American Pain Society
RESEARCH
EDUCATION
TREATMENT
ADVOCACY
PUBLISHED BY ELSEVIER

The Journal of Pain, Vol 16, No 4 (April), 2015: pp 357-366
*Available online at www.jpain.org and www.sciencedirect.com*

# Validation of the Short-Form McGill Pain Questionnaire-2 (SF-MPQ-2) in Acute Low Back Pain

Robert H. Dworkin,[*,†,‡] Dennis C. Turk,[§] Jeremiah J. Trudeau,[‖] Carmela Benson,[¶] David M. Biondi,[¶] Nathaniel P. Katz,[‖,#] and Myoung Kim[¶]

*Departments of *Anesthesiology and †Neurology, University of Rochester School of Medicine and Dentistry, Rochester, New York.*
*‡Center for Human Experimental Therapeutics, University of Rochester School of Medicine and Dentistry, Rochester, New York.*
*§Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, Washington.*
*‖Analgesic Solutions, Natick, Massachusetts.*
*¶Janssen Scientific Affairs, LLC, Raritan, New Jersey.*
*#Department of Anesthesiology, Tufts University, Boston, Massachusetts.*

**Abstract: The Short-form McGill Pain Questionnaire (SF-MPQ-2) assesses the major symptoms of both neuropathic and nonneuropathic pain and can be used in studies of epidemiology, natural history, pathophysiologic mechanisms, and treatment response. Previous research has demonstrated its reliability, validity, and responsiveness in diverse samples of patients with chronic pain. However, the SF-MPQ-2 has not been evaluated for use in patients with acute pain. Data were examined from a double-blind, randomized clinical trial of immediate-release tapentadol versus immediate-release oxycodone in patients with acute low back and associated radicular leg pain (N = 666). Analyses of internal consistency, convergent validity, and confirmatory factor structure were conducted using baseline data, and analyses of responsiveness were conducted using baseline and endpoint data. The SF-MPQ-2 total score and its 4 subscale scores (continuous pain, intermittent pain, predominantly neuropathic pain, and affective descriptors) generally showed good psychometric properties and 1) were internally consistent, 2) displayed good convergent validity, 3) fit the a priori factor structure, and 4) were highly responsive to analgesic treatment. These data extend previous evidence of the reliability, validity, and responsiveness of the SF-MPQ-2 in patients with chronic pain to those with acute low back and associated radicular leg pain.**

***Perspective:** Considered together with the results of other recent studies, the data suggest that the SF-MPQ-2 can provide a valid, responsive, and efficient assessment of both neuropathic and non-neuropathic pain qualities for clinical trials and other clinical research examining patients with various acute and chronic pain conditions.*



***Key words:** Short-form McGill Pain Questionnaire-2, SF-MPQ-2, acute pain, low back pain, pain quality.*

Received August 6, 2013; Revised December 23, 2014; Accepted January 15, 2015.

Support for the clinical trial from which the data analyzed in this article were derived was provided by Janssen Scientific Affairs, which also provided a research grant to Analgesic Solutions to support data analyses and publication preparation.

Permission to use the SF-MPQ-2 can be obtained from the Mapi Research Trust, Lyon, France (e-mail: PROinformation@mapi-trust.org; website: www.proqolid.com). Dr. Ronald Melzack and the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership with the U.S. Food and Drug Administration share licensing fees from for-profit organizations using the SF-MPQ-2 in their research. R.H.D. has received in the past 12 months a research grant from the U.S. Food and Drug Administration (grant no. U01FD004187) and compensation for activities involving clinical trial research methods from Acetylon, Astellas, AstraZeneca, Avanir, Axsome, Biogen, Centrexion, Charleston, Chromocell, Daiichi-Sankyo, Eli Lilly, Hydra, Johnson & Johnson, Lpath, Maxwell Biotech, Metys, Olatec, Phosphagenics, QRx, Relmada, Salix, Sorrento, Spinifex, Teva, and Virobay. D.C.T. has received in the past 12 months a research grant from the U.S. Food and Drug Administration (grant no. U01FD004187) and consulting fees or honoraria in the past year from Lilly, Mallincrodt, Orexo, Ortho-McNeil Janssen, Pfizer, and Xdynia. J.J.T. was a full-time employee of Analgesic Solutions at the time the study was conducted and the first draft of the manuscript was prepared. D.M.B., M.K., and C.B. are full-time employees of Johnson & Johnson. N.P.K. is the owner of Analgesic Solutions.

