SPINE SECTION

Original Research

Impact of a Functional Restoration Program on Pain and Health-Related Quality of Life in Patients with Chronic Low Back Pain

Volker Huge, MD,* Ulrike Schloderer, MD,* Martin Steinberger, MD,* Bernt Wuenschmann, MD,† Peter Schöps, MD, PhD,‡ Antje Beyer, MD,* and Shahnaz C. Azad, MD, PhD*

Departments of *Anaesthesiology and †Physical Medicine and Rehabilitation, Interdisciplinary Pain Clinic, Klinikum Grosshadern, Ludwig-Maximilians University, Munich, Germany; ‡Department of Physical Medicine and Rehabilitation, Krankenhaus Munich-Harlaching, Sanatoriumsplatz, Munich, Germany

ABSTRACT

Objective. Functional restoration programs for chronic low back pain (CLBP) have been shown to be successful in improving function and, to a lesser extent, in reducing pain. The Munich Functional Restoration Program (MFRP) is a 4-week outpatient program designed to reduce pain and to improve health-related quality of life in patients with a long history of CLBP.

Design. In a retrospective matched concurrent-controls therapeutic study, 44 patients with CLBP, who had either undergone MFRP or received an outpatient standard treatment (control) after initial evaluation at the pain center, completed questionnaires 1 year after the respective therapy (t1). The following parameters were assessed: health-related quality of life with Short Form-36 (SF-36), Pain Disability Index (PDI), Numeric Rating Scale (NRS) for pain, depression with the Center for Epidemiological Studies Depression Test (CES-D), and occupational situation. These data were compared with baseline values assessed by a questionnaire completed before starting the respective treatment (baseline, t0).

Results. Compared with control, NRS and PDI were significantly better in patients completing the MFRP. Patients of the MFRP group showed also a significant reduction in CES-D as well as an improvement in three of eight SF-36 subscales. No changes were detected in the control group receiving standard treatment.

Conclusions. Compared with standard treatment, a functional restoration program for CLBP significantly improves some aspects of health-related quality of life. It results in a decrease of pain and pain-related disability even in patients with a long history of CLBP.

Key Words. Chronic Low Back Pain; Health-Related Quality of Life; Functional Restoration Program; SF-36; Health Care System Utilization

Introduction

Chronic pain such as chronic low back pain (CLBP) causes tremendous costs for health care systems and economy [1,2], and shows very low rates of recovery in longitudinal studies [3]. It is a multidimensional phenomenon, impairing the patients’ social and psychological well-being [4,5].
Multiple therapeutic approaches for the treatment of CLBP have been proposed, most of them with only limited effectiveness, or a short duration of therapeutic effects [6]. Intensive functional restoration programs, which combine physical modules with psychological, occupational, and social components, have been shown to be effective in terms of improvement of function and, to a lesser extent, in the reduction of pain. It has been shown that functional restoration programs are also beneficial in terms of psychological distress. On the other hand, few trials report effects on health-related quality of life (HRQL) [7–10].

The Munich Functional Restoration Program (MFRP) is a multidisciplinary biopsychosocial rehabilitation program for patients with a long history of CLBP, who are referred to a university pain center after unsuccessful treatments by general practitioners (GPs), orthopedists, surgeons, and pain specialists. Besides a physical exercise program and occupational therapy, the MFRP emphasizes the psychosocial and educational aspects of chronic pain. Consequently, cognitive behavioral treatment is an important part of the program [11]. In this retrospective matched concurrent-controls therapeutic study, we compared pain, HRQL, depression, and utilization of the health care system in patients undergoing MFRP and those with a standard control treatment after initial supervision at the multidisciplinary pain center (MPC).

Material and Methods

Patients
The data were collected from all patients referred to the MPC from 1998 to February 2002 for the first time. All patients gave written informed consent to the use of the questionnaire data in an anonymous form for scientific purposes. The consent adhered to the requirements for publication of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals [12]. All patients with the diagnosis of nonmalignant chronic back pain of the lumbar spine underwent assessment for the MFRP. Assessment was performed by an evaluation group consisting of physicians (Anesthesiologists, Physicians for Physical Medicine and Rehabilitation) and a psychologist. To all eligible patients (Table 1), the participation in the MFRP was offered. Patients, who fulfilled the entry criteria for the MFRP program, but were not eligible due to problems concerning occupational situation or remoteness of residence, received standard treatment as described below, and served as control group. Patients who did not match the entry criteria, and those who were excluded from MFRP because of other reasons than noted above, received standard treatment, without being included into the control group.

