# PREDICTIVE FACTORS FOR 1-YEAR OUTCOME OF CHRONIC LOW BACK PAIN FOLLOWING MANIPULATION, STABILIZING EXERCISES, AND PHYSICIAN CONSULTATION OR PHYSICIAN CONSULTATION ALONE

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*Objectives:* To examine the relative influences of sociodemographic and episode-specific factors on change in low back pain intensity and self-rated disability.

*Methods:* Of 204 patients with chronic low back pain, 102 were randomized to a combined manipulation, exercise and physician consultation group and 102 to a consultation-alone group. These groups were each divided into 2 clusters based on change in both pain intensity and self-rated disability at 1 year. The first cluster included patients whose symptoms clearly decreased, and the second those whose trouble persisted. Association between sociodemographic and episode-specific factors and poor recovery from low back pain and disability were evaluated by univariate and multivariate analysis.

*Results:* Severe affective distress (OR 3.81; 95% CI 1.3–10.8) predicted poor response to the manipulative treatment. Over a 25-day sick leave during previous year (19.64; 3.8–102.5), poor life control (9.40; 1.9–47.0), and generalized somatic symptoms (3.18; 0.9–11.6) were the risk factors for not benefiting from the informative approach.

*Conclusions:* Psychosocial differences seem to be important determinants for treatment outcomes, and should be the focus of future studies.

Key words: low back pain, spinal manipulation, predictive analysis.

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# INTRODUCTION

Despite considerable efforts to solve the problem of chronic low back pain (cLBP), it still has a high prevalence and considerable socioeconomic consequences all over the industrialized world. It would be advantageous to identify at an early stage those patients at high risk of developing persistent or recurrent low back pain (LBP) and to direct the treatment (active or multidisciplinary) modalities to that group. However, at present, we have a large, diverse group of cLBP patients, for which we must

© 2004 Taylor & Francis. *ISSN 1650–1977* DOI 10.1080/16501970310019151 discover the correct type of treatment approaches. Some patients may benefit from short, low-cost outpatient approaches, and some other patients from multidisciplinary inpatient rehabilitation.

Previous studies on acute or subchronic patients with LBP in primary care have found several factors associated with persistence of symptoms and the progression to chronicity in LBP: high levels of psychological distress (1, 2); dissatisfaction with employment (1, 3); longer duration of symptoms (1, 4); a previous history of LBP (2, 3); radiating pain (1); higher initial disability level (3, 5); and high compensation status (3, 5). The study of Bendix et al. (6) identified young age, female gender, few sick-leave days before treatment, and low baseline severity of back pain as predictive of outcome in a functional restoration program, but also in shorter control outpatient programs and with no treatment at all. Hildebrandt et al. (7) showed the probability of a patient's return to work, and the reduction in pain intensity after an 8-week program of functional restoration and behavioral support, to be based mainly on reduction in subjective feelings of disability. Neither medical background, diagnosis, nor physical impairment had any predictive value. The results of other similar studies confirm that the changes in patients' beliefs about their pain are crucial in determining the success of a multimodal treatment program (8), or an active exercise program (9).

In our prospective randomized trial of combined manipulation, stabilizing exercises, and physician consultation compared with physician consultation alone for cLBP, we found the manipulative treatment more beneficial in reducing pain and disability (10). Both treatment modalities reduced pain, disability, and depression and increased health-related quality of life.

The aim of the present study was to examine the profile of those patients who derived no or little benefit from physician consultation alone, which included a clinical examination, information, encouragement, and advice, or from physician consultation plus a short, specific manipulative treatment. The instructions alone, or combined therapy and instructions, were applied according to the clinical examination and physical impairment of the patients without any multidisciplinary element. For that reason, we wanted to assess the significance of these clinical tests predicting the outcome following combined therapy and physician consultation or physician consultation alone compared with other sociodemographic, pain, disability, work-related and psychometric factors.

