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ORIGINAL ARTICLE

How much does the Dallas Pain Questionnaire score have to improve to indicate that patients with chronic low back pain feel better or well?

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Abstract
Purpose The Dallas Pain Questionnaire (DPQ) assesses the impact of low back pain (LBP) on four components (0–100) of daily life. We estimated the minimal clinically important improvement (MCII) and the patient acceptable symptom state (PASS) values of DPQ in LBP patients.
Methods 142 patients with LBP lasting for at least 4 weeks completed a battery of questionnaires at baseline and 6 months later. Questions for MCII addressed patient-reported response to treatment at 6 months on a five-point Likert scale, while a yes/no question concerning satisfaction with present state was used to determine PASS. MCII was computed as the difference in mean DPQ scores between patients reporting treatment as effective vs. patients reporting treatment as not effective, and PASS was computed as the third quartile of the DPQ score among patients who reported being satisfied with their present state.
Results MCII values were 22, 23, 2 and 10 for daily activities, work and leisure, social interest, and anxiety/depression, respectively. PASS values were 29, 23, 20 and 21 for the four components, respectively. The PASS total score threshold of 24 correctly classified 84.1 % of the patients who reported being unsatisfied with their present state, and 74.7 % of patients reported being satisfied.
Conclusions These values give information of paramount importance for clinicians in interpreting change in DPQ values over time. Authors should be encouraged to report the percentage of patients who reach MCII and PASS values in randomized clinical trials and cohort studies to help clinicians to interpret clinical results.

Keywords Low back pain · Outcome measures · Minimal clinically important change · Patient acceptable stable state · Dallas Pain Questionnaire

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Introduction

Chronic low back pain (LBP) is a very common health problem associated with high disability and considerable costs to society [1]. In chronic LBP patients, reducing pain and improving function and well-being remain the main objectives of treatment, because total recovery cannot be achieved in most cases. Patient-reported outcomes (PRO) are widely used in assessing the effect of care in clinical practice, epidemiological studies and clinical trials.

After an intervention, the question for many clinicians, researchers and health policy makers is whether observed changes in self-reported levels of pain, function and well-being are clinically important and reflect a meaningful improvement for the patient. A recent overview of responder analyses of patient-reported outcomes in randomized controlled trials for chronic LBP showed that the methods of classifying responders were inconsistent [2]. The cutoff used to define a response varied widely across studies and methodology to derive cutoff points was not founded on scientific evidence. One of the most appropriate methods to define such a threshold is to use the determination of the minimal clinically important improvement (MCII) [3–6]. The MCII reflects the concept of improvement (feeling better) and represents the minimal difference for patients to feel an improvement [7]. MCII is the smallest change in an outcome that a patient would identify as important. MCII offers a threshold above which outcome is experienced as relevant by the patient.

After therapeutic intervention, another question is whether the patient reaches a threshold that is acceptable to him. One of the most appropriate methods to define such a threshold is to use the determination of the patient acceptable symptom state (PASS) [3–6]. The PASS addresses the concept of partial symptomatic remission (feeling well) and represents the threshold where patients feel their state to be acceptable.

MCII and PASS are two relevant cutoffs from the patient's perspective [3–6]. The interest to determine such validated thresholds for each validated assessment tools is to use particularly in clinical studies or in cohorts of patients to identify those who feel better and those who feel well.

The concepts of MCII and PASS are complementary and provide an additional means of representing the patient's progress. In a clinical study, the primary end point could be the mean change between the average score of a tool (e.g., Visual Analog Scale of pain) between baseline and 6 months. But whatever the result obtained with this method, another way of interpreting results and providing further insight could be to present an analysis of responders (% of patients improving more than MCII threshold) and analysis of patients feeling well (% of patients reaching PASS threshold).

Among PRO, the 16-item Dallas Pain Questionnaire (DPQ) assesses the impact (expressed as a value between 0 and 100) of LBP on four components of daily life: daily activities, work and leisure activities, anxiety/depression, and social interest [8]. The French version of the DPQ has been validated in chronic LBP patients [9]. Considering that the MCII and PASS values of DPQ have never been defined, we sought to estimate the MCII and PASS values of the DPQ in patients with LBP. The English and the French versions of the DPQ were provided as supplementary web material.

