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Physiotherapy-Based Rehabilitation Following Disc Herniation Operation

Results of a Randomized Clinical Trial

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Study Design. Three-group, randomized, single blinded, controlled trial.

Objective. To test the effectiveness of physiotherapy-based rehabilitation starting 1 week after lumbar disc surgery. In addition, we tried to estimate the contribution of specific effects to the observed outcome (efficacy).

Summary of Background Data. Physiotherapy-based rehabilitation is usually recommended for patients following lumbar disc surgery. Few and conflicting data exist for the relative effectiveness of this intervention.

Methods. A total of 120 patients following first-time, uncomplicated lumbar disc surgery were randomly assigned to "comprehensive" physiotherapy, "sham" neck massage, or no therapy. Before enrollment, all subjects completed a minimal physiotherapeutic intervention. Physiotherapy was administered by experienced physiotherapists and consisted of 20 sessions per patient over 12 weeks. Masseurs administered "sham massage" to the neck. The amount of treatment time was equal to that of physiotherapy. The main outcome measure was the Low Back Pain Rating Score (LBPRS) at 6 and 12 weeks, and 1.5 years after randomization. Secondary parameters were patients' overall satisfaction with treatment outcome and socioeconomic and psychologic measures.

Results. At the end of therapy (12 weeks), the LBPRS revealed a significantly better improvement in the physiotherapy group than in the untreated group. LBPRS outcome, however, did not significantly differ between physiotherapy and "sham" therapy. There was a tendency toward significance between the sham therapy and no therapy. Within the 1.5-year follow-up, LBP rating scales remained significantly improved compared with baseline, but there were no significant outcome differences. No statistically significant between-group differences were found for the secondary outcome parameters.

Conclusion. As compared with no therapy, physiotherapy following first-time disc herniation operation is effective in the short-term. Because of the limited benefits of physiotherapy relative to "sham" therapy, it is open to question whether this treatment acts primarily physiologically in patients following first-time lumbar disc surgery, but psychological factors may contribute substantially to the benefits observed.

Key words: back surgery, disc herniation operation, rehabilitation, physiotherapy, randomized controlled clinical trial. **Spine 2007;32:2041–2049**

Lumbar radicular syndrome (LRS) is based on a lumbar disc prolapse. LRS is characterized by irradiating pain over the area of the buttocks or legs served by 1 or more spinal nerve roots of the lumbar vertebrae or sacrum, combined with neurologic deficits associated with nerve root compression.[1] LRS has a major effect on healthcare utilization and costs. In the Netherlands (16 million inhabitants), the annual cost of direct and indirect medical care for herniated lumbar discs was U.S. $1.6 billion in the mid-1990s[2]; and in the United Kingdom, those 1% of all patients with low back pain who undergo surgery account for approximately 30% of healthcare costs for spinal disorders.[3] Estimates on the incidence of lumbar disc herniation operations range from 25 to 40 operations per 100,000 inhabitants in Europe to 70 in the United States, respectively.[4–6]

In many Western countries, postoperative physiotherapy-based rehabilitation programs are generally recommended aiming to shorten the period of postoperative recovery. Not to offer rehabilitation after disc herniation surgery may be considered "unethical" by many clinicians.

Up to 60% of patients complain from troublesome postoperative symptoms after a first operation for intervertebral disc herniation.[7,8] Such low postoperative success rates have been related to the selection criteria for operation, to the techniques applied, and to the heterogeneity of postoperative rehabilitation programs offered.[1,7,9]

There is surprisingly little evidence on the effectiveness of postoperative rehabilitation programs for disc herniation patients, and the few existing randomized controlled trails (RCTs) are of unsatisfactory quality, heterogeneous with respect to the onset of postoperative therapy, and their results seem conflicting.

Rehabilitation interventions starting immediately after lumbar disc herniation operation were not more effective than respective control interventions.[10,11] Some

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Table 1. Therapeutic Goals of the Custom-Tailored Physiotherapy Based Rehabilitation Program

Phase	Goals
Early phase (beginning of the exercise program until the patient was able to perform exercises without pain (about end of 3rd week)	Instruction, supervision and training in ergonomics, *e.g.*, proper seating, standing or lifting techniques, and obstacle course simulations of home environments Reeducating paravertebral muscle activation using neurophysiotherapeutic techniques, such as, for instance, proprioceptive neuromuscular facilitation; physiotherapists were free to choose the techniques Improving muscular spine stabilization using static and dynamic exercises Instructing and supervising patients in performing stretching exercises in shortened muscle groups, performing strengthening and endurance exercises for the back and abdominal muscles, the hip muscles and leg muscles, including the paretic leg muscles
Intermediate phase (achieve pain free mobility of the spine)	Emphasis was put on improvement of spine range of motion and mobility; strengthening and endurance exercises were intensified, and strengthening was performed against progressive resistance Reeducating physiologic movement patterns Reducing fear from movements
Late phase (restoration of the physiological movement patterns and reintegration of patients)	Emphasis was put on improving muscle coordination and automatic trunk muscle responses, dynamic spine stability, and cardiovascular fitness Maintaining physiologic movement patterns Reducing fear from movement, if necessary Ergonomic instructions were now workplace related and ergonomic training provided facilitating the reintegration of the subjects at the workplace and prevention from work and leisure time activity-related injury

