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ORIGINAL ARTICLE

Validity of the French version of the Core Outcome Measures Index for low back pain patients: a prospective cohort study

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Abstract
Purpose Among the many questionnaires available to evaluate low back pain (LBP) patients, the Core Outcome Measures Index (COMI) has the unique advantage to investigate five dimensions using seven short questions. The aim of this study was to explore additional properties of the questionnaire in a French-speaking non-surgical population.
Methods This study was conducted on 168 patients suffering from subacute or chronic LBP and followed up for 6 months in three French-speaking countries. In addition to basic psychometric properties (e.g., construct validity, floor and ceiling effect, reproducibility), internal validity was analyzed by a factor analysis using Cronbach's alpha. Responsiveness and sensitivity to change were assessed through minimal detectable change (MDC), effect size, and Minimal Clinically Important Improvement (MCII). We used an anchor-based method with receiver operating characteristic (ROC) curve analysis to assess MCII and the Patient Acceptable Symptom State.
Results Construct validity, reliability (Cronbach's alpha = 0.87), reproducibility and the absence of floor and ceiling effects were confirmed. Factor analysis indicated a one-dimensional construct that validates the use of a sum score. The MDC (2.1) was inferior to the MCII (2.3). The limit below which the patient claims to be in a fair condition (Patient Acceptable Symptom State) was set at 3.
Conclusions The COMI is a self-report questionnaire with the capacity to easily and quickly explore several dimensions in patients with LBP that can be then summarized in a meaningful sum score. Additional knowledge

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provided by our study should encourage the widespread use of the COMI among the spine community.

Keywords Low back pain · Multidimensional assessment · Psychometrics · Self-report questionnaire

Introduction

There are many questionnaires available to assess patients with low back pain (LBP) [1]. Dimensions that are commonly considered important to assess include pain, symptom-specific function, generic well-being, social and work disability, and satisfaction with treatment [2], but using a specific questionnaire for each dimension leads to lengthy assessment that is difficult to achieve in practice. The Core Outcome Measures Index (COMI) was proposed originally to shorten the evaluation time when assessing pain, function, symptom-specific well-being, quality of life, and disability. This 7-item, short and easy to use questionnaire [2] appears to be a reliable and valid [3–5] instrument to assess these five dimensions in LBP patients and it is now routinely used by spine surgeons in the Spine Tango registry (European Spine registry) [6]. The French version of the COMI has been recently validated in patients mainly located in the French-speaking region of Switzerland [4]. However, important psychometric properties (e.g., sensitivity to change) could not be studied in the absence of follow-up after treatment.

The primary aim of this study was to acquire a deeper general knowledge of the measurement characteristics of this questionnaire, e.g., by defining the Patient Acceptable Symptom State (PASS) [7] with a special emphasis on non-surgical patients. In contrast with our previous study and in order to increase the generalizibility of the results, this study was performed in three different French-speaking populations.

Materials and methods

Study design/setting

A prospective 6-month multicenter cohort study was conducted in France, the French-speaking region of Belgium, and the French-speaking region of Switzerland. Patients were recruited from non-surgical spine centers. Inclusion criteria were LBP with or without leg pain for at least 4 weeks, a pain intensity score of at least 3 on a visual analog pain scale ranging from 0 to 10, and fluency in the French language. Exclusion criteria were a diagnosis of specific LBP (tumor, infection, spondyloarthropathy, or trauma) or the presence of co-morbidities severe enough to interfere with the evaluation of function (e.g., decompensated heart failure, symptomatic knee osteoarthritis). After written informed consent was obtained, patients were asked to complete a questionnaire booklet. To investigate the reproducibility, patients received a shorter booklet with the instruction to complete it a week later at home and then to returned it by mail (short-term follow-up). A full follow-up evaluation was scheduled 4–6 months later. The choice of treatment was left to the decision of each investigator. The sample size was determined according to quality criteria for health status questionnaires [8]. The study was approved by the Institutional Ethics Committee of the University of Geneva Hospitals, Geneva, Switzerland.

