Rehabilitation after lumbar disc surgery

Oosterhuis, T.

2016

document version
Publisher's PDF, also known as Version of record

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Early rehabilitation after lumbar disc surgery: the REALISE trial

Teddy Oosterhuis
Raymond W Ostelo
Wilco C Peul
Michiel R de Boer
Carmen L Vleggeert-Lankamp
Mark P Arts
Maurits W van Tulder

Oosterhuis T, Ostelo RW, van Dongen JM, Peul WC, de Boer MR, Bosmans JE, Vleggeert-Lankamp CL, Arts MP, van Tulder MW. Effectiveness and cost-effectiveness of early rehabilitation after lumbar disc surgery (REALISE): a randomised controlled trial. Submitted

Abstract

Background: for patients who underwent lumbar disc surgery for herniated discs, the two most common options for postoperative management are referral for rehabilitation starting immediately after discharge from the hospital or no referral. A direct comparison of the effectiveness of these two strategies is lacking.

Objective: to assess the effectiveness of early rehabilitation after lumbar discectomy.

Methods: patients who underwent lumbar discectomy were randomly assigned by use of computer-generated blocks to the rehabilitation or control group. Primary outcomes were the effect of treatment on global perceived effect, functional status, pain intensity and general physical and mental health. The primary analysis was by intention to treat, using multilevel analysis.

Results: there were no clinically relevant or statistically significant overall mean differences between the intervention (n=92) and control group (n=77) for any outcome: global perceived effect (GPE) OR 1.0; 95%CI 0.6, 1.7; functional status (ODI) MD 1.5; 95%CI -3.6, 6.7; leg pain (NRS) MD 0.1; 95%CI -0.7, 0.8; back pain (NRS) MD 0.3; 95%CI -0.3, 0.9; general physical health (SF12) MD -3.5; 95%CI -11.3, 4.3; general mental health (SF12) MD -4.1; 95%CI -9.4, 1.3.

Conclusion: the results show that referral for early rehabilitation is not more effective than no referral in patients who underwent lumbar discectomy.

Introduction

The lumbosacral radicular syndrome, also called sciatica, is commonly caused by a herniated disc [1]. The syndrome is characterised by lower limb pain radiating below the knee in an area of the leg served by one or more lumbosacral nerve roots. Sometimes there are neurological phenomena such as sensory and motor deficits. The incidence of sciatica is estimated at 5 per 1,000 in Western countries [2]. In the Netherlands, the incidence of sciatica increased from 75,000 to 85,000 cases per year over the past decade [3, 4]. The direct and indirect costs of patients suffering from sciatica approximate 1.2 billion Euros per year [3]. The natural course of sciatica is favourable in the majority of patients [5]. The international consensus is that surgical treatment is offered if the radiating leg pain persists despite a period of conservative management [6]. Rates of spinal surgery differ across countries and within one country [7]. Rates in the United States are 30% higher than in the Netherlands, 50–60% higher than in Canada and 80% higher than in the UK [2]. It is estimated that the surgery rate for herniated lumbar discs in the Netherlands is about 12,000 operations per year [4, 8]. Recovery rates after conventional microdiscectomy of 66% at 4 weeks and 75% at 8 weeks follow up have been reported [9] and return to work rates of 15% at 2 months follow-up [10]. As the group of patients with limited recovery highly contributes to the direct and indirect costs of lumbar disc surgery, an important aim of postoperative treatment is to prevent the development of chronic symptoms [11].

Currently, postoperative care and management, including referral for rehabilitation after discharge varies between hospitals and surgeons. A national survey in the UK showed that 55% of the surgeons did not send their patients for physiotherapy following any form of spinal surgery [12]. Another UK survey revealed considerable variation in access to postoperative physiotherapy for outpatients. Also, physiotherapists providing care to patients who had undergone lumbar disc surgery reported a wide variety of treatment contents being delivered [13]. A national survey in the Netherlands amongst spinal surgeons (both neurosurgeons and orthopaedic surgeons) showed that 65% of the surgeons always refer patients for postoperative physiotherapy after discharge, whereas 24% never refer patients for postoperative physiotherapy and 11% sometimes do. Also, 45% of the Dutch surgeons considered physiotherapy after discharge to be essential, but 30% of the surgeons strongly disagreed that physiotherapy would be essential [14]. During hospitalisations most patients receive some form of rehabilitation [14].

