Prognosis and Course of Disability in Patients With Chronic Nonspecific Low Back Pain: A 5- and 12-Month Follow-up Cohort Study

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Background. Few data are available on the course of and predictors for disability in patients with chronic nonspecific low back pain (CNSLBP).

Objective. The purpose of this study was to describe the course of disability and identify clinically important prognostic factors of low-back-pain–specific disability in patients with CNSLBP receiving multidisciplinary therapy.

Design. A prospective cohort study was conducted.

Methods. A total of 1,760 patients with CNSLBP who received multidisciplinary therapy were evaluated for their course of disability and prognostic factors at baseline and at 2-, 5-, and 12-month follow-ups. Recovery was defined as 30% reduction in low back pain–specific disability at follow-up compared with baseline and as absolute recovery if the score on the Quebec Back Pain Disability Scale (QBPDS) was ≤20 points at follow-up. Potential prognostic factors were identified using multivariable logistic regression analysis.

Results. Mean patient-reported disability scores on the QBPDS ranged from 51.7 (SD=15.6) at baseline to 31.7 (SD=15.2), 31.1 (SD=18.2), and 29.1 (SD=20.0) at 2, 5, and 12 months, respectively. The prognostic factors identified for recovery at 5 and 12 months were younger age and high scores on disability and on the 36-Item Short-Form Health Survey (SF-36) (Physical and Mental Component Summaries) at baseline. In addition, at 5-month follow-up, a shorter duration of complaints was a positive predictor, and having no comorbidity and less pain at baseline were additional predictors at 12-month follow-up.

Limitations. Missing values at 5- and 12-month follow-ups were 11.1% and 45.2%, respectively.

Conclusion. After multidisciplinary treatment, the course of disability in patients with CNSLBP continued to decline over a 12-month period. At 5- and 12-month follow-ups, prognostic factors were identified for a clinically relevant decrease in disability scores on the QBPDS.

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There is no strong evidence to support the claim that 80% to 90% of patients with low back pain (LBP) become pain-free within 1 month; on average, 62% (range=42%–75%) of the patients still experienced back pain after 12 months.[1] Studies following patients over a 12-month period have shown that LBP is characterized as having periodic attacks and temporary remissions, rather than being "chronic."[1–3] Shorter periods of temporary remissions are frequently seen in patients with chronic nonspecific low back pain (CNSLBP) (≥12 weeks) in combination with higher levels of limitations in activities.[4] A recent meta-analysis[5] reported that patients with acute, subacute (<12 weeks), and persistent (>12 weeks to 12 months) LBP experienced substantial reductions in pain and improvement in disability in the first 6 weeks, but only very small reductions in average pain and disability between 6 and 52 weeks were demonstrated. The course of limitations in activities among patients with CNSLBP varies per patient.[4,6] Therefore, knowledge of the course and prognostic factors of disability experienced by patients with CNSLBP might be clinically relevant for optimizing rehabilitation. The rehabilitation of normal patterns or activities of movements in patients with CNSLBP is a focus during multidisciplinary treatment.[7]

A systematic review[8] including patients experiencing LBP for less than 8 weeks identified risk factors for developing persistent, disabling LBP. Prognostic factors for the development of persistent LBP at 1-year follow-up were high maladaptive pain coping behaviors, presence of nonorganic signs, high baseline functional impairment, low general health status, and presence of psychiatric comorbidities. Low levels of fear avoidance and low baseline functional impairment were the most useful items for predicting recovery at 1 year. Our recent systematic review on prognostic factors in patients with CNSLBP (≥12 weeks) showed that, at short-term follow-up (≥6 months), there was no association between age and sex on disability and that, at long-term follow-up (≥12 months), there was no association among smoking, pain intensity, and fear of movement. Conflicting evidence was found at short-term follow-up for an effect of fear of movement on disability and at long-term follow-up for the factors of age, sex, work status, physical job demands, sick leave, and feelings of depression. Also, there was limited evidence for no association between the outcome disability and the factors of leg pain level and mobility. However, the methodological quality of the included studies was mostly poor (high risk of bias).[9]

Thus, overall, there is no strong evidence for associations that can help clinicians in their clinical decision making to influence modifiable prognostic factors that might have a positive effect on disability. Therefore, the aims of this study were: (1) to describe the course of disability in patients with CNSLBP (receiving multidisciplinary therapy) at 2-, 5-, and 12-month follow-ups and (2) to identify prognostic factors of LBP-specific disability at 5 and 12 months after completing a multidisciplinary therapy program.

Method

Study Design and Participants

Patients were recruited (January 2003–December 2008) at the Spine & Joint Centre (SJC), a multidisciplinary outpatient rehabilitation clinic in Rotterdam, the Netherlands. All participants provided informed consent. Detailed information on the study design has been published elsewhere.[7] Participants were evaluated using mailed questionnaires and physical examinations at baseline and at 2, 5, and 12 months.