The program was individually graded and adapted to the actual functional deficits of the patients. Physiotherapists were free to choose the physiotherapeutic treatment techniques. No passive physical modalities like electrotherapy or thermotherapy were performed. The type of exercises most appropriate for a patient was variable during the course of therapy as the type of exercise was adapted to the treatment progress of a patient.

intensive postoperative exercise programs starting several weeks after surgery were more effective in the short-term than less intensive ones[8,12] or than no therapy.[13] Other RCTs and controlled clinical trials, however, did not find supervised exercise,[14] multidisciplinary rehabilitation,[15] or specific interventions in addition to postoperative treatment programs[16] or horseback riding therapy[17] to be more effective than usual care,[15] home exercise,[14] or the treatment program alone.[16,17]

To our knowledge, only 2 small studies have so far evaluated the effects of physiotherapy-based postoperative rehabilitation *versus* the postoperative natural course[13] or "minimal intervention,"[18] respectively. Therefore, the present study was designed to investigate the effectiveness of a physiotherapy-based rehabilitation program starting 1 week after lumbar disc herniation surgery. In addition, we tried to estimate the contribution of specific effects to the observed outcome (efficacy).

■ Methods

Patients

Patients who had undergone a first uncomplicated disc surgery for lumbar vertebral disc herniation (standard laminectomy and either discectomy or microdiscectomy procedure) with a preoperative history of symptoms of less than 6 months were invited to take part in a randomized, controlled comparison of postoperative physiotherapeutic rehabilitation, neck-massage therapy (sham), or no further treatment. Enrollment took place over a 2.5-year period. Those interested were referred from the University of Vienna Hospital, Department of Neurosurgery to the outpatient clinic of the Department of Physical Medicine & Rehabilitation.

Other exclusion criteria were local complications in their operation area (such as discitis, local septic inflammation, *etc.*), postoperative muscle weakness in the legs (exceeding a force Grade 2/5), a sum score on the LBP rating scale exceeding 100 points, orthopedic conditions like spinal stenosis or spondylolisthesis, chronic pain disorders of the musculoskeletal system, defined neurologic diseases, or psychiatric disorders. All participants provided written, informed consent.

The ethics committee of the University of Vienna approved the study protocol. A public Austrian insurance company provided financial support but had no role in the study concept, design, data collection, data analysis, data interpretation, or the writing of the report.

Therapy

Physiotherapy Group. Patients in the physiotherapy group received 20 treatment sessions over 12 weeks of a physiotherapy-based rehabilitation program (Table 1) with custom-tailored instructions by the supervising physician, who discussed the course of therapy with every patient once a week. Each patient was treated by 1 physiotherapist only according to written prescriptions, each treatment session lasting 30 minutes.

Within the first weeks following the operation, patients performed with their physiotherapist isometric strengthening exercises for the back and hip extensors and the abdominal muscles, and stretching exercises for shortened muscles, respectively. From the very beginning, subjects were also supervised and trained in ergonomics such as proper seating, standing or lifting techniques, and obstacle course simulations of home environments. In the later course of the program, emphasis was put on improvement of the general mobility of the spine. In the late phase in addition to restoring physiologic movement pattern, exercises were started that aimed at improving muscle coordination and automatic muscle response time. Patients were advised to perform endurance exercises at home. Now the ergonomic instructions were workplace related and ergonomic training provided facilitating the reintegration of the subjects at the workplace and helped to prevent from work and leisure time activity related injury. Patients were instructed to engage

in a home exercise program and encouraged by their physiotherapist to regular home exercise.

Sham Treatment. Masseur specialists necessarily of the University Department of PM&R only administered during 20 sessions "sham" neck massage of 30 minutes' duration each with the patients lying in supine position on a massage bed and the head of the patient resting on the therapist's knees. No further therapies were provided.

No Treatment. Patients were asked to "wait and see" for the first 3 months after operation.

Cointervention

Before enrollment, all patients received a postoperative "minimal physiotherapeutic intervention" to homogenize participants for prior physiotherapeutic experience and to minimize potential disappointment with not receiving therapy (instructions on ergonomics, lifestyle changes, and isometric back extension exercises). All patients were encouraged to continue exercising twice daily after discharge from hospital. The patients received an information booklet dealing with the causes of disc herniation, operation techniques, postoperative prognosis, and suggested activities for promoting recovery and preventing relapse.

All patients were asked to restrict to on-demand analgesics for pain relief in addition to their study intervention.

Randomization and Blinding

Block randomization (SAS) was performed by the Department of Medical Statistics. Group allocation was provided in sequentially numbered, sealed opaque envelopes.

Baseline data were collected by the study physicians (C.B.E., G.R.E.) at the Department of PM&R. Thereafter, the study physician 1) documented the date and time of opening of the envelope, 2) signed it, and 3) finally opened the envelope. He handed out the treatment instructions and explained them to the patient and organized, if necessary, the respective therapy. Residents working under supervision at the Department of PM&R who were unaware of the treatment allocation and the primary aims of the study collected all follow-up data. The study physician who was not actively involved in the clinical examinations supervised assessments.

