Timing of surgery for sciatica

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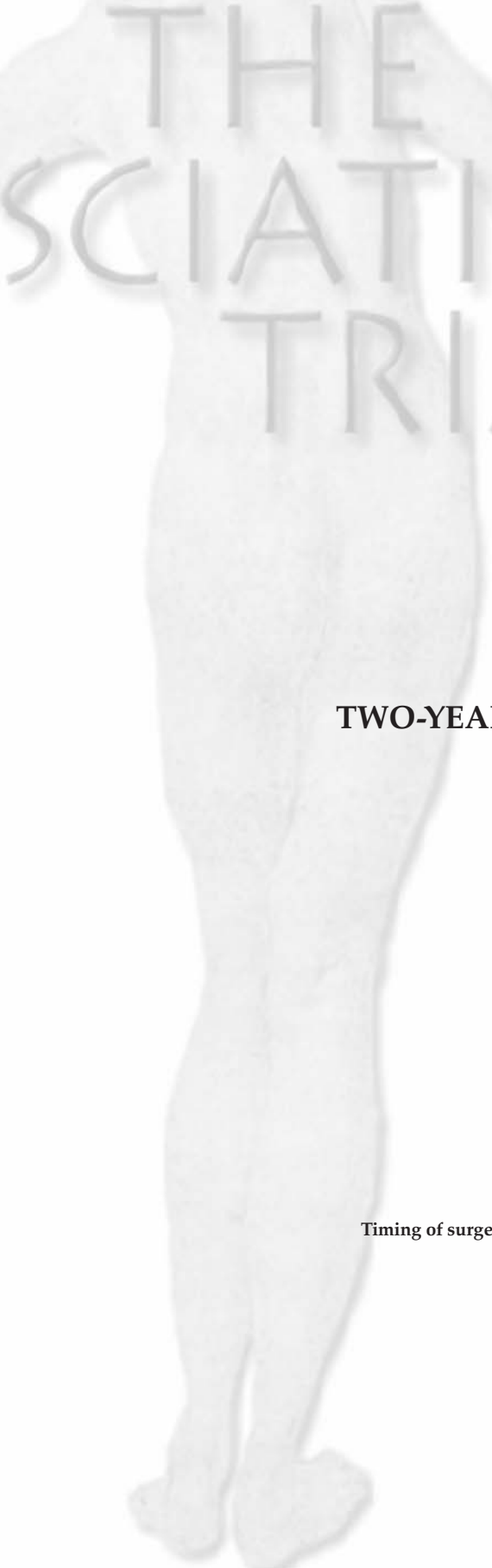

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TWO-YEAR RESULTS OF SCIATICA TRIAL

Timing of surgery for sciatica; 2-year results of a randomized controlled trial

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ABSTRACT

Study design: A randomized controlled trial with parallel group design comparing "early"surgery, following clinical guidelines, and prolonged conservative care for patients with sciatica.
Objective: To evaluate the effectiveness over a period of 2 years of timing of disk surgery for sciatica .
Summary of Background Data: Lumbar disk surgery is frequently performed on patients after elapse of at least 6 weeks of non abating sciatica, but the optimal timing of surgery is not known. One-year results of a randomized trial showed short-term effects in favor of early surgery. Two-year outcomes have not yet been described.
Methods: We randomized 283 patients with 6-12 weeks of sciatica to early surgery or an intended 6 months of continued conservative treatment, with delayed surgery if needed. Primary outcome measurements were the Roland Disability Questionnaire, Visual-Analogue-Scale for leg pain and Global Perceived Recovery. Repeated measurement analysis according to intent-to-treat was used to estimate the outcome curves for both groups.
Results: Of 141 patients assigned to undergo early surgery, 125 (89 %) underwent microdiskectomy after a mean of 2.2 weeks; of 142 patients designated for conservative treatment, 62 (44 %) were treated surgically after a mean of 18.7 weeks. There was no significant overall difference in disability scores during the first two years ($p=0.25$). Improvement of leg pain was faster for patients randomized to early surgery with a significant difference between areas under the curves over two years ($p=0.05$). Leg pain, back pain, functional disability and perceived recovery in both randomization groups showed similar results at 2 years. Twenty percent of the patients experienced unsatisfactory results at 2 years, as could be concluded from perceived recovery, pain and functional scores.
Conclusions: The two strategies, early surgery and prolonged conservative care, resulted in similar outcomes at two years but early surgery achieved more rapid relief of sciatica.
Summary: To evaluate the timing of lumbar disk surgery, a randomized trial with 283 patients with sciatica for 6 to 12 weeks was conducted, comparing early surgery with prolonged conservative care and possibly delayed diskectomy. Early surgery resulted in faster recovery, but with similar outcomes at 1 and 2 years.

