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Original article

Patient acceptable symptom state for patient-reported outcomes in people with non-specific chronic low back pain

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ABSTRACT

Background: The patient acceptable symptom state (PASS) is a treatment-response criterion developed to determine the clinical relevance of a treatment effect. Its estimates for some patient-reported outcomes (PROs) in non-specific chronic low back pain (cLBP) are lacking and the stability of PRO estimates between independent cLBP populations is unknown. We hypothesized that these PRO estimates will be stable.
Objectives: To estimate and compare the PASS for PROs between 2 independent cLBP populations.
Methods: We conducted a secondary analysis of a randomized controlled trial (PREDID) and a cohort of outpatients with non-specific cLBP. Using an anchoring question, participants who self-rated their health as "excellent", "very good" or "good" at 1 month were considered to have an acceptable symptom state. PASS estimates for 5 PROs were calculated by using the 75th percentile method. Estimates were compared between the 2 populations with bootstrap resampling.
Results: A total of 256 participants with non-specific cLBP were included: 135 patients with cLBP and active discopathy from the PREDID trial and 121 outpatients with cLBP without active discopathy followed up in an independent cohort. Overall, 137/256 (54%) participants had an acceptable symptom state at 1 month. PASS estimates were 47.5 (95% confidence interval [CI] 40.0 to 50.0)/100 for lumbar pain (0, no pain and 100, maximal pain), 30.5 (30.0 to 40.0)/100 for radicular pain, 39.3 (33.6 to 45.3)/100 for Quebec Back Pain Disability score (0, no disability and 100, maximal disability), 10.0 (9.2 to 10.0)/21 for the Hospital Anxiety Depression anxiety subscale (0, no anxiety, and 21, maximal anxiety) and 6.7 (6.0 to 8.0)/21 for the depression subscale (0, no depression, and 21, maximal depression). PASS estimates did not differ between the 2 populations.
Conclusions: Our study provides PASS estimates for 5 PROs commonly used in cLBP. Our estimates were stable between 2 independent populations of people with cLBP. The stability of our PASS estimates suggests that they are relevant for interpreting PRO values in clinical trials and practice. ClinicalTrials.gov no. (PREDID trial) NCT00804531.

1. Introduction

Low back pain (LBP) is a frequent musculoskeletal symptom. It can have specific and non-specific causes. The prevalence of non-specific LBP is 18% worldwide [1] but is higher in women and middle-aged individuals and varies across nations, with greater

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prevalence in high-income countries. Non-specific chronic LBP (cLBP), defined by the persistence of pain beyond 3 months, has a lower prevalence than LBP in general but is a well-known cause of disability and leads to high direct and indirect health-care costs. The burden of non-specific cLBP has markedly increased over the past decade worldwide and has become a major public health problem [2].

Because non-specific cLBP has a significant impact on patient functioning and health-related quality of life, improving individuals' self-opinion is an important target for patient care and for clinical trials. Patient-reported outcomes (PROs) have been developed to assess patients' opinions. PROs are considered accurate, valid, reproducible and sensitive-to-change tools. However, PRO values and their variations over time may be of uncertain clinical significance to assess the impact of a given intervention. To determine the clinical relevance of a treatment effect, 2 treatment-response criteria have been developed based on patients' perception of their functioning: the patient acceptable symptom state (PASS) [3] and the minimally clinically important improvement [4]. The PASS is defined as the highest symptom level below which a patient considers his/her symptom state as acceptable. The minimally clinically important improvement is the smallest change in score from which patients perceive a clinical benefit or the amount of change needed to reach the PASS [5]. State-attainment criteria may have a higher priority than state-responder criteria, because "feeling good" is more important than "feeling better" to patients. Therefore, the PASS could be more relevant than the minimally clinically important improvement [6]. In addition, for chronic symptoms and/or long-term follow-up, the interpretation of the PASS is easier than for the minimally clinically important improvement, because a patient can feel better than at the prior visit without feeling good at both visits.

PASS values for generic outcomes have been estimated in the most common rheumatic diseases, including cLBP, and used as response criteria [7]. However, non-specific cLBP covers heterogeneous populations of patients, including patients with active discopathy with a specific clinical and radiological phenotype. Variations of the PASS estimates between distinct populations with the same condition have not been assessed.

In the present study, we aimed to estimate and compare the PASS at 1 month for 5 PROs commonly used in cLBP, between 2 independent populations of people with non-specific cLBP. We also sought to determine which baseline variables were associated with reaching the PASS for each PRO at 1 month.