Study Design
The study is a retrospective matched concurrent-controls therapeutic study of data received from patient questionnaires used for assessment of demographic data and medical purposes.

Assessment Questionnaires
The German Pain Questionnaire “Deutscher Schmerzfragebogen” (DSF) assesses demographic data, pain variables such as Numeric Rating Scale (NRS) scores, pain-related disability by means of Pain Disability Index (PDI), and depression with the German version of the Center for Epidemiological Studies Depression Test (CES-D) [13]. Questions concerning drug medication, comorbid conditions, social factors, and HRQL by means of the German version of the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) [14] are also integrated.

Short Form-36
The SF-36 is a generic measure that is independent of age and underlying disease, which assesses in eight dimensions (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, mental health) and in two summary scores the generic HRQL [5]. The eight scales and the two summary scores are scored from 0 to 100, with 0 indicating the worst health and 100 the best [15].

Center for Epidemiological Studies Depression Test
The CES-D [16] combines 20 questions and was designed to measure the levels of depressive symptoms. The German version was implemented into

<table>
<thead>
<tr>
<th>Table 1 Inclusion criteria for the Munich Functional Restoration Program (MFRP)</th>
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<td>• Chronic low back pain for at least 12 weeks</td>
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<td>• Good cardiopulmonary capacity</td>
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<td>• Ergometry with at least 100 W and no signs of change in electrocardiogram (ECG)</td>
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<td>• No contraindication for physical therapy</td>
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<td>• No signs of inflammatory or rheumatic causes of back pain</td>
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<td>• No fibromyalgia</td>
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<td>• No malignant disease</td>
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<td>• No major segmental instability as cause for chronic back pain</td>
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the DSF because of its good properties in detecting even discrete tendencies to depressive behavior. A raw test score of 23 or more is considered to be a critical limit for the existence of a depressive episode in pain patients [17].

**Pain Disability Index**

The German version of the PDI [18,19] was used to measure the pain-related interference with seven distinct domains of daily life.

**Deutscher Schmerzfragebogen**

The DSF also evaluates the patients’ educational and occupational situation and their health system utilization. The DSF was validated for a German population [17]. For the follow-up assessment, a shorter form of the DSF (DSF Follow-Up Questionnaire), mainly consisting of the implemented tests, was completed by the patients.

**Data Collection**

All patients filled out the DSF before their first assessment at the MPC at the University of Munich, Grosshadern Hospital, Germany (baseline; t0). The DSF Follow-Up Questionnaire was mailed to the patients 1 year after the MFRP or the beginning of standard treatment (t1).

**Matching of Patients**

Patients were retrospectively matched by a blinded observer, according to sex and baseline NRS categories at rest at the time of first examination. For this purpose, pretreatment NRS scores were divided into three categories: Category 1: NRS 0–3; Category 2: NRS 4–7; Category 3: NRS 8–10.

**Procedures**

**Concept and Program of the MFRP**

The MFRP concept is based on the therapeutic procedures introduced by Mayer and Gatchel [20]. It has been further developed and adapted for a German population by Pfingsten et al. [21]. The MFRP was introduced into clinical practice by Schöps et al. in 1998 [11]. In a 4-week outpatient setting, six to eight patients participate from Monday to Friday for 6–8 hours per day.

The MFRP combines several modules:

**Information:** Patients receive information about anatomy and biomechanic principles of the spine, pain physiology, psychological factors of pain perception, and pharmacology of analgesics and other medication used for pain treatment.

**Force, endurance, and coordination:** Patients undergo a training program for improvement of force, endurance, and coordination, containing functional strength and endurance exercises, swimming, aerobics, and sauna.

**Ergonomics:** Posture and ergonomic movements are taught and trained with simulated workstations (work hardening).

**Psychological intervention and relaxation training:** Psychological intervention consists of cognitive behavioral group therapy. Using the cognitive behavioral model, a main goal of psychological intervention is to adjust the patients’ coping strategies [22]. Additionally, the patients are taught progressive muscle relaxation. All patients receive instructions for a home-training program during the MFRP. For further description of the concept see also Schöps et al. [11].

