Multidisciplinary Rehabilitation Treatment of Patients With Chronic Low Back Pain: A Prognostic Model for Its Outcome

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Objectives: (1) To determine if treatment outcome in chronic low back pain can be predicted by a predefined multivariate prognostic model based on consistent predictors from the literature and (2) to explore the value of potentially prognostic factors further.

Methods: Data were derived from a randomized controlled trial on the effect of a multidisciplinary rehabilitation program for chronic low back pain compared with usual care. The primary outcome measure was the Roland and Morris Disability Questionnaire and secondary outcomes were the Physical and Mental Component Summary Scales, derived from the Short Form Health Survey. Outcomes were expressed as the differences between baseline and follow-up (8 wk and 6 mo) values. A confirmatory and an exploratory model were defined. Baseline predictors included in the confirmatory model were pain intensity, work status, and Multidimensional Pain Inventory subgroup membership. The exploratory model included sick leave, compensation, depression, and fear-avoidance beliefs. Statistical analysis was performed using multiple linear regression analysis.

Results: One hundred and sixty-three patients participated in the study. More pain was prognostic for more improvement in the rehabilitation group. No value was found for work status or the Multidimensional Pain Inventory subgroups. For the exploratory model, more depression and fear-avoidance beliefs predicted more improvement after rehabilitation. The explained variance ranged from 18.5% to 43.8% depending on the length of follow-up evaluation, the treatment group, and the outcome variable of interest.

Discussion: The results of this study do not support the construction of a clinical prediction model. Future confirmative studies of homogeneous rehabilitation treatments and outcome measures are needed to shed more light on relevant prognostic factors.

Key Words: chronic low back pain, prognostic model, multidisciplinary treatment, outcome

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The chronic low back pain (CLBP) population is a heterogeneous one. Various treatment programs exist and it is obvious that 1 treatment does not fit all. Understanding of the factors that predict treatment outcome is important, and may enable clinicians to better select patients for the most suitable treatment modality.

There is a large research literature base concerning predictors of rehabilitation outcome in patients with chronic pain, focusing on different populations, treatments, and outcome measures. A recent systematic review of baseline predictors of rehabilitation treatment outcome in CLBP[1] showed that general evidence was limited owing to study heterogeneity. Treatment outcome, defined as activity limitation (ie, difficulties an individual may have in executing activities) and participation restriction (ie, problems an individual may experience in involvement in life situations), conforms the International Classification of Functioning, Disability and Health (ICF) model.[2] Despite this heterogeneity, consistent evidence was found for several predictors. Higher pain intensity at baseline predicted worse outcome, whereas several work-related parameters (eg, work satisfaction) predicted better outcome. Among the psychologic predictors, one of the measurement scales with potentially predictive value was the Multidimensional Pain Inventory (MPI), which identifies subgroups of patients with different characteristics.[3] In general, more improvement was seen in the subgroups ''dysfunctional'' (DYS) and ''interpersonally distressed'' (ID), compared with the ''adaptive copers'' (AC). DYS and ID patients are both characterized by high affective distress, high pain intensity, and low levels of life control. The DYS subtype has a highly supportive environment in contrast to the ID subtype, which has a low level of environmental support. The AC subtype shows relatively low levels of psychologic distress, pain intensity, and interference and high perceived life control.

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Other sociodemographic, psychologic, and physical variables lacked consistent predictive value. Remarkably, none of the authors studied predictors from these 3 domains simultaneously.

The above-mentioned systematic review focused specifically on multidisciplinary rehabilitation and the outcomes as proposed in the ICF model. There are also numerous reviews that have studied other predictive factors for different treatment modalities or outcome measures. Consistent results were found for maladaptive beliefs[4,5] and depression[5–7]; both were associated with poor outcome. Sick leave or compensation status were predictive of less return to work[4,6,8–10] and of reduced treatment response in general.[9,11]

Surprisingly, in the systematic review,[1] no studies were included that investigated the predictive value of fear-avoidance measures at baseline in CLBP. According to the fear-avoidance model,[12,13] a pain stimulus may lead to pain-related fear, avoidance behavior, and eventually disuse and disability. It has been shown that reduction of pain-related or movement-related fear during treatment is associated with improvement after active[14] and cognitive behavioral therapy.[15] The inclusion of fear as a possible important predictor for treatment outcome was also suggested in 2 reviews of (cognitive) behavioral treatment of patients with chronic pain.[5,16] Moreover, Schultz et al[17] pointed out that important missing determinants in their prognostic model for occupational low back disability were coping and fear-avoidance measures.

To confirm the value of consistent predictors found in the systematic review,[1] these variables should be tested in a longitudinal cohort study with a priori formulated hypotheses.[18] A previously published controlled clinical trial[19] studying the effectiveness of a multidisciplinary back school program was reanalyzed for this purpose. In short, the results of the trial showed no significant differences in improvement between the treatment and the control group for measures of activity limitation and health-related quality of life. However, subgroup analyses gave some first indications that multiaxial measurement instruments [eg, using the MPI-Dutch Version (MPI-DLV)], might be useful in identifying subgroups with differences in treatment effects.