Address reprint requests to Robert H. Dworkin, PhD, Department of Anesthesiology, University of Rochester Medical Center, 601 Elmwood Avenue, Box 604, Rochester, NY 14642. E-mail: robert_dworkin@urmc.rochester.edu

1526-5900/$36.00



http://dx.doi.org/10.1016/j.jpain.2015.01.012

The McGill Pain Questionnaire (MPQ) has been used for the assessment of the sensory, affective, and evaluative qualities of pain for more than 30 years,[36,38] and its reliability and validity have been extensively documented.[29] The Short-form McGill Pain Questionnaire (SF-MPQ) was developed to provide a less time-consuming measure that includes 15 pain descriptors,[37] and it has also shown excellent reliability and validity.[29]

Although the MPQ and SF-MPQ were developed for the assessment of all types of pain, they were not explicitly designed to assess the characteristics of neuropathic pain. This was probably because the prevalence of neuropathic pain in the general population and its adverse impact on quality of life were not widely recognized until the 1990s. In spite of this, the SF-MPQ has been used in a substantial number of studies of neuropathic pain, including evaluation of the responsiveness of different symptoms to treatment in clinical trials.[13,24] Nevertheless, the SF-MPQ does not include several symptoms that are very common in patients with neuropathic pain or that are thought to reflect its pathophysiologic mechanisms (eg, reports of allodynia).

There has been increasing interest in using symptoms and signs to identify pain mechanisms and thereby potentially provide therapeutic targets for a mechanism-based approach to the treatment of acute and chronic pain.[2,35,39,55] Multiple measures have been developed to assist in distinguishing neuropathic and nonneuropathic pain[3,9,18,32,44] and to assess characteristic symptoms of neuropathic pain.[8,21] Although these measures provide important information about neuropathic pain, they were not designed to assess the symptoms of nonneuropathic pain or to be used in randomized clinical trials (RCTs) and other clinical research on patients with nonneuropathic pain or with mixed nonneuropathic and neuropathic pain conditions.[4,26]

To provide a single measure of the major symptoms of both neuropathic and nonneuropathic pain for use in research on the epidemiology, natural history, mechanisms, and treatment response of acute and chronic pain conditions, the SF-MPQ was expanded by adding 7 symptoms relevant to neuropathic pain and by replacing its 4-point verbal rating scale with a 0 to 10 numerical rating scale (NRS), which potentially provides increased responsiveness.[15] The resulting Short-form McGill Pain Questionnaire-2 (SF-MPQ-2) has demonstrated evidence of reliability, validity, and/or responsiveness in a community sample of individuals with various chronic pain conditions[15]; in U.S. veterans[33] and Iranian multidisciplinary pain clinic patients[1] with a range of pain conditions; in individuals with irritable bowel syndrome,[49] persistent pain following cesarean delivery,[43] and advanced cancer[22,23]; and in clinical trials of fibromyalgia[11] and painful diabetic peripheral neuropathy.[15] The SF-MPQ-2 is being used in ongoing phase 2 and 3 RCTs, and it has been translated into 35 languages.

These previous and ongoing studies have examined the SF-MPQ-2 in patients with various *chronic* pain conditions. Because the SF-MPQ-2 is also intended for use in studies of *acute* pain conditions, the primary objective of the research described in this article was to determine the psychometric properties, including responsiveness to treatment effects, of the SF-MPQ-2 in an RCT of patients with acute low back and associated radicular leg pain.

## Methods

In this article, we describe secondary analyses of data from a 10-day double-blind, parallel-group RCT of immediate-release tapentadol versus immediate-release oxycodone in 666 patients with a clinical diagnosis of acute low back pain with associated radicular leg pain.[5] This sample of 666 patients includes 2 patients who were excluded from the primary study analyses (n = 664)[5] because they either did not take medication or had no verifiable drug exposure. Because these 2 patients did provide baseline data, they are included in the analyses in which baseline data are used. Institutional review board approval was obtained by all study sites prior to their initiating the clinical trial, and all subjects provided informed consent before beginning any study procedures.

### *Subjects*

Eligible patients were required to have had onset of their low back pain no more than 30 days prior to screening, a low back pain score at baseline of at least 5 on a 0 to 10 NRS, and associated radicular leg pain on at least one side. The clinical presentation was to be consistent with the Quebec Task Force Classification (QTFC) for Spinal Disorders categories 3, 4, and 6.[48] These QTFC categories include acute low back pain and pain radiating below the knee with or without neurologic signs on physical examination suggestive of lumbosacral radiculopathy with or without evidence of nerve root compression on imaging. If neurologic signs were present, the leg with these signs was considered the "index" leg; if no neurologic signs were present, the leg with more intense radiating pain was considered the "index" leg. Patients with neurologic signs in both legs were not eligible for the study.

### *Measures*

Analyses were conducted on study measures collected at baseline, except for analyses of responsiveness and predictive validity, both of which used data from day 5 of treatment, the time point used in defining the prespecified primary endpoint of the clinical trial from which these data are drawn.[5]

#### SF-MPQ-2

As described above, the SF-MPQ-2 is an expanded and revised version of the SF-MPQ that includes 7 symptoms relevant to neuropathic pain and uses a 0 to 10 NRS rather than a verbal rating scale.[15] There is a total of 22 items, each representing a different quality of pain or related symptoms. On the basis of the initial analyses, prior research on human experimental pain, and characteristic symptoms and signs in patients with neuropathic and nonneuropathic