The two most common options for management after discharge are referral or no referral for early rehabilitation. The first option consists of continued rehabilitation offered to all patients. The second option comprises the advice to return to an active lifestyle, with postoperative rehabilitation only for those patients having persisting symptoms after six to eight weeks. Several randomised controlled trials investigated the effectiveness of rehabilitation following primary lumbar disc surgery [15]. For exercise programs starting 4–6 weeks post-surgery, there is moderate evidence that they are more effective in improving physical function, and low quality evidence that they are more effective than no treatment in decreasing pain. There is moderate evidence that high intensity exercises starting 4-6 weeks post-surgery are more effective in improving physical function compared to low intensity exercises, and low quality evidence that they are more effective in decreasing pain. However, high quality studies assessing the effectiveness of immediate postoperative interventions are lacking [15]. Therefore, the aim of the Rehabilitation After Lumbar Disc Surgery (REALISE) study is to evaluate the effectiveness of early rehabilitation starting in the first week after surgery for lumbar disc herniation.

Methods

A multicentre randomised controlled trial was conducted with patient recruitment in 10 hospitals, both urban and regional, in three regions in the Netherlands. Primary care physiotherapists and exercise therapists in the catchment areas of these hospitals provided rehabilitation following lumbar disc surgery. Details of the design and methods have been published previously [16] and the trial has been registered (Netherlands Trial Register: NTR3156).The Medical Ethics Review Board of the VU University Medical Centre approved the study protocol in September 2011 (registration number NL35897.029.11). Subsequently, local review boards of all participating hospitals approved the protocol. Written informed consent was obtained from all patients.

Eligibility and randomisation

Eligible patients had a herniated lumbar disc confirmed by MRI and signs of nerve root compression corresponding to the level of disc herniation, were between 18 and 70 years of age and were able to fill out questionnaires in Dutch themselves. Neurosurgeons referred potentially eligible participants to

the research team. Research nurses checked eligibility criteria and excluded patients if they met any of the following criteria: cauda equina syndrome, neurogenic claudication, co-morbidities of the lumbar spine (e.g., fractures, carcinomas, osteoporosis), prior spinal surgery in the last 12 months, previous lumbar disc surgery at the same level and same side, pregnancy, or contra-indications for exercise therapy (e.g., acute respiratory or cardiovascular complaints, acute systemic infections). To conceal treatment allocation, randomisation lists per hospital were generated by computer prior to study commencement by an independent person. To achieve the predetermined size of treatment and control group, weighted block randomisation (blocks of four) was used. Directly after having received the completed baseline questionnaire and prior to surgery, the research nurse opened the next consecutive in advance prepared numbered opaque sealed envelope containing the assigned postoperative strategy.

Treatment

During hospitalisation all participants, regardless of treatment allocation, received usual hospital care. A physiotherapist or nurse provided advice and instructions for transfers (e.g., bed to stand, chair to stand) and performing activities of daily living, in preparation for discharge. At discharge patients received a booklet providing advice and suggestions for exercises.

