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Clinical Study

Exploring the prevalence and construct validity of high-impact chronic pain across chronic low-back pain study samples

Patricia M. Herman, ND, PhD[a,*], Nicholas Broten, MS[a], Tara A. Lavelle, PhD[a,b], Melony E. Sorbero, MPH, PhD[c], Ian D. Coulter, PhD[a]

[a] RAND Corporation, 1776 Main Street, PO Box 2138, Santa Monica, CA 90407-2138, USA
[b] Center for the Evaluation of Value and Risk in Health, Institute of Clinical Research and Health Policy Studies, Tufts Medical Center, 800 Washington St., Boston, MA 02132, USA
[c] RAND Corporation, 4570 Fifth Ave #600, Pittsburgh, PA 15213, USA
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Abstract

BACKGROUND CONTEXT: The US National Pain Strategy focused attention on high-impact chronic pain and its restrictions. Although many interventions have been studied for chronic low-back pain, results are typically reported for heterogeneous samples. To better understand chronic pain and target interventions to those who most need care, more granular classifications recognizing chronic pain's impact are needed.

PURPOSE: To test whether chronic pain impact levels can be identified in chronic low-back pain clinical trial samples, examine the baseline patient mix across studies, and evaluate the construct validity of high-impact chronic pain.

STUDY DESIGN/SETTING: Descriptive analyses using 12 large study datasets.

PATIENT SAMPLES: Chronic low-back pain patients in nonsurgical, nonpharmacologic trials in the US, Canada, and UK.

OUTCOME MEASURES: Preference-based health utilities from the SF-6D and EQ-5D, employment status and absenteeism.

METHODS: We used two logistic regression models to predict whether patients had high-impact chronic pain and whether the remainder had low- or moderate-impact chronic pain. We developed these models using two datasets. Models with the best predictive power were used to impute impact levels for six other datasets. Stratified by these estimated chronic pain impact levels, we characterized the case mix of patients at baseline in each dataset, and summarized their health-utilities and work productivity. This study was funded by a National Center for Complementary and Integrative Medicine grant. The authors have no potential conflicts of interest.

RESULTS: The logistic models had excellent predictive power to identify those with high-impact chronic pain. Although studies were all of chronic low-back pain patients, the baseline mix of patients varied widely. Across all datasets, utilities, and productivity were similar for those with high-impact chronic pain and worsened as chronic pain impact increased.

CONCLUSIONS: There is a need to better categorize chronic pain patients to allow the targeting of optimal interventions for those with each level of chronic pain impact.

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* Corresponding author. RAND Corporation, 1776 Main Street, PO Box 2138, Santa Monica, CA 90407-2138, USA. Tel.: 310-393-0411, 7129; fax: 310-260-8161.

E-mail address: pherman@rand.org (P.M. Herman).

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Introduction

High-impact chronic pain has been defined by the United States National Pain Strategy (NPS) as pain present on most days for six months or more that "is associated with substantial restriction of participation in work, social, and self-care activities."[1] This definition purposefully differentiates those with high-impact chronic pain from those experiencing chronic pain who are able to sustain normal activities in work, family, and social life. The NPS emphasized the importance of reducing high-impact chronic pain, and noted that data on prevalence and outcomes would be crucial to this effort.

The NPS's Population Research work group was given the task to determine how to best identify those with high-impact chronic pain [2]. There is not yet consensus on how persons with high-impact chronic pain should be identified, but several approaches have been proposed and used to estimate prevalence and patient characteristics [2−7]. For example, recent research from the National Center for Health Statistics, based on data from the National Health Information Survey (NHIS) Adult Functioning and Disability Supplement, shows that persons with high-impact chronic pain differ from those with lower impact chronic pain on diverse measures of physical and mental health status and functioning [5]. Studies using other algorithms to identify high-impact chronic pain have found that it is associated with worse health status and higher utilization of health care [2,5−13], and that the prevalence of high-impact chronic pain increases with age [6,14].

