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ORIGINAL RESEARCH ARTICLE

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Validation of the Modified Brief Pain Inventory-Exploratory Form in Surgery Patients

Wen-Hung Chen, PhD[a], Kitty S. Chan, PhD[b], Tong J. Gan, MD[c], Connie Chen, PharmD[d], Mani Lakshminarayanan, PhD[d,1], Dennis A. Revicki, PhD[a]

[a]Center for Health Outcomes Research, United BioSource Corporation, Bethesda, Maryland; [b]Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland; [c]Department of Anesthesiology, Duke University Medical Center, Durham, North Carolina; and [d]Pfizer, New York, New York

ABSTRACT

OBJECTIVE: An exploratory version of the Modified Brief Pain Inventory (mBPI-e) to measure acute post-operative pain, with new items on coughing, breathing, and concentration, was examined for their measurement properties.

STUDY DESIGN: This is a secondary study using data from two randomized clinical trials: general surgery trial (N=1050) and coronary artery bypass graft (CABG) surgery trial (N=1636). The measurements used in the two trials were: 1) mBPI-e; 2) clinician and patient global evaluations of medications; and 3) pain intensity diary. The mBPI-e and pain intensity were collected for 10 days. Clinician and patient global evaluations of medication were collected twice. The analyses conducted were: 1) exploratory factor analysis (EFA); 2) confirmatory factor analysis (CFA); 3) item response theory (IRT); 4) internal consistency; 5) test-retest reliability; 6) concurrent validity; 7) known-group validity; and 8) responsiveness.

RESULTS: Pain severity, pain interference, and coughing and breathing factors were identified. Pain severity and pain interference subscale scores were constructed for mBPI-e. IRT analyses showed all items exhibited good item characteristics. Internal consistency was 0.85 for severity and 0.87 for interference. Test-retest reliability was 0.81 for severity and 0.71 for interference. Both severity and interference scores were correlated with diary-based pain intensity ratings ($P < .0001$). Mean severity and interference scores varied by physician and patient global ratings ($P < .05$). Severity and interference scores were responsive to changes in pain diary scores and physician global ratings ($P < .001$). There were no substantive differences in reliability or validity for sub-samples of surgery patients.

CONCLUSIONS: The original BPI has been used in clinical studies, and the mBPI has demonstrated good reliability and validity in CABG patients. Based on this study, the mBPI-e has also demonstrated good reliability and validity for assessing postoperative acute pain in CABG and general surgery patients.

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KEYWORDS: Brief pain inventory; Measurement of pain; Modified brief pain inventory; Pain measure; Post operative pain

Postoperative pain is common after highly invasive procedures such as coronary artery bypass graft (CABG) surgery, abdominal surgery, major orthopedic surgery, and gynecologic surgery. Clinical trials comparing different analgesic medications require psychometrically sound assessments of pain severity and interference with everyday activities. The Brief Pain Inventory (BPI) has been used in numerous studies and clinical trials of chronic and acute pain.[1-7] In the postsurgical setting, ability to engage in normal daily activities is limited, and general pain assessments such as the pain interference scale from the BPI[2] may not be entirely applicable. Mendoza et al[8] developed a modified version of the BPI (mBPI) in CABG surgery patients, where items on general activity, normal work, and enjoyment of life were removed from the BPI and a new item on concentration was added. They found good evidence for internal consistency and test-retest reliability, confirmed the 2-domain factor structure and evidence supporting concurrent validity of the mBPI.

The objective of the current study was to evaluate the psychometric characteristics (ie, reliability, validity, responsiveness) of an exploratory modified version of the mBPI using data collected in two postoperative pain clinical trials. This study is the secondary data analysis of these 2 safety and efficacy trials. The exploratory version of the mBPI (mBPI-e) included 2 new items on interference related to coughing and deep breathing, which were intended to make the mBPI more relevant for assessing pain outcomes in postoperative analgesic clinical trials. The mBPI-e is based on the mBPI,[8] and retains the original 4 pain severity items from the original BPI (worst, least, and average pain in the past 24 hours, and pain right now). For the new pain interference scale, mBPI-e retains the original general activity item and added 2 new items on coughing and deep breathing. These new items were added aiming to enhance the instrument's ability in assessing acute pain outcomes in postoperative clinical studies. The assumption was that the interference associated with coughing and deep breathing can be very significant in many postoperative patients, depending on the type of surgery (eg, CABG, gastrointestinal [GI]). Figure 1 compares the items contained in BPI, mBPI, and mBPI-e.

	BPI	mBPI	mBPI-e
Severity			
Least pain	✓		✓
Worst pain	✓	✓	✓
Average	✓	✓	✓
Pain right now	✓	✓	✓
Interference			
General activity	✓		✓
Normal work	✓		
Enjoyment of life	✓		
Walking ability	✓	✓	✓
Mood	✓	✓	✓
Sleep	✓	✓	✓
Relations with others	✓	✓	✓
Ability to concentrate		✓	✓
Coughing			✓
Deep Breathing			✓

FIGURE 1: Items included in the BPI, mBPI, and mBPI-e.

METHODS

Data for this study were taken from 2 clinical studies with different inclusion/exclusion criteria. Study 069 was a randomized, double-blind, parallel-group, multicenter study of the safety and efficacy of parecoxib followed by valdecoxib compared with placebo in general surgery patients for treatment of postoperative pain. It was conducted in 113 centers in 14 countries from September 2002 to February 2003.[9] Study 071 was a randomized, double-blind, parallel-group, multicenter study of the safety and efficacy of parecoxib/valdecoxib and placebo/valdecoxib compared with placebo for treatment of postoperative pain in patients who had CABG. It was conducted at 175 centers in 27 countries from January 2003 to January 2004.[10] Both Phase

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