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Development and initial validation of an expanded and revised version of the Short-form McGill Pain Questionnaire (SF-MPQ-2)

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ABSTRACT

The objective of the present research was to develop a single measure of the major symptoms of both neuropathic and non-neuropathic pain that can be used in studies of epidemiology, natural history, pathophysiologic mechanisms, and treatment response. We expanded and revised the Short-form McGill Pain Questionnaire[1] (SF-MPQ) pain descriptors by adding symptoms relevant to neuropathic pain and by modifying the response format to a 0–10 numerical rating scale to provide increased responsiveness in longitudinal studies and clinical trials. The reliability, validity, and subscale structure of the revised SF-MPQ (SF-MPQ-2[1]) were examined in responses from 882 individuals with diverse chronic pain syndromes and in 226 patients with painful diabetic peripheral neuropathy who participated in a randomized clinical trial. The data suggest that the SF-MPQ-2 has excellent reliability and validity, and the results of both exploratory and confirmatory factor analyses provided support for four readily interpretable subscales—continuous pain, intermittent pain, predominantly neuropathic pain, and affective descriptors. These results provide a basis for use of the SF-MPQ-2 in future clinical research, including clinical trials of treatments for neuropathic and non-neuropathic pain conditions.

1. Introduction

The McGill Pain Questionnaire (MPQ) has been the preeminent measure of the sensory, affective, and evaluative qualities of pain since its publication over 30 years ago [31,33,36]. The MPQ has been used in the assessment of multiple types of acute and chronic pain, and its reliability and validity have been extensively documented [34]. Because the MPQ is time-consuming to use, Melzack [32] developed the Short-form McGill Pain Questionnaire[1] (SF-MPQ). The SF-MPQ includes visual analogue and verbal rating scales of pain intensity as well as 15 pain descriptors that are each rated on a four-point verbal scale; its reliability and validity are well established [22,34].

Since the MPQ and SF-MPQ were developed, there has been increasing interest in a mechanism-based approach to the assessment and treatment of neuropathic pain [2,30,39,51]. The assessment of the characteristics of neuropathic pain plays a critical role in research on its mechanisms and treatment. Over the past decade, nine measures have been developed to assess characteristic symptoms of neuropathic pain in studies of its mechanisms and treatment response [9,20] and to assist in distinguishing individuals with neuropathic pain from those with non-neuropathic pain [3,5,7,10,18,27,37].

These measures and the MPQ and SF-MPQ have features that limit their use across the entire spectrum of pain conditions. The neuropathic pain measures all provide important information about neuropathic pain, but were not designed to be used in the assessment of non-neuropathic pain qualities or in studies of

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patients with non-neuropathic pain or with mixed neuropathic and non-neuropathic pain conditions. In contrast, the MPQ and SF-MPQ were developed for the assessment of all types of pain, but were not explicitly designed to assess the characteristics of neuropathic pain. In spite of this, the SF-MPQ has been used in recent research on neuropathic pain, not only to characterize symptoms [38] but also to evaluate the responsiveness of different symptoms to treatment (e.g. [13,21]). However, several symptoms that are thought to reflect mechanisms of neuropathic pain or that are especially common in individuals with neuropathic pain are not included in the SF-MPQ, which thus may not adequately characterize neuropathic pain. Moreover, the SF-MPQ uses a four-point rating scale, which may limit its responsiveness in detecting small but meaningful changes in specific descriptors over time and following treatment.

The primary objective of the studies described in this article was to develop a comprehensive measure of pain quality that can be used in studies of the epidemiology, natural history, pathophysiologic mechanisms, and treatment response of both neuropathic and non-neuropathic pain conditions. We expanded the SF-MPQ by adding seven symptoms relevant to neuropathic pain and we replaced its four-point rating scale with a 0–10 numerical rating scale (NRS) for all 22 items to provide increased responsiveness. This article presents the results of initial studies of the development, reliability, and construct validity of the revised SF-MPQ (SF-MPQ-2[1]) that provide support for its use in both clinical research and clinical practice.

2. Methods

2.1. Overview

Current approaches to the assessment of pain and other patient-reported outcomes require that the first step in developing new measures is to determine what patients themselves consider important [1], an approach that has been endorsed by the United States Food and Drug Administration [47] and by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) [45]. We conducted focus groups to identify pain and related symptoms considered important from the perspective of individuals seeking treatment for a variety of chronic pain conditions, including neuropathic pain. These focus group discussions were conducted to identify descriptors of pain quality that were not included in the SF-MPQ and that were potentially relevant to the assessment of neuropathic pain. A web-based survey was then conducted in which the original SF-MPQ items, specific neuropathic pain descriptors, and the newly identified items were administered to a large sample of individuals with diverse chronic pain conditions. These data were used as a basis for final item selection and for evaluating the reliability and construct validity of the SF-MPQ-2. Following these analyses, the SF-MPQ-2 was included as a secondary outcome measure in a randomized clinical trial (RCT) in painful diabetic peripheral neuropathy (DPN). The data from this RCT were used to further evaluate the reliability and validity of the SF-MPQ-2 and to provide initial evidence of its responsiveness to change. Institutional Review Board approval was obtained prior to initiating each of these studies, and all participants gave informed consent before beginning any study procedures.