The objective of this study is to determine whether multidisciplinary rehabilitation outcome in CLBP, in comparison with usual care, can be predicted by a multivariate prognostic model on the basis of consistent predictors from literature (ie, pain, work status, and MPI classification). Furthermore, the value of other predictors was explored (ie, sick leave, compensation, depression, and fear-avoidance beliefs). The primary outcome measure in this study was activity limitation. Secondary outcomes include health-related quality of life. This study was a reanalysis of data from a controlled clinical trial. This allows for conclusions concerning prognostic factors for a specific treatment, as these may differ as a function of treatment. Our hypothesis was that patients with CLBP with less pain, who are able to work and are classified as DYS or ID, will improve more after multidisciplinary rehabilitation, compared with those with more pain, who are not able to work, and are classified as AC.

MATERIALS AND METHODS

Patients

Patients with nonspecific CLBP, who were admitted to an outpatient multidisciplinary back rehabilitation program by a physician in physical medicine and rehabilitation, were asked to participate in this study. Inclusion criteria were similar to the criteria for rehabilitation: duration of pain longer than 3 months, age between 18 and 60 years, and no surgery of the spine in the past 3 months. Patients with structural pathology like active radiculopathy, tumor of the spine, or severe deformities (spondylolisthesis grade 3) and patients with a medical contraindication for physical training were excluded.

Design

Data from a randomized controlled trial of a low back multidisciplinary rehabilitation program[19] were used for analysis. The original trial aimed at evaluating the effectiveness of rehabilitation. In this study, a multivariate predictive model was tested for outcome directly and 4 months after treatment.

Protocol

Patients who met the inclusion criteria and were willing to participate gave informed consent. After the baseline measurements, which were administered by the same researcher, patients were randomized to either the control group (ie, waiting list) or the treatment group. Randomization was performed using the minimization method as described by Pocock[20] and balanced for sex, work status, and low back muscle function as estimated by dynamometry (by using the Isostation B200[21]). To enable an adequate assignment procedure, a computer program was used. Patients were not blinded for the group they were randomized to, but the researchers conducting the measurements were. Measurements were performed before randomization (T0), in the week after treatment (T1), and 4 months after treatment (T5). For the control group, T1 was equal to 8 weeks after T0 and T5 was equal to 6 months after T0. Patients randomized to the control group (ie, waiting list) were allowed to apply for usual health care facilities outside the rehabilitation center. The medical consumption of the control group was assessed at T1 and every subsequent month till T5 by a questionnaire that was sent home. They could enter the back rehabilitation program after the 6-month follow-up period.

Treatment

Patients who were allocated to the treatment group began participating in the Roessingh Back Rehabilitation Program (RRP) within 2 to 3 weeks. The RRP was based on the Swedish back school[22] and multidimensional pain programs.[23] It assumes that many patients with CLBP

develop a deconditioning syndrome. Deconditioning is hypothesized as part of a vicious circle consisting of back pain, inactivity owing to back pain and fear, lowered physical capacity, and overloading. During treatment one tries to influence the patient's health and perceived disabilities by upgrading physical conditioning and activity level, by reducing fear of movement, and by upgrading knowledge about back pain. The treatment program consists of a combination of physiotherapy, sport, education, and occupational rehabilitation. Education aims at enlarging the patients' knowledge of development of chronic back pain and how to influence recovery by physical training. Education also aims at teaching skills concerning the optimum use of any remaining physical capabilities.

The RRP is provided on the basis of a standardized protocol. Patients are not allowed to be absent more than 10% of the time. An RRP group consists of 8 patients and comprises 3 hours of conditional training and sport, 0.5 hours of swimming, 1.5 hours of occupational therapy, and 4 hours of physiotherapy each week for 7 weeks. Patients with problems at work, related to back pain, may also receive individual occupational rehabilitation after the program. Treatment is under the supervision of a specialist in physical and rehabilitation medicine and conducted by a team consisting of a physiotherapist, an occupational therapist, a sport therapist, and, if necessary, a psychologist and a dietician.

Measurement Protocol

Predictor Variables

On the basis of our hypothesis, 2 multivariate predictive models were tested. Model 1 was a confirmatory model and included the consistent predictors (ie, pain, work status, and MPI classification) found in the systematic review.[1] Model 2 was exploratory and included the other predictors (ie, sick leave, compensation, depression, and fear-avoidance beliefs). The selection of variables was, therefore, not on the basis of significant univariate associations, but was hypothesis driven. This is the preferable method if study power is sufficient.[24] Treatment modality was added as an independent factor to both models as it was expected to impact the outcome.