Back pain is the most common type of chronic pain [15−17]. Numerous studies have assessed the effectiveness of a variety of interventions for this condition, and systematic reviews [18,19] and guidelines [20−22] now recommend a number of effective interventions. However, while it is widely recognized that chronic pain is not a uniform concept [2,15], these studies typically report results based on their full samples (eg, average reduction in pain, or percent of patients who had a clinically meaningful improvement in function across all participants no matter their chronic pain impact level). To better understand chronic pain, the effectiveness of interventions targeting these conditions, and to better target interventions to those most in need of care, we need to look beyond undifferentiated classifications of chronic pain (eg, low back pain of at least 3 months duration) to one which is more granular that recognizes the different levels of impact caused by this pain. Studies which differentiate chronic pain impact are needed to identify optimal interventions for different patients. Such analyses would also permit assessment of the relative effects of interventions for patients who start treatment at different chronic pain impact levels.

As a first step toward understanding treatment outcomes by chronic pain impact level, this study used 12 datasets that were gathered to create a comparative model of nonsurgical treatments for chronic low back pain to do three things. First, we examined whether high-impact chronic pain can be identified in individuals included in clinical trial datasets. Second, across studies we report on the variation in the baseline mix of participants with each chronic pain level. Third, as a test of validity of this construct, we estimate and examine two measures of overall health (preference-based utility scores and measures of work productivity) by chronic pain impact level to see if these estimates are similar across datasets for those in each chronic pain level.

Methods

We examined the characteristics and prevalence of high-impact chronic back pain using datasets from 12 studies (10 randomized trials and two observational studies) of chronic back pain. These datasets were gathered as part of a larger project examining the use of spinal manipulation and mobilization for chronic low-back pain [23,24]. The studies were chosen based on the following criteria: large sample sizes (eg, at least 50 per arm in a randomized trial), all (or most) of the subjects had chronic low-back pain of ≥3 months duration, subjects were followed for at least 6 months, and US-, Canada- or UK-based to ensure ease of acquisition, similar usual care and consistent IRB requirements. We also required that the study measured variables that were useful to the estimation of chronic pain impact levels as described below.

Relevant datasets were identified through published systematic reviews. For each dataset, we first obtained permission from the study principal investigator to reuse their data and then obtained human subjects protection approval for the data reuse from the RAND Institutional Review Board (IRB), and when requested, also from the sponsoring institution's IRB. In addition, when requested, we established a data use agreement. The dataset was then transferred to a secure server at RAND for analysis.

Subject characteristics

Table 1 shows the characteristics of the 12 study datasets utilized for this study. Each dataset contained between 100 and 800 subjects with 37% to 66% women and average ages from 41 to 51. There was also some variation in the inclusion and exclusion criteria used.

Measuring chronic pain impact

As discussed above, there is not yet consensus on how persons with high-impact chronic pain should be identified and several alternative approaches have been proposed and studied [2−7]. In this study we employ a well-validated and widely-used classification of chronic