Therapy Program

The multidisciplinary treatment at the SJC used a biopsychosocial approach to stimulate patients to adopt adequate (movement) behavior aimed at physical and functional recovery. Patients with CNSLBP not recovering after primary or secondary care were referred by their general practitioner (GP) or specialist to the SJC for a diagnostic consultation. Diagnostic consultation consisted of a 3-hour intake session in which the patient completed several questionnaires and undertook history taking and a physical examination. The physician could request an additional consultation with a psychologist or manual physical therapist before deciding on treatment management. When patients were eligible for treatment, they were invited to participate in the study and informed consent was obtained. In the present study, LBP was defined as "nonspecific" (ie, without a specified physical cause, such as nerve root compression, trauma, infection, or the presence of a tumor). Pain in the lumbosacral region is the most common symptom in patients with nonspecific LBP. Pain also may radiate to the gluteal region or to the thighs, or to both.[10] Patients with CNSLBP (complaints lasting ≥3 months) and not improving in primary care (monodisciplinary) with the influence of psychological and social factors besides the physical factors on their complaints were invited to participate in the multidisciplinary treatment program. Those not eligible or not wanting to participate in this study were referred back to their GP.[7]

The sample in the current study consisted of a survival cohort with the following inclusion criteria: (1) men and women aged 18 years and over,

(2) having CNSLBP (defined as LBP with a duration of ≥3 months), (3) previous and unsuccessful treatment in primary or secondary care (eg, physical therapy), and (4) signed informed consent.

Exclusion criteria were: (1) insufficient knowledge of the Dutch language; (2) signs indicating radiculopathy, asymmetric Achilles tendon reflex, or passive straight leg raise test restricted by pain in the lower leg; (3) positive magnetic resonance imaging findings for disk herniation; (4) recent (<6 months) fracture or neoplasm or recent previous surgery (<6 months) of the lumbar spine, the pelvic girdle, the hip joint, or the femur; (5) specific causes such ankylosing spondylitis and systemic disease of the locomotor system; and (6) being pregnant or ≤6 months postpartum at the time of consultation.

The therapy program consisted of 16 sessions of 3 hours each during a 2-month period (a total of 48 hours) coached by a multidisciplinary team (physical therapist, physician, health scientist, and psychologist). Behavioral principles were applied to encourage patients to adopt adequate normal behavioral movement aimed at physical recovery. The Quebec Back Pain Disability Scale (QBPDS) was used to identify and measure limitations in activity.[7]

Five months after the start of the therapy program (2 months at the SJC + 3 months self-supporting activity), the patients were measured at the 5-month follow-up at the SJC. At the 12-month follow-up, the measurement was performed by means of questionnaires mailed to the patients.

Outcome Criteria

Outcome criteria were based on a minimally important change in LBP as described by Ostelo and colleagues[11,12] and Helmhout et al[13] for LBP disability. The QBPDS is a 20-item self-administered instrument designed to assess the level of functional disability in patients with back pain (score range=0–100). Higher scores indicate more disability. The QBPDS has been shown to be a reliable, valid, and responsive measure.[14] The QBPDS was completed by the patients; therefore, the scores were not blinded for putative prognostic factors. Recovery from disability was operationalized into 2 definitions: (1) 30% improvement in recovery compared with baseline[11,12] (the QBPDS scores [0–100] were dichotomized into "no improvement in disability" and "improvement in disability" using a reduction of 30% at follow-up compared with baseline as a clinically relevant difference[11–13]) and (2) "absolute recovery," which was defined as a QBPDS score of ≤20 points at follow-up.[11,15–17]

Prognostic Factors

The baseline values of 47 prognostic factors were included in the analyses as important or potential prognostic factors. To comply with the rule of at least 10 events per variable in the analysis (which avoids incorrect estimation of variables), we had to restrict the total number of potential prognostic factors.[18] The choice for eligible factors was made: (1) using a policy Delphi procedure in which the factors were independently scored (on a 4-point Likert scale ranging from 1=very important to 4=not important) by 8 experts[9,19,20] and (2) based on the results of a systematic review on prognostic factors for recovery.[9,19,20] On the basis of the experts' opinions and the systematic review, 23 potential prognostic factors were included (Tab. 1).

The continuous variables were: age, duration of back pain in years, present pain intensity (visual analog scale [VAS]: 0–100 mm), degree of present fatigue (VAS: 0–100 mm), QBPDS score (range=0–100), Tampa Scale for Kinesiophobia (TSK) score (range=17–68), 36-Item Short-Form Health Survey (SF-36, Physical Component Summary [PCS] and Mental Component Summary [MCS]) scores, Symptom Checklist–90 (SCL-90; item 9: psychoneurosis) score, B200 Isostation (Isotechnologies, Hillsborough, North Carolina) (back extension strength in newtons), and work participation (0%–100%). Work participation was measured by dividing current work hours by former work employment hours prior to CNLBP. Some of the patients were on partial sick leave due to back pain. Patients who were retired, not seeking work, or unemployed as they have family care responsibilities gave no information.

The categorical variables were: body mass index (BMI: ≤24.9, 25–29.9, ≥30 kg/m^2); cause of back pain (accident or wrong move made by the patient, after physical load, during pregnancy or after delivery, unknown, pelvis or back surgery, or herniated nucleus pulposus); course of pain in the previous 3 months (stable, increased, decreased); and the duration of walking, sitting, and standing (0–15, 16–30, 31–60, >61 minutes) during daily activities.

The dichotomized variables were: sex, comorbidity (none versus having one or more comorbidities), level of education (less than high school versus high school/university), married or living with one adult (yes/no), previous rehabilitation treatment (none versus one or more previous rehabilitation treatments), and employment status benefit (none versus different types of government welfare benefits).

We excluded the following factors: weight, height, alcohol consumption, smoking, drug consumption,

Table 1.