Method

Data from the cohort designed to validate the French version of the Core Outcome Measures Index (COMI) were used [10, 11].

Study design

A prospective, 6-month, multicenter cohort study involving patients from non-surgical spine centers was conducted in France, Belgium and the French-speaking part of Switzerland. Inclusion criteria were LBP with or without leg pain for at least 4 weeks, an intensity of at least 3 on a visual analog pain scale (VAS) rating from 0 to 10 and fluency in the French language. Exclusion criteria were a diagnosis of LBP related to tumor, infection, spondyloarthropathy or trauma and the presence of serious co-morbidities (e.g., heart failure, infection). During their appointment at one of the consultation centers, patients were invited to participate. Having obtained their signed informed consent, patients were instructed to complete a questionnaire booklet. The follow-up evaluation was scheduled 4–6 months later. To facilitate reading of this paper, the follow-up evaluation is called 6-month follow-up (FU). The choice of treatment was left to the discretion of each investigator. The sample size was determined according to quality criteria for the health status questionnaire [12]. The study was approved by the Medical Ethics Committee of the University Hospitals of Geneva, Switzerland.

Assessment of patients

At baseline, the questionnaire booklet included questions about socio-demographic variables (age, gender, education, work status), LBP history (type of LBP, time since the first episode of LBP, duration of the present episode), previous back surgery, intensity of pain on a five-item Likert scale (no pain to extreme pain) for back-related pain during the past week, the French version of the back pain-related disability questionnaire, Roland and Morris Disability Questionnaire (RMDQ) [13], the French version of the Core Outcome Measures Index (COMI) [10, 11], the French version of DPQ [9] with its 4 components, and the French version of the EQ-5D questionnaire for assessment of health-related quality of life [14]. At 6-month FU, in addition to the administration of the questionnaire booklet used at baseline, treatments administered since inclusion were recorded. Treatment efficacy and perceived effect were self-assessed by patients on a five-point Likert scale

(from no effect to excellent effect, almost no symptoms at all) and on a seven-point Likert scale (from marked improvement to marked deterioration), respectively [15]. Patients were also asked to state whether they considered their present state as satisfactory, using the following question: "Taking into account everything that you have to do in your daily life, your pain and disability, is your present state satisfactory?" (yes/no answer) [5].

Dallas Pain Questionnaire

The DPQ is a self-administered specific questionnaire that assesses the impact of LBP on four components of daily life: daily activities, work and leisure activities, anxiety/depression, and social interest. It was first developed by Lawlis et al. [8]. The daily activities component (items 1–7) evaluates pain severity, personal care, lifting, walking, sitting, standing and sleeping. The work leisure component (items 8–10) focuses on social life, traveling, and work-related activities. The anxiety/depression component (items 11–13) investigates anxiety, mood, emotional control and depression. The social interest component (items 14–16) covers interpersonal relationships, social support and punishing responses. Each item is rated by the patient using a visual analog scale that has 0 % with words such as "no pain" or "not at all" at one end and 100 % with words such as "all the time" at the other end. Each component is divided into five to eight segments. Each segment is assigned a value from 0 to 7 (0 to the left-hand segment, 1 to the next segment and so on). For each component, the sum of scores for each item is calculated and multiplied by a constant (3 for items 1–7, 5 for items 8–10, 11–13, and 14–16). Each component is expressed as a percentage (0 % indicating good health, 100 % poor health). The French version of the DPQ used in the present study has been validated in chronic LBP patients [9].

Statistical analysis

Sample size

To validate the COMI, a study sample of 150 patients was calculated. Missing data were treated according to the specific recommendations for each questionnaire. DPQ scores were computed only when all data were present for each component.

Change between inclusion (M0) and 6-month FU

Paired *t* tests were used to test changes in pain, function and quality of life-related characteristics of patients at baseline and after treatment.

Analyses on DPQ

Floor and ceiling effects Floor and ceiling effects were determined for the DPQ total score and for each of the items by computing the percentage of answers at both extremities of the total score and items.

Internal validity The reliability of the component was determined using Cronbach's alpha for each component and for the total score.