2.2. Participants

2.2.1. Focus groups

As previously described in detail [46], focus group participants were recruited from four clinics and had to be at least 21 years of age, have a history of chronic pain for at least 6 months, and be able to speak and understand English. A total of 31 individuals participated in the focus groups, and they reported having chronic pain for an average of 8 years. A content analysis approach was used to analyze the discussions, and themes, recurrent words, issues, and concerns were identified and used to generate potential descriptors for the SF-MPQ-2.

2.2.2. Web survey

Individuals with chronic pain were invited to complete a survey posted on the American Chronic Pain Association (ACPA) website, and respondents were asked to complete an initial eligibility screening that required participants to be 21 years of age or older and to have at least one chronic pain condition for at least 3 months prior to the survey date. Those who met these criteria were provided further explanation of the study and were asked to complete an informed consent form. Once this was completed, participants immediately began the survey.

2.2.3. DPN clinical trial

Patients were recruited for a 4-week, double-blind, placebo-controlled Phase II RCT of a topical combination of amitriptyline and ketamine in painful DPN by clinical research centers in India. The major inclusion criteria were 18 years of age or older; bilateral pain in the lower extremities persisting for at least 6 months associated with a diagnosis of Type 1 or Type 2 diabetes mellitus and distal symmetric sensorimotor polyneuropathy diagnosed by a physician who was trained and experienced in endocrinology, neurology, or pain management; and a mean of $\geqslant 4$ for the baseline week of daily diary ratings on a 0–10 NRS of average lower-extremity pain associated with diabetes mellitus during the past 24 h. The major exclusion criteria were HbA1c $\geqslant 11\%$ at screening; not agreeing to maintain systemic pain treatments at stable dosages during the study; and other pain more severe than lower extremity pain. No rescue medication was allowed for pain other than approved dosages of aspirin, acetaminophen, or non-steroidal anti-inflammatory medications.

The informed consent form and all primary and secondary outcome measures were translated into 11 vernacular languages (Hindi, Bengali, Marathi, Urdu, Gujarati, Kannada, Malayalam, Oriya, Tamil, Telugu, and Punjabi); translation and back-translation certificates were obtained from the translating agency that documented the accuracy of the translations of the English-language versions of the measures. Efficacy and safety analyses of the data from this RCT will be presented elsewhere.

2.3. Measures

2.3.1. Preliminary version of SF-MPQ-2

The preliminary version of the SF-MPQ-2 used in the web survey consisted of 24 items. Given the well-established reliability and validity of the SF-MPQ and the numerous studies in which it has been used [34], the original 15 items were retained to enable comparison with previous literature and to ensure comprehensive assessment of non-neuropathic sensory and affective descriptors. On the basis of the results of research on neuropathic pain and the authors' clinical experience, seven items were added to those included in the SF-MPQ (i.e., "dull", "electric-shock", "cold-freezing", "pain caused by light touch", "itching", "tingling or 'pins and needles'", "numbness"). Two additional items were added on the basis of the focus group discussions (i.e., "squeezing-pressure", "piercing"). To provide increased responsiveness in longitudinal studies and clinical trials, a 0–10 NRS (0 = none; 10 = worst possible) was used. Items that refer to pain were distinguished from those that refer to related symptoms by adding the word "pain" to the original SF-MPQ sensory descriptors (except for "tender")

and to four of the nine new items (“dull pain”, “electric-shock pain”, “cold-freezing pain”, “pain caused by light touch”), but not to the original SF-MPQ affective items or five of the new items (“itching”, “tingling or ‘pins and needles’”, “numbness”, “squeezing-pressure”, “piercing”). In addition, the instructions referred to “different qualities of pain and related symptoms”.

2.3.2. Other measures included in the web survey

The Brief Pain Inventory (BPI) [11] rating of average pain was administered to assess pain intensity during the past week, and the BPI and Multidimensional Pain Inventory (MPI) [25] interference scales were administered to assess the impact of pain on physical and emotional functioning, as recommended by IMMPACT [15]. The Medical Outcomes Study Short Form Health Survey (SF-12) [49] was administered as a generic measure of health-related quality of life, and Physical Component Summary (PCS) and Mental Component Summary (MCS) scores were calculated. In addition, several items from the National Health Interview Survey [35] were included to assess the impact of chronic pain, specifically, the number of days during the past 4 weeks that participants missed work, were late to work, spent part or all of the day in bed, and were kept from usual activities due to their pain.