Outcome Measures

Primary and secondary outcome measures were assessed at baseline, 6 and 12 weeks thereafter, and at the 1.5-year follow-up visit, respectively.

The primary outcome measure was changes in ratings on the Low Back Pain Rating Scale (LBP-RS).[19] The LBP-RS was developed as a comprehensive assessment tool and is in accordance to the ICF prior ICIDH-2 concept for patients with LBP with disc herniation. It measures the health concepts of pain, disability, and physical impairment.[19,20] The LBP-RS has been validated in German.[20] Scores range from 130 (worst) to 0 (best). A score of 0 indicates that the patient is free from pain, able to perform all activities of daily living, does not need pain medication, and is unrestricted in physical functioning. One recent study demonstrated good sensitivity and acceptable specificity for the LBP-RS.[19] Both the original and the translated version of the LBP rating scale were highly reliable within and between raters, uni-dimensional, and construct valid.[19,20] Furthermore, responsiveness of the LBP-RS was demonstrated in several clinical trials.[21–23]

Secondary outcome measures included assessments of 1) patients' overall satisfaction with treatment outcome rated on a 5-point Likert scale (1 = completely recovered to 5 = dramatically worse as compared with baseline), 2) compliance concerning back exercise training at home, 3) socioeconomic parameters, and 4) psychologic parameters.

Socioeconomic parameters were assessed at 1.5-year follow-up and included the time elapsed to return to work or (if retired or unemployed) to usual activities, return to previous job or retraining for different job or retirement due to back problem, and the use of healthcare resources and type of treatment for postoperative back pain and sciatica.

The German version of the State Trait Anxiety Inventory (STAI)[24,25] was used at baseline, 3 months, and 1.5 years to assess situational state components and general trait components of anxiety, and the Giessen Test, widely used in German speaking countries,[26] to assess personality (baseline, follow-up).

Statistical Analysis

Based on findings from a pilot study that included 10 patients and revealed a SD of 8.1, sample size was calculated for the pairwise between-group comparisons of changes of the LBP-RS score at 12 weeks with unpaired t tests. Assuming a common standard deviation of 15 points,[19,23] a sample size of 40 patients per group was deemed sufficient to detect a difference of less than 10 points (two thirds of SD) in LBP-RS changes with a statistical power of 80% and an alpha of 0.05. We assumed that a between-group difference of 10 points on the LBP-RS was less than 15% of the baseline mean LBP-RS score would be of clinical relevance.

Primary analyses were the comparisons of LBP-RS changes from baseline to 12 weeks on an intention-to-treat basis (with the last observation carried forward where necessary) between 1) the physiotherapy and the "no therapy" group, 2) the physiotherapy and the sham treatment group, and 3) the sham treatment and "no therapy" group. To account for multiple pairwise group comparisons, hypothesis tests were performed in the above hierarchical order.[27]

Secondary analyses included group comparisons at week 6 and after 1.5 years. Paired t tests to examine changes within, and 2-sample t tests to compare changes between groups were applied. Ordinal secondary outcome variables were analyzed using Mann-Whitney U tests, categorical outcome parameters with, Fisher exact test, and χ^2 tests, respectively. A per-protocol analysis was done as a sensitivity analysis (data not shown).

Days to return to work were compared between groups by means of Kaplan-Meier survival curves and assessed by log-rank test. Two-sided tests and a significance level of 5% were used for all statistical analyses.

■ Results

Baseline Evaluation

A total of 120 consecutive patients were enrolled (flow chart: Figure 1). Of these, 111 patients (92.5%) completed the protocol. All 9 dropouts did so soon after the first session. Their characteristics were not apparently different from those who completed the study. A total of 99 patients (82.5%) also completed a 1.5-year follow-up. Patients' characteristics at baseline (except for body weight) and mean follow-up times were comparable between groups (Table 2).