- Treatment was defined as "back rehabilitation" or "usual care."
- For current pain intensity, the Visual Analog Scale (VAS, range: 0 to 10) was used. The VAS has been found to be valid, reliable, and responsive to change.[25]
- Work status was measured by a questionnaire, developed for this study, with the following response options: "yes" = full-time or part-time work; "no" = not able to work because of illness (predominantly CLBP), unemployment, retirement, or involvement around the household.
- The MPI, originally developed by Kerns et al,[3] was used to measure psychosocial aspects of pain. The MPI-Dutch Version (MPI-DLV) has been shown to be valid and reliable.[26] The profile classifications (ie, DYS, ID, and AC), as described by Turk and Rudy,[27] were used. These clusters were replicated for the Dutch version of the MPI[28,29] in which a fourth cluster was added, labeled "average" (AV), which shares characteristics with the other profiles. In general, the AV type experiences less pain severity and interference, and more pain control compared with the ID and DYS type. An additional category of "anomalous" (AN) exists for patients who cannot be classified into one of the mentioned profile types.
- Sick leave was reported by the employee by scoring the number of days of sick leave in the past 8 weeks, normalized to a full time job (0 to 40 h/wk).
- Receiving financial compensation was scored by a questionnaire, developed for this study with the following response options: "yes" = compensation from the employer or government because of (chronic) illness or pain, "no" = no compensation. In the Netherlands, the employer is responsible for 70% of the salary during the first 2 years of illness. Afterwards, financial compensation is provided by the government. The amount depends on the percentage of lost work ability, assessed by a physician specialized in work and insurance.
- Depression was measured using the Symptom Checklist-90 subscale depression (SCL-90-Dep) (range: 16 to 80). The SCL-90-Dep consists of 16 items, each scored on a 5-point Likert scale with scoring alternatives ranging from "totally not" to "very." Validity and reliability have been supported for both the overall score[30,31] and for the SCL-90-Dep.[30]
- Fear of physical activity or (re)injury was measured with the Tampa Scale of Kinesiophobia-Dutch Version (TSK-DV, range 17 to 68), which has been found to be internally consistent and valid.[32] It consists of 17 items, each scored on a 4-point Likert scale with scoring alternatives ranging from "strongly disagree" to "strongly agree."

Outcome Parameters

For primary and secondary outcomes, the difference in scores between T1-T0 and T5-T0 were used. Change scores were chosen because a reduction of 2 or more points on the Roland Morris Disability Questionnaire (RMDQ) is defined as a clinically relevant change.[33,34] The primary outcome parameter in the present study was the RMDQ. The RMDQ[35] was derived from the Sickness Impact Profile (SIP),[36] using 24 yes/no items of the Sickness Impact Profile relevant for back pain. An individual patient's score can vary from 0 (no disability) to 24 (severe disability). The RMDQ-Dutch version is a reliable[37] and valid instrument to assess functional status in CLBP and is responsive to change.[38]

As secondary outcome parameter, "health-related quality of life" was measured with the Dutch translation of the Short Form Health Survey (SF-36),[39] originally developed by Ware and Sherbourne.[40] It is a self-report questionnaire that contains 36 items, measuring 8 domains of health. Outcome is expressed on a scale from

0 to 100, with higher scores indicating higher levels of functioning. Psychometric properties have been found to be adequate.[39,41–43] Physical component scale (PCS) and mental component scale (MCS) health measures can be derived and scored using principal component analysis.[44] Each scale has a range from 0 to 100. The mean norms in the general US population with CLBP are 46 (PCS) and 48 (MCS).[44] Very low scores on the PCS indicate severe physical dysfunction, severe social and role limitation, distressful back pain, frequent tiredness, and unfavorable evaluation of health status. Very low scores on the MCS indicate frequent psychologic distress and severe social and role limitation because of emotional problems. The PCS and MCS have a reliability comparable with the original SF-36[45] and validity is sufficient.[46] A clinically relevant improvement for these scales has not yet been defined.

Data Analysis

Baseline values of predictor and outcome variables of both groups were calculated. Baseline differences between groups were tested with independent *t* tests or the Mann-Whitney *U* test for continuous data and χ^2 tests for categorical data. Collinearity between variables was checked with scatter plots or correlation coefficients for continuous variables and with cross tables for categorical variables. Multiple imputation methods were used to complete missing data using the algorithm MICE V1.13 in S-Plus.[47,48] The algorithm MICE is a so-called Fully Conditional Specification Method. Imputation was carried out for all variables with 1 or more missing values. If data are missing at random, the multiple imputation technique is an appropriate method to deal with missing data.[49]

First, model 1 and 2 were analyzed using multivariate linear regression analysis for the total group (ie, back rehabilitation and usual care). Baseline values of outcome measures were included to correct for a regression to the mean effect.[50] Model 1 was nested in model 2. In step 1, variables from model 1 (baseline value of outcome, treatment, pain, work status, and MPI-DLV) were entered and in step 2, variables from model 2 (sick leave, compensation, SCL-90-Dep, and TSK-DLV). In step 3, interactions of predictors with treatment were added. Significance level was set at $P = 0.05$.

The 5-profile classifications of the MPI (ie, ID, DYS, AC, AV, and AN) were dichotomized into 2 groups: ID/DYS versus AC/AV/AN. This dichotomization was necessary to reduce the number of predictor variables and thus the chance of a type I error. This choice was considered legitimate as literature has shown that ID/DYS profiles both benefit more from treatment than the AC/AV profiles.[19,51] Furthermore, ID and DYS subtypes share common characteristics of high pain intensity and low levels of control, in contrast to AC and AV with lower levels of pain intensity and interference, but higher life control.