# PATIENTS AND METHODS

## Study sample

The study included 24- to 46-year-old employed subjects who suffered from cLBP (with or without sciatica) of more than 3 months' duration and at least moderate disability ( $\geq$ 16%) according to Oswestry Disability Index (ODI)). Exclusion criteria were previous spinal operation, severe sciatica in the straight-leg raising test with less than 35°, or weakened general condition (such as inflammatory or malignant states or recent vertebral fractures) for which manipulation is considered to be contraindicated.

#### Intervention

A total of 204 patients with cLBP completed questionnaires and underwent a set of clinical measurements and evaluations of spinal mobility, muscle balance, neurodynamics, coordination, and pain provocation. Of these, 102 patients were randomized to a combined manipulation, exercise, and physician consultation group, and 102 to a consultationalone group. All measures were repeated at 5 months and the questionnaires at 1 year after randomization. The Hospital Medical Ethics Review Board approved the study. Eight patients dropped out leaving 196 to complete 1-year follow-up assessments.

The 2 study groups were comparable in age, sex, duration and localization of LBP, pain intensity, self-rated disability, depression, and HRQOL (10).

## Questionnaires

Questionnaires inquired about the following factors:

- Sociodemographic characteristics: age, gender, marital status, level of education and vocational training, work status, and smoking habits.
- Characteristics of LBP: pain intensity on Visual Analogue Scale (VAS), duration, frequency (daily, weekly, monthly, or at least 3 times yearly) and localization of pain (local LBP, radiculation of LBP above or below the knee), and use of pain medication.
- Back-specific disability: Oswestry Low Back Pain Disability Questionnaire (11): a 10-item questionnaire recommended for assessment of disability due to LBP in relation to various daily functions (12) (Score 0–100 with score increasing with severity of disability) and Pain Disability Index (13): a 7-item questionnaire for the assessment of overall perceived disability (Score 0–70 with score decreasing with severity of disability).
- Health-related quality of life (HRQOL) (14): a 15-item questionnaire (Score 0–1; higher score = increased HRQOL).
- Variables related to work ability: Work Ability Index (15) (Score 7–49; higher score = increased work ability; 7–27 reduced; 28–43 average; 44–49 good) and days on sick leave.
- Psychological variables: Modified Somatic Perception Questionnaire (MSPQ) (16): a 13-item questionnaire designed to measure heightened somatic awareness among chronic back pain patients (Score 0–39; higher score = higher frequency of somatic symptoms), the Finnish Depression Questionnaire (17) (Score 0–30; higher score = increased psychological distress), and the Finnish version of the Multidimensional Pain Inventory (18) assessing pain severity, interference, life control, affective distress, support, punishing responses, solicitous responses, distracting responses, and general activity.
- Physical activity at work, at leisure, and during commuting: MetPro (19).

## Functional assessments

Functional assessments included the following tests:

Mobility of the spine in forward flexion (20) and in lateral flexion (21)
was measured with a tape-measure. Sacroiliac joint motion was
assessed by the forward flexion (the Piedallu sign (22) occurs when the
posterior superior iliac spine (PSIS) reverses in height as the patient
bends forward, reflecting asymmetric motion of the sacroiliac joints),
backward and lateral flexion, and by the contralateral test (with patient

standing and lifting the opposite knee, sacroiliac motion is assessed with one thumb on the sacrum and the other on the PSIS; in sacroiliac joint dysfunction, the asymmetric motion is indicated by less motion on the affected side).