Responsiveness, sensitivity to change The standardized variation in the items and the total score were assessed by effect size (mean difference divided by the standard deviation) to assess sensitivity to change. Effect size was interpreted as small $\geq$0.20, medium $\geq$0.50 or large $\geq$0.80 [16].

MCII The MCII for each component and the total score were determined using an anchoring method based on the patient's assessment of response to treatment at 6 months using a five-point Likert scale (0 = no effect, 1 = slight effect, 2 = moderate effect, could be better, 3 = good effect, still with some symptoms, 4 = excellent effect) [5]. These results were then divided into patients for whom the treatment did not produce a change (0 and 1) and patients for whom the treatment produced a change (2–4), and the threshold was determined by subtracting the mean change in score of the group reporting change from that of the group reporting no change. The relationship between the change in DPQ components and total score and MCII was also assessed using receiver operating characteristic (ROC) curves and by determining the area under the curve.

PASS PASS was assessed using an anchoring method based on the patient's answer to the question: "Taking into account all the activities you have to perform in your daily life, the amount of pain you experience, and the level of physical disability, if you were to remain the same for the next few months, would this be acceptable to you?" The threshold for PASS was determined as being the 75th percentile of the DPQ components or total score at 6-month FU of patients answering "yes" to the previous question. The relationship between the change in the scores and PASS was also assessed using ROC curves and the area under the curve.

Results

Eleven centers (Belgium, Switzerland, and France) recruited 168 patients from May 2009 to June 2010. Four centers recruited 5 patients or fewer, and there were at least 2 centers in each country recruiting more than 15 patients. The 6-month FU was completed by 142 patients (mean number of months between baseline and FU was 5.5, SD 1.5).

Table 1 Baseline characteristics of patients ($n = 142$)

Characteristics	N (%)[b]
Age (year), mean (SD)	45.7 (12.1)
Sex, male	61 (43.0)
Type of LBP[a]	
LBP without radiating pain	62 (45.6)
No radiation below gluteal fold	27 (19.9)
No radiation below the knee	25 (18.4)
Radicular pain	22 (16.2)
Missing data	6 (4.2)
Duration of pain	
4–7 weeks	15 (10.6)
7–3 months	7 (4.9)
>3 months	120 (84.5)
Previous episode of LBP	
Yes	119 (83.8)
Level of education	
Obligatory school (9 years of education)	32 (23.0)
Professional diploma	49 (35.3)
University	58 (41.7)
Missing data	2 (1.4)
Work status	
Working	77 (54.6)
Unemployed	9 (6.4)
Insurance beneficiary (disease, accident, invalidity)	37 (26.2)
Retired/no paid activity/other	18 (12.6)
Missing data	1 (0.7)
% of patients with sick leave	
Yes	39 (43.4)

SD standard deviation, *LBP* low back pain

[a] According to the Paris Task Force classification

[b] Unless otherwise specified

Patient characteristics at baseline

Table 1 gives the baseline characteristics of the patients. Patients ($n = 142$) had a mean (SD) age of 45.7 (12.1) years; there were slightly more females than males (57.0 versus 43.0 %). For the vast majority of patients (84.5 %), the present episode lasted for more than 3 months. Sixteen percent of the patients had symptoms and signs compatible with lumbar radiculopathy. Twenty-two patients had previous back surgery (discectomy in 52.2 % of them).

Patient outcomes

Table 2 gives the clinical characteristics of patients at baseline and at 6-month FU as measured using the full-length questionnaire. Improvements were observed between M0 and 6-month FU for back pain, leg pain, RMDQ and COMI.