INTRODUCTION

In Western countries surgical removal of the herniated nuclear part of the disk is routinely performed to relieve sciatica. The complex of symptoms encompassing sciatica, more accurately called the lumbosacral radicular syndrome (LSRS), is characterized by radiating pain in an area of the leg typically served by one lumbar or sacral spinal nerve root in combination with motor, sensory or tendon reflex abnormalities. It is estimated that 5 to 10 out of every 1000 inhabitants in western society develop sciatica each year with variable pain intensities and disease courses[127]. During the first 6 weeks the leg pain diminishes in 70 percent of the patients[182]. Most guidelines recommend surgery for the remainder of patients[44;45;47;183]. The unknown number of months needed for spontaneous recovery from pain and the lack of scientifically proven efficacy of alternative therapies, in combination with the personal treatment preference of the attending physician, hinder the patient who must decide about the possibility of surgical treatment. Until a few years ago, only one landmark randomized trial[40] could be retrieved showing that conservative treatment and surgery had similar results after 4 years of follow-up among patients with moderate pain intensities[78]. Patients with intense sciatica fear chronic disability. Without any outlook for short-term pain relief, most of them choose surgery. The continuing uncertainty around the optimal timing of surgery for sciatica probably results in large variations in the frequency of low back surgery between countries[46]. Recently extensive data became available from a randomized trial comparing early surgery with prolonged conservative care and possibly delayed surgery for patients with severe sciatica[129]. While substantially fewer operations were performed during a strategy of prolonged conservative care, early surgery resulted in faster recovery from leg pain but failed to yield higher recovery rates at one year . The 2-year follow-up results of this trial are presented here.

MATERIAL AND METHODS

We conducted a multicenter prospective randomized trial among patients with 6 to 12 weeks of severe sciatica to determine whether a strategy of early surgery leads to better outcomes during the first year compared to a strategy of conservative treatment for an additional 6 months and performing delayed surgery for patients with persisting pain. The medical ethics committee at each of 9 participating hospitals approved the protocol. Written informed consent was obtained from all patients. Details of the design and study protocol have been published previously[118]. The current study evaluates the 2-year follow-up data on these patients and focuses on differences between the long terms results of the two strategies.