Baseline Characteristics of Study Participants With Chronic Nonspecific Low Back Pain (CNLBP)[a]

Characteristic	Patients (n=1,760)	Missing Value, n (%)
No. of female patients	1,307 (74.3)	0
Age (y), $\bar{X}$ (SD)	40.1 (10.6)	0
Demographic factors		
Low education	716 (40.7)	71 (4.0)
Marital status, living with 1 adult	1,515 (86.1)	46 (2.6)
Clinical status		
BMI >25 kg/m^2	783 (44.5)	88 (5.0)
Duration of complaints (y), $\bar{X}$ (SD)	7.7 (8.8)	0
Cause reported by patient:		23 (1.3)
Accident/wrong movement	374 (21.3)	
After physical overload	73 (4.1)	
During pregnancy or after delivery	586 (33.3)	
Unknown	672 (38.2)	
Pelvis/back surgery or after HNP	32 (1.8)	
Previous revalidation program	186 (10.6)	101 (5.7)
Comorbidity	275 (15.6)	88 (5.0)
LBP intensity (VAS in mm), $\bar{X}$ (SD)		
Present pain intensity	55.5 (23.0)	5 (0.3)
Course of pain intensity due to CNLBP in the previous 3 mo		52 (3.0)
Stable pain intensity	865 (49.1)	
Increased pain intensity	723 (41.1)	
Decreased pain intensity	120 (6.8)	
Degree of fatigue due to LBP (VAS in mm), $\bar{X}$ (SD)	56.5 (26.6)	118 (6.7)
Disability (QBPDS), $\bar{X}$ (SD)	51.7 (15.6)	8 (0.5)
Psychological factors		
Fear avoidance (TSK), $\bar{X}$ (SD)	36.7 (7.3)	50 (2.8)
SCL-90 (item 9), $\bar{X}$ (SD)	149.3 (39.7)	227 (12.9)
SF-36 (health-related quality of life)		
PCS	31.8 (7.1)	493 (28.0)
MCS	46.5 (10.3)	493 (28.0)
Work-related factors		
Employment status benefit	924 (52.5)	353 (20.1)
Work participation		161 (9.1)
100% working	391 (22.2)	
0%–99% working	1,059 (60.2)	
Not working[b]	149 (8.5)	
Physical examination		
ADL function, duration >31 min without pain increase		
Walking	410 (23.3)	10 (0.6)
Sitting	432 (24.5)	13 (0.7)
Standing	106 (6.1)	9 (0.5)
B200 Isostation (strength) (N), $\bar{X}$ (SD)		
Extension	81.6 (45.8)	107 (6.1)

[a] Values are numbers (percentages), unless stated otherwise, of the entire data set of 1,760 patients. BMI=body mass index, HNP=herniated nucleus pulposus, LBP=low back pain, VAS=visual analog scale, QBPDS=Quebec Back Pain Disability Scale, TSK=Tampa Scale for Kinesiophobia , SCL-90=Symptom Checklist–90, SF-36=36-Item Short-Form Health Survey, PCS=Physical Component Summary, MCS=Mental Component Summary, ADL=activities of daily living. Missing values ranged from 0.5% (n=9) to 28% (n=493).

[b] Not working=currently not working because in search of new work or not seeking work due to family care responsibilities or being retired.

patient's gradual or sudden onset of symptoms, pain intensity minimal and maximal (VAS: 0–100 mm), degree of fatigue minimal and maximal (VAS: 0–100 mm), and less work due to complaints, unemployment, fully working, other reasons.

The following physical examination tests were performed: long dorsal sacroiliac ligament test, mobility by video registration, active straight-leg-raising (ASLR) test, performance of activities of daily living without an increase in pain, posterior pelvic pain provocation (PPPP) test, and isometric force of hip abduction. The long dorsal sacroiliac ligament test (0=no pain; 1=complaint of pain without grimace, flinch, or withdrawal [mild]; 2=pain plus grimace or flinch [moderate]; 3=the examiner is not able to complete the test because of withdrawal [unbearable] score is positive when the bilateral sum score is ≥2 (score range=0–6; higher score indicates severity of the pain provocation test). Mobility by video registration assessed range of motion of the pelvis in flexion, the low back in flexion, and the pelvis + low back in flexion. The ASLR test was scored by the GP and the patient (0=not difficult at all, 1=minimally difficult, 2=somewhat difficult, 3=fairly difficult, 4=very difficult, 5=unable to do) is positive when the bilateral sum score is ≥2 (score range=0–10; higher score indicates the severity of the load transfer disturbance from the LBP). Activities of daily living (eg, walking or bicycling in minutes [0–15, 16–30, 31–60, ≥61]) without an increase in pain were assessed. The PPPP test, unilateral or bilateral (0=no pain, 1=pain unilaterally, 2=pain bilaterally) is positive when the bilateral sum score is ≥2 (0–2). Finally, isometric force of hip abduction (score: best to worse >196–0 N) and adduction (score: best to worse >129–0 N) were measured.[7]

Statistical Analyses

Course of disability. Descriptive analyses were used to describe the patients' scores on disability at baseline and at 2-, 5-, and 12-month follow-ups. Also described were the 2 definitions of recovery: 30% improvement in QBPDS score compared with baseline and absolute recovery (≤20 points on the QBPDS at follow-up measurement). These analyses were done on the entire dataset, including missing values.