For the categorical variables, the following coding was used:

- Treatment: (0) usual care, (1) back rehabilitation
- MPI: (0) AC/AV/AN, (1) ID/DYS
- Work status: (0) not working, (1) working
- Compensation: (0) no compensation, (1) receiving compensation. Second, interactions between treatment modality and prognostic variables from the models were studied for statistical significance ($P < 0.05$) to determine the value of the prognostic variables for the specific treatment.

Unstandardized β coefficients and standard errors will be presented. To give an indication of the predictive power of the model, the percentage of explained variance (R^2) of the complete model and of the significant predictors for rehabilitation treatment will be shown. Linear assumptions will be checked with residual and normal probability plots. If prediction of outcome is possible, the models will be internally validated by bootstrapping.

RESULTS

Study Population

All patients who were admitted to the back rehabilitation program met the inclusion criteria, of which < 5% refused to participate. Of the 163 patients who were included in the trial, 21 patients were lost during follow-up (13%). There was no difference in loss to follow-up between the groups.[19] The number of missing variables per case was marginal. The only exception was the variable sick leave, which was missing in 48 cases. Under the hypothesis that the data were missing at random, multiple imputation techniques were used to be able to build a prognostic model[47,48] for the total study group (N = 163). Baseline characteristics are reported in Table 1. There were no significant differences in baseline characteristics between the treatment and the control group implying that randomization appeared to be successful.

Cointerventions

The mean medical consumption in the usual care group was low with the exception of physical therapy. The mean number of visits to the physiotherapist was 11 to 15 times, but these visits were mainly attributed to only a few patients. Results of the questionnaire sent home monthly showed that the mean number of visits to specialists, general practitioners, manual therapists, or other therapy forms was about 0.1 (SD < 1) and thereby negligible. The mean number of visits to the physiotherapist was slightly higher and about 0.5 (SD = 3), but also considered negligible.

Outcome

Outcome variables are reported in Table 2. The mean RMDQ, PCS, and MCS scores for both groups were largely similar at admission. At 8 weeks and 6 months follow-up, patients with CLBP experienced on average less activity limitation and higher health-related quality of life than at baseline, regardless of the type of treatment.

TABLE 1. Baseline Characteristics (Mean and SD or Percentages) of the Back Rehabilitation (RRP) and Usual Care Group (Nonimputated Data)

	RRP N = 79	Usual Care N = 84
Age (y)	38 (10)	40 (10)
Duration of symptoms (mo) median*/range	72 (380)	48 (559)
Sex		
Male	60%	62%
Female	40%	38%
RMDQ (0-24)	13 (4)	13 (5)
SF-36: PCS (0-100)	31 (7)	32 (7)
SF-36: MCS (0-100)	49 (10)	52 (10)
VAS (0-100) median*/range	5 (0-10)	5 (1-9)
MPI-DLV		
Dysfunctional	30%	26%
Interpersonally Distressed	12%	15%
Adaptive copers	15%	26%
Average	39%	31%
Anomalous	4%	2%
Work status		
Working	21%	20%
Not working	79%	80%
Sick leave [0-40 h(s)/wk] median*/range	26 (0-40)	20 (0-40)
Compensation		
Yes	70%	66%
No	30%	34%
SCL-90 total score (90-450)	140 (39)	136 (35)
SCL-90-Dep (16-80)	25 (9)	24 (8)
TSK (17-68)	39 (7)	39 (7)

*The median value is reported if this parameter is not normally distributed.

MCS indicates Mental Component Scale; MPI-DLV, Multidimensional Pain Inventory Dutch Language version; PCS, Physical Component Scale; RMDQ, Roland Disability Questionnaire; RRP, Roessingh Back Rehabilitation Program; SF-36, Short Form Health Survey; SCL-90, Symptom Check List; SCL-90-Dep, Symptom Check List subscale depression; TSK, Tampa Scale for Kinesiophobia; VAS, Visual Analog Scale.

Prognostic Factors for Change in Outcome

Owing to high collinearity between the categorical variables "work status" and "compensation," the variable compensation was left out of the model. The variable work status was preferred to compensation as it had showed consistent results in literature for the outcomes of interest.[1] Most patients working received no compensation and most patients not working did. Model 1 (the confirmative model) was nested in model 2 (the exploratory model). The complete models are presented in Table 3. Table 3 presents the predictor model without interactions and Table 4 the final model including interactions with treatment. Overall, the percentage of explained variance for the different outcome measures was moderately low and varied from 18.5% to 42.3%.