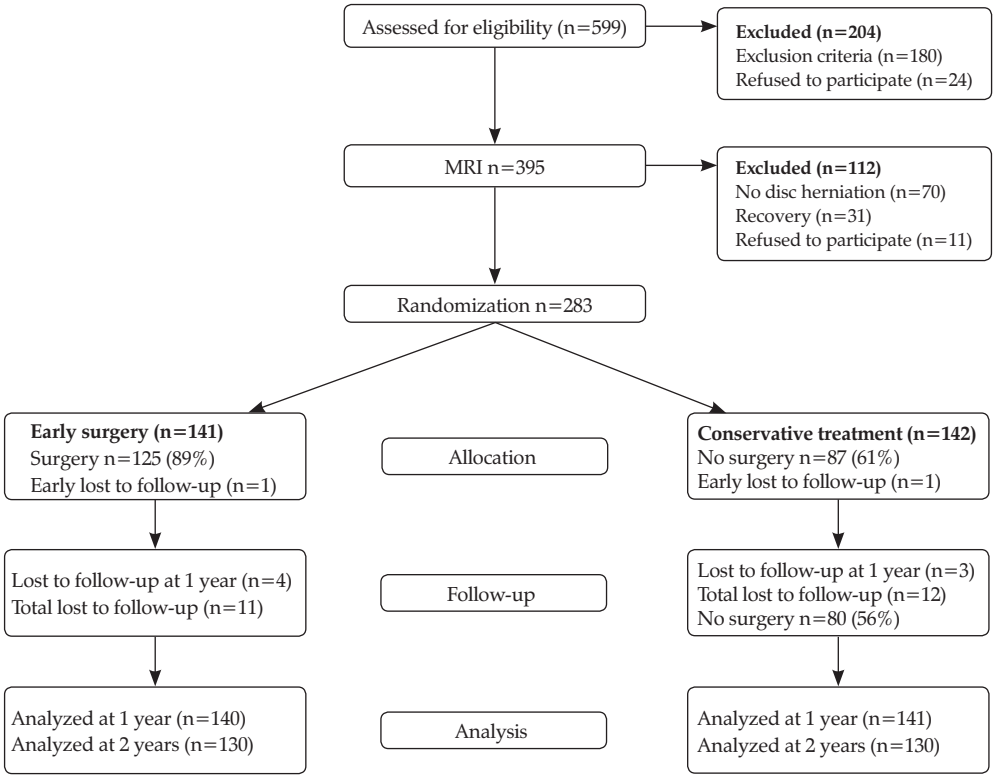


*Figure 1. Flow-diagram for 2 years of follow-up **

** Data of patients lost to follow-up were carried forward for 2 year analysis. No difference was registered between Mantel Haenszel analyses with or without these patients.*

Eligibility and Randomization

Eligible patients were between 18-65 years of age, had been diagnosed with an incapacitating LSRS by an attending neurologist and had a radiologically confirmed disk herniation. Patients presenting with a cauda-equina syndrome or severe paresis (MRC<3) were excluded as well as those with identical complaints in the past twelve months, or a history of spinal surgery, spinal stenosis, deformity or severe comorbidity.

A computer-generated permuted-block scheme was used for randomization, stratified according to center (n=9). One hour before randomization patients were again evaluated by independent research nurses. If at that moment, eligibility criteria were no longer met due to recovery, patients were as yet excluded. Otherwise successive numbered opaque envelopes containing the assigned strategy were opened.

Beforehand patients were notified that they were participating in a study comparing 2 different strategies for timing-of-intervention strategies rather than comparing surgery with non-surgical treatment. Obviously patients could not be blinded to the assigned treatment arm.

Treatment

Early surgery was preferably scheduled within 2 weeks of assignment and only cancelled if spontaneous recovery occurred before the date of surgery. The disk herniation was removed through an unilateral transflaval approach using magnification. Occasionally, at the discretion of the surgeon, a bilateral exploration was performed . After annular fenestration and decompression of the nerve root the risk of recurrent disk herniation was reduced by removal of loose degenerated disk material out of the disk space using curette and rongeur, without striving for a subtotal diskectomy. The duration of the hospital stay depended on the patient's functional ability to mobilize. At home the rehabilitation process was supervised by the physiotherapist. Depending on the nature of their work patients were advised to resume their regular jobs after 6 weeks onwards.

Prolonged conservative management was provided by the family practitioner. Ample information was supplied about the favorable prognosis. Treatment encompassed the prescription of effective painkillers according to prevailing guidelines and the advice to resume daily activities if feasible. A mobilisation scheme, based on time rather than pain, was recommended without checking the compliance. If considerable fear of movement was present, guidance of a physiotherapist was recommended. If sciatica persisted 6 months after randomization microdiskectomy was considered. Increasing leg pain not responsive to medications and progressive neurological deficit were indications to perform surgery earlier, within 6 months.