Table 2 Pain, function and quality of life-related characteristics of patients at baseline and after treatment (assessment between M4 and M6)

	Baseline ($n = 142$)	M4–M6 ($n = 142$)	P value*
Back pain (0–10)	5.5 (2.0)	3.7 (2.6)	<0.001
Leg pain (0–10)	3.7 (3.0)	2.6 (2.8)	<0.001
Roland and Morris Disability Questionnaire (0–24)	13.2 (4.5)	7.5 (6.5)	<0.001
Core Outcome Measures Index (COMI)			
Pain (0–10)	6.0 (2.0)	4.0 (2.6)	<0.001
Disability (0–10)	5.0 (3.6)	2.7 (3.3)	<0.001
Function (0–10)	6.0 (2.2)	3.9 (2.9)	<0.001
Well-being (0–10)	8.4 (1.8)	5.6 (3.3)	<0.001
Quality of life (0–10)	5.9 (2.1)	4.2 (2.8)	<0.001
EuroQol-5D (0–1)	0.4 (0.2)	0.6 (0.3)	<0.001

Figures are means (SD)

* Paired t test

Dallas Pain Questionnaire properties

Floor and ceiling For each item of the DPQ, there were missing answers in between 3.0 and 6.5 % of cases. Floor and ceiling effects were low for the total score and for each component, except for anxiety/depression and social interest, which had a slight floor effect, respectively, 6.0 and 9.5 % of the answers at the lowest level.

Internal validity Reliability, as measured using Cronbach's alpha, was 0.90 for daily activities, 0.88 for leisure activities, 0.89 for anxiety/depression, 0.75 for social interests, and 0.93 for the total score. Reliability can be considered as good.

Responsiveness, sensitivity to change The effect sizes ranged between 0.41 (small) for social interest and 0.86 (large) for daily activities, and were equal to 0.85 for the total score (Table 4).

MCII The MCII values were 22. 2 for daily activities, 23.1 for leisure activities, 9.5 for anxiety/depression, and 2.00 for social interest and 14.2 for the total score (Table 4). The area under the curve for the prediction of the patient's own assessment of response to treatment by the change in DPQ daily activity score was 0.82, meaning that a patient who reported no or little effect had an 82 % chance of having a lower daily activities score than a patient who reported a treatment effect. The area under the curve was 0.79 for the change in leisure activities, 0.64 for anxiety/depression, 0.58 for social interest, and 0.75 for the total DPQ score.

PASS The PASS values were 29.4 for daily activities, 23.1 for leisure activities, 21.2 for anxiety/depression, 20.0 for social interest and 23.9 for the total score (Table 4).

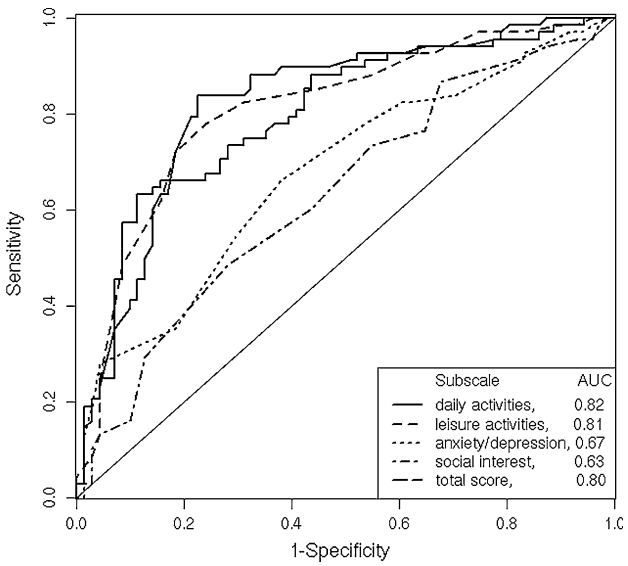

Fig. 1 Relationship between the change in the four subcomponents of DPQ and total score of DPQ and the patient acceptable symptom state (PASS) assessed using receiver operating characteristic (ROC) curve analysis. The area under the curve for the prediction of PASS by the change in DPQ components varied from 0.63 for social interest to 0.82 for daily activities meaning, for example, that a patient who is unsatisfied has an 82 % chance of having a smaller change in daily activities score than a patient who is satisfied

This threshold in the total score at 6-month FU correctly classified 84.1 % of the patients who reported being unsatisfied with their present state and 74.7 % of patients who reported being satisfied (Table 4).

The area under the curve for the prediction of PASS by the change in DPQ component ranged from 0.63 for social interest to 0.82 for daily activities (Fig. 1), meaning, for example, that a patient who is unsatisfied has an 82 % chance of having a smaller change in daily activities score than a patient who is satisfied.