Model building. All of the measures used in this study were conducted during normal daily practice of the rehabilitation center. Relevant factors were categorized or dichotomized to enhance clinical interpretation of the results. Model building was done using the following steps:

Step 1. Eligible prognostic factors were identified that were highly correlated ($r>.8$). This was the case for the B200 Isostation (strength in flexion, extension, lateroflexion, rotation) and the SCL-90 (items 1–8). Only the B200 Isostation extension score and total score for item 9 of the SCL-90 were included in the analysis.[21]

Step 2. Continuous factors were checked for linearity using spline regression curves. This step revealed a nonlinear relationship between the BMI and the QBPDS score for disability. Therefore, BMI was changed to a categorical variable, which eases clinical interpretation.[21]

Step 3. Imputation of missing values in the data was carried out by multiple imputation. As a primary analysis, a total of 5 imputed datasets were used.[21–23] As a sensitivity analysis, the results were compared when 40 datasets were imputed. This number was selected because in the initial analysis, before backward selection (as a next step), about 40% of the patient data was missing. We also compared the results with complete-case analysis (CCA) (ie, all patients with missing data were excluded from the analyses).[21–23]

Step 4. The most important prognostic variables were selected using a multivariable logistic regression analysis (stepwise method, backward: likelihood ratio, $P<.157$).[24–27] The selection of variables was performed over all the imputed datasets using Rubin's rules of multiple imputation.[28] To assess whether the level of significance influenced the selection of predictors in the final prognostic model for all methods described in step 3, the selection of variables was repeated with P values of .05 and .157. A sensitivity analysis also was performed using QBPDS cutoff values of ≤10 and ≤39 points.[11]

Model Performance

We checked the performance of the model with regard to the goodness of fit (Hosmer-Lemeshow test), the explained variation, and the discriminative ability. The explained variation of the model was estimated using Nagelkerke's R^2 statistic. Explained variation is the extent to which the outcome can be predicted by the model in the current datasets. The discriminative ability is reflected by the area under the receiver operating characteristic curve (AUC). The AUC represents the ability of the prognostic model to discriminate between patients who will recover from disability and those who will not recover from disability and ranges from 0.5 (chance) to 1.0 (perfect discrimination).[29]

Bootstrapping techniques were used to internally validate our models (ie, to simulate the performance with respect to the explained variance and the AUC in comparable patient datasets).[25,26,30,31] All analyses were done using SPSS version 18.0 (SPSS Inc, Chicago, Illinois) and R software

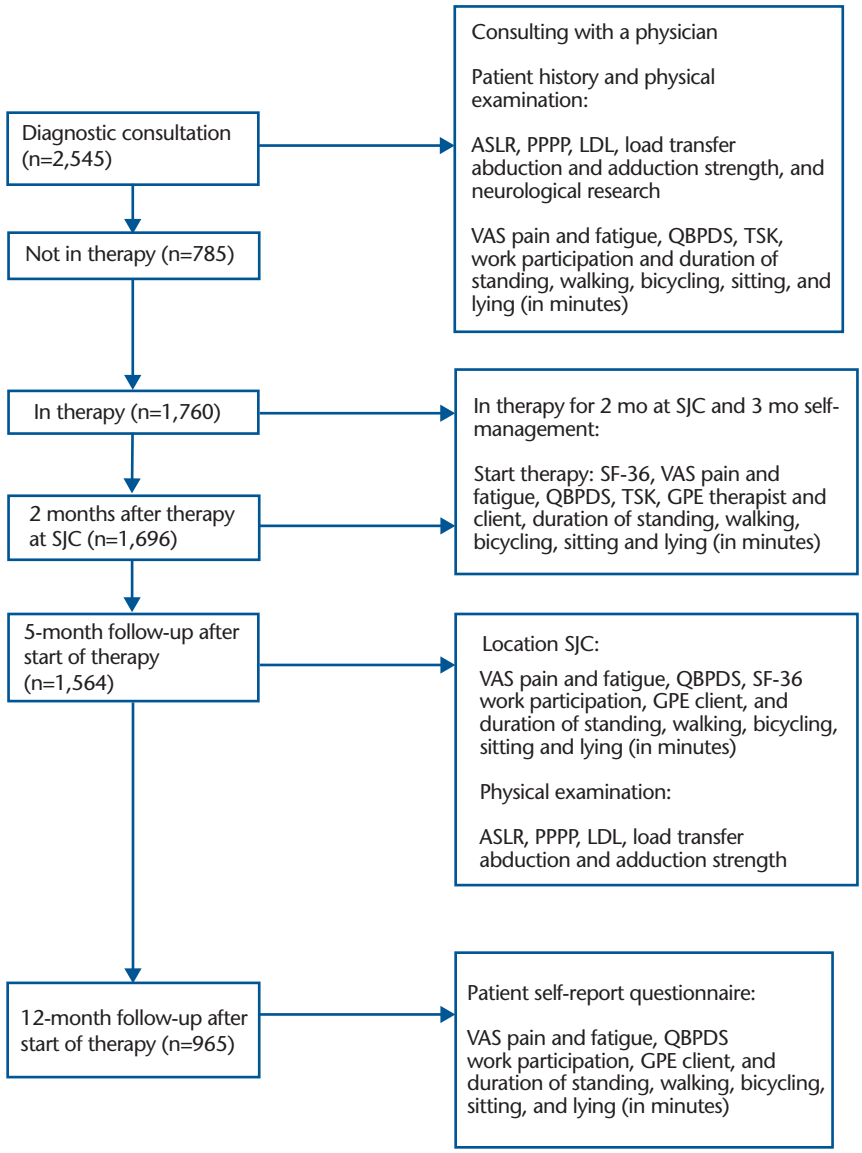

Figure.
Flowchart of the study design. ASLR=active straight-leg-raising test, PPPP=posterior pelvic pain provocation test, LDL=long dorsal sacroiliac ligament, VAS=visual analog scale, QBPDS=Quebec Back Pain Disability Scale, SF-36=36-Item Short-Form Health Survey, TSK=Tampa Scale for Kinesiophobia, GPE=global perceived effect, SJC=Spine & Joint Centre.