Intervention group: referral for rehabilitation

Participants in the intervention group received a referral for post-operative exercise therapy in primary care starting the first week after discharge. During a six to eight week period, participants received one or two exercise therapy sessions per week, information and advice about rehabilitation, conform a standardised treatment protocol based on a national clinical guideline [17]. The six to eight week period reflects the period before patients consult their neurosurgeon again after surgery. The exact duration of this period depended on the organisation in the hospital in which the patient was treated. The main goal was to gradually extend activities of daily living from personal care to housekeeping tasks in the short term, and return to work and prepare for sports and leisure activities in the long term. In the first week, therapists performed physical examinations and focussed treatment on the ability and possibility to execute personal care activities and perform transfers in the home situation. From the second week onward, exercises were taught with

gradually increasing intensity targeting limitations that were found in the initial postoperative assessment. The exact type of exercises was left to the therapists' discretion, based on the outcomes of the physical examination and taking patients' preferences into account. Therapists provided tailored advice on lifestyle and the execution of activities of daily living. Exercises aimed to prepare for and support the resumption of daily activities. Treatment could be terminated before the end of the six to eight week period if the patient was fully recovered. Per treatment session, participating therapists filled out a registration form including amongst others, treatment goals on both a global and more specific level, whether a home exercise regimen was prescribed or not and, if applicable, the reason for terminating the treatment.

Control group: no referral for early rehabilitation

Participants assigned to the control group were not referred for rehabilitation after discharge from the hospital. Patients could consult their neurosurgeon or general practitioner in case of recurring or increasing complaints, but no exercise therapy or other allied health care intervention was initiated in the six to eight week period before consulting the neurosurgeon again after surgery. The research nurses limited the extent to which they provided advice in case they were called by patients allocated to the control group. To prevent diminishing contrast between groups, only advice that had been given during the clinical phase was repeated.

Follow-up consult neurosurgeon

Six to eight weeks after discharge a follow-up consult with the neurosurgeon took place. Whether participants in the intervention group continued rehabilitation or control group participants started rehabilitation after this follow-up consultation was left to the neurosurgeons' discretion. We measured all health care consumption in both groups using cost questionnaires.

Outcomes

Baseline assessments took place preoperatively, and follow-up measurements at three days (pain intensity only) and 3, 6, 9, 12 and 26 weeks post-surgery. The study used standardised instruments with demonstrated validity, reliability and responsiveness. Outcomes were measured using online questionnaires, but postal questionnaires were available if requested. The baseline measures