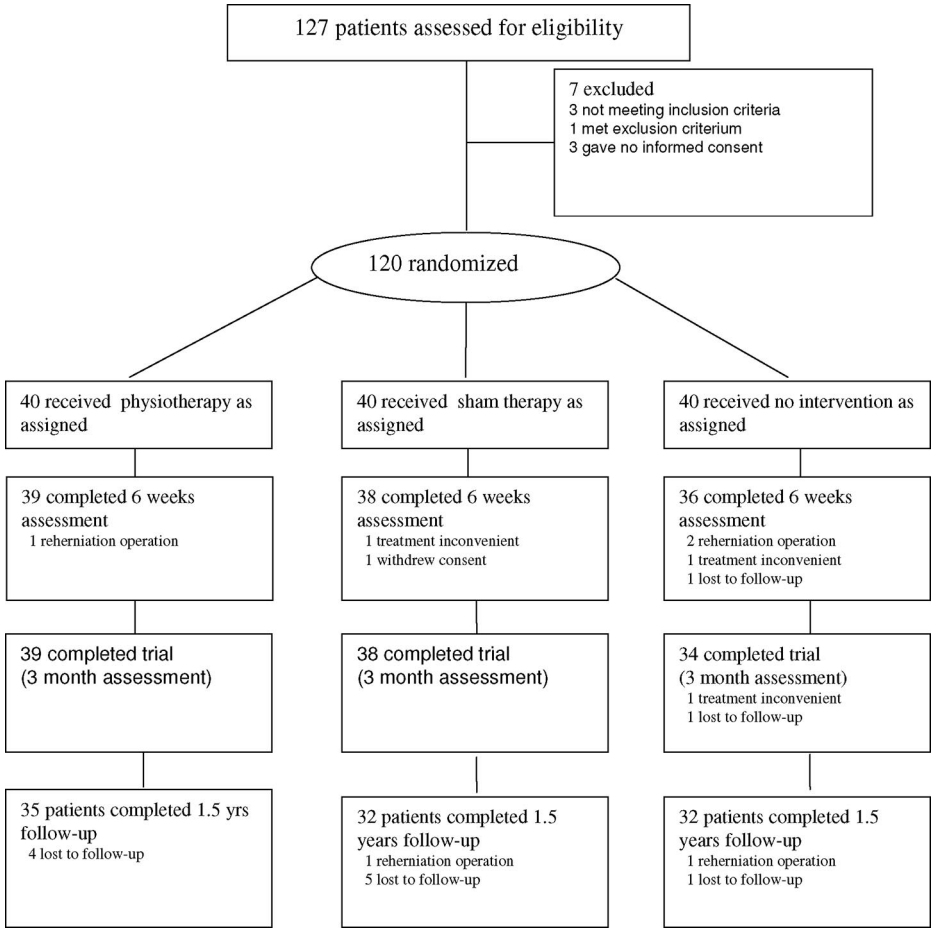

Figure 1. Flow of participants through the trial.

Effect of Therapy: LBPRS

Primary Analysis. At the end of treatment (12 weeks), the LBP-RS sum score of physiotherapy-treated patients was significantly better than that of the untreated patients (mean difference, 11.24; 95% confidence interval [CI], 3.4 to 19.1; $P = 0.005$). There was no statistically significant difference between the physiotherapy-treated and the sham-treated groups (mean difference, 4.14; 95% CI, −3.69 to 19.3) nor between the sham-treated and "no therapy" groups. However, patients with sham therapy tended to improve more than untreated patients (mean difference, 7.09; 95% CI, −1.4 to 15.6).

Secondary Analysis. Within-group analyses showed significant improvements of the LBP-RS sum scores in all 3 groups at all time points compared with baseline (Table 3). In the between-group analysis at 6 weeks and at the 1.5-year follow-up, physiotherapy as well as sham-treated patients showed a tendency to improve more than patients without therapy, but the differences did not reach the level of significance. Also, the differences between the physiotherapy and the sham-treated groups were not significant. An overview of all between-group comparisons of the LBP-RS scores is presented in Table 3 (Statistical analyses of the subscores are presented in Table 4).

At the end of therapy, the LBP-RS sum score had returned to normal (*i.e.*, <13 points) in 12 physiotherapy, 11 sham therapy, and 10 untreated patients. At the 1.5-year follow-up, the respective values were 14, 16, and 13. The respective differences between the physiotherapy-treated and untreated groups were not significant at any time-point.

Average consumption of analgesics during treatment was low. A total of 8 untreated (22.9%), 9 sham-treated (23.7%), and 10 physiotherapy-treated (24.2%) patients occasionally took nonsteroidal anti-inflammatory drugs during the first 6 weeks of the intervention. During the following 6 weeks of the intervention, the respective values were 9 (24.7%), 8 (21.6%), and 7 (18.4%).

Secondary Outcome Parameters

Patients' ratings of general improvement (5-point Likert scale) did not differ between groups at any time (Table 5).

During the first 3 months after operation, 56 patients (50.5%) regularly performed exercises at home either as recommended by a booklet all patients had received before randomization or by the physiotherapist. A further 40 (36%) patients performed exercises at irregular intervals; 1.5 years later, 25 patients (25.3%) still regularly performed home exercises, and another 33 patients (33.3%) at irregular intervals. At no time point did the proportions differ significantly between groups nor did the time dedicated to exercises.

Within the 1.5-year follow-up period, more than 4 of 5 patients returned to work or resumed normal daily activities (Figure 2), 4 subjects had received job retraining (1 untreated, 2 sham, and 1 physiotherapy-treated).