TABLE 2. Outcome Parameters [Mean and SD, Number of Cases (N)] of the Back Rehabilitation (N = 79) and Usual Care Group (N = 84) at Baseline (T0), Discharge (T1) and 4-Months Follow-up After Treatment (T5) (Nonimputated Data)

Outcome	Group	Baseline	T1	T5
RMDQ	RRP	13 (4), N = 79	11 (5), N = 72	10 (5), N = 68
	Usual care	13 (4), N = 83	13 (5), N = 79	11 (5), N = 72
SF-36: PCS	RRP	31 (7), N = 73	35 (8), N = 66	37 (9), N = 64
	Usual care	32 (7), N = 81	33 (9), N = 75	35 (9), N = 67
SF-36: MCS	RRP	49 (10), N = 73	53 (9), N = 66	54 (9), N = 64
	Usual care	52 (10), N = 81	52 (10), N = 75	53 (10), N = 67

MCS indicates Mental Component Scale; PCS, Physical Component Scale; RMDQ, Roland Disability Questionnaire; RRP, Roessingh Back Rehabilitation Program; SF-36, Short Form Health Survey.

Predictors for Change in Outcome Regardless of Treatment Modality (Table 3)

For the primary outcome variable (RMDQ), participation in back rehabilitation and a higher baseline RMDQ score both predicted improvement at short-term follow-up. Higher RMDQ scores at baseline predicted improvement for the long term as well. For the secondary outcome parameters (PCS and MCS), higher baseline values predicted deterioration at short-term and long-term follow-up, whereas participation in back rehabilitation predicted improvement for the PCS in the short term. Being at work predicted an improvement for the PCS in the long term, whereas higher depression scores predicted deterioration for the MCS at short-term and long-term follow-up.

Predictors for Change in Outcome for a Specific Treatment (Table 4)

Interactions of several prognostic variables with the variable treatment were significant, depending on the outcome measure and duration of follow-up. A significant interaction with treatment implies that a variable has a different prognostic value for improvement after back rehabilitation treatment compared with usual care. The percentage of explained variance added by the significant interactions was very low and varied from 2.2% to 4.9%. Owing to these low percentages, the value of the prognostic model was very modest. Therefore, internal validation had limited additional value and was not carried out.

Pain intensity showed significant interactions with treatment, but the MPI and work status did not. More pain at baseline was predictive of improvement in physical health (PCS) after back rehabilitation for short-term follow-up (T1). A higher baseline VAS score of approximately 3 points predicted an improvement of 2 points for the PCS. Depression and fear-avoidance beliefs (TSK) also showed significant interactions with treatment. Higher depression scores at baseline were prognostic for improvement after back rehabilitation in the long term (T5). A 20-point higher baseline score predicted a decrease of 2 points for the RMDQ. If persons with SCL-depression scores higher than the average of a chronic pain population (>28)[30] were classified as depressed, depressed persons showed mean RMDQ scores of 15 at baseline and 10 at long-term follow-up. Those with low depression scores (≤ 28) showed mean RMDQ scores of 12 at both baseline and long-term follow-up. Finally, a higher level of fear-avoidance beliefs also predicted improvement after back rehabilitation at long-term follow-up. A TSK score of

TABLE 3. Complete Predictor Model for Change in Outcome Regardless of Treatment (Imputated Data)

Outcomes	RMDQ		PCS		MCS	
Follow-up	T1-T0	T5-T0	T1-T0	T5-T0	T1-T0	T5-T0
Predictors	β (SE)	β (SE)	β (SE)	β (SE)	β (SE)	β (SE)
Intercept	4.59 (2.19)	2.02 (2.57)	14.63 (5.33)	19.14 (6.46)	57.85 (8.54)	51.27 (9.47)
Treatment†	− 1.89 (0.67)**	− 0.63 (0.71)	2.34 (1.15)*	1.35 (1.28)	0.55 (1.37)	1.47 (1.47)
Pain	− 0.19 (0.17)	− 0.11 (0.19)	0.18 (0.30)	0.20 (0.37)	0.34 (0.32)	− 0.13 (0.36)
Work status‡	− 0.52 (1.08)	− 1.72 (1.31)	1.61 (1.88)	6.16(2.20)**	− 1.51 (2.29)	− 1.31 (2.71)
MPI-DLV§	− 0.76 (0.80)	− 1.31 (0.92)	0.94 (1.39)	1.54 (1.51)	− 2.45 (1.57)	− 0.78 (1.69)
Baseline value‖	− 0.35 (0.10)***	− 0.38 (0.11)***	− 0.38 (0.10)***	− 0.54 (0.11)***	− 0.87 (0.10)***	− 0.83 (0.10)***
Sick leave	0.03 (0.03)	− 0.01 (0.03)	− 0.03 (0.04)	0.08 (0.05)	− 0.04 (0.05)	− 0.07 (0.07)
SCL-90-Dep	0.04 (0.05)	0.01 (0.05)	− 0.09 (0.08)	− 0.03(0.10)	− 0.29 (0.13)*	− 0.35 (0.13)**
TSK	− 0.07 (0.05)	0.05 (0.06)	− 0.02 (0.08)	− 0.05 (0.11)	− 0.11 (0.10)	0.10 (0.12)
R^2	23.5%	19.0%	18.5%	24.2%	42.3%	39.0%

Outcome is expressed as change between discharge (T1) or 4-mo follow-up after treatment (T5) and baseline (T0).