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Results
This study included 1,760 patients with CNSLBP (mean age=40.1 years, SD=10.6; 74.3% women) (Figure). Of these patients, 1,696 (96.4%) completed the 2-month multidisciplinary treatment, 1,564 (88.9%) participated in the 5-month follow-up, and 965 (54.8%) completed the 12-month follow-up. Table 1 presents the baseline characteristics of the 1,760 patients and the distribution of the candidate prognostic factors.

Course of Disability
At the 2-month follow-up (n=1,696), the disability scores on the QBPDS decreased to a mean of 31.7 (SD=

Table 2.
Course of Disability Scores in Patients With Chronic Nonspecific Low Back Pain at 2-, 5-, and 12-Month Follow-ups[a]

Measure	Baseline (n=1,752)	2 Months (n=1,696)	5 Months (n=1,564)	12 Months (n=965)
Disability (QBPDS), $\bar{X}$ (SD)	51.7 (15.6)	31.7 (15.2)	31.1 (18.2)	29.1 (20.0)
30% improvement in disability (QBPDS), %		62.6%	61.3%	63.4%
Absolute recovery on disability score (≤20 points on QBPDS), %	2.6%	24.1%	30.9%	38.3%
Back pain (VAS), $\bar{X}$ (SD)	55.5 (23.0)	37.0 (23.8)	35.3 (26.1)	32.3 (26.9)
Quality of life (SF-36)				
PCS, $\bar{X}$ (SD)	31.9 (7.1)	40.7 (8.2)	42.1 (10.1)	
MCS, $\bar{X}$ (SD)	46.6 (10.3)	49.2 (9.4)	50.4 (9.8)	
Work participation,[b] $\bar{X}$ (SD)	38.3 (43.1)		73.4 (44.9)	81.7 (52.9)

[a] QBPDS=Quebec Back Pain Disability Scale (range=0–100, higher score means more disability), VAS=visual analog scale (0–100, 0=no pain), SF-36=Medical Outcomes Study 36-Item Short-Form Health Survey (range=0–100, higher score means better quality of life), PCS=Physical Component Summary, MCS=Mental Component Summary. Missing values ranged from 0.5% to 35.2%.
[b] Work participation (0%–100%) included those patients with paid work (n=1,608).

15.2) versus a mean of 51.7 (SD=15.6) at baseline. At 5- and 12-month follow-ups, these scores decreased to a mean of 31.1 (SD=18.2) and 29.1 (SD=20.0), respectively (Tab. 2).

The predefined outcomes regarding recovery on the QBPDS disability score at follow-up showed the following results: (1) compared with baseline, 1,058 patients (62.6%) reported a 30% improvement in disability after 2 months of therapy, 955 patients (61.3%) reported improvement at the 5-month follow-up, and 611 patients (63.4%) reported improvement at the 12-month follow-up; and (2) for absolute recovery, 46 patients (2.6%) had a score of ≤20 on the QBPDS at baseline. This finding, however, is explained by the fact that additional patients were included for therapy based on other outcomes, such as pain intensity, quality of life, or work participation.[7] After 2 months therapy, 409 patients (24.1%) scored ≤20 on the QBPDS; at the 5- and 12-month follow-ups, these numbers were 484 patients (30.9%) and 370 patients (38.3%), respectively.

30% Improvement Between Baseline and 5- and 12-Month Follow-ups

Table 3 shows the results of the multivariable logistic regression analyses of the potential prognostic factors regarding recovery defined as a 30% improvement in disability measured on the QBPDS at 5- and 12-month follow-ups.

At the 5-month follow-up, the prognostic factors were: being married or living with one adult, shorter duration of back complaints at baseline, younger age, higher disability score at baseline, no previous rehabilitation, decreased course of pain in the 3 months prior to baseline, more work participation at baseline, and higher scores on the SF-36 PCS and MCS. The AUC of this model was 0.68, and the explained variance was 12.8%.

At the 12-month follow-up, the prognostic factors were: being married or living with one adult, having no comorbidity, younger age, a higher education level, higher disability score at baseline, no previous rehabilitation, reporting low pain intensity at baseline, and a higher score on the SF-36 PCS. The AUC of this model was 0.66, and the explained variance was 10.7%.

With regard to internal validation of the model, the explained variance at the 5-month follow-up was 12.8%, and the AUC was 0.68 (before and after analyzing the internal validation); at the 12-month follow-up, these data were 10.7% and 0.66, respectively.

Sensitivity analysis. Repeating the analysis with *P* values of .05 or .157, and using a CCA or 5 or 40 imputed datasets, resulted in more or less similar prognostic factors for a 30% improvement in recovery at the 5- and 12-month follow-ups (Tab. 3). At the 5-month follow-up, only being married or living with one adult was excluded in all final models. At the 12-month follow-up, the SF-36 MCS score and previous rehabilitation were included only once. The various models included 5 to 10 factors with an AUC range of 0.64 to 0.68 (exact data can be provided by the first author).