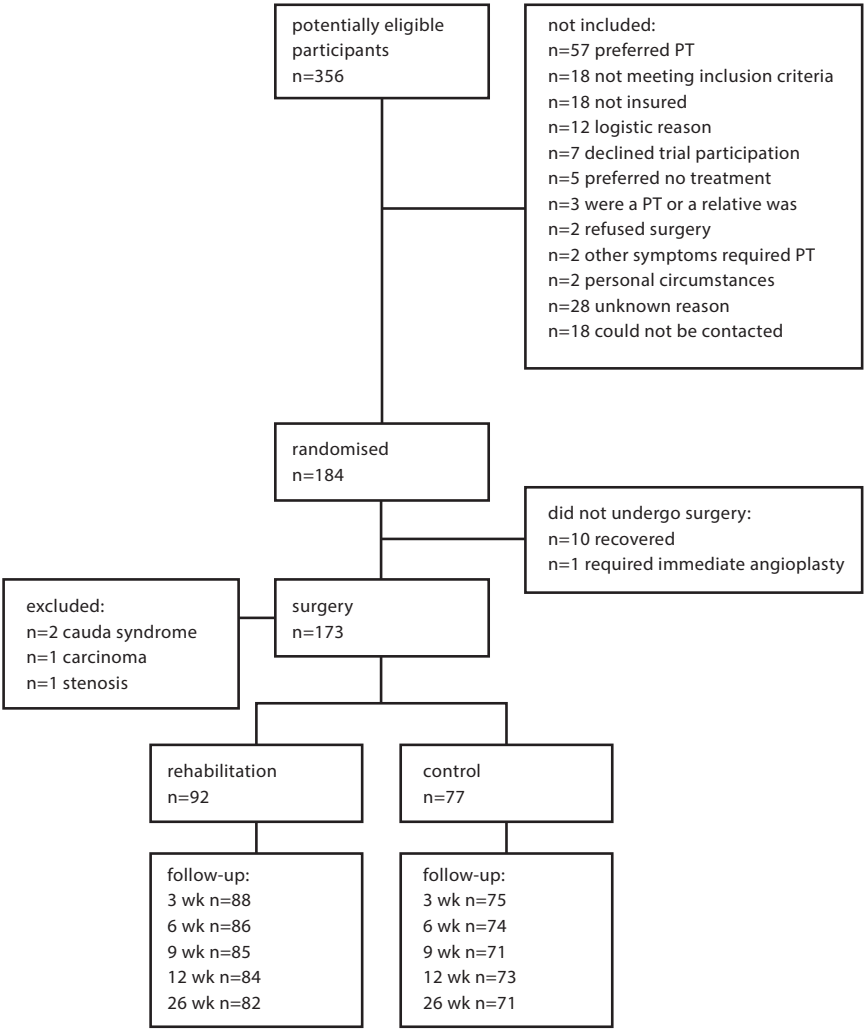

Figure 1 flow diagram

included demographic data (such as age, gender and education), relevant prognostic factors and primary outcomes.

Prognostic factors

Prognostic factors indicating unfavourable outcome after lumbar disc surgery included duration and severity of complaints preceding surgery and complications during surgery [18]. At baseline, scores were also obtained on the following instruments: credibility/expectancy questionnaire (CEQ) [19], the Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ) [20], the Fear- Avoidance Beliefs Questionnaire (FABQ) [21] and the Pain Coping Inventory (PCI) [22].

Primary outcome measures

The recommended core set of outcomes for low back pain research [23] was used, and all measures were self-reported. Functional status was assessed by the Oswestry Disability Index (ODI, version 2.1.a) [24]. Average pain intensity over the preceding week was measured for leg pain and low back pain on an 11-point numerical rating scale (NRS; 0=no pain to 10=worst imaginable pain) [25]. Global perceived effect was evaluated with the seven-point Global Perceived Effect scale (GPE), ranging from "completely recovered" to "worse than ever". This was dichotomised into success (completely and much recovered) and non-success (slightly recovered, no change, slightly worse, much worse and worse than ever).

Secondary outcome measures

The Medical Outcome Study Short Form 12 (SF-12) was used to assess general physical and mental health [26]. Questionnaires were used to check compliance to the allocated treatment and possible cross-over.

Blinding

Neurosurgeons were blinded for group allocation, as randomisation and group allocation were performed after their involvement in participant recruitment. The nature of the postoperative strategies precluded blinding of the patient and the therapist. All measures were patient reported outcomes, and outcome assessment was consequently not blinded. The unequal size of intervention

and control group, due to a multilevel structure in the intervention group only (because of the various primary care therapists involved in providing the rehabilitation), prevented blinding of the researcher and the statistician involved in outcome analyses.

Sample size

Power calculations were based on a Cochrane review assessing the effectiveness of rehabilitation following lumbar disc surgery [27] and were performed for the three main outcomes (for all: power 0.9; alpha 0.05). To detect clinically relevant mean differences in a multi-level analysis the following numbers of participants were needed: 165 patients for an 8-point difference on the ODI, 105 patients for a 2-point difference on the NRS, 150 patients for a 20% difference on the dichotomised GPE. Anticipating 15% potential study withdrawal, a total of 200 patients was needed, with an unequal number per group (109 intervention vs. 91 control) taking into account the multilevel structure of the data in the intervention group.