2.3.3. Other measures included in the DPN clinical trial

The primary efficacy outcome measure for the painful DPN trial was a 0–10 NRS of daily diary ratings of average lower extremity pain associated with diabetes mellitus during the past 24 h (0 = “no pain”; 10 = “pain as bad as you can imagine”) administered throughout the RCT. Secondary efficacy outcome measures included a 0–10 NRS of daily diary ratings of sleep interference (0 = “none”; 10 = “unable to sleep”) administered throughout the RCT, and the BPI [11] interference scale, SF-36 [50] measure of health-related quality of life, Patient Global Impression of Change (PGIC) [17] rating of overall improvement, and Hospital Anxiety and Depression Scale (HADS) [52], which were administered at the baseline visit (except for the PGIC) and at the end of treatment four weeks later.

2.4. Statistical analysis

The overall approach to the development of the SF-MPQ-2 involved a stepwise process in which the results of item analyses and conceptual considerations were used in tandem as a basis for selecting the items included in the final version of the measure and its subscales. Responses to the 24 candidate items administered in the web survey were first examined in item analyses conducted to evaluate distributional characteristics and item–item correlations to assess redundancies in item content. Next, *t*-tests, χ^2-analyses, and analyses of covariance controlling for age, sex, race/ethnicity, and BPI average pain intensity were used to compare participants with and without neuropathic pain. Finally, exploratory factor analyses (EFAs) with two- and three-factor solutions with varimax and promax rotations were conducted on the item responses of all web survey participants and the subgroups with and without neuropathic pain.

The results of these EFAs and of prior research on human experimental pain and on characteristic symptoms and signs in patients with neuropathic and non-neuropathic pain provided the basis for identifying four SF-MPQ-2 subscales comprising a total of 22 items. Confirmatory factor analysis (CFA) was performed with EQS version 6.1 [8] for Windows using the web survey and RCT data to evaluate these SF-MPQ-2 subscales. Acceptability of fit of the factor solutions for the CFA was evaluated based on the Goodness of Fit Index (GFI; >0.90), on the standardized root mean residuals (SRMR; <0.08), and on the root mean square error of approximation (RMSEA; <0.10).

Descriptive statistics and internal consistency reliability coefficients (i.e., Cronbach’s alpha) were calculated for the SF-MPQ-2 total and subscale scores. Construct validity was evaluated by examining the associations between the SF-MPQ-2 total and subscale scores and other measures of pain and its impact in the web survey data (i.e., BPI pain intensity, BPI interference scale, MPI interference scale, SF-12 PCS and MCS scales, number of activity limitation days, and number of bed days) and in the RCT data (i.e., baseline daily diary pain intensity and sleep interference, BPI interference scale, SF-36, PGIC, and HADS).

In addition, analysis of variance was performed using the web survey data to examine the association between the SF-MPQ-2 total and subscale scores and the BPI pain intensity ratings (categorized as none/mild, moderate, or severe) and the number of chronic pain conditions (categorized as one, two, or three). Finally, the responsiveness to change of the SF-MPQ-2 total and subscale scores was evaluated by determining whether these five scores improved from baseline to the end of the RCT and also by examining the associations between change in these scores and the PGIC ratings.

3. Results

A total of 882 participants completed the preliminary version of the SF-MPQ-2 that was included in the web survey (demographic and clinical characteristics of these individuals are presented in Appendix 1, available on-line). They had experienced chronic pain for an average of over 8 years, and a majority reported three pain conditions, the maximum permitted for survey eligibility. Participants were categorized as having self-reported neuropathic pain if they reported at least one neuropathic pain condition (i.e., “painful diabetic neuropathy”, “other neuropathic pain/nerve damage”; $n = 349$) and as non-neuropathic pain if they did not report any neuropathic pain condition ($n = 533$). In accordance with current approaches to the definition of neuropathic pain [44], fibromyalgia, migraine headache, and low back pain were considered non-neuropathic pain conditions. Participants with neuropathic pain were significantly older and had significantly greater BPI average pain intensity in the past week than those with non-neuropathic pain, but the groups did not differ significantly in race/ethnicity, number of painful conditions reported, or duration of chronic pain. There was a significant sex difference, with male participants being equally likely to have neuropathic or non-neuropathic pain but female participants being more likely to have non-neuropathic pain than neuropathic pain.

A total of 226 patients with painful DPN were enrolled in the RCT. On average, these individuals were 55.6 (SD = 10.2) years of age; 46.0% were female and almost all had Type 2 diabetes (97.3%). The patients had diabetes for a mean of 8.8 (SD = 6.6) years, DPN for a mean of 2.4 (SD = 2.4) years, and their mean HbA1c was 8.1% (SD = 1.3).