2. Methods

Participants. Patients included in the present study participated in the PREDID trial (NCT00804531) or were followed up in a cohort of outpatients with non-specific cLBP. Briefly, the PREDID trial was a 12-month multicenter randomized controlled trial conducted in France from April 2009 to June 2014 that compared the efficacy of a single glucocorticoid intradiscal injection to contrast alone in a population of 135 patients with cLBP and active discopathy [8]. Inclusion criteria were age $\geq$ 18 years, LBP duration $\geq$ 3 months, LBP intensity $>$ 40 points on an 11-point numeric rating scale (NRS: from 0, no pain to 100, maximal pain) and Modic I changes on MRI of $<$ 6 months. An independent cohort, started in a single center (Cochin Hospital, Paris, France) in September 2011, enrolled 121 patients, age 18 to 60 years old, with non-specific cLBP, with LBP intensity $>$ 30 points on an 11-point NRS (from 0, no pain to 100, maximal pain) and without active discopathy. All participants in the cohort received supervised outpatient sessions of rehabilitation along with usual care. No participant overlap occurred between the 2 groups. Disease-related characteristics and socio-demographic data were collected at inclusion in both populations. The human experimentation was approved by the local institutional review board (comité consultatif de protection des personnes en recherche biomédicale d'Île-de-France, CPP2233) and conformed to the Helsinki Declaration. Our study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [9] (E-component 1).

Patient-reported outcomes. PROs were available at baseline and at 1 month after enrolment in the PREDID trial and in the cohort. They included mean LBP intensity in the previous 48 hr assessed on an 11-point NRS, mean radicular pain intensity in the previous 48 hr assessed on an 11-point NRS [10], LBP-specific activity limitation assessed by the Quebec Back Pain Disability scale (QBPDs, from 0, no limitation to 100, maximal limitation) [11], clinically significant symptoms of anxiety and depression assessed by the Hospital Anxiety and Depression scale (HADs) with 2 subscales (HADa for anxiety, from 0, no symptoms of anxiety, to 21, maximal symptoms of anxiety, and HADd for depression, from 0, no symptoms of depression, to 21, maximal symptoms of depression), and health-related quality of life assessed by the Medical Outcome Study Short-form 12 (MOS SF-12) with 2 subscores, the Physical Component Score (PCS, from 9.95, worse quality of life, to 70.02, best quality of life) and the Mental Component Score (MCS, from 5.89, worse quality of life, to 71.97, best quality of life) [12].

Anchoring question. To estimate the PASS for each PRO at 1 month, we used an external anchoring method [13,14]. The anchor was extracted from the MOS SF-12 general health question with its 5-class answer ("In general, would you say your health is: excellent/very good/good/fair/poor?"). Patients who self-rated their health as "excellent", "very good" or "good" were considered to have an acceptable symptom state. Patients who self-rated their health as "fair" or "poor" were considered not to have an acceptable symptom state.

Statistical analysis. Statistical analyses were performed with R 3.3.1. Analyses involved using the data for participants for whom the answer to the anchoring question was available at 1 month. Quantitative variables are described with means (SD) and qualitative variables with absolute frequencies (%). PASS estimates were calculated in the whole population and in the PREDID population and the cohort population, respectively, as the 75th percentile of the distribution of values for each PRO for participants who considered themselves as having an acceptable symptom state [3,14,15]. The 95% confidence interval (CI) of the PASS estimate for each PRO was calculated by using bootstrap resampling because the non-Gaussian distribution of the results did not allow a normal approach. A univariate analysis was performed to evaluate the association between the PRO baseline values, participation in the PREDID trial, clinical and demographical variables (i.e., age, sex, LBP duration and socio-economic status) and having an acceptable symptom state at 1 month. Qualitative variables were compared by chi-square test or Fisher's exact test (as appropriate). Quantitative variables were analyzed by Student's t test or non-parametric Wilcoxon-Mann-Whitney test (if normality could not be established). For each PRO, a logistic regression was conducted to assess which baseline variables were associated with having an acceptable symptom state at 1 month. Additional variables with a $P < 0.2$ on univariate analysis could have been included in the multivariate analysis.

3. Results

Participants. A total of 256 participants with non-specific cLBP were included: 135 patients with cLBP and active discopathy from the PREDID trial and 121 outpatients with cLBP without active

Table 1
Baseline demographic characteristics.