- Neurodynamic symptoms (neural tissue irritation) and findings were assessed with the straight-leg raising test in a supine and with SLUMP (23) test in a sitting position. Tension of the rectus femoris was measured with a goniometer (24). Tendon reflexes and sensory and motor function of the lower limbs were evaluated.
- Centralization phenomenon was assessed by repetitive end-range lumbar flexion and extension movements in the standing and prone position (25).
- Pain provocation tests were performed with palpation of the spinous processes of the lumbar vertebrae. Intradiscal pain was assessed with a bony vibration stimulation test (26). Sacroiliac provocation tests included palpation of the inferior and medial point of PSIS (Fortin sign) (27), sacral thrust (28), and a bony vibration stimulation test of the sacroiliac joint.
- Postural control and co-ordination were assessed by measurement of the time the patient could stand on one leg with eyes open and closed (29).

#### **Statistics**

K-means cluster analysis was conducted based on change both in pain intensity (visual analogue scale, VAS 0-100) and in self-rated disability (Oswestry Questionnaire) at 1 year. K-means cluster analysis is a multivariate method also referred to as unsupervised pattern recognition. Profiles for subjects being studied are compared, and subjects who are close together are classified as being in the same cluster or group (30). It is a maximum likelihood technique, which iteratively seeks for optimal grouping so that inter-group deviation is maximized compared to intragroup deviation. The first cluster included patients whose pain and disability clearly decreased, and the second those whose trouble persisted. Association between poor recovery from LBP and disability and sociodemographic, pain characteristic, disability, work-related and psychometric factors, and physical examination tests were first evaluated by univariate analysis. Significance was considered at the 5% level. However, the meaningful level of association in univariate analysis (assessed as odds ratios) was determined with  $p \leq 0.10$ . Each factor with p < 0.10 was included in the multivariate analysis in a stepwise logistic regression procedure. It is a conventional technique to use  $p \le 0.10$  as an initial cutoff point for multivariate analysis to include all factors that may have correlations to other factors. Correspondingly, the cut-off level for excluding variables once they have been entered in regression model was considered 10% as well.

A discriminant analysis using a jack-knife technique was performed to test the accuracy of the resulting model. Jack-knifing is a method of validating or assessing the fit or appropriateness of a model, using the same sample which was used to derive the model, as opposed to using an independent sample (30). The principle behind the method is to omit each sample member in turn from the data, thereby generating *n* separate samples, each of size n - 1.

The data were analysed by SYSTAT 10 for Windows software (31).

# RESULTS

#### Outcome of low back pain intensity and disability

At the 1-year follow-up, the percentage of patients who reported major recovery from both pain intensity and self-rated disability was 60% in the manipulative-treatment group and 51% in the consultation-alone group (p > 0.10). The mean change in VAS score was 49 (SD 16) and in ODI 19 (SD 11) in the first cluster (n = 112), called good responders. The mean changes in the second cluster (poor responders; n = 84) were -1 (SD 19) in VAS and 8 (SD 11) in ODI (Fig. 1). The VAS and Oswestry delta scores were roughly normally distributed around the means.



*Fig. 1.* Division into 2 clusters by K-means cluster analysis. Cluster 1 = good responders, cluster 2 = poor responders.

Both the univariate and multivariate analyses were performed for the whole study population (n = 196) and for the 2 study groups as well.

## Univariate analysis

Of sociodemographic factors unmarried status and high level of education predicted poor recovery from pain and disability. The strongest single predictive factor was low to moderate level of back pain intensity (score 0–49 in VAS), which was associated with 5-fold increase in odds of persistence of symptoms (Table I).

Over 25 days of sick leave due to LBP during the year before the study was associated with an up to threefold increase in odds of a poor outcome in the whole study population and with a sevenfold increase in odds for the consultation group (Table I).

Poor life control and weak social support at baseline were associated with a twofold increase in odds of a poor outcome in the whole study group. Severe affective distress was associated with an almost threefold increase in odds of a poor outcome in the manipulative-treatment group. Poor life control, weak social support, and a risk score on the MSPQ were associated with a twofold increase in odds of a poor outcome in the consultation group (Table I).

Non-centralization phenomenon was associated with a more than twofold increase in odds of a poor outcome in the manipulative-treatment group. Normal neurophysiological findings in SLUMP test were associated with 1.89 increase in odds for the whole study population (Table I).

