Brief Methodological Report

One, Two, or Three? Constructs of the Brief Pain Inventory Among Patients With Non-Cancer Pain in the Outpatient Setting

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Abstract

Context. Either a two-factor representation (pain intensity and interference) or a three-factor representation (pain intensity, activity interference, and affective interference) of the modified Brief Pain Inventory (BPI) is appropriate among cancer patients.

Objectives. To evaluate the extent to which a three-factor representation (pain intensity, activity interference, and affective interference) is appropriate for BPI among patients with noncancer pain seen in an outpatient setting.

Methods. We conducted a prospective, multicenter, observational, nonrandomized study using patient pain registry data from outpatient settings. Seven hundred forty-one patients with acute episodes of noncancer pain requiring treatment with a prescription medication containing oxycodone immediate-release on an as-needed basis for at least five days participated. Baseline measurements included the modified BPI pain intensity (right now, average, and worst in 24 hours) and pain interference with general activities, walking, work, mood, relations with others, sleep, and life enjoyment. Confirmatory factor analysis was conducted for the overall sample and among postoperative patients ($n = 133$), patients with back and neck pain ($n = 202$), patients with arthritis ($n = 148$), and patients with injury or trauma ($n = 204$).

Results. Both the two-factor and three-factor models were statistically better than the one-factor model ($P < 0.05$), with the two-factor model performing better than the three-factor model. Configural invariance, but not metric invariance by patient cohort group was demonstrated.

Conclusion. Consistent with analyses among cancer patients, a two-factor representation of BPI is appropriate for noncancer patients seen in an ambulatory setting. This work lends additional support for the psychometric properties of BPI. J Pain Symptom Manage 2014;47:325–333. © *2014 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.*

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Pain, psychometric properties, ambulatory care, opioids, registry

Introduction

The U.S. Food and Drug Administration and the European Medicines Agency have recognized the importance of patient-reported outcomes in clinical trials.[1] Both regulatory agencies have released guidelines stressing the importance of content validity and construct validity of patient-reported outcome instruments.[2,3] Content validity provides evidence that the instrument measures the concept of interest.[4] Such evidence can come from qualitative studies that demonstrate that the items and domains of an instrument are significant and relevant, given the patient condition, patient concerns, and the instrument's intended use.[2] Construct validity provides evidence that relationships among items, domains, and concepts are consistent with a priori hypotheses about logical relationships among the concepts.[4] Given the increasing importance of patient-reported outcomes and the regulatory agency guidance related to validity of instruments assessing patient-reported outcomes, studies documenting both content and construct validity of commonly used patient-reported outcome instruments are needed.

One important patient-reported outcome is pain. In research studies, a commonly used pain instrument is the Brief Pain Inventory (BPI).[5] Although a single item is often used (pain at its worst in the last 24 hours),[5] there is growing support of three relevant constructs derived from BPI: 1) pain intensity, 2) activity interference (walking, work, general activities), and 3) affective interference (relations with other people, mood, sleep, enjoyment of life).[6–8] Research supporting the three constructs of BPI has been conducted in patients with cancer[6–8] or HIV/AIDS.[7] Yet, the extent to which these findings extend to patients with other conditions remains unknown.

Using data from a comprehensive prospective, multicenter, observational, nonrandomized patient pain registry, we examined the extent to which psychometric properties regarding three distinct domains of BPI (intensity, activity interference, and affective interference) observed in a sample of patients with cancer or HIV/AIDS extend to patients with noncancer pain being seen in an outpatient setting. By examining the construct validity of the instrument using confirmatory factor analysis, we hypothesized that two acceptable models would emerge: 1) a two-factor representation (pain intensity and interference) and 2) a three-factor representation (pain intensity, activity interference, and affective interference). Confirmatory factor analysis is a commonly used method[9] to investigate construct validity.

Methods

Study Sample

The Oxycodone Users Registry (OUR) study,[10] a prospective registry designed to provide detailed assessments of patient-reported outcomes beyond those typically available from a retrospective chart review, was used for the current analysis. Adult patients were enrolled from 48 clinical sites (providing geographic variation) during six months of 2009. Patients were eligible if their pain level required the start of a Schedule II medication containing immediate-release oxycodone (either alone or in combination with aspirin, ibuprofen, or acetaminophen) within three days after the baseline visit (or day of surgery) and to continue as needed for at least five days. Patients who reported use of a Schedule II opioid within 30 days before providing informed consent or had planned to use a Schedule II-V opioid during the study period were excluded. However, patients who switched from a Schedule III-V opioid or a non-opioid analgesic were included. Participants had pain as a result of: 1) injury or trauma of the head, neck, back, chest, or extremities; 2) fibromyalgia; 3) arthritis; 4) neuropathic pain; 5) other back or neck pain; or 6) postoperative pain after outpatient orthopedic surgery. These were typical conditions for which short-acting opioids were prescribed. Prescribers treated patients according to their usual practice with no restrictions on the dose and schedule of oxycodone. Patients used the study Web site on Days 1 (record