Table 1
Characteristics of the datasets included in this study

Main paper on each study, N	Intervention tested	Age (SD); % female	Inclusion/exclusion
Cassidy et al (2005), n = 792	Observational study	44 (14); 55%	Chronic low back pain; aged 20-69 years; Excluded if institutionalized.
Haas et al (2014), n = 400	Spinal manipulation	41 (14); 50%	Chronic low back pain of mechanical origin; at least 18 years; Excluded if LBP on <30 days of past 6 weeks, LBP index <25 on 0-100, received manual therapy in past 90 days, contraindications or complicating factors—e.g., active cancer, spine pathology, coagulation disorder, pain radiating below knee, disability compensation.
Mehling et al (2012), n = 255 with chronic pain at 2 years	Observational study	51 (13); 56%	Chronic low back pain; aged 18-70 years; Excluded if previous spine surgery; did not exclude if sciatica; 2 years earlier (study start) had LBP of ≤30 days duration.
Moore et al (2000), n = 226	CBT-based educational program	49 (11); 54%	Chronic low back pain; aged 25-70 years; Excluded those who reported they were being considered for surgery.
UK BEAM (2004), n = 747 with chronic pain	Spinal manipulation and exercise	43 (11); 56%	Chronic low back pain; aged 18-64 years; Excluded leg pain below knee, RMDQ <4, non-consistent pain, serious spinal disorder (e.g., cancer, osteoporosis, infection), severe psychiatric or psychological disorder, long-term coagulation disorder, previous spinal surgery, previous use of specialized pain clinic, received physical therapy or acupuncture in previous 3 months.
Von Korff et al (2005), n = 240	Brief multidisciplinary intervention	50 (9); 63%	Chronic low back pain; aged 25-64 years; Excluded if RMDQ<7, being considered for back surgery, currently being managed by a physical therapist or psychologist.
Cambron et al (2006), n = 235	Spinal mobilization and exercise	42 (12); 37%	Chronic low back pain; at least 18 years; Excluded those with contraindications (e.g., fracture, dislocation, localized acute infection), failed fusion surgery with unstable joints, chiropractic or physical therapy treatment in past 6 months or current back treatment from any provider, NYHA grade III or IV.
Cherkin et al (2001), n = 262	TCM, acupuncture, and massage	45 (12); 58%	Persistent back pain; aged 20-70 years; Excluded sciatica, acupuncture or massage or specialist back care in past year, involvement with litigation or compensation claims, coagulant disorders, lumbar surgery in past 3 years, bothersomeness of back pain <4 on 0-10 scale.
Cherkin et al (2009), n = 638	Acupuncture	47 (13); 62%	Chronic low back pain; aged 18-70 years; Excluded if specific causes (e.g., cancer, fracture, spinal stenosis), complicated cases (e.g., sciatica, prior back surgery, medicolegal issues), treatment could be difficult (e.g., paralysis, psychosis), possibly contraindication (e.g., coagulant disorders), concurrent care, previous acupuncture for any condition.
Cherkin et al (2011), n = 401	Two types of massage	47 (11); 64%	Nonspecific chronic low back pain; aged 20-65 years; Excluded if 2+ pain-free weeks in past 3 months, pain bothersomeness <4 on 0-10 scale, specific causes (e.g., cancer, fracture, spinal stenosis), complicated cases (e.g., sciatica, back surgery in past 3 years, medicolegal issues), treatment could be difficult (e.g., paralysis, psychosis), plans to visit provider for back pain, massage in past year.
Hurwitz et al (2002), n = 681	Chiropractic care and physical therapy	51 (17); 52%	Low back pain with or without leg pain; at least 18 years; Excluded if received treatment for LBP in previous month, had LBP from a non-mechanical cause (e.g., tumor, infection), severe coexisting disease, being treated by medical devices, progressive unilateral muscle weakness, coagulation disorder, liability or workers' compensation claim.
Sherman et al (2005), n = 101	Yoga	44 (13); 66%	Chronic low back pain; aged 20-64 years; Excluded if pain bothersomeness <3 on 0-10 scale, specific cause (e.g., fracture, spondylolisthesis, cancer), complex (e.g., sciatica, spinal stenosis, medicolegal issues, previous back surgery), contraindicated (e.g., severe disk disease), major depression, other current treatments, yoga or other exercise for back pain in past year.

CBT, cognitive behavioral therapy; LBP, low back pain; NYHA, New York Heart Association; RMDQ, Roland-Morris Disability Questionnaire; TCM, Traditional Chinese medicine.

pain impact, the Graded Chronic Pain Scale (GCPS), to identify persons with varying levels of chronic pain [7,11,13,25,26]. We defined those with Grades III and IV in the GCPS (those whose chronic pain moderately or severely interferes with their daily activities) as having high-impact chronic pain [7,13]. In contrast, Grades I and II include those with no or minimal interference with daily activities, but with low or high levels of pain intensity, respectively. These groups were defined as having low- (Grade I) and moderate-impact (Grade II) chronic pain. Despite this separation between activity limitations and pain intensity across grades/impact levels, the GCPS was found to be a unidimensional scale with good internal consistency [7,11]. The GCPS has also been shown to be correlated with a number of other related measures, including the Roland-Morris Disability Questionnaire (RMDQ) [25,27], and the various subscales of the SF-36 [11,25,26,28]. Therefore, we required each study dataset we acquired to have either the GCPS or measures of pain intensity, the RMDQ, and the SF-36 [28] or SF-12 [29]. Six of the datasets we used included the GCPS. For the others, we imputed chronic pain impact levels.

Utilities or preference-based measures of health-related quality of life

"Utilities" in health economics are quality of life weights "that represent the strength of an individual's preference for different health outcomes under conditions of uncertainty." [30] p241 The conventional utility scale allocates a utility of 1.0 for complete or perfect health, and 0.0 for being dead. Utility values are used as the health-related quality-of-life weights when calculating quality-adjusted life-years, a recommended measure of health outcomes in health economic evaluations [31,32], p11.