3.1. Item selection

Item descriptive statistics and response distributions indicated that participants in the web survey used the full range of response options. Mean scores ranged widely from 2.3 for “itching” (SD = 3.31) and “cold-freezing pain” (SD = 3.45) to 7.7 (SD = 2.52) for “aching pain” and 7.77 (SD = 2.73) for “tiring-exhausting”. Missing data for the items ranged from 10% to 13%, suggesting that participants generally found the items understandable and applicable to their pain conditions.

Because web survey participants with self-reported neuropathic pain had greater pain intensity than those with non-neuropathic pain, we statistically controlled for age, sex, race/ethnicity, and

BPI average pain intensity in analyses of differences between these two groups for each of the SF-MPQ-2 items. Significant differences in mean scores were observed for each of the nine new items in the preliminary version of the SF-MPQ-2 except "dull pain" and "squeezing-pressure" as well as for six of the original 15 SF-MPQ items (Appendix 2, available on-line).

Item-item correlations ranged from 0.00 (between "shooting pain" and "dull pain") to 0.77 (between "numbness" and "tingling and 'pins and needles'"). EFAs were conducted using the survey data for the 20 sensory items from the preliminary version of the SF-MPQ-2; because of the well-established reliability and validity of the SF-MPQ affective subscale, the four affective descriptors were not included in these EFAs in order to retain the affective subscale in its original form. A three-factor solution appeared best in terms of the scree test, eigenvalues, and simple structure criteria, and accounted for 41% of the variance. "Stabbing pain" and "sharp pain" loaded most highly on the first factor, "aching pain" and "heavy pain" loaded most highly on the second factor, and "tingling or 'pins and needles'" and "numbness" loaded most highly on the third factor. EFAs were also conducted separately for participants with and without neuropathic pain, and generally comparable solutions with some minor variations were found. On the basis of psychometric and conceptual considerations, two of the new items—"dull pain" and "squeezing-pressure"—that did not differ significantly between individuals with neuropathic and non-neuropathic pain and that both loaded moderately on the second factor were excluded from the final version of the SF-MPQ-2, which consists of 22 items (Fig. 1).

3.2. SF-MPQ-2 subscales

EFAs of the final 18 SF-MPQ-2 sensory items were conducted using the survey data, and the three-factor solution explained 43% of the variance and again appeared best in terms of the scree test, eigenvalues, and simple structure criteria. As in the previous analysis, the three sensory factors reflected stabbing and sharp pain, aching and heavy pain, and tingling and numbness. Although commonly thought to be characteristic of participants with neuropathic pain, "pain caused by light touch" and "cold-freezing pain" loaded more highly on the aching and heavy pain factor; however, these factor loadings were only 0.36 and 0.38, respectively. When EFAs were conducted separately for participants with and without neuropathic pain, the three-factor solutions were generally similar to the analysis involving the entire sample. One noteworthy exception was that for the participants with neuropathic pain, "pain caused by light touch" loaded more highly on the factor on which tingling and numbness loaded highly.

On the basis of the results of these EFAs and of prior research on human experimental pain and on characteristic symptoms and signs in patients with neuropathic and non-neuropathic pain, four SF-MPQ-2 subscales were established. Three of these subscales consist of sensory descriptors and one consists of the original four SF-MPQ affective descriptors, as follows: (1) *continuous pain descriptors* (6 items): "throbbing pain", "cramping pain", "gnawing pain", "aching pain", "heavy pain", and "tender"; (2) *intermittent pain descriptors* (6 items): "shooting pain", "stabbing pain", "sharp pain", "splitting pain," "electric-shock pain", and "piercing"; (3) *predominantly neuropathic pain descriptors* (6 items): "hot-burning pain", "cold-freezing pain", "pain caused by light touch", "itching", "tingling or 'pins and needles,'", and "numbness"; and (4) *affective descriptors* (4 items): "tiring-exhausting", "sickening", "fearful", and "punishing-cruel".

The results of the CFA conducted using the web survey data demonstrated good fit for each of these four subscales (Appendix 3, available on-line). The GFIs were all >0.90, as follows: continuous pain descriptors scale (GFI = 0.98, SRMR = 0.04, RMSEA = 0.07), intermittent pain descriptors scale (GFI = 0.96, SRMR = 0.06, RMSEA = 0.07), predominantly neuropathic pain descriptors scale (GFI = 0.93, SRMR = 0.08, RMSEA = 0.14), and affective descriptors scale (GFI = 0.98, SRMR = 0.04, RMSEA = 0.13).

The results of the CFA conducted using the painful DPN clinical trial data also demonstrated good fit for each of these four subscales (Appendix 3, available on-line). The GFIs were all >0.90, as follows: continuous pain descriptors scale (GFI = 0.98, SRMR = 0.03, RMSEA = 0.05), intermittent pain descriptors scale (GFI = 0.93, SRMR = 0.05, RMSEA = 0.14), predominantly neuropathic pain descriptors scale (GFI = 0.96, SRMR = 0.04, RMSEA = 0.09), and affective descriptors scale (GFI = 0.99, SRMR = 0.01, RMSEA = 0.04).