Patient-based outcome measures

The domains included in the COMI are pain symptoms (two items related to back and leg pain, respectively), function, symptom-specific well-being, generic quality of life (QoL) (all in the past week), and work and social disability in the previous month. Pain scores are indicated on a 0–10 numeric rating scale. Response categories for other items are 5-point adjectival or Likert scales (The French version is available online as a supplementary file; for English version see [9]). The two disability items asked patients to record the number of days that back pain affected their work and daily activities during the previous 4 weeks. These two variables were recorded into categorical variables of five points (0, 1–7, 8–14, 15–21, $\geq$22 days). The pain score is recorded as the higher of the two pain scale scores (back or leg). For the remaining items, each incremental step is allocated 2.5 points and range from 0 ("excellent condition") to 10 ("worst condition"). Scores for social and work disability are averaged to form one disability score. The COMI sum score is computed by the addition of the five subscales (pain, function, symptom-specific well-being, general QoL, and disability) divided by five and thus ranges from 0 ("best health status") to 10 ("worst health status") [5].

In the present study, the French version of the COMI used was identical in the three countries. The validation process of the English to French translation has been previously reported and basic psychometric properties of this version (construct validity and reproducibility) were shown to be acceptable in a small cohort of LBP patients recruited from orthopedic and non-surgical spine centers [4].

At baseline, the questionnaire booklets included questions about sociodemographic variables (age, gender, family status, education, work status), pain characteristics (time since the first episode of LBP, duration of the present episode, previous back surgery, intensity of back-related pain during the past week ranked on a 5-item Likert scale ["no pain" to "extreme pain"]), back pain-related

disability [French version [10] of the Roland and Morris disability questionnaire (RMDQ)], daily life activity, work and leisure, anxiety and depression, social interest [French version [11] of the Dallas Pain Questionnaire (DPQ), which enables to calculate a subscore for each four subscales as well as the sum score], and health-related QoL [French version [12] of the Euroquol 5 Dimensions Questionnaire (EQ-5D)]. In addition to the COMI, the clinical evolution was evaluated at short-term follow-up by a transition question on a 7-point Likert scale (from "strong improvement" to "strong worsening").

At 6-month follow-up, patients were asked to complete the same questionnaire booklet as at baseline; treatments administered since study inclusion were also recorded. Treatment efficacy was assessed on a 5-point Likert scale (from "no effect" to "excellent effect, almost no symptoms at all") and patient global perceived effect by the same 7-point Likert scale as used at short-term follow-up (from "strong improvement" to "strong deterioration") [13]. Patients were asked also whether they considered their present state as satisfactory through the following question: "Taking into account all what you have to do in your daily life, your pain, and your disability, is your present state satisfactory?" (yes/no answer) [14].

Statistical analysis

According to recommendations [8], a minimum study sample size of 150 patients was required to ensure sufficient power. Missing data were treated according to the specific recommendations for each questionnaire. COMI scores were computed only when all data were present. Floor and ceiling effects were determined for the COMI total score and for each of the five subscales by computing the percentage of answers at both extremities of the total score and each subscale.

The construct validity of the COMI was explored by investigating the correlations between the COMI subscales and their corresponding validated full-length questionnaire (e.g., RMDQ for the function subscale) using Spearman rank correlation coefficients, corrected for ties. Spearman's Rho coefficients were interpreted as follows: Rho 0.81–1.0="excellent"; 0.61–0.80="very good"; 0.41–0.60= "good"; 0.21–0.40 = "fair"; and 0–0.20 = "poor" [15, 16]. Pre-specified hypotheses were made and good correlations were expected at least between the COMI pain and the 5-item Likert pain scale, the COMI function and the RMDQ or daily life activity subscale of DPQ, the COMI disability and the DPQ work and leisure subscale, the COMI QoL and the EQ-5D, as well as between the COMI sum score and DPQ total score. No specific correlation was expected for the COMI well-being as it has been reported in several studies that this specific scale is not related to other commonly used questionnaires [3–5]. The unidimensionality of the COMI score was first assessed using principal component analysis (PCA). Reliability of the scale was then determined using Cronbach's alpha.