There are several instruments available to calculate utilities. The measures of utilities most commonly used are the EuroQol EQ-5D [33], and the SF-6D [34−36] which can be calculated from the various versions of the SF-12 [29] and SF-36 [28]. We report the average utility value by chronic pain impact level for the datasets that utilized these instruments.

Productivity

Health-related productivity loss (ie, indirect costs [30]) is a cost to employers and society [37]. Productivity loss can result from both absenteeism (the employee missing work because of back pain) and from presenteeism (lower productivity while at work because of back pain). As possible, we examined three measures related to productivity by chronic pain impact level across the available datasets: baseline employment, the number of days participants reported being absent from work, and reported productivity while at work.

Analyses

We used two logistic models to predict chronic pain impact level in the datasets that did not contain the GCPS. The first model estimated the probability that an individual had high-impact chronic pain. The second model subdivides those who do not have high-impact chronic pain into those who have low- or moderate-impact pain. We initially estimated and tested these models using two of our datasets that contained the GCPS as well as the RMDQ and a measure of pain intensity [38,39]. Given the form of the GCPS (that the highest grades, our measure of high-impact chronic pain, depend on activity limitations and the lower two grades/impact levels depend on pain intensity), these variables were considered the most important to include in the prediction models. Once these models were estimated for each dataset, we calculated both in-sample and out-of-sample areas under the receiver operating curves (ROC AUCs; a measure of predictive ability) and chose the models and dataset with the best predictors. A ROC AUC of 0.5 indicates no predictive ability. Higher values have been classified as follows: 0.6 to 0.7 as having poor predictive ability, 0.7 to 0.8 as acceptable, 0.8 to 0.9 as excellent, and more than 0.9 as outstanding [40]. Since high-impact chronic pain was the focus of the NPS [1], we put more emphasis on the ability to predict this impact level than on predicting moderate- versus low-impact chronic pain.

We also examined whether adding SF-36/SF-12 items would improve the predictive ability (significantly increase the ROC AUCs) of our models. In this test we only used the items in the SF-36 [28] that were also in the SF-12 [29] so that imputations could be made in datasets that used either measure. Because this was longitudinal data, some individuals achieved a no pain state at one or more postbaseline data collection points. These "no pain" data points were excluded from model estimation. The optimal cut points for classifying patients based on predicted probabilities in the final models were chosen to maximize the sensitivities and specificities (ie, minimize false positives and negatives) of the two models [41]. We used the best predictive models to impute chronic pain impact levels in the six datasets that did not include the GCPS.

Once chronic pain impact levels were available for all datasets, we examined the proportion of patients at baseline with each chronic pain impact level and estimated means and standard errors for each measure of overall health for each chronic pain impact level. For each dataset, we used one-way ANOVA and Tukey-Kramer pair-wise comparisons to examine differences in each health measure across the chronic pain impact levels. Analyses were performed using Stata/IC 14.2 for Windows (64-bit x86-64), College Station, TX.

Results

Table 2 shows the results of the predictive ability of our models within sample and out-of-sample for the two datasets that contained the GCPS, pain intensity, and the

Table 2
Areas under the receiver operator curves (ROC AUCs; a measure of predictive ability) with 95% confidence intervals

	N	UK BEAM	Mehling
Predicting high-impact chronic pain			
UK BEAM	3,855	**0.89** (0.88, 0.90)	0.86 (0.85, 0.87)
Mehling	255	0.76 (0.67, 0.86)	**0.79** (0.70, 0.87)
UK BEAM + SF-12	3,572	**0.92** (0.91, 0.93)	
Predicting moderate-impact chronic pain among those not predicted to have high impact pain			
UK BEAM	2,396	**0.90** (0.89, 0.92)	0.89 (0.88, 0.90)
Mehling	211	0.82 (0.71, 0.93)	**0.82** (0.68, 0.96)
UK BEAM + SF-12	2,353	**0.92** (0.91, 0.93)	

Bold ROC AUCs are in-sample estimates (i.e., the success of predictions made within the dataset which was used to estimate the predicting models) and the others are out-of-sample estimates (i.e., the success of predictions made in datasets other than the one used to estimate the predicting models).