Table 3.
Multivariable Models of Prognostic Factors for 30% Improvement in Chronic Nonspecific Low Back Pain (CNLBP) Disability at 5- and 12-Month Follow-ups[a]

Variable	5-Month Follow-up			12-Month Follow-up		
	OR	95% CI	*P*	OR	95% CI	*P*
Married/living with 1 adult (yes/no)	1.32	0.93–1.87	.12	1.54	0.88–2.68	.12
Age	0.97	0.96–0.98	<.001	0.98	0.97–0.99	≤.01
Disability at baseline (QBPDS)	1.04	1.03–1.04	<.001	1.03	1.01–1.04	≤.001
Previous revalidation program (yes/no)	0.52	0.37–0.74	<.001	0.72	0.48–1.08	.11
Work participation	1.42	1.02–1.96	.04			
SF-36 PCS	1.08	1.06–1.11	<.001	1.06	1.04–1.09	<.001
SF-36 MCS	1.03	1.02–1.04	<.001	1.02	1.00–1.03	.05
Course of pain intensity due to CNLBP in the previous 3 mo (1=increase of pain)	1.05	0.84–1.32	.65			
Course of pain intensity due to CNLBP in the previous 3 mo (2=decrease of pain)	1.66	1.05–2.62	.03			
Duration of complaints	0.98	0.97–0.99	.01			
Comorbidity				0.61	0.42–0.90	.02
Education level				1.45	1.01–2.07	.04
Pain intensity at baseline (VAS)				0.99	0.99–1.00	.09

[a] 95% CI= 95% confidence interval, OR=odds ratio (an OR >1 reflects a higher probability of 30% recovery for the outcome of back pain disability and an OR <1 reflects a lower probability of 30% recovery for the outcome of back pain disability compared with the reference category; OR estimated after multiple imputation [n=5 datasets] with *P* value of .157), VAS=visual analog scale, QBPDS=Quebec Back Pain Disability Scale, SF-36=36-Item Short-Form Health Survey, PCS=Physical Component Summary, MCS=Mental Component Summary. The variable "course of pain intensity due to CNLBP in the previous 3 mo" is a category value of 3 (0=stable, 1=increase of pain, 2=decrease of pain).

Absolute Recovery (QBPDS Score ≤20 Points) at 5- and 12-Month Follow-ups

Table 4 shows the results of the multivariable logistic regression analyses of the potential prognostic factors for absolute recovery (QBPDS score ≤20 points) at the 5- and 12-month follow-up. The final prognostic model at the 5-month follow-up included shorter duration of complaints at baseline, younger age, lower disability score at baseline, no psychoneurosis (SCL-90 item 9), and higher scores on the SF-36 PCS and MCS. The AUC of this model was 0.58, and the explained variance was 2.7%.

At the 12-month follow-up, absolute recovery was associated with greater baseline strength in the trunk (B200 Isostation), no comorbidity, ≤60-minute walking duration at baseline, shorter duration of complaints at baseline, younger age, lower disability score at baseline, lower pain intensity at baseline, and higher scores on the SF-36 PCS and MCS. The AUC of this model was 0.66, and the explained variance was 10.7%.

With regard to internal validation of the model, the explained variance at the 5-month follow-up was 2.7%, and the AUC was 0.58; for the 12-month follow-up, these data were 18.6% and 0.72, respectively.

Sensitivity analysis. Repeating the analysis with *P* values of .05 or .157 and using a CCA or 5 or 40 imputed datasets resulted in more or less similar results for the prognostic factors as reported in the 5-month follow-up model (Tab. 4). At the 12-month follow-up, comorbidity, lower pain intensity (VAS), and the SF-36 MCS score were included in all final models (except for 1 or 2 of the models). The other factors mentioned above for a QBPDS score of ≤20 points were reported or excluded only once or twice. The various models had 4 to 11 factors, with an AUC range of 0.70 to 0.76.

Performing the sensitivity analysis with QBPDS cutoff scores of ≤10 and ≤39 points yielded similar results. Only at the cutoff score of ≤39 points did some new prognostic factors emerge (ie, higher education and previous rehabilitation at the 5-month follow-up, no psychoneurosis [SCL-90 item 9] at the 12-month follow-up, and more work participation at baseline). At the 12-month follow-up, the SF-36 MCS was excluded at the QBPDS cutoff score of ≤39 points. The various models had 5 to 9 factors, with an AUC range of 0.68 to 0.82 (exact data can be provided by the first author).

Table 4.
Multivariable Models of Prognostic Factors for Absolute Recovery on Chronic Nonspecific Low Back Pain Disability (CNLBP) (QBPDS <20 Points) at 5- and 12-Month Follow-ups[a]

Variable	5-Month Follow-up			12-Month Follow-up		
	OR	95% CI	*P*	OR	95% CI	*P*
Duration of complaints	0.98	0.97–1.00	.05	0.98	0.97–1.00	.05
Age	0.98	0.96–0.99	<.001	0.98	0.97–0.99	<.01
Disability at baseline (QBPDS)	0.97	0.96–0.98	<.001	0.99	0.98–1.00	.09
SF-36 PCS	1.07	1.04–1.10	<.001	1.05	0.99–1.11	.05
SF-36 MCS	1.03	1.01–1.05	.01	1.03	1.00–1.06	.05
SCL-90 (item 9)	0.99	0.99–1.00	.08			
B200 Isostation extension				1.00	1.00–1.01	.09
Comorbidity				0.62	0.37–1.03	.07
Duration of walking 1 (0–15 min)				1.13	0.85–1.49	.40
Duration of walking 2 (16–30 min)				1.46	0.86–2.49	.15
Duration of walking 3 (31–60 min)				1.63	1.00–2.66	.05
Pain intensity at baseline (VAS)				0.99	0.98–1.00	.08