β indicates regression coefficient; MCS, Mental Component Scale (derived from Short Form Health Survey); MPI-DLV, Multidimensional Pain Inventory Dutch Language version; PCS, Physical Component Scale; R^2, percentage of explained variance; RRP, Roessingh Back Rehabilitation Program; RMDQ, Roland Disability Questionnaire; SCL-90-Dep, Symptom Check List, subscale depression; SE, standard error; TSK, Tampa Scale for Kinesiophobia; VAS, Visual Analog Scale.

†Treatment: 0 = usual care, 1 = back rehabilitation.

‡Work status: 0 = not working, 1 = working.

§MPI-DLV: 0 = Adaptive Coper/Average/Anomalous, 1 = Interpersonally Distressed/Dysfunctional.

‖Baseline value RMDQ, PCS, MCS.

*P value < 0.05, **P value < 0.01, ***P value < 0.005.

β positive: unfavorable change in RMDQ (favorable in PCS/MCS) per unit of the independent predictor.

β negative: favorable change in RMDQ (unfavorable in PCS/MCS) per unit of the independent predictor.

TABLE 4. Complete Predictor Model for Treatment Outcome: Prognostic Variables and Interactions With Treatment (Imputated Data)

Outcomes	RMDQ		PCS		MCS	
Follow-up	T1-T0	T5-T0	T1-T0	T5-T0	T1-T0	T5-T0
Predictors	β (SE)	β (SE)	β (SE)	β (SE)	β (SE)	β (SE)
Intercept	1.75 (2.93)	− 3.17 (3.40)	23.29 (6.40)	27.55 (7.88)	59.17 (9.67)	47.62 (11.32)
Treatment†	4.87 (4.45)	10.22 (4.60)*	− 16.93 (7.91)*	− 17.08 (9.59)	− 1.05 (9.53)	7.85 (10.65)
Pain	− 0.19 (0.22)	− 0.34 (0.24)	− 0.35 (0.40)	0.32 (0.46)	0.49 (0.48)	− 0.54 (0.52)
Work status‡	− 1.74 (1.45)	− 3.20 (1.71)	1.56 (2.49)	7.93 (3.20)*	− 2.29 (3.12)	− 0.08 (3.81)
MPI-DLV§	− 0.54 (1.08)	− 1.70 (1.27)	− 0.15 (1.73)	1.20 (2.03)	− 0.27 (2.17)	1.77 (2.41)
Baseline value‖	− 0.36 (0.10)***	− 0.40 (0.11)***	− 0.39 (0.10)***	− 0.55 (0.11)***	− 0.88 (0.10)***	− 0.83 (0.10)***
Sick leave	0.03 (0.03)	− 0.02 (0.04)	− 0.04 (0.06)	0.07 (0.08)	− 0.04 (0.07)	− 0.02 (0.10)
SCL-90-Dep	0.13 (0.07)	0.17 (0.07)*	− 0.15 (0.11)	− 0.12 (0.14)	− 0.40 (0.16)*	− 0.42 (0.18)*
TSK	0.016 (0.07)	0.13 (0.08)	− 0.11 (0.12)	− 0.23 (0.15)	− 0.12 (0.15)	0.23 (0.18)
Treatment × Pain	0.01 (0.33)	0.43 (0.34)	**1.07 (0.54)***¶	− 0.17 (0.62)	− 0.16 (0.72)	0.94 (0.71)
Treatment × work status	2.31 (2.08)	2.96 (2.22)	0.15 (3.44)	− 3.98 (4.29)	1.89 (4.54)	− 1.25 (4.73)
Treatment × MPI-DLV	− 0.51 (1.51)	0.24 (1.59)	1.54 (2.59)	0.83 (2.95)	− 4.33 (3.26)	− 5.76 (3.57)
Treatment × sick leave	− 0.01 (0.05)	0.00 (0.06)	0.06 (0.08)	0.04 (0.10)	0.01 (0.11)	− 0.06 (0.12)
Treatment × SCL-90-dep	− 0.15 (0.10)	**− 0.28 (0.10)****#	0.11 (0.16)	0.14 (0.22)	0.16 (0.21)	0.10 (0.24)
Treatment × TSK	− 0.08 (0.10)	− 0.18 (0.10)	0.24 (0.17)	**0.39 (0.19)***††	− 0.01 (0.21)	− 0.24 (0.22)
R^2	28.9%	29.5%	26.6%	30.2%	43.8%	41.8%

Significant interactions of predictors with back rehabilitation treatment are noted in bold with explained total variance and added variance at the bottom of the table. Outcome is expressed as change between discharge (T1) or 4-mo follow-up after treatment (T5) and baseline (T0).

β indicates regression coefficient; MCS, Mental Component Scale (derived from Short Form Health Survey); MPI-DLV, Multidimensional Pain Inventory Dutch Language version; PCS, Physical Component Scale; R^2, percentage of explained variance; RMDQ, Roland Disability Questionnaire; RRP, Roessingh Back Rehabilitation Program; SCL-90-Dep, Symptom Check List, subscale depression; SE, standard error; TSK, Tampa Scale for Kinesiophobia; VAS, Visual Analog Scale.