RMDQ [38,39]. As can be seen, the UK BEAM [39] dataset provided better predictions both in terms of higher ROC AUCs and narrower confidence intervals. The ROC AUCs for predicting high-impact chronic pain were both excellent: 0.89 in-sample and 0.86 out-of-sample. The ROC AUCs for predicting moderate-impact chronic pain were even better: 0.90 in-sample and 0.89 out-of-sample. Adding the SF-12 variables to the prediction models significantly improved the predictions to 0.92 (outstanding) for both models, and we included these in the final models. Because the Mehling et al [38] dataset did not contain the SF-12 items, and no other datasets contained the RMDQ, SF-12 and GCPS, testing the addition of the SF-12 variables out-of-sample was not possible. The coefficients estimated for the final prediction models are shown in the Appendix.

Six of the datasets in our study included direct measurement of chronic pain impact [38,39,42−45]. We used the models shown in the Appendix to impute chronic pain impact levels in six others. Table 3 shows the proportions of participants reported or estimated to be in low-, moderate-, and high-impact chronic pain at baseline. Because of the inclusion criteria for the trials and the subsets we used from the observational studies, no database has participants in the no pain group at baseline. Table 3 shows the proportions of those in the three chronic pain impact levels at year 2 for the Mehling et al [38] study; the only time period when that study measured the GCPS. The proportions in each study sample with each level of chronic pain impact vary widely. For example, the proportions of each study sample with high-impact chronic pain ranged from 15.2% to 62.2%. This information could help explain any differences seen in these studies' outcomes.

Table 4 shows the estimated utilities for those with no pain and low-, moderate- and high-impact chronic pain using the utility measures available in eight datasets and including all data collection points. The estimates for no pain here are based on participants who improved to that impact level during the trial. We were able to calculate utilities from the SF-6D [34] for all eight datasets, and utilities using the EQ-5D [33] in one [39]. The utility estimates using the SF-6D were similar across datasets, especially for those with high-impact chronic pain. Utility estimates based on the SF-6D for those with high-impact chronic pain ranged from 0.531 to 0.610, and ranged from 0.660 to 0.767 for those with low-impact chronic pain. Most of the differences in the utility estimates across impact levels within each dataset were statistically significant, and the differences in the utility estimates between those with

Table 3
Number (%) participants reported or estimated to be in each chronic pain impact level at baseline for each dataset

Dataset	Low impact chronic pain	Moderate impact chronic pain	High Impact chronic pain
Datasets that contained direct measurement of chronic pain impact level			
Cassidy et al (2005)	530 (66.9%)	136 (17.2%)	126 (15.9%)
Haas et al (2014)	105 (26.3%)	46 (11.5%)	249 (62.2%)
Mehling et al (2012)*	176 (69.0%)	39 (15.3%)	40 (15.7%)
Moore et al (2000)	55 (24.3%)	43 (19.0%)	128 (56.6%)
UK BEAM, 2004	170 (22.7%)	295 (39.5%)	282 (37.8%)
Von Korff et al (2005)	47 (19.8%)	48 (20.2%)	144 (60.1%)
Datasets in which chronic pain impact level was imputed			
Cambron et al (2006)	125 (53.1%)	73 (31.0%)	37 (15.9%)
Cherkin et al (2001)	33 (12.5%)	109 (41.6%)	120 (45.9%)
Cherkin et al (2009)	209 (32.7%)	279 (43.8%)	150 (23.5%)
Cherkin et al (2011)	114 (28.5%)	176 (43.8%)	111 (27.7%)
Hurwitz et al (2002)	121 (17.8%)	309 (45.4%)	251 (36.8%)
Sherman et al (2005)	20 (19.7%)	66 (65.2%)	15 (15.2%)

* The Mehling et al.(2012) dataset only measured chronic pain impact levels at 2 years.

Table 4
Estimated utilities (health-related quality of life) by chronic pain impact level for each dataset that measured these outcomes, mean (SE)