Reproducibility was determined by comparing baseline scores to those reported at short-term follow-up (scheduled 1 week later) among patients who reported no or only minimal change from the time of inclusion. The weighted kappa for single items and the intraclass coefficient of correlation (ICC) for the total score were used, as well as the Bland–Altman plotting method which indicates the smallest detectable difference (SDD; i.e., the amount of detectable change above the random measurement error). The 95 % limits of agreements were calculated by the Bland and Altman method [17] i.e., the mean of the difference between the two measures $\pm 1.96 \times$ the standard deviation (SD) of this difference.

Assessment of the minimal detectable change (MDC) was done by multiplying 1.96 to the difference in score between baseline and short-term follow-up among patients declaring no or minimal improvement [15, 18]. The minimal clinically important improvement (MCII) was determined using an anchor method based on the patient's assessment in response to the treatment at 6 months by a 5-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") [19]. These results were then divided into patients for whom the treatment did not result in any change (0 and 1) and those for whom the treatment provided change (2–4). The threshold was determined by subtracting the mean change score of the group of patients who observed a treatment effect from that of the group who did not report any treatment effect. The relationship between the change in COMI sum score and MCII was assessed also by receiver operating characteristic (ROC) curve analysis and the determination of the area under the curve (AUC). The standardized variation of the items and the total score was assessed by effect sizes (mean difference divided by the SD).

PASS was determined using an anchor method based on the patient's answer to the statement: "Taking into account all activities you have to perform in your daily life, your amount of pain, and the level of physical disability, if you were to remain the same for the next months, would this be acceptable for you?" [20]. The threshold for PASS was determined as being the 75th percentile of the COMI sum score at 6-month follow-up of patients answering "yes" to this statement [20]. The relationship between the change in COMI sum score and PASS was also assessed by ROC and AUC curve analyses.

Results

Eleven centers recruited 168 patients from May 2009 to June 2010. There were at least two centers in each country (France, Belgium, and Switzerland) recruiting more than 15 patients. The short-term questionnaire (for the reproducibility study) was completed by 138 of 168 patients (mean number of days between baseline and short-term questionnaire, 12.8; SD, 32.0). Long-term follow-up was completed by 142 patients (mean number of months between baseline and long-term follow-up, 5.5; SD 1.5).

Patient baseline characteristics

Patients ($n = 168$) had a mean (SD) age of 45.5 (12.2) years; 56.1 % were female. The current episode of back pain of most patients (82 %) had lasted for more than 3 months (Table 1). Fifteen percent had symptoms and signs compatible with lumbar radiculopathy. Twenty-five patients had undergone previous back surgery (a discectomy for half of them). Pain, function, and QoL-related characteristics of patients at baseline and after treatment at 6-month follow-up are given in Table 2.

Acceptability and floor and ceiling effect

The number of missing items ranges from 2.4 to 3.6 % with 4.8 % of questionnaires having at least one missing item (Table 3). Although several items presented with some significant floor or ceiling effect, no such effect was observed for the COMI sum score (Table 3).

Internal validity

The first PCA of the five items explains 64.3 % of variance. While the eigen value for the second factor was

Table 1 Baseline characteristics of patients ($n = 168$)