During the 1.5-year follow-up, 33 of 99 patients received additional therapy because of postoperative com-

Table 2. Baseline Characteristics and Follow-up Intervals of the Study Patients

	No Therapy (n = 40)	Sham Therapy (n = 40)	Physiotherapy (n = 40)
Sex (male/female)	25/15	21/19	21/19
Age (yr)	41.8 ± 10.4	42.3 ± 9.8	39.8 ± 10.5
Body mass index (kg/m^2)	27.4 ± 4.5*	25.0 ± 3.3*	24.4 ± 3.0*
Duration of preoperative symptoms (wk)	6.5 ± 4.3	5.8 ± 4.4	5.9 ± 3.4
Preoperative absence from work (wk)	3.8 ± 2.9	3.5 ± 3.3	3.5 ± 2.3
Regular sports activities (yes/no)	27/13	30/10	29/11
Employment status: self-employed/employed/retired (unemployed)	4/28/8	4/32/4	8/30/2
Physical workload (high/low)	15/25	11/29	18/22
Disc herniation caused by trauma (yes/no)	24/16	19/21	26/14
Disc herniation due to work related trauma (yes/no)	19/5	12/7	19/7
Preoperative therapy (yes/no)	34/6	35/5	37/3
Drugs	16	16	14
Physical therapy	4	8	5
Drugs and physical therapy	14	11	18
Preoperative physiotherapy (yes/no)	2/38	1/39	6/34
Segmental level of disc operation (L3–L4; L4–L5; L5–S1)	3/18/19	1/20/19	3/17/20
Lasegue			
Left leg (yes/no)	33/7	32/8	29/11
Right leg (yes/no)	26/14	30/10	28/12
Postoperative paresis (yes/no)	21/19	20/20	16/24
Segmental level of paresis (L3/L4/L5/S1)	0/3/10/8	1/1/11/5	0/0/8/8
Psychometric measures			
State trait anxiety scores			
State anxiety	38.2 ± 10.6	39.0 ± 11.4	39.1 ± 10.2
Trait anxiety	38.0 ± 10.3	36.7 ± 11.3	37.6 ± 9.6
Giessen test			
Social response	29.9 ± 5.9	30.8 ± 5.3	30.9 ± 4.6
Dominance	27.2 ± 4.8	27.3 ± 5.3	26.5 ± 4.5
Self-control	27.5 ± 5.9	26.6 ± 5.4	25.9 ± 4.8
Basic mood	23.6 ± 6.0	22.4 ± 5.9	23.8 ± 5.6
Permeability	22.3 ± 5.6	20.3 ± 7.1	19.5 ± 5.5
Social potency	20.1 ± 4.9	18.2 ± 5.1	18.5 ± 5.9
Quality of life (VAS cm, 10 best value)	6.5 ± 2.0	6.2 ± 1.9	5.8 ± 1.8
Time elapsed from operation to baseline (days)	6.7 ± 2.2	6.2 ± .9	6.3 ± 1.4
Time elapsed from baseline to:			
1st follow-up (days)	42.0 ± 4.2	43.8 ± 6.1	42.5 ± 3.9
2nd follow-up (mo)	2.99 ± .24	3.09 ± .41	3.03 ± .27
3rd follow-up (mo)	18.75 ± 2.12	18.77 ± 2.85	18.31 ± 2.86

*Significant between-group differences.

plaints (10 untreated group, 11 sham-treated, and 12 physiotherapy-treated). Groups did not differ concerning additional demand of different intervention options (Table 5).

Psychologic variables of the STAI (Table 5) and Giessen inventory (data not shown) remained unchanged both at the end of therapy (STAI only) and at 1.5-year follow-up with no difference between groups.

Table 3. Results of the Statistical Analysis of the LBPRS Sum Scores (Intention-to-Treat Analysis)

	Baseline (mean ± SD)	Baseline to 6-Week Therapy (mean, 95% CI)	Baseline to End of Therapy (mean, 95% CI)	Baseline to 1.5-Year Follow-up (mean, 95% CI)
No therapy	53.4 ± 10.9	−14.4 (−9.3, −19.5)	−20.3 (−14.2, −26.4)	−19.4 (−11.5, −27.3)
Sham therapy	56.1 ± 10.8	−20.7 (−14.7, −26.8)	−27.4 (−21.3, −33.5)	−29.4 (22.0, −33.5)
Physiotherapy	57.5 ± 10.8	−20.2 (−15.3, −25.0)	−31.6 (−26.4, −36.7)	−28.0 (−20.4, −35.5)
Physiotherapy *vs.* no therapy (primary analysis)				
Difference between mean scores (95% CI)		5.72 (−1.17 to 12.61)	11.24 (3.41 to 19.07)	8.55 (−2.21 to 19.3)
P		0.102	0.005	0.118
Physiotherapy *vs.* sham treatment (secondary analysis)				
Difference between mean scores (95% CI)		−0.59 (−8.22 to 7.04)	4.14 (−3.69 to 11.98)	−1.49 (−11.92 to 8.94)
P		0.88	0.296	0.777
Sham treatment *vs.* no therapy (secondary analysis)				
Difference between mean scores (95% CI)		6.31 (−1.49 to 14.12)	7.09 (−1.39 to 15.57)	10.04 (−0.6 to 20.67)
P		0.111	0.10	0.064

Table 4. Results of the Primary and Secondary Statistical Analysis of the Low Back Pain Rating Scale Subscores