Dataset	Instrument used	No pain	Low impact chronic pain	Moderate impact chronic pain	High impact chronic pain
Datasets that contained direct measurement of chronic pain impact level					
Cassidy et al (2005)[*,†]	SF-6D from SF-36v1	0.806 (0.004)	0.763 (0.003)	0.704 (0.006)	0.610 (0.007)
Haas et al (2014)[*,‡]	SF-6D from SF-12v2	0.778 (0.024)	0.753 (0.004)	0.681 (0.005)	0.606 (0.009)
UK BEAM (2004)[*,†]	SF-6D from SF-36v1UK	0.779 (0.008)	0.664 (0.002)	0.603 (0.002)	0.531 (0.002)
UK BEAM (2004)[*,†]	EQ5D	0.944 (0.016)	0.767 (0.004)	0.625 (0.007)	0.409 (0.012)
Datasets in which chronic pain impact level was imputed					
Cambron et al (2006)[*,†]	SF-6D from SF-36	0.683 (0.008)	0.660 (0.002)	0.643 (0.004)	0.565 (0.005)
Cherkin et al (2001)[*,‡]	SF-6D from SF-12v1	0.801 (0.008)	0.743 (0.006)	0.738 (0.005)	0.553 (0.005)
Cherkin et al (2009)[*,†]	SF-6D from SF-36v2UK	0.831 (0.009)	0.743 (0.003)	0.715 (0.004)	0.565 (0.005)
Cherkin et al (2011)[*,‡]	SF-6D from SF-12v2	0.693 (0.014)	0.683 (0.004)	0.719 (0.005)	0.602 (0.004)
Sherman et al (2005)[*,‡]	SF-6D from SF-36	0.799 (0.020)	0.746 (0.011)	0.711 (0.010)	0.590 (0.012)

* According to one-way ANOVA, the means by chronic pain impact group are significantly different across all chronic pain impact levels at $p < .001$.
† Tukey-Kramer pair-wise comparisons indicate that the means for each impact level group are significantly different from each of the other impact level groups at $p < .05$.
‡ Tukey-Kramer pair-wise comparisons indicate that the means for high-impact chronic pain are significantly different than seen for each of the other impact levels at $p < .05$.

high-impact chronic pain and other chronic pain impact levels were statistically significant in all datasets. Also, according to estimates of minimally important differences in SF-6D-based utilities (ranging from 0.010 to 0.048 [46]) the differences seen in utilities across impact levels in this study were clinically significant as well.

Table 5 shows the productivity measures available in the datasets and their average values for those with no pain, and with low-, moderate- and high-impact chronic pain. One dataset reported employment levels and six datasets provided measures of absenteeism. Absenteeism for those with high-impact chronic pain was significantly higher than for those with other impact levels in five of the six datasets that measured this aspect of productivity and full-time employment was significantly lower for those with high-impact chronic pain in the dataset where employment was measured. No study had a measure of presenteeism (ie, productivity while at work).

Discussion

Our analyses of 12 datasets of chronic pain patients indicate that: (1) chronic pain impact levels as defined by the GCPS can be imputed with excellent predictive power in datasets that did not measure the GCPS; (2) the baseline mix of chronic low back pain patients across these 10 trials varied widely in terms of chronic pain impact levels; (3) there was a consistent pattern of significantly worse health-related quality of life and measures of work productivity in those with high-impact chronic pain relative to persons with clinically significant, but lower impact pain. Therefore, although these datasets were all of patients with chronic low back pain, they were made up of different mixes of individuals in terms of chronic pain impact levels and those in each impact level were experiencing clinically and statistically significant different levels of overall health (as measured by utility and work productivity). Different

Table 5
Measures of productivity available in each dataset by chronic pain impact level, mean (SE)

Dataset[*]	No pain	Low impact chronic pain	Moderate impact chronic pain	High Impact chronic pain
During the past 4 weeks how many days did your low back pain keep you from going to work or school?				
Cherkin et al (2001)[†,‡]	0.00 (0.00)	0.15 (0.04)	0.28 (0.10)	2.28 (0.40)
Cherkin et al (2009)[†,‡]	0.03 (0.03)	0.16 (0.05)	0.32 (0.08)	1.71 (0.31)
Cherkin et al (2011)[†,‡]	0.03 (0.03)	0.10 (0.03)	0.23 (0.05)	1.34 (0.28)
Sherman et al (2005)	0.00 (0.00)	0.09 (0.06)	0.05 (0.03)	0.19 (0.14)
How many days did back pain keep you from going to work or school during the past month?				
Hurwitz et al (2002[†,‡]	0.01 (0.01)	0.13 (0.06)	0.20 (0.04)	1.67 (0.29)
Proportion employed full time				
Hurwitz et al (2002)[†,‡]	0.72 (0.03)	0.61 (0.02)	0.61 (0.02)	0.44 (0.02)
Number of days kept from activities in last 3 months				
Von Korff et al (2005)[†,‡]	0.00 (0.00)	0.88 (0.09)	1.70 (0.15)	34.36 (1.45)

* All but the last (Von Korff) are datasets in which chronic pain impact level was imputed.
† According to one-way ANOVA, the means by chronic pain impact group are significantly different across all chronic pain impact levels at $p < .001$.
‡ Tukey-Kramer pair-wise comparisons indicate that the means for high-impact chronic pain are significantly different than seen for each of the other chronic pain impact groups at $p < .05$.

baseline patient mixes in terms of chronic pain impact level could be one reason why otherwise similar studies have different outcomes, especially if those in each impact level improve at a different pace.