**Standard Treatment**

Patients of the control group were seen by a physician and a psychologist (60–90 minutes each) for a detailed physical examination and standardized psychological interview. Afterwards, a therapeutic plan consisting of physical therapy, psychological intervention, and relaxation was worked out for every patient. The recommended treatments leaned on the multimodal therapeutic concepts used in the MFRP as described above. The implementation of the proposed therapy was left to the discretion of the patient and his primary care physician. No evaluation of the patients’ compliance concerning the suggested therapy was made.

**Statistics**

The questionnaire data were extracted into the statistical package for further analysis. Analysis of data was performed with SPSS 13 software (SPSS Inc., Chicago, IL, USA). Categorical data were analyzed using the chi-square test. Nonparametric Mann–Whitney U-test was performed to compare the demographic data of MFRP and controls. To address the question whether there was more change in the MFRP group than in the controls, we used a general linear model with analysis of covariance (ANCOVA). ANCOVA was performed with the t1 data as the dependent variable and t0 data as the covariate. If data were not suitable for an ANCOVA due to distribution, we subtracted t0 from t1 data and performed a Mann–Whitney U-test on the differences. For analysis of SF-36 results, we used a multivariate ANCOVA (MANCOVA) including all
scales in an overall analysis, in order to control type I error. Data are presented as mean ± SD. An alpha level of $P < 0.05$ was considered statistically significant.

Results

Patients

Eighty-three patients, who completed the MFRP, were addressed at least 1 year after MFRP, and asked to fill out the DSF Follow-Up Questionnaire. Forty-one patients answered and thereby completed both questionnaires. Ninety-nine patients with CLBP, who were eligible for control, were similarly addressed by mail at least 1 year after their first visit, and asked to complete the DSF Follow-Up Questionnaire. Thirty-eight patients responded and were eligible for control. There were no close differences ($P < 0.1$) between responding and nonresponding patients in their baseline questionnaires. However, the MFRP patients, who did not respond to the t1 questionnaire, were slightly younger (mean age MFRP: $52.6 ± 11.3$ years; MFRP nonresponders: $47 ± 8.2$ years, $P = 0.08$). However, as MFRP treatment requires good general health, the influence of this difference on the outcome should be minimal. Overall, 79 (MFRP: 41/control: 38) patients completed both questionnaires.

Matching

Starting from these 79 patients, 22 pairs could be matched. One pair was matched for NRS Category 1, 16 pairs were matched for NRS Category 2, and five pairs were matched for NRS Category 3.

Demographic Data

The demographic data of the two groups are shown in Table 2. There were no differences concerning age, educational or occupational level, but control patients had a significantly more remote residence ($65.4 ± 72.1$ km) than MFRP patients ($17.3 ± 16.1$ km) ($P < 0.05$). Patients in both groups had a remarkably long history of CLBP ($10.3 ± 7.5$ years in MFRP/$6.9 ± 3.3$ years in control), with a tendency toward a longer duration of low back pain in patients attending the MFRP ($P = 0.37$). About one-third of patients in each group had a history of surgery due to chronic pain of the lower spine.

Pain Measurements

Baseline NRS scores at rest did not differ between groups due to the matching protocol (MFRP: $5.9 ± 1.8$; control: $6.7 ± 1.5$). However, 1 year after attending the MFRP, patients had a substantial lower NRS scores ($4.3 ± 2.1$), compared with patients in the control group ($6.7 ± 2.6$). The difference in NRS scores from pre- to post-treatment was significant using the Mann–Whitney $U$-test ($P = 0.02$) (Figure 1). Pain-related disability (Table 3) showed a significant change 1 year after the beginning of MFRP or control treatment, and the PDI was lower in those patients undergoing the MFRP treatment (between-group analysis: sum of squares $= 1,277.795$; df $= 1$; $F = 8.313$; $P = 0.008$; ANCOVA).