3.2.1. Reliability and validity

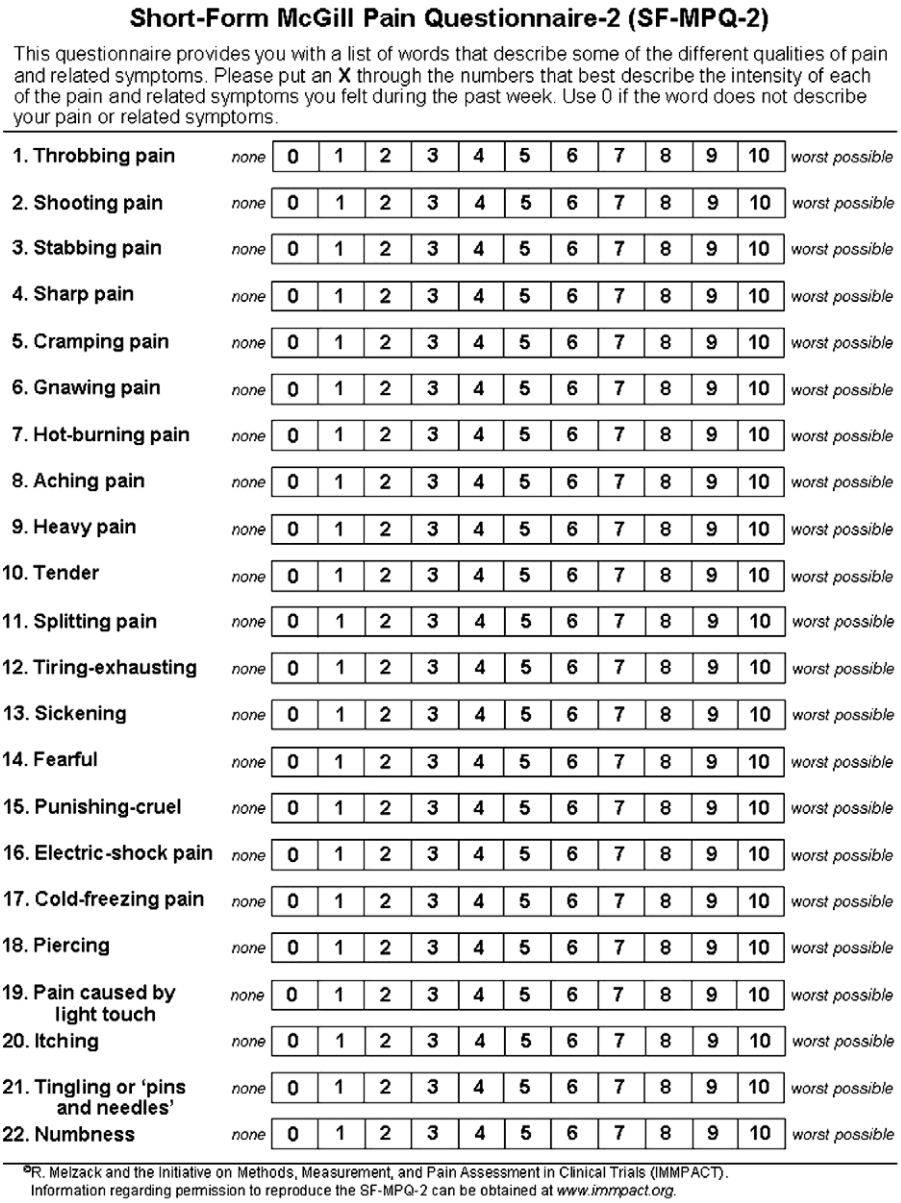
Descriptive statistics for the SF-MPQ-2 total and subscale scores for the web survey data and for the data from the RCT of painful DPN are summarized in Table 1. For each of these scales, scores were calculated by taking the mean of the item ratings included in the scale. Few participants had scores at the ceiling or floor for either the total or subscale scores. Internal consistency reliability for the total score was high and ranged from acceptable to high for the four subscale scores in the web survey data and in the data from the RCT.

In analyses of the web survey data, the SF-MPQ-2 total and subscale scores were significantly correlated with BPI average pain intensity and interference scale scores, MPI interference scale scores, the SF-12 PCS and MCS scores, and the numbers of activity limitation and bed days (Appendix 4, available on-line). Initial support for discriminant validity was provided by the somewhat higher correlations between the three sensory subscales (continuous pain, intermittent pain, and neuropathic pain) and PCS scores (which reflect physical functioning) compared to MCS scores (which reflect mental functioning) whereas the affective descriptors subscale was more highly correlated with MCS scores than with PCS scores. The correlations between the SF-MPQ-2 total score and the PCS and MCS scores, however, were equivalent.