Data analysis

Baseline characteristics in both groups were compared to check prognostic comparability. The primary analysis was an intention-to-treat analysis. All continuous outcomes were analysed in a linear mixed model with responses at baseline, 3, 6, 9, 12 and 26 weeks. In these analyses the levels of hospital, therapist, patient and time of measurement were taken into account. Log likelihood ratios of naïve models were compared with models including an intercept for hospital or therapist. Time by treatment interactions were tested. Overall mean differences were presented or mean differences per time point in case of significant time by treatment interactions. Regression coefficients with 95% confidence intervals (CI) between baseline and follow-up measurements were calculated. Analyses were adjusted for confounders, defined as variables that changed the regression coefficient with ≥10%. For the dichotomous outcomes we used a generalised mixed model (logit link) with the same multilevel structure. Odds ratios with 95% CI were calculated. A per protocol analysis was performed to estimate the extent to which protocol deviations influenced the results. A protocol deviation was defined as receiving one or more sessions of exercise therapy in the first six to eight weeks after surgery in the control group, or not receiving any sessions of exercise therapy in the first six to eight weeks post-surgery by participants

Table 1 Baseline characteristics

characteristic	rehabilitation n=92	control n=77
Age in years	46.9 (11.6)	46.7 (12.2)
Female (n, %)	54 (58.7)	44 (57.1)
Living alone (n, %)	16 (16.3)	8 (10.4)
Education (n, %)		
low	20 (21.8)	17 (22.1)
middle	47 (51.1)	35 (45.5)
high	25 (27.1)	25 (32.5)
Employment (n, % yes)	74 (80.4)	57 (74.0)
Level of herniation (n, %)		
L2-3	1 (1.1)	2 (2.6)
L3-4	10 (10.9)	4 (5.2)
L4-5	31 (33.7)	42 (58.3)
L5-S1	48 (52.2)	29 (37.7)
L5-6	1 (1.1)	2 (2.6)
Type of herniation (n, %)		
sequester	34 (37.0)	34 (44.2)
bulging disc	57 (62.0)	46 (59.7)
extraforaminal	1 (1.1)	2 (2.6)
Functional status (ODI, 0-100)	48.6 (17.3)	50.4 (15.6)
Pain intensity leg (NRS, 0-10))	7.8 (1.9)	7.7 (1.8)
Pain intensity back (NRS, 0-10))	6.5 (2.5)	6.1 (2.6)
General physical health (SF12, 0-100)	26.2 (16.1)	26.7 (15.4)
General mental health (SF12, 0-100)	51.6 (21.5)	50.3 (21.8)
Psychosocial status (OMPSQ, 0-210)	109.0 (24.9)	114.2 (20.5)
Fear avoidance beliefs physical activity (FABQ, 0-24)	16.1 (4.4)	15.4 (5.4)
Fear avoidance beliefs work (FABQ, 0-24)	16.8 (11.0)	18.5 (11.3)
Expectation: expectancy surgery (CEQ, 3-27)	23.2 (2.8)	22.9 (3.0)
Expectations : credibility surgery (CEQ, 3-27))	22.0 (3.2)	21.7 (3.7)
Expectations: credibility item intervention (CEQ 1-9)	6.5 (1.8)	6.3 (1.8)
Expectations: credibility item control (CEQ 1-9)	6.4 (1.6)	6.5 (1.4)
Pain Coping : active (PCI)	6.7 (1.3)	6.5 (1.3)
Pain Coping: passive (PCI)	6.5 (1.3)	6.5 (1.2)

Duration of complaints (n, %)		
0-1months	2 (2.2)	0
1-2 months	6 (6.6)	3 (3.9)
2-3 months	1 (1.1)	7 (9.1)
3-6 months	35 (38.0)	29 (37.7)
6-9 months	18 (19.6)	13 (16.9)
9-12 months	6 (6.5)	7 (9.1)
> 12 months	24 (26.1)	18 (23.4)
Severity of complaints: medication use (n, %)		
every day	56 (60.9)	47 (61.0)
not every day	18 (19.6)	14 (18.2)
no	18 (19.6)	16 (20.8)
Surgical complications (n, %)		
nerve root injury	1 (1.1)	1 (1.3)
dural tear	2 (2.2)	2 (2.6)
increase in sensimotor deficit	0	1 (1.3)