| Table 2 | Demographic data of patients in the MFRP and control group |
|-----------------|------------------|----------------|---|
| **Age (years), mean ± SD** | MFRP (N = 22) | Control (N = 22) | $P$ |
| Age (years), mean ± SD | 52.6 ± 11.3 | 59.1 ± 13.9 | 0.12 |
| Sex (male/female), N | 11/11 | 11/11 | 1.00 |
| Height (cm), mean ± SD | 175.5 ± 9.1 | 171.6 ± 11.4 | 0.18 |
| Weight (kg), mean ± SD | 81.6 ± 21.9 | 80.2 ± 14.3 | 0.80 |
| Educational level (%) | 0.19 |
| No completion of training | 0 | 14.3 | |
| 1. Level grade school | 59.1 | 42.9 | |
| 2. Level grade school | 22.7 | 33.3 | |
| High school grade | 13.6 | 0 | |
| University grade | 4.5 | 9.5 | |
| Distance to pain center (km), mean ± SD | 17.3 ± 16.1 | 65.4 ± 72.1 | $<0.05$ |
| Duration of low back pain (years), mean ± SD (median) | 10.3 ± 7.5 (6) | 6.9 ± 3.3 (6) | 0.37 |
| Patients with surgery due to low back pain (%) | 36.4 | 26.3 | 0.36 |
| Occupational situation (%) | 0.19 |
| Blue collar | 5.6 | 21.1 | |
| White collar | 50 | 31.6 | |
| Federal employees | 16.7 | 0 | |
| Pensioned | 5.6 | 15.8 | |
| Housewife | 22.2 | 26.3 | |
| Self-employed | 0 | 5.3 | |
The level of depression, as indexed by the CES-D, was comparable between groups before beginning of treatment (Table 3). However, patients in the MFRP group had a significant change in their CES-D (14.1 ± 9.3) at t1. The CES-D level in the control group remained unchanged (25.6 ± 10.3) (between-group analysis: sum of squares = 747.338; df = 1; F = 12.594; P = 0.001; ANCOVA) (Table 3).

Health-Related Quality of Life

Table 4 shows the results of the SF-36 tests for the MFRP and the control group. One year after the program, three subscales of the SF-36 were significantly better in the MFRP group compared with the controls (Role Limitations Physical; General Health; and Social Functioning) (between-group analysis: P < 0.05; MANCOVA; see Table 4 for details). Furthermore, a strong trend toward an improvement in both the Physical and the Mental Component Summary Score, as well as for the subscale Emotional Well-Being, could be detected (between-group analysis: P < 0.1; MANCOVA; see Table 4 for details). There was no significant change in the MFRP group in the other subscales of the SF-36.
Utilization of Health System

Unexpectedly, there was no difference for overall appointments to the attending physician (MFRP: 4.6 ± 4/ control: 14.2 ± 27.1) and frequency of treatments (MFRP: 14.3 ± 10.3/control: 16.8 ± 25) related to the patients’ CLBP (P > 0.05). However, the number of patients, who underwent inpatient pain treatment during the 6 months before t1, was significantly higher in the control group (P < 0.05). Nine patients of the control group, but only one patient of the MFRP group, required an inpatient pain treatment. Finally, there was also a difference in the overall number of physicians consulted by the patients in the 6 months before t1 (MFRP: 1.9 ± 1.4/control: 3.2 ± 2.4; P < 0.05).

Success of Treatment

At t1, all patients were asked whether they considered the applied therapy successful. While 66.7% of the MFRP patients rated the success as very good or good, only 16.7% of the control patients did so. In contrast, one-third of the control patients judged the success of treatment as bad, whereas only 4.6% of MFRP patients complained about a bad outcome of treatment (P < 0.05).

Discussion

The results of the current study indicate that an intensive multimodal biopsychosocial functional rehabilitation program is capable to increase some aspects of HRQL and to decrease pain and pain-related disability in selected patients with CLBP. The observed results were obtained about 1 year after the program. In contrast, an outpatient standard treatment program, although containing modules similar to those of multimodal functional restoration program, neither improved HRQL nor resulted in a significant reduction of pain. We therefore conclude that multimodal assessment and outpatient treatment alone is not enough to be successful. These findings are in accordance with the results of the meta-analysis by Guzman et al. [7], which showed that intensive daily multidisciplinary rehabilitation programs for CLBP successfully reduce pain, whereas less intensive programs do not. There might be several reasons for the success of the MFRP: a 160-hour program as the MFRP is one of the most intensive functional restoration programs found in the literature [7]. In contrast, the proposed therapies for the patients in the control group might not have been carried out completely, or the outpatients’ interventions might not have been performed by therapists as highly specialized as the staff involved at a MPC. However, we cannot completely rule out that treatment failure in the control group was caused by applying treatment approaches different from the suggested multimodal approach.

Although NRS ratings were still considerably high and the pain relief was less than 30% as recommended for clinical significance, pain relief was significant in the MFRP group. Even more important than a reduction of the patients’ NRS score is the decrease in the PDI (Table 3). Disability refers to the patients’ behavioral manifestations of their clinical symptoms such as pain [23]. The results of our study indicate that the degree to which pain interferes with various daily activities, such as recreation, social activities, and occupation, was significantly reduced by the MFRP. Hildebrandt et al. [24] were able to show that a decrease in patients’ disability is one of the determining factors for the return to work after a multimodal treatment program.