In general, participants in the web survey who reported a greater number of chronic pain conditions also reported greater pain intensity on the SF-MPQ-2 total and subscale scores, with the differences most pronounced between those with either one or two pain conditions and those with three pain conditions (data not shown). Because web survey participants with self-reported neuropathic pain had greater pain intensity than those with non-neuropathic pain, analyses of covariance were performed to examine differences between individuals with and without self-reported neuropathic pain controlling for age, sex, race/ethnicity, and BPI average pain intensity. Participants with neuropathic pain had significantly higher SF-MPQ-2 total, intermittent pain, and neuropathic pain subscale scores than those with non-neuropathic pain; however, these two groups did not differ significantly in their continuous pain or affective descriptors subscale scores (data not shown).

Low back pain was considered a non-neuropathic pain condition in the analyses of the survey data, but an appreciable percentage of chronic low back pain patients have lumbosacral radiculopathy and many others appear to have a mixture of neuropathic and non-neuropathic pain [18,19]. Sensitivity analyses were therefore conducted in which all individuals who reported low back pain were excluded. The principal results of these analyses remained the same as the results of the analyses of the entire sample; that is, the CFAs continued to demonstrate good fit for the SF-MPQ-2 subscales, and five of the neuropathic pain descriptors as well as the intermittent pain and neuropathic pain subscales remained significantly different between those with and without neuropathic pain (data not shown).

In the baseline data from the painful DPN trial, the SF-MPQ-2 total and subscale scores were significantly correlated with the



Short-Form McGill Pain Questionnaire-2 (SF-MPQ-2)

This questionnaire provides you with a list of words that describe some of the different qualities of pain and related symptoms. Please put an **X** through the numbers that best describe the intensity of each of the pain and related symptoms you felt during the past week. Use 0 if the word does not describe your pain or related symptoms.

1. Throbbing pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
2. Shooting pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
3. Stabbing pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
4. Sharp pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
5. Cramping pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
6. Gnawing pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
7. Hot-burning pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
8. Aching pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
9. Heavy pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
10. Tender	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
11. Splitting pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
12. Tiring-exhausting	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
13. Sickening	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
14. Fearful	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
15. Punishing-cruel	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
16. Electric-shock pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
17. Cold-freezing pain	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
18. Piercing	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
19. Pain caused by light touch	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
20. Itching	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
21. Tingling or 'pins and needles'	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*
22. Numbness	*none*	0	1	2	3	4	5	6	7	8	9	10	*worst possible*

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Fig. 1. Short-Form McGill Pain Questionnaire-2(SF-MPQ-2).

Table 1
Descriptive statistics and internal consistency reliability for SF-MPQ-2 total and subscale scores.

Total score/subscale score	*N*	Mean	SD	Floor[a] (%)	Ceiling[b] (%)	Range	Cronbach's alpha
Web survey data							
Total score	853	4.93	2.04	0.0	0.0	0.3–9.4	0.91
Continuous pain	867	5.82	2.28	0.2	1.8	0.0–10.0	0.73
Intermittent pain	863	4.92	2.72	3.9	1.7	0.0–10.0	0.85
Neuropathic pain	870	4.26	2.57	4.1	0.9	0.0–10.0	0.78
Affective descriptors	868	5.46	2.84	3.2	6.5	0.0–10.0	0.77

Total score/subscale score	Baseline			Endpoint			
	N	Mean	SD	N	Mean	SD	Cronbach's alpha[c]
Clinical trial data							
Total score	226	3.47	2.07	223	2.13	1.75[d]	0.95
Continuous pain	226	3.62	2.26	223	2.20	1.88[d]	0.87
Intermittent pain	226	2.89	2.11	223	1.82	1.73[d]	0.87
Neuropathic pain	226	3.77	2.22	223	2.29	1.88[d]	0.83
Affective descriptors	226	3.69	2.52	223	2.28	2.17[d]	0.86

[a] Responded with minimum value.
[b] Responded with maximum value.
[c] For baseline data.
[d] $p < .0001$, two-tailed, for decreases from baseline to endpoint mean score.

mean of 7 daily diary ratings of pain and sleep interference, and with BPI interference scale scores, the SF-36 PCS and MCS scores, and the HADS anxiety and depression subscale scores (Appendix 5, available on-line). The correlation between the SF-MPQ-2 affective descriptors subscale and the MCS scores was somewhat higher than the correlation between the affective descriptors subscale and the PCS scores, providing some evidence for the discriminant validity of this subscale.