### Multivariate analysis

The final model of the whole study population comprised 6 factors: university education, mild to moderate level of LBP intensity (score 0–49 in VAS), 2 work-related factors (absence of over 25 days from work during the previous year and poor

self-evaluated prognosis for work ability after 2 years), plus poor life control, and normal SLUMP test findings in the physical examination (Table II). The potential confounding factors (age, gender) did not change the final model significantly (>5%). With the jackknife classification matrix, the outcome of 74% of the patients was correctly classified, with a lower positive predictive (72%) than negative predictive value (75%).

In the manipulative-treatment group, the final model comprised 3 factors: mild to moderate level of pain intensity, severe affective distress, and non-centralization phenomenon in the physical examination (Table III). With the jackknife classification matrix, the outcome of 69% of the patients was correctly classified, with a higher positive predictive (72%) than negative predictive value (68%). The non-centralization phenomenon was left in the final model even though it exceeded the cut-off level of 10% for exclusion criteria. It was considered clinically important, and omitting that factor, the predictive value of the final model would have deteriorated significantly to 55%.

In the consultation-only group, the final model included 5 factors: university education, mild to moderate level of pain intensity, over 25 days of sick leave during the previous year, a risk score of MSPQ, and poor life control (Table IV). With the jack-knife classification matrix, the outcome of 76% of the patients was correctly classified, with a higher positive predictive (78%) than negative predictive value (75%).

# DISCUSSION

Psychometric factors, longer previous sick-leave days, and a low to moderate level of pain intensity proved to predict strongly poor treatment outcome. These psychometric factors included poor life control, poor self-evaluated prognosis of work ability in the future, and severe affective distress. University education and unmarried status were the only sociodemographic factors that predicted persistence of symptoms. Although the patients in the present study were carefully examined, only normal neurodynamic findings and normal range of forward flexion predicted poor recovery in the whole study group. Explanations for the weak prediction power of the sociodemographic and clinical findings remain speculative.

It is quite natural that a lower initial pain level results in smaller changes, even after effective treatment. Todd (32) found the minimal clinically important difference (MCID) of change in VAS pain score to be 13 mm in patients with a VAS score of less than 34 mm. Patients with VAS scores between 34 and 66 mm reported a MCID of  $17 \pm 10$  mm, whereas in the most severe VAS score of  $\geq 67$  mm a MCID was  $28 \pm 21$  mm. Furthermore, as the changes in VAS were larger than in ODI, the influence of initial pain intensity was also more significant than initial disability level in prediction of outcome.

Centralization phenomenon has served to classify patients as either centralizers or non-centralizers. This trait has been reported to be a prognostic factor for developing cLBP (33), and a predictor of outcome in conservative treatment of cLBP (34). For centralizers, the McKenzie techniques with repetitive

