opioid replacement therapy. The study was approved by the institutional review board at each institution and all procedures contributing to this work complied with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All participants provided written informed consent after a discussion of the risks and benefits of study participation.

2.2. Assessments

At baseline, standard demographic information (e.g., gender, race, ethnicity) was collected from all participants. DSM-IV-TR illicit drug abuse and dependence were assessed with the substance abuse modules of the World Health Organization (WHO) Composite International Diagnostic Interview (CIDI) version 2.1; this instrument determines “abuse” and “dependence” independently and not hierarchically. The Short Form Health Survey (SF-36; Ware and Sherbourne, 1992) is a 36-item questionnaire with a total score of 0–100 with components that assess perception of mental and physical health and a subscale that assesses bodily pain; lower scores indicate worse health status. The physical component subscale consists of 10 items and the bodily pain subscale consists of 2 items. Each subscale is normed with a mean value of 50 and a standard deviation of 10. Both of these instruments are commonly used and have good psychometric properties (Trivedi et al., 2011). Cocaine and methamphetamine craving were each assessed with one item contained in the Stimulant Selective Severity Assessment (SSSA; Kampman et al., 1998). This scale asks participants to rate level of craving for each drug in the preceding 24 h by marking a 90 mm modified visual analogue scale rated from 0 “no desire at all” to 90 “unable to resist.”

The P-FIBS consists of 4 items, each rated on a 0–8 Likert scale, with lower scores indicating less pain or burden during the past week. The score is computed by summing responses to each item. Frequency and intensity of pain are measured with one item each. Burden of pain is assessed with two items, one assessing the extent to which pain interferes with daily life and one assessing the use of medications or other treatment to manage pain. The full scale is shown in Fig. 1.

2.3. Data analysis

Classical test theory (CTT) analysis was used to generate the mean, item–total correlation (r_{it}) for each item, and Cronbach's α as a measure of internal consistency. Principle components analysis was used to define the number of dimensions on the P-FIBS scale. Pearson correlation coefficients were used to assess correlations between measures. Because all assessments were collected at baseline, test-retest and predictive validity were not examined.

3. Results

As presented in Table 1, the sample contained 302 participants, the minority of whom were female. More participants identified as White than another race, although the number of White and Black participants was similar. Participants were, on average, middle aged

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