Published results for two other chronic pain datasets confirm the variation in baseline mixes seen in our study. The mix of chronic pain impact levels in the observational dataset of back pain patients upon which the GCPS was developed (n = 1,213) was 34.9% low-impact chronic pain, 27.9% moderate-impact chronic pain, and 37.2% high-impact chronic pain [7,13]. And another large population in the United Kingdom (n = 1445) had 48.7% low-impact chronic pain, 24.4% moderate-impact chronic pain, and 26.9% high-impact chronic pain [47]. The variety seen in these percentages, and in the proportions across our datasets, indicate that chronic pain samples are made up of different mixes of patients experiencing each of the chronic pain impact levels, that is, chronic pain samples are not homogeneous. Since the health status and health-care impacts of these different subgroups of chronic pain patients differ substantially it is important that the classification and severity of chronic pain samples be acknowledged. This study shows chronic pain impact levels can be determined in clinical samples using commonly measured variables.

Other studies have found that depression increases with chronic pain impact level [7], health status, mood and disability all worsen with increased impact level [5], and bodily pain, physical function, social function, physical role, and emotional role scales of the SF-36 all worsen as impact level increases [11]. However, we did not find other studies that measured health-related quality of life (utilities) by chronic pain impact level. As expected, utilities decreased as chronic pain impact increased. These decreases in the SF-6D were also generally clinically significant, that is, greater than the minimally important difference.

We found that absenteeism increased and employment decreased as chronic pain impact level increased. We found one other study that reported unemployment increases by chronic pain impact level [7] and another that estimated higher costs from productivity losses in those who reported severe pain in response to a question regarding their “having moderate or severe pain on the SF-12.” [10], p716 However, we found no other studies that examined the association between chronic pain impact and absenteeism.

This study has several limitations. We used Grade III/IV from a previously developed and well-validated set of chronic pain grades as our proxy for high-impact chronic pain since no agreed-upon measure has been developed, and since our datasets did not include the variables needed to follow the other approaches to identifying chronic pain impact levels [2−6]. Although we included datasets from several studies that directly measured chronic pain grades/impact, we estimated these impact levels in several others. We had two datasets where we could test the within sample and out-of-sample predictive ability of pain intensity and the RMDQ for chronic pain impact levels and found that the predictive ability was excellent for both. We were also able to significantly improve that predictive ability by adding in SF-12 variables. However, we had no other dataset that contained all the variables to retest the full models out-of-sample. Nevertheless, despite this and variations seen in trials’ inclusion/exclusion criteria, the consistent utility and productivity results seen for each level of chronic pain impact across datasets supports the validity of the impact level construct. We should also note that our datasets were mainly from trials of nonsurgical, nonpharmacologic therapies in the US, UK, and Canada. Results may not be as consistent when examining trials of surgical or pharmaceutical interventions or trials held in other countries. Finally, none of the datasets we obtained contained any useable data on presenteeism, which can be substantial [48,49]. However, given that baseline employment and absenteeism is related to impact level, it is likely that presenteeism is also related.

Conclusions

This and other studies have validated the construct of high-impact chronic pain as a health state where patients experience substantially worse health according to many measures and as compared to those with low- or moderate-impact chronic pain. We have also shown that the mix of patients included in intervention trials for chronic low back pain can vary widely in terms of their baseline chronic pain impact levels. These analyses call attention to the need to better categorize chronic pain patients to allow the eventual targeting of optimal interventions for those with each level of chronic pain impact. Fortunately, it seems that chronic pain impact levels can be estimated in existing clinical samples with excellent predictive power using commonly measured variables. The identification of high-impact chronic pain and the reporting of trial outcomes by chronic pain impact level could help ensure that adequate resources are directed toward improving outcomes of the chronic pain patients in greatest need.

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Supplementary materials

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