	Odds ratios (95% CI)			
Characteristic	Both groups $(n = 196)$	Manipulative-treatment group $(n = 96)$	Consultation-only group $(n = 100)$	
Treatment group Manipulative- Consultation <i>p</i> -value	1 1.54 (0.9–2.7) >0.10			
Married Single or divorced <i>p</i> -value	1 2.28 (1.2–4.4) 0.01	1 2.19 (0.9–5.3) 0.08	1 2.77 (1.0–7.6) 0.04	
University education No Yes <i>p</i> -value	1 2.65 (1.3–5.3) 0.005	1 2.65 (1.0–6.7) 0.04	1 3.00 (1.0–8.6) 0.03	
Visual analogue scale ( 50–100 0–49 <i>p</i> -value	0–100) 1 5.22 (2.8–9.8) <0.001		1 4.73 (2.0–11.4) <0.001	
Sick-leave days during $0-24 \ge 25$ <i>p</i> -value	previous year 1 3.45 (1.3–9.0) 0.005	1 1.27 (0.3–5.2) >0.10	1 7.33 (1.7–32.2) 0.001	
Work ability index Good or moderate Poor <i>p</i> -value	1 1.70 (1.0–3.0) 0.07	1 1.07 (0.5–2.4) >0.10	1 2.55 (1.1–5.8) 0.02	
Self-rated prognosis of Good or moderate Poor <i>p</i> -value	work ability after 2 years 1 1.75 (0.9–3.4) 0.10	1 1.15 (0.4–3.3) >0.10	1 2.18 (0.9–5.4) 0.09	
Life control Good or moderate Poor <i>p</i> -value	1 1.96 (0.9–4.2) 0.08	1 1.77 (0.6–5.2) >0.10	1 2.17 (0.7–6.4) >0.10	
Affective distress Mild or moderate Severe <i>p</i> -value	1 1.28 (0.7–2.3) >0.10	1 2.65 (1.1–6.2) 0.02	1 0.65 (0.3–1.5) >0.10	
Social support Good or moderate Weak <i>p</i> -value	1 1.85 (1.0–3.3) 0.03	1 1.81 (0.8–4.1) >0.10	1 2.07 (0.9–4.6) 0.07	
$MSPQ* \\ \leq 8 \\ \geq 9 \\ p -value$	1 1.57 (0.8–3.1) >0.10	1 0.89 (0.3–2.5) >0.10	1 2.53 (1.0–6.7) 0.06	
Finger-floor distance in $\geq 20 \text{ cm}$ < 20  cm <i>p</i> -value	forward flexion 1 1.75 (0.9–3.3) 0.08	1 1.20 (0.5–2.9) >0.10	1 2.52 (1.0–6.1) 0.04	
Centralization phenome In extension Yes No <i>p</i> -value	non 1 1.60 (0.8–3.1) >0.10	1 2.60 (0.9–7.2) 0.05	1 1.05 (0.4–2.6) >0.10	
SLUMP test† Abnormal Normal <i>p</i> -value	1 1.89 (1.1–3.3) 0.03	1 2.02 (0.9–4.6) 0.09	1 1.78 (0.8–3.9) >0.10	

Table I. Association between poor recovery from low back pain (LBP) and disability and the following: sociodemographic, pain characteristic, disability, work-related, and psychometric factors, and physical examination tests (univariate analysis)

\*MSPQ = Modified Somatic Perception Questionnaire is a 13-item questionnaire designed to measure heightened somatic awareness among chronic back pain patients.

†SLUMP test evaluates nerve root or neural tissue irritation in a sitting position.

Table II. Predictors of poor recovery from low back pain and disability in the whole study group. Sociodemographic, pain characteristic, disability, work-related and psychometric factors, and physical examination tests included in stepwise logistic regression model (multivariate analysis)

Predictive factor	Odds ratios (95% CI)	n
University education No Yes <i>p</i> -value	1 2.80 (1.1–6.9) 0.02	150 46
Visual analogue scale 50–100 0–49 <i>p</i> -value	1 6.33 (2.8–14.3) <0.001	123 73
Sick-leave days durin 0–24 25- <i>p</i> -value	g previous year 1 4.19 (1.5–11.3) 0.005	164 32
Self-rated prognosis of Good or moderate Poor <i>p</i> -value	f work ability after 2 years 1 2.11 (0.9–5.0) 0.09	149 47
Life control Good or moderate Poor <i>p</i> -value	1 2.77 0.04	162 (1.0–7.4) 34
SLUMP test* Abnormal Normal <i>p</i> -value	1 1.96 (0.9–4.1) 0.07	95 109

\*SLUMP test evaluates nerve root or neural tissue irritation in a sitting position.

back or forward flexions have been considered the treatment of choice. In the present study, patients with radiating pain, positive SLUMP test, restriction in forward flexion, and with centralization phenomenon benefited from our treatment approach. Non-centralizers, on the other hand, seem not to improve either from the manual treatment in the present study