	All participants $n = 256$	PREDID participants $n = 135$	Outpatients $n = 121$
Men, *n* (%)	110 (43)	53 (39)	57 (47)
Age (years), mean (SD)	45.7 (9.0)	47.1 (8.3)	44.2 (9.6)
Clinical characteristics, mean (SD)			
Body mass index (kg/m^2)	25.6 (4.8)	25.3 (4.2)	26.0 (5.5)
Low back pain duration (months)	10.5 (1.0)	14.5 (12.8)	6.7 (2.8)
Imaging findings, *n* (%)			
Active discopathy	135 (53)	135 (100)	0 (0)
Degenerative disc disease	74 (29)	0 (0)	74 (61)
Discoradicular conflict	11 (4)	0 (0)	11 (9)
Facet joint osteoarthritis	11 (4)	0 (0)	11 (9)
Scoliosis	5 (2)	0 (0)	5 (4)
Spondylolisthesis	3 (1)	0 (0)	3 (3)
Spinal stenosis	2 (1)	0 (0)	2 (2)
Scheuermann disease	1 (0)	0 (0)	1 (1)
Unknown	14 (6)	0 (0)	14 (12)
Professional status, *n* (%)			
Employment status			
Sick leave	68 (27)	44 (33)	24 (20)
Employed	172 (67)	75 (56)	97 (80)
Invalidism	6 (2)	6 (4)	0 (0)
Unemployed	3 (1)	3 (2)	0 (0)
Retired	7 (3)	7 (5)	0 (0)
Professional categories			
High professional occupation	59 (23)	33 (24)	26 (22)
Intermediate occupation and employees	176 (69)	89 (66)	87 (72)
Labourer, craftsman, farmer	17 (7)	10 (7)	7 (6)
Unemployed or retired	4 (2)	3 (2)	1 (1)
Patient-reported outcomes values at baseline, mean (SD)			
Lumbar pain numeric rating scale (0–100)	63.1 (15.5)	68.6 (13.9)	56.9 (14.9)
Radicular pain numeric rating scale (0–100)	29.3 (25.4)	34.2 (26.4)	23.8 (23.1)
Quebec Back Pain Disability scale (0–100)	43.9 (17.1)	49.2 (14.9)	38.4 (17.5)
Hospital Anxiety Depression scale, anxiety subscale (0–21)	10.2 (3.8)	10.6 (3.9)	9.7 (3.7)
Hospital Anxiety Depression scale, depression subscale (0–21)	6.9 (3.7)	7.3 (3.8)	6.5 (3.7)
Medical Outcome Study Short Form-12 Physical Component subscore (9.95–70.02)	33.7 (7.5)	32.0 (7.1)	35.4 (7.4)
Medical Outcome Study Short Form-12 Mental Component subscore (5.89–71.97)	39.2 (10.6)	37.4 (10.3)	41.2 (10.7)

discopathy from the independent cohort. For the whole population, the mean (SD) age was 45.7 (9.0) years, 110/256 (43%) participants were men, mean body mass index was 25.6 (4.8) kg/m^2 and mean LBP duration was 10.5 (1.0) months (Table 1).

Patient acceptable symptom state (PASS). Overall, 137/256 (54%) patients self-rated their health as acceptable at 1 month: 75/137 (55%) in the PREDID trial and 62/137 (45%) in the cohort. In the whole population, PASS (95% CI) estimates at 1 month were 47.5 (40.0–50.0)/100 for lumbar pain, 30.5 (30.0–40.0)/100 for radicular pain, 39.3 (33.6–45.3)/100 for QBPDs, 10.0 (9.2–10.0)/21 for HADa score, and 6.7 (6.0–8.0)/21 for HADd score. In the PREDID trial and in the cohort, PASS (95% CI) estimates at 1 month were 45.4 (30.0–65.3)/100 and 49.2 (40.0–60.0)/100 for lumbar pain, 30.7 (20.0–40.0)/100 and 28.9 (20.0–40.0)/100 for radicular pain, 43.5 (34.0–50.0)/100 and 36.3 (32.0–40.0)/100 for QBPDs, 9.8 (8.0–10.0)/21 and 10.3 (9.0–11.0)/21 for HADa score, and 6.4 (5.0–8.0)/21 and 7.1 (6.0–8.0)/21 for HADd score, respectively. The PREDID and cohort populations did not differ in PASS estimates for any of the PROs at 1 month, as indicated by the overlapping 95% CIs for the PASS estimate for each PRO (Table 2).