[a] 95% CI=95% confidence interval, OR=odds ratio (an OR >1 reflects a higher probability of <20 point Quebec Back Pain Disability Scale [QBPDS] for the outcome of back pain intensity and an OR <1 reflects a lower probability of <20 point QBPDS for the outcome of back pain intensity compared with the reference category; OR estimated after multiple imputation [n=5 datasets] with *P* value of .157), VAS=visual analog scale, SCL-90 (item 9)=Symptom Checklist–90, SF-36=36-Item Short-Form Health Survey, PCS=Physical Component Summary, MCS=Mental Component Summary. The variable "duration of walking" is a category value of 4 (1=0–15 min, 2=16–30 min, 3=31–60, 4=>61 min).

Discussion

Main Study Findings

After 2 months of multidisciplinary therapy, patients with CNSLBP showed a decrease in mean reported disability. At the 5- and 12-month follow-ups, this trend continued but with a slight decrease in 30% improvement and in absolute recovery (QBPDS score ≤20 points).

The present study explored potential prognostic factors at 5- and 12-month follow-ups for the outcome 30% improvement in recovery from baseline and absolute recovery (QBPDS score ≤20 points). All patients received multidisciplinary therapy based on behavioral principles.[7]

For 30% improvement in recovery compared with baseline, the prognostic factors at both 5- and 12-month follow-ups ($P<.157$) were married or living with one adult, younger age, higher disability at baseline, no previous rehabilitation, and higher baseline scores on the SF-36 PCS and MCS.

Younger age, less disability at baseline, shorter duration of back complaints at baseline, and higher baseline scores on the SF-36 PCS and MCS were predictors of absolute recovery (QBPDS score ≤20 points) at both 5- and 12-month follow-ups. Despite having either severe or less severe disability at baseline, the difference between the 30% improvement (odds ratio >1) and absolute recovery (odds ratio <1) was relatively small (ie, an odds ratio of around 1.0). We can expect that patients with severe disability (high scoring on the QBPDS) at baseline will change 30% over time easier than going from a high score to ≤20 points. For example, a patient with a baseline score of 80 points on the QBPDS will easily decrease 30% (around 24 points) on his disability scale at follow-up, then go from 80 points to less than 20 points. Thus, the choice of outcome definition makes the difference.

The sensitivity analysis shows similar prognostic factors for the defined recovery at both 5- and 12-month follow-ups; this finding indicates that the outcome recovery defined with QBPDS disability scores and the identified prognostic factors are similar, regardless of the duration of follow-up within 1 year. At the 5-month follow-up, a shorter duration of back complaints at baseline was a positive prognostic factor for both 30% improvement and absolute recovery. At the 12-month follow-up, having no comorbidity and less pain at baseline were positive prognostic factors for both outcomes. In general, younger patients and those with higher scores on the SF-36 PCS and MCS had a higher odds ratio to recover from CNSLBP.

Strengths and Limitations

Prognostic model research includes 3 main phases: model development (including internal validation), external validation, and investigations of impact in clinical practice.[32] To improve the quality of a prognostic study, the following considerations are important: (1) dealing with missing data, (2) modeling continuous prognostic factors, (3) the complexity of the model, and (4) checking the model assumptions.[32] Our study aimed to develop several models and to determine the internal validation of these models. To our knowledge, this is one of the first studies that examined prognostic factors for good recovery of patients with CNSLBP treated by a multidisciplinary team.

In the present study, one of the limitations was that several factors had missing values (range=0.5%–28%). We decided to impute the missing data using information on the other variables in the dataset.[33] At the 5- and 12-month follow-ups, 11.1% and 45.2% of the patients, respectively, failed to return the follow-up questionnaires for a variety of reasons (eg, vacation, envelope not stamped, recovered from disability, did not find it necessary, starting another intervention). The multiple imputation procedure is assumed to be more valid than simply omitting these participants from the analysis. Also, not including the full study sample but only those patients with complete data reduces the sample size and power and thus the model's validity.[24,30,33] In addition, performing sensitivity analyses that compare the data with more imputed datasets (n=40 and n=5), with *P* value levels of .05 and .157, and the CCA improves the validation of the model.[21,23,29,30] The sensitivity analysis revealed little or no difference in the identified prognostic factors. This finding indicates that the selection of the most important predictors was not strongly influenced by the selection criteria or by the amount of missing data. In all analyses, the CCA showed slightly higher standard errors (SEs) and coefficients compared with the imputed datasets. This finding indicates that, as expected, both the power and precision were increased by imputation.[34]

We dichotomized the outcome disability as recommended in some studies of LBP[11,35,36] for ease of interpretation by clinicians and patients. Dichotomizing continuous variables such as the QBPDS has some implications for the results: (1) information loss on patient outcome, (2) patients close to but on opposite sides of the cutoff of 30% improvement are characterized as being very different rather than very similar, and (3) using 2 groups (eg, improved versus not improved) conceals any nonlinearity in the relationship between the variable and outcome.[37]

Furthermore, the odds ratio (95% confidence interval), variance, and AUC demonstrated in this study remained quite similar. An AUC of 0.5 to 0.7 is considered moderate discrimination; the explained variance ranged between 2.7% and 12.8%, which indicates that other potential prognostic factors (eg, physical parameters) should be considered to predict recovery of a patient. However, other studies in the field showed similar low ranges of explained variance.[9]

This current survival cohort represents patients with CNSLBP persisting over a long time (mean=7.7 years). Thus, the clinical course could differ in patients recruited in an inception cohort, those with more complex conditions, and those having more complex factors that influence recovery.[38] However, this study represented patients who did not recover in the Dutch primary care system and were eligible for rehabilitation. Therefore, comparison of the baseline characteristics may differ from other cohorts with CNSLBP because most of them are inception cohorts and recruited in primary care settings.[5] The generalizability of the results is limited because the patients were recruited in a rehabilitation center for tertiary care and received multidisciplinary therapy. However, this is a group of patients who some patients as well as clinicians would believe cannot recover, whereas the present study shows potential for the future.