	Baseline (mean ± SD)	Baseline to 6-Week Therapy (mean, 95% CI)	Baseline to End of Therapy (3 mo) (mean, 95% CI)	Baseline to 1.5-yr Follow-up (mean, 95% CI)
Pain maximum = 60 points (worst)				
No therapy	12.95 ± 8.05	1.35 (−1.55, 4.24)	0.82 (−2.8, 4.43)	1.2 (−3.29, 5.68)
Sham therapy	13.92 ± 8.27	−1.00 (−4.70, 2.69)	−2.91 (−6.53, 0.7)	−3.81 (−8.18, 0.56)
Physiotherapy	14.68 ± 8.07	0.20 (−2.76, 3.16)	−4.1 (−6.59, −1.61)	−2.05 (−6.27, 2.17)
Physiotherapy *vs.* no therapy (primary analysis)				
Difference between mean scores (95% CI)		−1.14 (−5.22 to 2.93)	−4.92 (−9.23 to −.60)	−3.24 (−9.31 to 2.82)
P		0.58	0.026	0.29
Physiotherapy *vs.* sham therapy (secondary analysis)				
Difference between mean scores (95% CI)		1.21 (−3.46 to 5.87)	−1.19 (−5.51 to 3.14)	1.77 (−4.21 to 7.74)
P		0.608	0.59	0.56
Activity of daily living maximum = 30 points (worst)				
No therapy	17.4 ± 3.86	−6.93 (−8.58, −5.27)	−8.8 (−10.69, −6.91)	−9.8 (−12.12, −9.86)
Sham therapy	18.6 ± 3.63	−9.2 (−10.98, −7.42)	−11.33 (−13.42, −9.23)	−12.42 (−14.6, −10.25)
Physiotherapy	18.13 ± 3.6	−7.65 (−9.51, −5.79)	−11.48 (−13.39, −9.56)	−12.8 (−14.19, −9.96)
Physiotherapy *vs.* no therapy				
Difference between mean scores (95% CI)		−.73 (−3.18 to 1.73)	−2.67 (−5.32 to −.03)	−2.27 (−5.37 to .82)
P		0.56	0.047	0.15
Physiotherapy *vs.* sham therapy				
Difference between mean scores (95% CI)		1.55 (−.99 to 4.08)	−0.15 (−2.94 to 2.64)	.35 (−2.63 to 3.33)
P		0.227	0.92	0.82
Physical function maximum = 40 points (worst)				
No therapy	23.1 ± 3.9	−8.85 (−10.88, −6.82)	−12.15 (−14.59, −9.71)	−11.37 (−14.16, −8.58)
Sham therapy	23.6 ± 4.5	−10.48 (−12.54, −8.41)	−13.23 (−15.35, −11.1)	−13.2 (−15.66, −10.74)
Physiotherapy	24.4 ± 4.0	−12.7 (−14.53, −10.87)	−15.98 (−18.02, −13.9)	−13.83 (−16.71, −10.94)
Physiotherapy *vs.* no therapy				
Difference between mean scores (95% CI)		−3.85 (−6.54 to −1.16)	−3.82 (−6.96 to −.69)	−2.45 (−6.41 to 1.50)
P		0.006	0.017	0.220
Physiotherapy *vs.* sham therapy				
Difference between mean scores (95% CI)		−2.22 (−4.94 to 0.49)	−2.75 (−5.65 to 0.15)	−.63 (−4.36 to 3.11)
P		0.11	0.063	0.74

■ Discussion

To our knowledge, this is the first rigorous randomized clinical trial to test the effectiveness of physiotherapeutic rehabilitation following back surgery with, in parallel, a view on the mode of action. Results of this study provide evidence that physiotherapy-based rehabilitation following acute first-time lumbar disc herniation surgery starting 1 week after operation results in a more pronounced improvement than no therapy in the short term, confirming the results of 2 previously published less rigorous RCTs.[13,18]

These positive overall effects of physiotherapy, however, were similar to those of postoperative sham therapy, suggesting the mode of action of physiotherapy to be possibly mainly nonspecific. Indeed, 2 previous studies, in which no relative effectiveness of postoperative physiotherapeutic rehabilitation could be observed, seem to confirm this.[10,11] Studies, however, where rehabilitation interventions were superior to the control interventions[12,13,23,28] might question neck massage as a sham intervention. Neck massage might have had indirect effects on postoperative recovery *via* neuropsychophysiologic pathways.[29] Both the empathy of the therapist and the mechanical manipulation may reduce anxiety, relax the mind, and reduce distress.[30,31] These factors had been suggested to affect the perception of back pain and motor performance.[19,32] However, in this study, patients' anxiety, depressive mood, and personality profiles remained unaffected by the different interventions rendering such mechanisms unlikely. Most studies finding which rehabilitation interventions were superior to control interventions were probably not well comparable to our study for several reasons: 1) interventions started only several weeks after surgery,[12,13,23,28] 2) postoperative complaints several weeks after surgery was an inclusion criterion,[13,23,28] and 3) patients with acute as well as with chronic preoperative symptoms were included.[12,13,23,28] Our study included patients with acute and subacute preoperative symptoms only.