Baseline variables associated with acceptable symptom state. On univariate analysis, reaching the PASS for radicular pain at 1 month was associated with baseline radicular pain and symptom duration, reaching the PASS on the QBPDs at 1 month was associated with baseline QBPDs and sex, and reaching the PASS on the HADa and HADd subscales at 1 month was associated with baseline HADa and HADd scores. Reaching the PASS for lumbar pain at 1 month was not associated with any of the baseline variables tested. On multivariate analysis, only the corresponding PRO baseline value was associated with reaching the PASS at 1 month for radicular pain, QBPDs, and HADa and HADd subscales (Table 3).

4. Discussion

In the present study, we provide PASS estimates for 5 PROs commonly used in clinical trials for cLBP. PASS estimates did not

Table 2
Patient acceptable symptom state at 1 month.

	All participants, $n = 137$	PREDID participants, $n = 75$	Outpatients, $n = 62$
Lumbar pain numeric rating scale (0–100)	47.5 (40.0–50.0)	45.4 (30.0–65.3)	49.2 (40.0–60.0)
Radicular pain numeric rating scale (0–100)	30.5 (30.0–40.0)	30.7 (20.0–40.0)	28.9 (20.0–40.0)
Quebec Back Pain Disability scale (0–100)	39.3 (33.6–45.3)[a]	43.5 (34.0–50.0)[b]	36.3 (32.0–40.0)
Hospital Anxiety Depression scale, anxiety subscale (0–21)	10.0 (9.2–10.0)	9.8 (8.0–10.0)	10.3 (9.0–11.0)
Hospital Anxiety Depression scale, depression subscale (0–21)	6.7 (6.0–8.0)	6.4 (5.0–8.0)	7.1 (6.0–8.0)

Values are the 75th percentile (95% confidence interval) of the distribution of values for each patient-reported outcome in the group of patients who considered themselves as having an acceptable symptom state. Data missing for one patient in the PREDID group.
[a] $n = 136$.
[b] $n = 74$.

Table 3
Patient-reported outcome multivariate regression final model.

Independent variables	OR	95% CI	*P*-value
PASS lumbar pain numeric rating scale			
Trial	1.44	(0.52–3.98)	0.484
Female sex	2.43	(0.97–6.07)	0.057
Low back pain duration	1.05	(0.98–1.11)	0.150
Lumbar pain intensity at baseline	0.98	(0.94–1.00)	0.137
PASS radicular pain numeric rating scale			
Trial	1.13	(0.41–3.08)	0.817
Female sex	1.33	(0.53–3.35)	0.539
Low back pain duration	1.08	(0.98–1.19)	0.104
Radicular pain intensity at baseline	0.97	(0.95–0.99)	<0.01
PASS Quebec Back Pain Disability scale			
Trial	0.40	(0.14–1.16)	0.909
Female sex	1.44	(0.56–3.73)	0.451
Low back pain duration	0.99	(0.96–1.03)	0.681
Quebec Back Pain Disability score at baseline	0.94	(0.90–0.97)	<0.001
PASS Hospital Anxiety Depression scale, anxiety subscale			
Trial	0.25	(0.07–0.90)	0.035
Female sex	0.48	(0.16–1.41)	0.181
Low back pain duration	1.02	(0.94–1.12)	0.601
Hospital Anxiety Depression scale, anxiety subscale at baseline	0.64	(0.53–0.78)	<0.001
PASS Hospital Anxiety Depression scale, depression subscale			
Trial	0.40	(0.12–1.30)	0.127
Female sex	0.55	(0.19–1.55)	0.254
Low back pain duration	0.97	(0.92–1.02)	0.200
Hospital Anxiety Depression scale, depression subscale at baseline	0.59	(0.48–0.72)	<0.001

OR, odds ratio–95% CI, 95% confidence interval.

differ between 2 independent populations of people with non-specific cLBP, and the main contributor to reaching the PASS at 1 month for a given PRO was the corresponding PRO baseline value.

Patients' opinion must be taken into account in clinical practice and therapeutic choices, particularly for subjective symptoms such as pain, activity limitations and participation restrictions. The PASS is a recent concept that approaches the concept of being well [6,16]. The PASS is defined as a state of attainment for a patient, acceptable for a given period, namely days, months or years, depending on the anchoring question chosen. The PASS can be used as a clinically relevant target to treatments for clinicians or as a relevant tool providing a proportion of patients with an acceptable state to interpret results in clinical trials.