†Treatment: 0 = usual care, 1 = back rehabilitation.

‡Work status: 0 = not working, 1 = working.

§MPI-DLV: 0 = Adaptive Coper/Average/Anomalous, 1 = Interpersonally Distressed/Dysfunctional.

‖Baseline values of RMDQ, PCS, MCS. R^2 RMDQ (T1) = 7.3%, (T5) = 8.0%; R^2 PCS (T1) = 9.3%, (T5) = 13.2%; R^2 MCS (T1) = 34.0%; (T5) = 29%.

¶R^2 VAS + interaction with treatment = 2.2%.

#R^2 SCL-Dep + interaction with treatment = 4.9%.

††R^2 TSK + interaction with treatment = 2.2%.

*P value < 0.05, **P value < 0.01, ***P value < 0.005.

β positive: unfavorable change in RMDQ (favorable in PCS/MCS) per unit of the independent predictor.

β negative: favorable change in RMDQ (unfavorable in PCS/MCS) per unit of the independent predictor.

6 points higher at baseline predicted an improvement of 1 point for the PCS.

DISCUSSION

The results of this study showed very limited predictive value of a predefined multivariate prognostic model for patients with CLBP, for multidisciplinary rehabilitation outcome compared with usual care. The percentage of explained variance of the models was moderately low and varied from 18.5% to 43.8%. Our hypothesis that less pain, the ability to work, and classification as DYS or ID predict more improvement after rehabilitation treatment was not supported. However, the value of several predefined predictors for improvement after rehabilitation treatment was partly confirmed.

Prognostic Factors for Change in Treatment Outcome—Confirmatory Model (Model 1)

For the confirmatory model, pain had a different prognostic value for the rehabilitation and usual care group than we hypothesized. Higher pain intensity predicted improvement in physical health (PCS) after back rehabilitation, which was different from the findings of others.[52,53] It was not clear what caused this discrepancy. The main difference with our study was that different outcome measures were used [ie, ADL scores (Activity of Daily Living)[52] and Million/WHO (World Health Organization) Handicap Indexes],[53] which may have influenced the prognostic value of pain. Although the direction of the prognostic value was different than expected, the results supported that pain intensity had prognostic value for change in outcome after rehabilitation.

The results showed that ''being at work'' did not affect improvement after rehabilitation. However, being at work predicted improvement for the PCS in long term, regardless of treatment. It could be that those at work are healthier and more physically active, which may be related to higher physical well being. However, the lack of prognostic value for improvement after rehabilitation should be interpreted with caution. There was only a small percentage of patients at work (20%), which might have limited the predictive power of this variable. Another explanation may be that work status was not the same as ''work ability''. For example, the category ''not working'' also included persons who were retired or involved around the household. These people (N = 10) may have been able to work that may have biased the results. This possible misclassification was checked by reanalyzing the data. Classifying ''household'' or ''retired'' as ''working'' did not change overall results. Therefore, possible bias caused by misclassification seems to be small.

No significant interaction between the MPI and the treatment was found, which is inconsistent with our hypothesis. This means that improvement after rehabilitation treatment did not differ between the MPI subgroups. We expected that DYS and ID profiles would improve more after rehabilitation than AC profiles as measured with the RMDQ, which was based on the results of Talo et al[51] and Vollenbroek-Hutten et al.[19] Other studies,[54,55] however, involving other patient groups than only CLBP, but the same outcome parameters, have also found no significant predictive value for treatment outcome.

An explanation could be that dichotomizing the MPI (ID/DYS vs. AC/AV/AN) resulted in loss of discriminative ability and thus predictive power. Owing to the small sample size of the study group, dichotomization was necessary to reduce the number of predictor variables. Voerman et al[56] also collapsed the ID and DYS together and were able to demonstrate more improvement after treatment for the ID/DYS compared with the AC/AV profiles in people with neck-shoulder complaints. Future studies of larger comparable patient samples and outcome measures are needed to study the value of all different MPI profiles, besides other relevant prognostic factors.

Prognostic Factors for Change in Treatment Outcome—Exploratory Model (Model 2)

For the exploratory model, depression and fear-avoidance beliefs showed prognostic value for improvement after rehabilitation. Higher depression scores at baseline predicted improvement for the RMDQ after rehabilitation in the long term. Patients who were more depressed at baseline also had a better absolute outcome at follow-up [mean RMDQ (T5) = 10] than those who were less depressed at baseline [mean RMDQ (T5) = 12]. This is in contrast to the literature that has shown that more depressive symptoms are prognostic for worse outcome. Most studies,[5,6,57] however, used return to work as outcome measure, which may explain the difference. It may be that more depressed patients gain more from treatment, although this does not necessarily lead to return to work. Also, our study population had lower mean scores (SCL-Dep = 25) than a norm population of patients with chronic pain (SCL-Dep = 28).[30] So, the included patients had only mild depressive symptoms that may have influenced its prognostic value. It is interesting that more depressive symptoms were not predictive of mental health after rehabilitation, although depression predicted worsening for the MCS at follow-up, regardless of treatment. This could be because of the lack of difference in treatment effect between the 2 groups as measured with the MCS.