Table 5. Results of the Statistical Analysis of the Secondary Parameters as at the End of Therapy and as at the 1.5-Year Follow-up Observations

	No Therapy	Physiotherapy	Sham Therapy	Physiotherapy *vs.* No Therapy
Likert scale (3 mo) (very much improved/improved/unchanged/worse/much worse)	15/11/1/6/2	22/11/1/1/3	16/14/5/2/1	0.16*
Likert scale (1.5 yr) (very much improved/improved/unchanged/worse/much worse)	13/13/3/3/0	17/15/2/0/2	18/12/2/0/1	0.47*
Discectomy related pain during 1.5-yr follow-up (never/seldom/often/permanent)	8/8/9/7	5/16/11/3	4/19/6/3	0.63*
Back pain/sciatica/or both of them during 1.5-yr follow-up	14/3/7	12/1/16	15/3/10	0.12†
Additional treatment during 1.5-yr follow-up (yes/no)	19/13	19/16	12/20	0.81‡
Use of analgesics during 1.5-yr follow-up (never/sporadic/often/always)	18/5/3/6	26/6/1/2	27/3/1/1	0.07*
Sought physical therapy during 1.5-yr follow-up (physiotherapy, massage, hot packs, *etc.*)	18	19	12	1.0‡
Sought treatment in a rehabilitation hospital during 1.5-yr follow-up (outpatient/inpatient/both)	9/4/5	6/8/5	6/3/3	0.39†
State anxiety (mean longitudinal changes, 95% CI)				
3-mo follow-up	−0.91 (−3.87; 2.04)	−2.27 (−5.65; 1.10)	1.54 (−1.54; 4.62)	0.56§
1.5-yr follow-up	−2.70 (−8.00; 2.60)	−1.19 (−4.58; 2.19)	0.76 (−3.31; 4.83)	0.64§
Trait anxiety (mean longitudinal changes, 95% CI)				
3-mo follow-up	1.57 (−4.63; 1.49)	−0.55 (−3.24; 2.13)	1.03 (−1.15; 3.20)	0.62§
1.5-yr follow-up	−1.30 (−5.27; 2.67)	0.09 (−2.97; 3.16)	0.26 (−2.36; −2.88)	0.64§

P values are indicate significant difference between physiotherapy and the untreated group: *Mann-Whitney *U* test; †Pearson χ^2; ‡Fisher exact test; §2-sided *t* test.

The proportion of patients who performed their exercises on a regular or irregular basis was surprisingly high and exceeded 85% within the first 12 weeks of our study trial. Such adherence with home exercises was either as high as, or clearly higher than, previously reported in the literature.[33,34] As control patients performed their home exercises as frequently as the physiotherapy-treated did, one might argue that our minimal physiotherapeutic intervention, which was administered before patients' enrollment, might have had an effect *per se*, thus reducing the treatment effects observed for the physiotherapy group relative to the 2 control groups. All patients received 1 or 2 physiotherapy sessions starting with the second day following operation and a booklet that included 4 isometric back and abdominal strengthening exercises, which they could perform themselves at home in a safe way. These 4 exercises were unlikely sufficient to address and train all the impaired functions observed in patients following lumbar discectomy in an adequate way.[35–37] In contrast, the physiotherapy-instructed home exercises were individually tailored, multifaceted, and adapted to the patients' treatment progress. In addition, physiotherapists did not only supervise the cor-

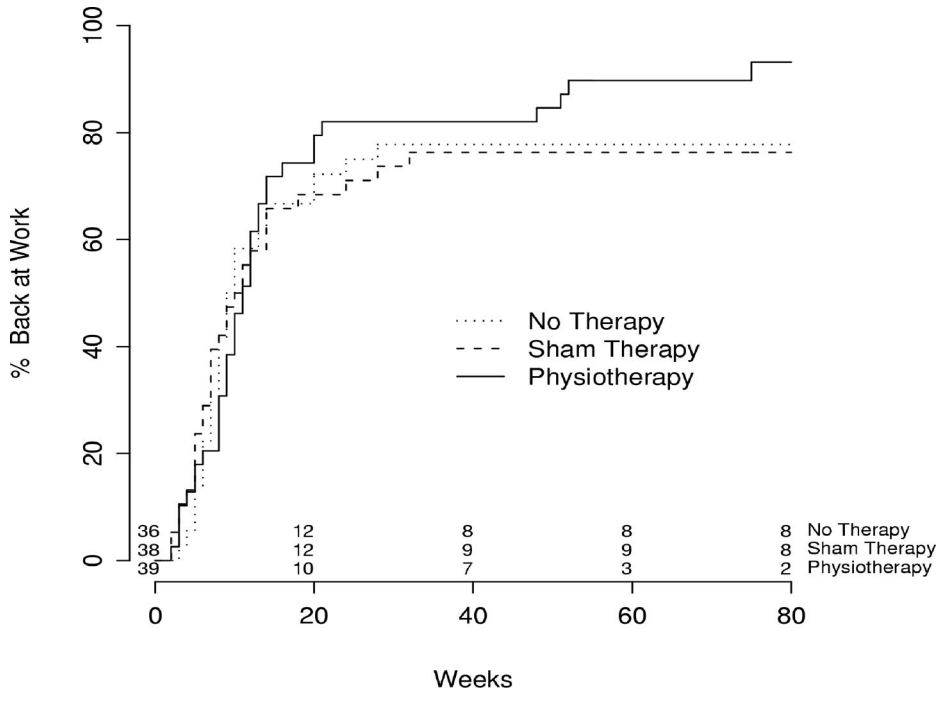

Figure 2. Back at work: Time to return to work by Kaplan-Meier plots for the 3 treatment groups. The numbers above the time axis give the number of patients still on sick leave at the respective time points. Curves after about 20 weeks are based on few observations and give unreliable estimates. Between-group differences were assessed with the log-rank test. Differences were not significant ($P > 0.05$).