Characteristics	Categories	*N* (%)
Gender, female ($n = 168$)		96 (56.1)
Type of LBP[a] ($n = 158$)	LBP without radiating pain	76 (48.1)
	Non-specific radiation below gluteal fold	31 (19.6)
	Non-specific radiation below the knee	27 (17.1)
	Radicular pain	24 (15.2)
Duration of pain ($n = 164$)	4–7 weeks	18 (11.0)
	7 weeks–3 months	11 (6.7)
	3–6 months	30 (18.3)
	6–18 months	32 (19.5)
	>18 months	73 (44.5)
Previous episode of LBP ($n = 168$)		138 (85.2)
Level of education ($n = 160$)	Obligatory schooling (9 years of education)	36 (22.5)
	Professional diploma	58 (36.3)
	University	66 (41.3)
Type of usual work ($n = 159$)	Sedentary	48 (30.2)
	Physical	61 (38.4)
	A mix of both	50 (31.4)
Work status ($n = 163$)	Employed	90 (55.2)
	Unemployed	11 (6.7)
	Insurance beneficiary (disease, accident, invalidity)	42 (25.8)
	Retired	10 (6.1)
	No paid activity	5 (3.1)
	Other	5 (3.1)
Duration of sick leave ($n = 155$)	None	51 (32.9)
	<7 weeks	24 (15.5)
	7 weeks–3 months	10 (6.5)
	3–6 months	19 (12.3)
	6–18 months	19 (12.3)
	>18 months	16 (10.3)
	Not applicable	16 (10.3)

LBP low back pain

[a] According to the Paris Task Force classification [26]

slightly above 1, the screen plot clearly favored a one-factor solution. Reliability measured by Cronbach's alpha was 0.87.

Construct validity

All hypotheses were fulfilled for construct validity. The COMI sum score and all subscales of the COMI, except COMI well-being, had a good or very good correlation with their respective reference questionnaire ranging from 0.52 (between COMI function and RMDQ) to 0.65 (between COMI sum score and DPQ sum score). As expected, COMI well-being showed a low correlation with all reference questionnaires, the highest correlation being with EQ-5D (0.39).

Table 2 Pain, function, and quality of life-related characteristics of patients at baseline and after treatment at 6-month follow-up (mean [SD])

	Baseline ($n = 168$)	Follow-up ($n = 142$)
Back pain (0–10)	5.5 (2.0)	3.7 (2.6)
Leg pain (0–10)	3.6 (2.9)	2.6 (2.8)
Roland and Morris disability questionnaire (0–24)	12.9 (5.0)	7.5 (6.5)
Dallas pain questionnaire		
Daily activities (0–100)	60.5 (17.6)	40.6 (25.9)
Work and leisure (0–100)	57.8 (23.5)	37.2 (29.8)
Anxiety and depression (0–100)	42.5 (26.4)	29.4 (28.6)
Social interest (0–100)	34.1 (24.2)	24.5 (24.7)
Euroquol 5 dimensions questionnaire (0–1)	0.4 (0.2)	0.6 (0.3)
COMI sum score	6.3 (1.8)	4.0 (2.6)

Reproducibility

Of the 138 patients who responded to the short-term follow-up questionnaire, 132 reported no or only minimal change from inclusion and were thus included in the test–retest analysis. Test–retest agreement was high for all items (range 0.66–0.88) except for the item on well-being (weighted kappa, 0.48). The test–retest agreement for the total score was very high at 0.81 (95 % CI, 0.74–0.86). The Bland–Altman plotting method indicating the SDD was 2.09 (Fig. 1).

Responsiveness, sensitivity to change, and additional characteristics

The MDC for single items was less than 2.5 points on the 10-point scale, except for the questions on pain (MDC for COMI back pain = 2.9; COMI leg pain = 3.7; COMI pain = 2.7). The MDC for the COMI sum score in this population was 2.1. However, the mean difference between scores among stable patients was very low. By contrast, the MCII for the sum score was 2.3. The AUC for the prediction of patient's own assessment in response to treatment by the change in COMI sum score was 0.80, meaning that a patient reporting no or a slight effect had a 80 % chance of having a lower COMI sum score change than a patient who reported at least a moderate treatment effect. The effect size of the COMI sum score was 1.01.