Furthermore, more fear-avoidance beliefs predicted improvement in the PCS after rehabilitation in the long term. This is in line with what we expected. The RRP has shown to reduce the amount of fear-avoidance beliefs significantly.[19] This finding supports one of the theoretical principles the RRP is based on, that is, reduction of fear-avoidance beliefs improves physical functioning of patients and lessens the deconditioning syndrome.

Sick leave had no predictive value in this study. The number of missing values of this variable was high (48/163 cases), and missing values were completed with imputation techniques. Inevitably, this caused increased

unreliability in the independent variable and is a possible explanation for not finding a significant prognostic value. Also, the validity of this measure could be questioned. The reported amount of sick leave showed great discrepancies between employer and employee, so it is uncertain if the employees' report was the most valid measure of sick leave.

Methodologic Considerations

The very low use of services by the usual care group (eg, "waiting list group") may suggest that this group did not need much treatment. However, from a clinical point of view, this is not likely. The results showed that the usual care group did not use other services (mainly physiotherapy), during the waiting list period. Almost all patients already had had monodisciplinary treatment (eg, physiotherapy) before referral without success. The knowledge that rehabilitation treatment would start at the end of the trial possibly explains the low use of medical services in the usual care group.

The percentages of explained variance of the prognostic models were low and an accurate prediction of outcome was, therefore, not possible. However, these low percentages have also been found in other multivariate prognostic models of treatment outcome (activity limitation or health-related quality of life) in chronic (low back) pain.[14,53,58–63] A few authors showed percentages of explained variance up to 60% to 70%.[15,64–66] Woby et al[15] were able to explain 71% of variance. They found that reduction of fear-avoidance beliefs and increased perceptions of control over pain were uniquely related to reductions in disability of CLBP after cognitive-behavioral treatment. The main differences with our study is that Woby et al[15] studied a different type of treatment (cognitive-behavioral), studied changes in predictors instead of baseline values, and did not include a control group. It is likely that including changes in predictor values contributes to a higher level of explained variance because the effects of treatment processes are included in the prognostic model. However, knowledge of the predictive value of baseline, and not change of, parameters is preferred to be able to select patients for a suitable treatment modality.

Different explanations might contribute to the relatively low predictive power found in this study. First, there may be other important factors that were not investigated in this study. The problem is that there is no clear consensus regarding the predictors that should be used. It is also possible that the variance in outcome measures was too small for accurate prediction. This was most evident for the MCS, for which no predictors of treatment were found. For the MCS, mean differences before and after treatment were comparable with the differences at baseline between the 2 groups. Changes in the MCS in time were, therefore, probably too small to find significant prognostic factors.

The use of change scores as outcome measures is debatable, both from a clinical and a statistical point of view. Clinically, improvement in outcome parameters does not necessarily mean that the persons recover. For instance, persons may show a large improvement for the RMDQ, but still have high absolute scores (ie, experience more limitation) after treatment. These persons have a poorer prognosis than those with less improvement, but lower absolute scores (ie, less limitation) after treatment. Statistically, change scores can be influenced unduly by baseline levels.[24] It may be argued to use absolute scores as outcome measures instead. However, if analyzed with multiple regression analysis or analysis of covariance, it makes no difference if absolute outcomes or change scores are used.[50,67] Both absolute outcomes (T1, T5) and change scores are influenced by their baseline scores. To correct for a possible regression to the mean effect, the analysis of covariance or multiple regression analysis should include baseline levels of the outcome measures[50] as was carried out in this study. However, even multiple regression analysis does not correct for the strong correlation between baseline and change in outcome. The regression coefficients of the baseline values of the RMDQ, PCS, and MCS probably do not truly predict improvement, but reflect this statistical phenomenon. This study also showed that these baseline values contributed to relatively high percentages of explained variance, which may have overestimated the explained variance of the prognostic model. It was not the purpose of this study to explore the predictive value of baseline levels of the outcome measures. Inclusion of the baseline levels was needed to correct for baseline heterogeneity.

CONCLUSIONS

The results of this study did not support the construction of a clinical prediction model. However, this study showed that high scores of pain intensity, depression, and fear-avoidance beliefs may contribute to the prediction of improvement after a rehabilitation program for patients with CLBP.

Future Recommendations

A generic set of predictors may be difficult to find. Prognostic factors should be tested and compared for the same population, treatment, and outcome measures before it is possible to develop a generic prediction model. This underlines the importance of (inter)national consensus about treatment modality and outcome measures. Even if consensus is reached about outcome measures, it is likely that rehabilitation treatments will differ. This is partly because of its multidisciplinary character. The first step may be to conduct confirmative studies of prognostic factors in CLBP for a specific rehabilitation treatment in an effort to increase treatment homogeneity.

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