Point estimates are in means (SD) unless stated otherwise

Table 2 Primary and secondary outcomes

outcome	rehabilitation n=92	control n=77	mean difference (95%CI)
Primary outcomes			
Functional status (ODI)			
baseline	48.6 (17.3)	50.4 (15.6)	
3 weeks	29.5 (18.9)	29.6 (19.0)	
6 weeks	20.3 (16.2)	19.3 (16.9)	
9 weeks	16.6 (16.9)	15.2 (17.1)	
12 weeks	15.4 (15.6)	13.5 (17.0)	
26 weeks	14.3 (16.6)	14.3 (18.0)	
			crude 1.0 (-3.7, 5.7)
			adjusted 1.5 (-3.6, 6.7)[1]
Pain intensity leg (NRS)			
baseline	7.8 (1.9)	7.7 (1.8)	
3 weeks	2.7 (2.9)	3.1 (3.0)	
6 weeks	2.1 (2.5)	2.1 (2.5)	
9 weeks	1.8 (2.5)	2.1 (2.7)	
12 weeks	2.0 (2.7)	1.8 (2.6)	
26 weeks	2.0 (2.7)	2.0 (2.7)	
			crude -0.1 (-0.8, 0.6)
			adjusted 0.1 (-0.7, 0.8)[2]
Pain intensity back (NRS)			
baseline	6.5 (2.5)	6.1 (2.6)	
3 weeks	3.5 (2.4)	3.3 (2.4)	
6 weeks	2.9 (2.1)	2.8 (2.3)	
9 weeks	2.8 (2.5)	2.2 (2.4)	
12 weeks	2.9 (2.5)	2.4 (2.5)	
26 weeks	2.9 (2.4)	2.4 (2.6)	
			crude 0.4 (-0.3, 1.0)
			adjusted 0.3 (-0.3, 0.9)[3]
Global perceived recovery (GPE, n % recovered)			
3 weeks	54 (58.7)	44 (57.1)	
6 weeks	64 (69.6)	53 (68.8)	
9 weeks	61 (66.3)	53 (68.8)	
12 weeks	62 (67.4)	60 (77.9)	
26 weeks	60 (65.2)	50 (64.9)	
			OR 1.0 (0.6, 1.7)

Secondary outcomes			
General physical health (SF-12)			
baseline	26.2 (16.1)	26.7 (15.4)	
3 weeks	38.2 (22.3)	36.5 (23.7)	
6 weeks	47.9 (26.3)	48.7 (26.2)	
9 weeks	53.5 (29.6)	54.3 (31.0)	
12 weeks	57.8 (30.2)	62.2 (33.4)	
26 weeks	63.0 (31.8)	63.0 (34.5)	
			crude -1.1 (-8.5, 6.3)
			adjusted -3.5 (-11.3, 4.3)[4]
General mental health (SF-12)			
baseline	51.6 (21.5)	50.3 (21.8)	
3 weeks	58.1 (21.7)	61.2 (22.6)	
6 weeks	70.0 (21.8)	71.7 (22.1)	
9 weeks	73.9 (20.2)	73.1 (23.5)	
12 weeks	77.4 (21.0)	78.5 (23.3)	
26 weeks	77.6 (20.8)	76.1 (23.0)	
			crude -0.9 (-6.8, 5.0)
			adjusted -4.1 (-9.4, 1.3)[5]

Point estimates are in means (SD) unless stated otherwise, OR = odds ratio

[1] adjusted for functional status at baseline, age, gender, employment, leg and back pain, general mental health, psychosocial profile, fear avoidance, expectancy and credibility surgery, credibility rehabilitation

[2] adjusted for leg pain at baseline, living status, employment, psychosocial profile, general mental health, fear avoidance, expectancy and credibility surgery

[3] adjusted for back pain at baseline, psychosocial profile, fear avoidance

[4] adjusted for general physical health at baseline, age, living status, functional status, back pain, general mental health, psychosocial profile, fear avoidance, expectancy surgery, credibility rehabilitation and watchful waiting , pain coping