Only a few PASS estimates for PROs are available for non-specific cLBP. In an international study by Tubach and colleagues, conducted in secondary health care centres in Australia and European and Mediterranean countries, PASS estimates for LBP were 39.0 (95% CI 38.0–41.0)/100 mm with a pain visual analog scale and 40.0 (38.0–42.0)/100 for spine-specific activity limitations with the Rolland and Morris Disability questionnaire. All participants (n = 186) had a chronic disease and mean age was 56 years [15]. In a Moroccan hospital population, the PASS estimate for LBP was 50.0/100 mm with a pain visual analog scale. Participants (n = 137) had a chronic disease and mean (SD) age was 53.5 (11.5) years [17]. In musculoskeletal disorders other than non-specific cLBP, PASS estimates for pain VAS vary across conditions, ranging from 41.0 to 50.0 mm for inflammatory back pain in ankylosing spondylitis [15,18] and from 26.0 mm in France to 53.0 mm in Italy for lower-limb osteoarthritis-related pain [15,19]. Overall, our PASS estimate for LBP intensity is of the same magnitude as previously reported estimates.

Of note, our PASS estimates for PROs did not vary across 2 independent populations of people with non-specific cLBP, with (n = 135) and without active discopathy (n = 121). Our findings suggest that the PASS estimates are reliable and consistent for a given condition, across populations, in a same country and in similar academic settings and reinforce the relevance and robustness of the PASS concept. However, the consistency of inter-individual PASS estimates is unknown. In our study, wide 95% CIs and ranges of values for participants with an acceptable symptom state suggest that the concept of the acceptability of symptoms may vary among individuals. On multivariate analysis, the only variable associated with reaching the PASS at 1 month for a given PRO was the corresponding PRO baseline value. This result is not surprising: participants with PRO baseline values close to the PASS may be more likely to reach the PASS during follow-up.

Our study has limitations. To calculate our PASS estimates, we used an external anchoring question extracted from the MOS SF-12 survey: "In general how would you say your health is?". There is no consensual validated anchoring question to estimate the PASS, but it is commonly accepted that the anchor should consider a period, namely months or years, during which the health status will be acceptable for the patient [16]. The wording of our anchoring question is contestable. Because it was chosen retrospectively, we were not able to use a more suitable anchoring question, such as "Think only about your low back pain during the last 48 hours. If you were to remain for the rest of your life with the same level of pain, would this be acceptable for you?" with a yes/no answer. This wording was used in previous study [20]. The wording of the anchoring question may have distorted our results. The question we used was general (i.e., not addressing a particular symptom) and had no timeframe. Patients may have rated their general health status as acceptable despite a non-acceptable level of specific impairment. Therefore, our results may be overestimated because of the non-specific external anchoring question (i.e., confusion with other health issues, discrepancy between general health status and LBP, lack of defined timeframe for the perceived health status) and the short-term delay of measurements (i.e., results at 1 month may legitimize the results with LBP improvement despite no change in health status). Another limitation is the allocation to a specific intervention for the purpose of a trial: participants in the PREDID trial were randomly assigned to an experimental or control intervention. To what extent intervention-related events, responses or side effects might have influenced PASS estimates is unknown. For example, patients receiving an intervention may have had higher expectations for treatment efficacy, which may have affected their perceived-health status [14]. Finally, participants in the present study were recruited from tertiary care centres and may not have been fully representative of the French population with non-specific cLBP.

5. Conclusions

In summary, despite some limitations including non-specific anchorage, timeframe and some design choices, our study provides PASS estimates for 5 PROs commonly used in cLBP. Our estimates did not vary across 2 independent populations of people with cLBP. Stability of the PASS estimates suggests that they are robust and relevant for interpreting PRO values in clinical trials conducted in similar settings and for patient healthcare.

Authors' contributions

Conception and design of the study: CD, SP, CN.
Drafting of the original protocol: CD, SP, CN.
Obtaining of funding: SP.
Coordination of the study: CN.
Acquisition of data: MMLC, SP, FR.
Design of the statistical analysis plan: CD, HA, FF, CN.
Analysis of data: CD, HA, FF, CN.
Drafting of the present manuscript: CD, CN.
Final approval: CD, HA, FF, MMLC, SP, FR, CN.

Disclosure of interest

The auhors declare that they have no competing interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.rehab.2020.10.005.

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