As shown in Table 1, the SF-MPQ-2 total and subscale scores all significantly improved from baseline to the end of the trial four weeks later in the RCT of painful DPN. The mean reductions in the SF-MPQ-2 total and subscale scores in patients who reported that they were "much" or "very much" improved on the PGIC were all significantly greater than the mean reductions in these five scores in patients who reported that they were minimally improved, unchanged, or worse (Table 2). Considered together, these data suggest that the SF-MPQ-2 total and subscale scores are responsive to change and that changes in these scores are meaningful to patients, both of which are considered very important criteria in the development of outcome measures for clinical trials of chronic pain treatments [15,16,45].

4. Discussion

We have presented the development of an expanded and revised version of the SF-MPQ and the results of analyses of its reliability and construct validity. It is very important to emphasize that it was not our objective to develop a measure for diagnosing neuropathic pain or for differentiating patients with neuropathic pain from those who do not have neuropathic pain. A number of validated screening measures for neuropathic pain already exist [6], and the SF-MPQ-2 was not designed to be another such measure. Rather, our objective was to revise the SF-MPQ so that it would provide a comprehensive assessment and characterization of the symptoms of *both* neuropathic and non-neuropathic pain. It is important to emphasize that we compared the responses of individuals with self-reported neuropathic and non-neuropathic pain solely to identify new items relevant to the assessment of neuropathic pain, not to evaluate group differences that would provide a basis for selecting items that could be used in screening for neuropathic pain.

Although the initial development of the SF-MPQ-2 was based on focus groups and a web survey that included 882 people with a variety of chronic neuropathic and non-neuropathic pain conditions, these data have a number of limitations. The focus group participants were seeking treatment at specialized pain facilities and may not be representative of those who are not being treated or who receive treatment outside such settings. In addition, our survey was conducted on the ACPA website and the sample included individuals with chronic pain who were generally younger, Caucasian, and well-educated. The results may therefore not be representative of those who lack familiarity with the ACPA or who choose not to complete a web survey. Because of the characteristics of the survey sample we examined, the results may also not be representative of minority groups, the elderly, individuals with more than three chronic pain conditions, and those lacking access to the Internet or who do not use it. Although focus groups were conducted to identify items that individuals with chronic pain themselves consider important, it must be acknowledged that measures such as the SF-MPQ-2 do not provide patients with the opportunity to indicate which specific types of pain are most important to them, an approach that has been used in developing patient-centered measures of health-related quality of life [40,41].

We were also unable to confirm that respondents to the web survey actually experienced chronic pain themselves, as opposed to, for example, being the significant others of individuals with chronic pain who completed the survey on behalf of their partners. Furthermore, no attempt was made to verify the chronic pain conditions that participants reported. It is therefore impossible to determine whether our categorization of individuals with neuropathic vs. non-neuropathic pain conditions—which was based on reports by the respondents themselves—reflects clinician diagnoses that would be made on the basis of a history and physical examination. However, there was a significant Spearman rank-order correlation between the SF-MPQ-2 item ratings in the painful DPN sample and the web survey neuropathic pain subgroup (0.42; $p = 0.05$), but not between the DPN sample and the web survey non-neuropathic pain subgroup (0.33; $p = 0.14$). In addition, the patterns of group differences we found in specific pain qualities controlling for overall pain intensity [4] were consistent with results of previous research (e.g. [6,10,14,29]). Considered together, these data provide support for the validity of the web survey participants' self-reports of their pain conditions.

To reflect the co-morbidity of chronic pain in the general population, we included individuals who reported up to three chronic pain conditions; however, including people in the survey who had both neuropathic and non-neuropathic pain conditions may have attenuated group differences in our analyses comparing those with and without self-reported neuropathic pain. Although our distinction between neuropathic and non-neuropathic pain was based on current diagnostic approaches [44], its validity is further mitigated by the heterogeneity of neuropathic pain and its underlying mechanisms and the existence of chronic pain conditions—for example, low back pain—that have a mixture of neuropathic and non-neuropathic mechanisms and that therefore may or may not be predominantly neuropathic in origin [7,43]. We considered low back pain to be a non-neuropathic condition in our analyses of the survey data, but the principal results remained the same when sensitivity analyses were conducted in which all individuals with low back pain were excluded.

The data from the web survey did not address the responsiveness of the SF-MPQ-2 to change and to treatment effects, a primary

Table 2
Change in SF-MPQ-2 total and subscale scores relative to PGIC score in the clinical trial data.