The PASS for the sum score (scale from 0 to 10) was 3.05. This threshold on the COMI sum score at follow-up correctly classified 90.6 % of the patients who declared to be dissatisfied with their present state and 74.3 % of patients reporting as satisfied. The AUC for the prediction of PASS by the COMI sum score at follow-up was 0.84 (Fig. 2), meaning that a patient who is dissatisfied with his/

Table 3 Item characteristics of the Core Outcome Measures Index (COMI) at baseline ($n = 168$ patients)

	Missing (%)	% at lowest value	% at highest value	Lowest value	Highest value	Mean[a] (SD)	Loading of PCA
COMI back pain	3.0	0.6	0.6	0	10	5.5 (2.0)	–
COMI leg pain	3.6	21.4	0.6	0	10	3.6 (2.9)	–
COMI pain	2.4	0.0	1.2	2	10	6.0 (1.9)	0.70
COMI social disability	3.0	13.7	32.1	0	10	5.6 (3.7)	–
COMI work disability	3.0	33.9	31.0	0	10	4.5 (4.3)	–
COMI disability	3.0	13.1	25.0	0	10	5.1 (3.7)	0.60
COMI function	2.4	0.6	9.5	0	10	6.0 (2.1)	0.87
COMI well-being	2.4	0.0	49.4	2.5	10	8.4 (1.9)	0.59
COMI quality of life	2.4	1.2	7.7	0	10	5.8 (2.1)	0.78
COMI sum score	4.8	0.0	0.6	2.4	10	6.3 (1.8)	–

SD standard deviation, *PCA* principal component analysis

[a] Each scale rated from 0 to 10

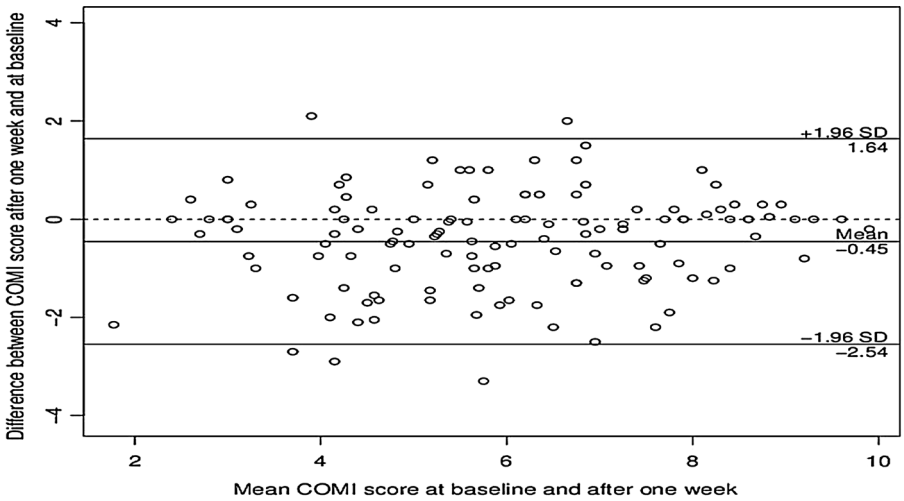

Fig. 1 Bland–Altman plotting showing limits of agreement between the Core Outcome Measures Index (COMI) mean score at baseline and at short term (average time 12 days) among stable patients