Comparison With the Literature

In the present study, more patients were improved during the 12-month follow-up based on a cutoff of 30% improvement compared with baseline than on a score of ≤20 points on the QBPDS. However, patients with a lower baseline score have less potential for improvement, and patients with more severe baseline disability need to perceive a greater improvement in order to feel that it is relevant.[39] These findings promote discussion as to which cutoff point to use in daily practice: the clinical change (30%) that can be measured to show that someone is improving or consideration of the wish of the patient who wants an absolute recovery. One possibility is to discuss these options in relation to the wishes and objections of the patient and clinician over time and perhaps combine these outcomes.

Our results do not support the findings of our previous systematic review,[9] except that fear of movement is not associated with disability at the 5- and 12-month follow-ups. Perhaps, as reported by other authors,[4,40,41] the impact of fear of movement only plays a role in the transition from subacute pain to CNSLBP. Nevertheless, because several multidisciplinary programs for patients with CNSLBP mainly focus

on fear of movement, the question arises whether this is an optimal choice for patients in this phase. Furthermore, we found several prognostic factors that have a positive association with disability such as younger age, and less pain intensity and more work participation at baseline; our systematic review found no studies with these associations with disability.[9] In another study (149 patients with acute pain or CNSLBP for 1 month, treated with manual therapy and spine strengthening exercises until discharge), the outcome disability was measured with the Oswestry Disability Index at a mean follow-up of 35.7 days (SD= 29.9); the reported prognostic factors, similar to those in the present study, were shorter duration of symptoms, lower Oswestry Disability Index score at baseline, and younger age.[42] In essence, prognostic factors based on a single outcome measure may not fully represent all aspects of recovery from a multidimensional condition such as CNSLBP.[42] Our previous review also indicated that disability is not an "isolated" condition but is associated with, for example, the degree of pain.[9]

Outcome Measurement

This study benefited from the large sample size, its prospective design, and patients' self-report. In the study of Davidson and Keating,[43] the Oswestry Disability Questionnaire, the SF-36 Physical Functioning scale, and the QBPDS had sufficient reliability and scale width to be applied in an ambulatory clinical population with low back problems. The responsiveness of the questionnaires was similar, and the authors concluded that one questionnaire cannot be preferred over another based on the magnitude of the absolute values of responsiveness indexes.[43]

The present study shows that, when determining the cutoff point for a clinically relevant recovery from disability, there is little difference between the 2 definitions used (ie, 30% improvement and absolute recovery defined as a QBPDS score of ≤20 points) with regard to the identified prognostic factors. However, Table 2 shows that fewer patients were recovered at the 12-month follow-up based on the absolute recovery compared with the 30% improvement option (ie, 38.3% versus 63.4%, respectively). Undoubtedly the cutoff points will differ based on the severity of symptoms within the study population, the condition of interest, and other factors.[42] A study in which the global perceived effect scale of the patient (eg, "completely recovered") is compared with the score on the QBPDS may provide more insight into the most relevant cutoff point.

Clinical Value

This study shows that in patients with CNSLBP, positive predictors for recovery at 5- and 12-month follow-ups are: younger age, higher scores on the SF-36 PCS and MCS and scoring higher on disability at baseline. For the 5-month follow-up, these positive predictors are shorter duration of complaints, and at 12-month follow-up, they are having no comorbidity and less pain at baseline. For daily practice, this study provides preliminary evidence for clinicians to estimate the prognosis for disability over a 1-year period based on easy-to-obtain baseline data. We have developed an internally validated prognostic model for recovery at 5- and 12-month follow-ups for patients with CNSLBP in tertiary care. However, because the explained variance ranged from 2.7% to 12.8%, the results must be interpreted with caution.

Future Research

Future studies should identify the potential prognostic factors in different settings and over a longer period of time. These factors may provide more insight into the validity of the presented models. A subsequent step is external validation of the prognostic models with the aim to use them in daily practice.[25] Overall, the results of this study indicate that biopsychosocial factors may be important in the course of and changes in disability level at 5- and 12-month follow-ups and that some preliminary prognostic factors can be identified.

Ms Verkerk, Dr Luijsterburg, and Professor Koes were involved in the concept/idea/research design and project management. Ms Verkerk, Dr Luijsterburg, Dr Heymans, Dr Pool-Goudzwaard, and Professor Koes contributed to manuscript writing. Ms Verkerk and Ms Ronchetti undertook data collection. Ms Verkerk, Ms Ronchetti, and Dr Heymans performed the data analysis. Dr Miedema provided facilities/equipment. Dr Luijsterburg, Dr Heymans, Dr Miedema, Dr Pool-Goudszwaard, and Professor Koes provided advice (including reviewing the manuscript before submission). The authors thank the Spine & Joint Centre and the patients who participated in this study.

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