Compared with the general population, the prevalence of psychological distress such as anxiety and depression is higher in patients with CLBP and other chronic pain states [1,25]. Patients attending the MFRP showed a significant reduction in their CES-D scores, which indicates a reduction in their depressive cognitions. This is remarkable, because other authors failed to show a constant reduction of depressive signs after multidisciplinary pain treatment [10]. However, Lang et al. used a community setting for their multidisciplinary program, and the intensity of the treatment was much lower. The mechanisms that substantially reduce the depressive thinking of the MFRP group remain unclear. The reduction of pain-related disability and concomitant increase in quality of life can also be responsible for the measured reduction of emotional distress.

Health-related quality of life measures to what degree a person’s ability to fulfill a normal role is impaired by disease. It is the patients’ subjective assessment of their actual condition [23]. The SF-36 has been shown to be a suitable instrument for outcome measurements regarding functional health status in patients with CLBP [26] and other chronic pain patients [27]. However, it is known that self-report measures of the SF-36 concerning patients’ physical functioning are sometimes distinct from objective performance tests [28]. Gatchel et al. detected that improvements in most SF-36 subscales are associated with outcome variables such as return to work and health care utilization. They therefore recommended to asses the
SF-36 routinely when performing therapeutic interventions in patients with CLBP [9]. In both groups, the baseline measurements for all SF-36 subscales were comparable to other chronic pain patients entering an interdisciplinary pain management program [29]. Significant changes in SF-36 occurred in the subscales “Role Limitation Physical” and “Social Functioning.” These results are in accordance with results from a study conducted by Lang et al. [10], which assessed a multidisciplinary rehabilitation program for CLBP in an outpatient community-based setting. Our results confirm the study performed by Becker et al. [30] comparing the outcome of a multidisciplinary pain center treatment (MPT) for chronic pain conditions with a treatment by a GP after initial supervision by a pain specialist group. In this study, the authors found a significant improvement in HRQL and a pain reduction only in patients receiving outpatient MPT, but not in GP patients.

In terms of health system utilization, a reduction in the use of inpatient pain treatment programs could be measured in the year after completion of the MFRP. This might be explained by the improvements of HRQL and pain-related disability due to MFRP. This is underlined by the fact that the majority of patients in the MFRP rated the applied program as successful, whereas most control patients rated the treatment as not successful. Furthermore, the significant reduction in the number of visits to different physicians indicates that the MFRP reduces “doctor shopping” behavior. “Doctor shopping” can be found in many patients with chronic pain syndromes [31]. However, there might be an alternative explanation for the decrease in inpatient pain treatment programs: patients already having undergone a multidisciplinary functional restoration program are less likely to be allotted to another cost-intensive treatment by their health insurance company within a short period of time. This is underlined by the result that no reductions in the overall appointments with physicians, and the overall number of treatments in the 6-month before t1 could be shown. Due to the high level of retired patients and household workers, which exceeded 40% of the control group, return to work was not a primary study goal.

The patients assessed at the MPC showed a very long history of CLBP, and might not be representative for patients with CLBP in general. Due to the limited capacity of the pain clinic, the GPs might refer only patients who had numerous treatments without improvements. Patients with claims for disability pension or workers compensation were excluded from the study, because these sociodemographic factors are known to influence outcome in chronic nonmalignant pain patients [21,32]. All results must be interpreted in the light of a potential bias caused by the retrospective study design. We, therefore, used a matched case design to minimize the possible overestimation of treatment effects caused by observational studies [33]. The return rate of questionnaires was in the range of return rates of other studies using mail surveys in comparable settings, considering the fact that there was no inpatient appointment at the time of the second assessment [34]. Patients were matched according to their gender, as this parameter has been found to influence the outcome in a study investigating the impact of different components of a behavioral medicine rehabilitation program for CLBP [35]. As the reduction of pain was one of the main outcome parameters, matching according to preintervention NRS scores was performed to achieve comparable preintervention pain levels.

In conclusion, the results of this study indicate that even in patients with a very long history of CLBP, a multimodal functional restoration program can improve some aspects of HRQL, reduce pain and pain-related disability. These effects appear to be sustained for at least 1 year after the end of the program.

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