Total score/subscale score change[a]	Improved[b] mean (SD) ($N = 79$)	Unimproved[c] patients, mean (SD) ($N = 144$)	t	DF	P
Total score	−1.98 (1.51)	−0.99 (1.46)	4.76	221	<0.0001
Continuous pain	−2.04 (1.69)	−1.10 (1.71)	3.96	221	<0.0001
Intermittent pain	−1.52 (1.47)	−0.84 (1.58)	3.14	221	0.0019
Neuropathic pain	−2.24 (1.77)	−1.07 (1.56)	5.10	221	<0.0001
Affective descriptors	−2.18 (2.09)	−0.95 (1.94)	4.40	221	<0.0001

PGIC, Patient Global Impression of Change.
[a] Baseline subtracted from endpoint score.
[b] PGIC response of "much improved" or "very much improved".
[c] PGIC response of "minimally improved", "no change", "minimally worse", "much worse", or "very much worse".

consideration in evaluating outcome measures for use in clinical trials [15,45]. To evaluate responsiveness in a carefully diagnosed sample of patients with neuropathic pain, we examined SF-MPQ-2 responses from an RCT that enrolled 226 patients with painful DPN, a prevalent and very well studied peripheral neuropathic pain condition. One potential limitation of these data is that translated versions of the SF-MPQ-2 were used and that the generalizability of the results to other languages could therefore be questioned. Nevertheless, these clinical trial data not only confirmed the psychometric properties and factor structure of the SF-MPQ-2, but also provided evidence that the total and subscale scores were responsive to change, and that changes in these scores were associated with patient ratings of global improvement, a well-established criterion of clinical importance [15–17]. It is important to emphasize, however, that these analyses examined responsiveness to change, whatever its source, and did not evaluate whether the SF-MPQ-2 was successful in distinguishing between the active treatment and placebo, a second aspect of responsiveness required of clinical trial outcome measures [15,42,44].

Importantly, in the procedure we used to develop the SF-MPQ-2, the analyses were guided by and then revised on the basis of conceptual considerations, the authors' clinical experience, input from focus groups, the results of human experimental pain studies, and clinical research on characteristic symptoms and signs in patients with neuropathic and non-neuropathic pain. Because of this, the SF-MPQ-2 and its subscale structure can be expected to have greater generalizability to different samples and different types of chronic pain than if we had used an approach based solely on empirical findings, which has greater potential for sample specificity. Although the SF-MPQ-2 has seven more items than the SF-MPQ, we found no evidence of participant fatigue; there were virtually no missing responses in the RCT data, and the rate of missing data in the web survey did not differ depending on whether items were closer to the beginning or to the end of the questionnaire.

The European Federation of Neurological Societies guidelines for the assessment of neuropathic pain note that although the MPQ and SF-MPQ provide data on the sensory and affective dimensions of pain, neither measure is specifically designed to assess neuropathic pain [12]. Following a review of limitations of existing measures of neuropathic pain [5,20,27,28], the authors concluded that a measure of neuropathic pain was needed that is "sufficiently complete, reasonably easy, and properly validated" ([12]; p. 156). We expanded the SF-MPQ to include seven symptoms that either had discriminated individuals with neuropathic and non-neuropathic pain in previous research or that are thought to reflect mechanisms of neuropathic pain. Our objective was to develop a single measure that would reliably and validly assess the major symptoms of both neuropathic and non-neuropathic pain for diverse types of research, including studies of mechanisms and treatment response. Importantly, future use of the SF-MPQ-2 should ideally be preceded by qualitative research in the target population to confirm that the item content is appropriate, meaningful, interpretable, and complete given the specific intended use of the measure.

Besides the MPQ and the SF-MPQ, there are at present only two other measures that provide a comprehensive assessment of pain symptoms. The Multidimensional Affect and Pain Survey and its short form [23,26] appear to provide a reliable and valid assessment of various pain qualities and pain-associated affects, but neither has been studied in patients with neuropathic pain. The Pain Quality Assessment Scale (PQAS) [24,48] is a revision of the Neuropathic Pain Scale [20] to which non-neuropathic pain symptoms have been added. Although generally similar pain qualities are assessed by the SF-MPQ-2 and the PQAS, the SF-MPQ-2 not only has an affective descriptors subscale but the wording of some items is also quite different. For example, the PQAS assesses numb, itchy, and tingling pain, whereas these symptoms are not described as painful in the SF-MPQ-2, which considers them non-painful dysesthesias and paresthesias. In addition, the PQAS assesses skin sensitivity to light touch without using the word pain, whereas the SF-MPQ-2 assesses "pain caused by light touch"; although this phrase was used to adhere to the current definition of allodynia, it may not be the optimal wording to assess what is typically considered a sign rather than a symptom.

In conclusion, we developed the SF-MPQ-2 to provide a single measure of the major sensory and affective symptoms of both neuropathic and non-neuropathic pain that can be used in studies of epidemiology, natural history, pathophysiologic mechanisms, and treatment response. Our data suggest that the SF-MPQ-2 has generally excellent reliability and validity, and the results of factor analyses provided support for four readily interpretable subscales—continuous pain, intermittent pain, predominantly neuropathic pain, and affective descriptors. These results provide a basis for use of the SF-MPQ-2 in future clinical research, including clinical trials of treatments for neuropathic and non-neuropathic pain conditions.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.pain.2009.02.007.

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