Discussion

Using anchor-based methods, we have estimated the MCII and PASS values of the DPQ in patients with LBP. We propose use of the following values in clinical practice: 22 for daily activities, 23 for leisure activities, 2 for social interest, 10 for anxiety–depression and 14 for total score (Table 3). For PASS, we suggest use of the following values (MCII) in clinical practice: 29 for daily activities, 23 for leisure activities, 20 for social interest, 21 for anxiety–depression and 24 for the total score (Table 4).

MCII has been estimated for the main outcomes in LBP. In their review of LBP pain intensity, Ostello et al. [17] estimated MCII as 20 mm for chronic LBP patients and 35 mm for acute LBP patients, using a 0–100 VAS, and 2.5 points for chronic LBP patients and 3.5 mm for acute LBP patients when pain is using a 0–10 numerical rating scale. Maugham and Lewis [18] found a similar value of 2.4 when pain is assessed using a 0–10 numerical rating scale. For the Oswestry Disability Index (ODI), which ranges from 0 to 100, the MCII was estimated to be 10 for all types of LBP Ostello et al. [17]. Maugham and Lewis [18] found a value of 8. For the Roland–Morris Disability Questionnaire (RMDQ), which ranges from 0 to 24, the MCII was estimated as between 2 and 4 (Bombardier et al [3], Maugham and Lewis [18], Ostello et al. [17]). PASS of the main outcomes in LBP has been investigated much less often.

A number of caveats need to be noted regarding the present study. The first limitation concerns the relatively small number of patients, which could lead to over or underestimation of MCII or PASS values because of lack of precision. Nevertheless, the chosen method was valid and allows us to consider these values as relevant for clinical research or clinical practice. Second, the 26 patients who were not included in the analysis at 6 months

Table 3 Dallas Pain Questionnaire: MCII and PASS values observed in the study

	M0 ($n = 142$)	M6 ($n = 142$)	Effect size	MCII value	PASS value	% unsatisfied patients correctly classified by PASS value	% satisfied patients correctly classified by PASS value
Daily activities (0–100)	60.7 (17.4)	40.6 (25.9)	0.86	22.2	29.4	91.9	72.4
Leisure activities (0–100)	58.8 (23.6)	37.2 (29.8)	0.81	23.1	23.1	89.2	75.0
Anxiety/depression (0–100)	43.3 (26.1)	29.4 (28.6)	0.58	9.5	21.2	71.6	75.0
Social interest (0–100)	34.0 (24.2)	24.5 (24.7)	0.41	2.0	20.0	71.6	69.7
Total score (0–100)	49.1 (19.2)	32.4 (24.6)	0.85	14.2	23.9	84.1	74.7

Figures are means (SD) unless otherwise specified

MCII minimal clinically important change, *PASS* patient acceptable stable state

Table 4 Dallas Pain Questionnaire: MCII and PASS values proposed for clinical practice

	MCII value	PASS value
Daily activities (0–100)	22	29
Leisure activities (0–100)	23	23
Anxiety/depression (0–100)	10	21
Social interest (0–100)	2	20
Total score (0–100)	14	24

Figures are means

MCII minimal clinically important change, *PASS* patient acceptable stable state

could generate a potential bias in the estimate, but this is highly unlikely because patients who did not respond at the 6-month FU had similar initial values in DPQ and other variables. Furthermore, patients were not included in a clinical trial and it was difficult to impose their return whatever their condition. The majority of these patients did not wish to be represented at the follow-up visit. But as this study was not designed to confirm a hypothesis, as in a randomized clinical trial, the fact that these patients are not reviewed does not affect the relevance of the results.

It is critical to interpret correctly the results of analyses performed using MCII in randomized clinical trials. In carrying out a responder analysis, MCII should be used to express the proportions of patients in each group that achieved outcomes reaching or exceeding the lower bound of the MCII margin [2]. Then, in RCT, it is improper to use MCII values to estimate between-group clinical relevant difference in quantitative analysis, because the cutoff values of MCII were derived from within-patient comparisons [19].

The MCII and PASS values of DPQ can be used in clinical practice, epidemiological studies and clinical trials to provide useful secondary qualitative analyses with validated cutoffs.

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