[5] adjusted for general mental health at baseline, age, living status, employment, functional status, back pain, general physical health, psychosocial profile, fear avoidance, credibility and expectancy surgery, credibility rehabilitation and watchful waiting, pain coping

in the intervention group. A subgroup analysis was performed including only participants who potentially could benefit most from rehabilitation. In order to do so, predictors of recovery post-surgery from an earlier study [den Boer] that were measured at baseline were tested in the control group of the current study by means of univariate regression analysis. Recovery was defined as ODI scores of 0-20 at 3 weeks post-surgery. Significant predictors were then used to select participants in both groups for the subgroup analysis. Analyses were performed using STATA/SE12.

Results

From May 2012 to December 2014, 356 patients were referred to the research team and of those, 172 were not included for various reasons (figure 1). Of the remaining 184 participants, 10 recovered before surgery could be performed and one participant did not undergo surgery because immediate angioplasty was required for an acute vascular complication unrelated to the disc herniation. Of the 173 participants that underwent surgery 4 participants were excluded due to cauda equina syndrome (n=2), carcinoma (n=1), and undergoing decompression for stenosis (n=1). Baseline characteristics of the rehabilitation (n=92) and control (n=77) group are described in table 1. Baseline measures were taken on average (SD) 13 (14.5) days pre-surgery. Participants in the rehabilitation and control group, respectively, were on average 46.9 and 46.7 years, 58.7% and 57.1% were female. Pain duration was 0-3 months in 9.9% and 13.0%, 3-6 months in 38.0% and 37.7%, 6-9 months in 19.6% and 16.9%, 9-12 months in 6.5% and 9.1%, >12 months in 26.1 and 23.4%, for rehabilitation and control group, respectively. Scores for functional status (ODI) were 48.6 (SD 17.3) and 50.4 (15.6). Leg pain was 7.8 (1.9) and 7.7 (1.8), back pain was 6.5 (2.5) and 6.1 (2.6) on a 0-10 NRS, for rehabilitation and control group, respectively.

Treatment content

For 51 participants (55%) in the rehabilitation group we obtained registration forms from the treating therapists. Focus of the treatment was primarily on stabilisation and coordination (73% of the sessions), mobility (72%), strength (66%), endurance (54%) and instructions regarding lifestyle and posture (45%). Therapists prescribed homework in 91% of the sessions. In 41% of the participants treatment was ended at 6-8 weeks post-surgery because treatment goals were reached. At 6 weeks follow-up, participants

in the intervention group reported having received on average (SD) 6.5 (3.7) treatment sessions.

Co-interventions during the first 6 weeks were limited, did not greatly differ between the groups and included (rehabilitation vs control): visits to an occupational physician 35 vs 31%, general practitioner 21 vs 17%, >1 visit to a neurosurgeon 9 vs 4%, other allied health professional 3 vs 1%, complementary/alternative health professional 1 vs 4%. Health care utilisation during the 26 weeks follow-up: X-ray 2 vs 4%, MRI 8 vs 7%, revision surgery 3 vs 5%, physio- or exercise therapy after 6 weeks 57 vs 31%.

Intention-to-treat analysis

Log likelihood ratios of naïve models were compared with models including an intercept for hospital and showed to be equal. Furthermore, five therapists treated two participants each and all other therapists treated one participant each. Hospital and therapist were, therefore, not included as a level. Interaction terms for time by treatment were not significant, and therefore not included. Multilevel analyses showed no clinically relevant or statistically significant overall mean differences between groups on any outcome (table 2). Recovery rates for the rehabilitation and control group, respectively, were 58.7% and 57.1% at 3 weeks, 69.6% and 68.8% at 6 weeks and then plateaued, except for a temporarily increased recovery at 12 weeks in the control group. A similar pattern of early decrease in pain and increase in functional status was seen in both groups. For the subgroup analysis, leg pain at three days post-surgery predicted recovery at 3 weeks follow-up. Including only participants with leg pain scores of >0 (n=156), >1 (n=142) or >2 (n=119) respectively, yielded similar results, with the exception of a significant difference in general mental health (a secondary outcome measure) when only participants were included with leg pain >1 or >2 (MD=-7.7; 95%CI -14.6 to -0.9 and MD=-7.1; 95%CI -14.1 to -0.1).