Table III. Predictors of poor recovery from low back pain and disability in the manipulative-treatment group. Sociodemographic, pain characteristic, disability, work-related, and psychometric factors, and physical examination tests included in stepwise logistic regression model (multivariate analysis)

Predictive factor	Odds ratios (95% CI)	n
Visual analogue scale		
50-100	1	63
0–49	5.99 (2.0-18.3)	33
<i>p</i> -value	0.002	
Affective distress		
Mild or moderate	1	56
Severe	3.81 (1.3-10.8)	40
<i>p</i> -value	0.01	
Centralization phenomen	on	
In extension		
Yes	1	22
No	2.71 (0.8–9.6)	74
<i>p</i> -value	>0.10	

Table IV. Predictors of poor recovery from low back pain and disability in consultation group. Sociodemographic, pain characteristic, disability, work-related and psychometric factors, and physical examination tests included in stepwise logistic regression model (multivariate analysis)

Predictive factor	Odds ratios (95% CI)	n
University education		
No	1	80
Yes	7.93 (1.6–39.7)	20
<i>p</i> -value	0.01	
Visual analogue scale		
50-100	1	60
0–49	5.38 (1.5–19.3)	40
<i>p</i> -value	0.01	
Sick-leave days during	previous year	
0–24	1	80
≥25	19.64 (3.8–102.5)	20
<i>p</i> -value	< 0.001	
MSPQ*		
<u>&lt;8</u>	1	75
$\leq 8 \geq 9$	3.18 (0.9–11.6)	25
<i>p</i> -value	0.08	
Life control		
Good or moderate	1	83
Poor	9.40 (1.9-47.0)	17
<i>p</i> -value	0.006	

\*MSPQ = Modified Somatic Perception Questionnaire is a 13-item questionnaire designed to measure heightened somatic awareness among chronic back pain patients.

or the McKenzie exercises (25, 33). Surprisingly, overall baseline level of physical activity during the daily life failed to predict the outcome, unlike in the study of Thomas et al. (1).

Work-related factors including longer previous absence from work, poor present work ability, and poor self-predicted future work ability turned out to be strong determinants for poor treatment outcome in the whole study group and in the consultation group. The association found in earlier studies was confirmed. However, these work-related factors did not hinder success of recovery when the manipulative and exercise treatment were added.

Poor life control, weak social support, and a risk score on the MSPQ, referring to affective distress, were essential determinants for poor response in the consultation group. Correspondingly, in the manipulative-treatment group, severe affective distress was a significant predictor of poor outcome. The Multidimensional Pain Inventory classifies patients into 3 groups, labeled "adaptive copers, dysfunctional and interpersonally distressed" patients. Dysfunctional patients are characterized by a higher level of pain severity, life interference, and affective distress, and a lower level of life control and activity (18). Psychometric predictors in the consultation group fitted well to this dysfunctional patient group, except for severe pain. They are suggested to benefit from interventions focusing on psychosocial distress and stress management in addition to functional restoration.

In the present study, we found 2 descriptive groups predicting minimal improvement after short, outpatient approaches. First group included high-educated patients with minimal or moderate symptoms according to VAS score and absence of radiating pain according to neurodynamic evaluation (SLUMP test). Second group included those with a plenty of psychosocial burden, work absenteeism and poor subjective expectation of future work ability. For the first group of patients, short, outpatient informative consultation resulting in slight improvement may be sufficient. The second group of patients, on the other hand, probably needs, besides information, manual treatments and exercises, some type of psychosocial approach as well. Implications for the clinical practice are that we should, besides the clinical testing, pay more attention to psychometric evaluation by careful interviewing and using standardized questionnaires in determining the appropriate intervention. For future studies, these findings raise interest on psychosocial differences as predictors of treatment outcome for cLBP patients.

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