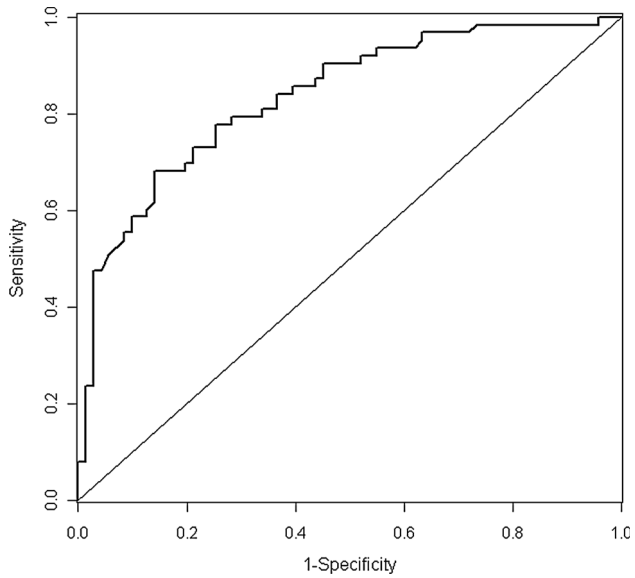

Fig. 2 Relationship between the change in the Core Outcome Measures Index (COMI) sum score and the Patient Acceptable Symptom State (PASS) assessed using ROC curve analysis. The area under the curve for the prediction of PASS by the COMI sum score at follow-up was 0.84, meaning that a patient who is dissatisfied has a 84 % chance of having a higher COMI sum score at follow-up than a patient who is satisfied

her present back condition has an 84 % chance of having a higher COMI sum score at follow-up than a patient who is satisfied.

Discussion

The basic psychometric properties (internal consistency, reproducibility, floor and ceiling effect) of the French adaptation of the COMI were confirmed in a prospective cohort of non-surgical patients. The recruitment performed in three different French-speaking countries is an important point for the generalizability of the questionnaire. More importantly, it provides additional clinically meaningful psychometric properties that have not been previously reported in any other language [3–5]. It is the first time that a factor analysis is reported for the COMI. Although it is in essence a multidimensional tool, this analysis surprisingly indicates that the COMI has a one-dimensional construct. We hypothesize that this may refer to the fact that this questionnaire captures something unique for all these patients (i.e., they are all suffering from LBP) and might indicate that the investigated dimensions have been adequately chosen to provide a comprehensive evaluation of these patients. Importantly, this finding validates the use of a sum score that effectively represents the patient's global state. Interestingly, this has been already reported for a version of the COMI specifically developed for neck pain patients [21].

PASS is an emerging concept that has recently been reported for other self-report questionnaires in the field of musculoskeletal diseases [22, 23], but was not previously determined for the COMI. Patients with a COMI sum score equal or inferior to 3 can be confidently considered as having reached an acceptable symptom state (AUC = 0.84). Complementary to MCII, which characterizes an improvement from a previous state, PASS is characteristic of a present state of being. PASS appears to be less influenced by baseline characteristics than MCII [23] and to be stable over time [24]. PASS scores are increasingly used to report results in clinical trials [25] and are proposed as a tool to help guide clinical and surgical decisions [26].

In our patient cohort, the value from which an improvement can be considered to have clinical relevance (MCII) is 2.3. The fact that the MCII is above the MDC

(2.1) confirms that MCII can be adequately used in clinical research and practice. The AUC (0.80) for the change in the COMI sum score is high and shows a good ability to predict the patient's assessment in response to the treatment at 6 months. The value of MCII in this study is similar to the value found (2.6) in a large cohort of surgical patients [27]. The effect size of the COMI sum score (1.01) is large and similar to that obtained in other studies [3, 5], thus indicating that this questionnaire has also a good responsiveness (sensitivity to change) in non-surgical patients.

Some of the new psychometric properties of the COMI described in this study, like the PASS score, should be replicated in other populations (e.g., surgical patients) before being generalized. Other important results like factor analysis should not be influenced by translation or clinical characteristics of the patients and are thus be valid for all translations. Lastly, for parameters like ICC MDC and MCII, our results confirm those reported in other cross-cultural adaptations and thus can be considered reliable [3, 5, 9, 28, 29].

In conclusion, the French cultural adaptation of this self-report questionnaire has adequate psychometric properties to study and follow-up subacute and chronic LBP patients in large cohort studies as presently done in Spine Tango [6]. Furthermore, considering its intrinsic qualities, namely brevity, multidimensionality, ease of application and scoring, the COMI has all the necessary criteria to be used in daily practice care by spine specialists or even general practitioners. The COMI is a useful instrument providing a comprehensive evaluation that helps to document treatment efficacy in a patient population notoriously difficult to treat.

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Conflict of interest None.

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