Per-protocol analysis

In the intervention group 6 participants did not receive any treatment by a physiotherapist or exercise therapist. Seven participants in the control group received physiotherapy during the first 6 weeks post-surgery. The per-protocol analysis therefore included 156 participants. Baseline characteristics were largely similar to the intention to treat analysis and multilevel analyses

showed no relevant or statistically significant overall mean differences between groups on any outcome (data not shown).

Discussion

This is the first reported multicentre randomised trial of rehabilitation immediately after surgery for lumbar disc herniation versus no rehabilitation. Our study demonstrated no clinically relevant or statistically significant differences on any clinical outcome during a 6-month follow-up period. In both groups the main decrease in pain and increase in functional status scores was obtained in the first weeks after surgery. This pattern of early recovery resembles the pain decrease and functional status increase during the first 1-2 months post-discectomy in two surgical trials that were performed in the same group of hospitals as the current study [9, 28]. Post-operative treatment in these trials was usual care, defined as either referral to physiotherapy for an exercise program or recommendations to perform exercises. The rationale for the intervention in the current study was that early rehabilitation aimed at resumption of daily activities prescribed to all patients might accelerate recovery including return to work. However, this was not found in the current trial. The predominantly early decrease in pain and increase in functional status without relevant between-group differences was also reported in earlier trials that compared rehabilitation with no treatment starting one [29] and six weeks post-surgery [30].

This trial aimed to investigate the effectiveness of an early functional training program, but the content of the intervention seemed to deviate from the protocol, with a focus on isolated exercises rather than the resumption of ADL activities. The intervention investigated in this trial might have been too generic and this may have influenced effectiveness of the program. Besides, insight into the mechanisms of recovery is limited, which precludes the use of a more specific program. The prediction rule for limited recovery post-discectomy [11] is not externally validated, and the variables in this rule were, apart from pain 3 days post-surgery, not confirmed in our trial. These secondary analyses showed a significant difference on general mental health for the subgroup with leg pain >1 or >2 in favour of the control group. It is, however, unclear if this constitutes a relevant difference. Besides, general mental health was not a primary outcome. It is, therefore, still unclear which subgroups, if any, may benefit most from post-operative rehabilitation.

Further research may contribute to the clarification of mechanisms of recovery and identifying subgroups and subsequently designing potentially effective interventions for those with residual complaints, which could then be tested in further trials.

This study had a few limitations. Firstly, due to the nature of the intervention, patients and care providers could not be blinded. However, this affected both groups. Moreover, credibility scores for both intervention and control were similar in both groups. Therefore, a lack of blinding is not likely to have had much impact. Secondly, baseline measures and randomisation took place before surgery for logistic reasons (i.e., treatment started a few days post-surgery) and to prevent patients' uncertainty during and after hospitalisation about the postoperative management. Eleven patients did not receive surgery and were excluded. This may have influenced the results. However, as Fergusson et al. [31] suggested, excluding these prematurely randomised patients does not bias the analysis if treatment allocation could not influence the likelihood of undergoing surgery. Patients in both arms declined surgery, and that was due to recovery. There are no reasons to assume that recovery before surgery could be performed would be associated with group allocation. In the present study, patients who underwent discectomy were either referred or not referred for rehabilitation immediately after discharge. In both groups the main decrease in pain and increase in functional status was noted in the first few weeks with large differences in recovery within both groups, as shown by the large variance. However, there were no clinically relevant differences between the groups. Therefore, referral for post-discectomy rehabilitation starting immediately after discharge cannot be recommended.

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