rect performance of these exercises but also promoted adherence to home exercises in every treatment session, whereas the control patients were encouraged to perform their exercises at baseline and the follow-up examinations only. Such qualitative differences between the home exercise programs suggest that the home exercise performed by the control groups were unlikely a source of bias that would have minimized the treatment effects observed for the physiotherapy group relative to the 2 control groups.

Our observation of a clinical relevant, but statistically not significant, better improvement of the LBP-RS in sham-treated than in untreated patients seems to confirm that of others who reported effects of placebo interventions (*vs.* no treatment) on continuous outcome variables like pain,[38] supporting assumptions of others of the importance of both the personality of the therapists and the patient–therapist relationship on the overall perceived treatment effect.[39]

Independent of the type of postoperative care, approximately 40% of patients reported frequent or permanent postoperative complaints at 1.5-year follow-up. Others have seen similar rates.[8,40] Although different physical and psychosocial mechanisms have been suggested,[41–46] making a case for comprehensive biopsychosocial rehabilitation, the mechanisms of generation, and perpetuation of postoperative back complaints remain speculative.

There are persistent concerns of reinjury, reherniation, or instability with active rehabilitation and prevention programs or recommendations of early return to work after lumbar disc surgery. Our complication rate over 1.5 years was low and is in keeping with the results of 1 recent meta-analysis, which found no evidence that patients need to restrict their activities following first-time disc surgery.[1] Most of the patients in this study were integrated in work-life, either employed or self-employed. Return to work was comparable between the 3 groups at the end of the intervention with more than 80% back to work or, if retired or unemployed, able to perform usual activities of daily living. A further reduction of the length of sick leave might have been possible,[47] although all patients were encouraged to early return to work.

Limitations

This study has several limitations. We did not assess the type of disc herniation and the competence of the disc anulus intraoperatively, findings that, according to 1 recent study, may be more predictive for the long-term postoperative outcome than demographic, socioeconomic, or clinical variables.[9]

Survival curves for return to work suggest roughly a 15% unit difference in return to work during the 1-year follow-up period. One might assume that the sample size was insufficient to detect a clinically meaningful difference between groups. The primary endpoint of this study was to observe the changes on the LBP-RS at the 12-week follow-up examination. Our sample size estimate was based both on a pilot study and on findings from pervious studies that used the LBP-RS as an outcome parameter. A sample size of more than 40 patients thus would have led to the detection of between group differences at the 12-week follow-up examination that were clinically irrelevant. The survival analysis for return to work presented in Figure 1 was a secondary outcome parameter and included the follow-up time of 1.5 years. At 12 weeks, approximately 60% of the subjects were back at work independently from the intervention they had received. From the remaining 40% of patients, clearly more patients from the physiotherapy group seemed to return to work within the remainder of the 1.5-year observation period. This observed difference, which was statistically not proven with our sample size, might favor rehabilitation in the intermediate and long term. A future study, however, will need to clarify whether or not savings for the society concerning disability costs would probably make it worthwhile to provide physiotherapy-based rehabilitation to all discectomy patients.

Neither patients nor physiotherapists were blinded. Patients' blinding was impossible as all patients were fully informed about the aims and the nature of the study. In this study, blinding of the clinical examiners may easily have become unsuccessful as intensive communication can be expected to happen between the assessing physiatrist and the patients. Patients' assessments were therefore performed by trainee physiatrists who were unaware of the aims of the study and supervised by the study physicians who was a silent observer. Before an assessment, patients were instructed not to provide information about treatment allocation to the clinical examiner. The success of blinding was not assessed in order to keep the primary aims of the study covert to clinical examiners. Excellent interrater reliability scores for the LBP rating scale[19,20] indicate reliable assessment of the data.

■ Key Points

- Most rehabilitative physiotherapeutic interventions following disc herniation operation are empirically based but have become accepted by both patients and physicians to an extent that questioning the use of such interventions or withholding physiotherapy-based rehabilitation following disc herniation operation would be considered unethical.
- Evidence for the effectiveness of postoperative/rehabilitative interventions for different conditions is sparse, and the vast majority of randomized controlled trials available are of limited methodologic quality.
- To our knowledge, this is the first rigorous randomized clinical trial to test the effectiveness of physiotherapeutic rehabilitation following back surgery with, in parallel, a view on the mode of action.
- Physiotherapy-based rehabilitation following first-time disc herniation operation is effective in the short-term when compared with no therapy.

• Psychologic factors might contribute substantially to the benefits observed in comparison with receiving no therapy.

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