Outcomes

Primary outcomes were measured by means of the Roland Disability Questionnaire for Sciatica (RDQ)[114], 100 mm visual analogue scale for leg pain (VAS-leg)[109] and a 7-point Likert self-rating scale of global perceived recovery. The questionnaires were assessed at 2, 4, 8, 12, 26, 38, 52, 78 and 104 weeks.

Secondary outcomes, such as a repeated neurological examination, VAS back pain, functional-economic observational assessments (PROLO[104] by the independent Research Nurse, as well as Quality of Life scales[107]were filled out at monitoring visits scheduled at 8, 26, 52, 78 and 104 weeks. Research Nurses observed their own patients at the planned follow-up moments and were aware of the patient's treatment assignment.

Table 1 Baseline and Follow-up Characteristics of Patients with Sciatica*

Table 1 Patient Characteristics	Early Surgery (N=141)	Conservative (N=142)
Age (yr)	41.7 ± 9,9	43.4 ± 9,6
Male sex —no (%)	89 (63)	97 (68)
Quetelet-index†	25.9 ± 4.1	25.8 ± 4.0
Duration of sciatica in weeks	9.43 ± 2.37	9.48 ± 2.11
Took sick leave from work, no (%)	107 (76)	116 (82)
Duration sick leave in weeks	5.32 ± 2.78	5.28 ± 2.62
Radiating pain left leg-no (%)	67 (48)	73 (51)
Positive straight leg-raising test % ‡	100 (71)	104 (73)
Positive crossed straight leg-raising test % ‡	71 (50)	70 (49)
Sensory loss, no (%)	123 (87)	128 (90)
Dermatome anaesthesia, no (%)	31 (22)	33 (23)
Muscle weakness, no (%)	93 (66)	99 (70)
Knee tendon reflex difference, no (%)	54 (38)	51 (36)
Ankle tendon reflex difference, no (%)	75 (53)	107 (75)
Clinically suspected level herniated disk		
Clinically suspected disk level L3-L4 no (%)	6 (4)	5 (4)
Clinically suspected disk level L4-L5 no (%)	69 (49)	57 (40)
Clinically suspected disk level L5-S1 no (%)	66 (47)	83 (58)
Preference conservative treatment-no (%)	42 (30)	43 (30)
Surgical Treatment during follow-up	**Early Surgery**	**Conservative**
Surgery actually performed in first year (%)	125 (89)	55 (39)
Surgeries during 2 years (%)	125 (89)	62 (44)
Mean time to surgery in weeks (CI)	2.2 (1.9-2.5)	18.7 (14.3-23.0)
Median time in weeks (Interquartile Range)	1.9 (1.1-2.4)	14.6 (6.4-26.0)
Recurrent disk surgery (%)	7 (6)	4 (6)
Roland Disabilty Questionnaire Score §	16.5 ± 4.4	16.3 ± 3.9
Score on visual analogue scale ¶		
VAS leg pain	67.2 ± 27.7	64.4 ± 21.2
VAS back pain	33.8 ± 29.6	30.8 ±27.7
Short Form-36 Scores ‖		
SF-36 bodily pain	21.9 ± 16.6	23.9± 18.1
SF-36 physical functioning	33.9 ± 19.6	34.6 ± 19.0

* Plus-minus value are means ± SD. There were no significant differences among the two groups on any of the baseline characteristics.

† Quetelet-Index or Body-Mass Index is calculated by dividing the weight in kilograms by the squared length in meters. Higher scores define overweight.

‡ Lasègue's sign was defined positive if the examiner observed a typically dermatomal area of pain reproduction and pelvic muscle resistance during unilateral provocative straight leg raising below an angle of 60 degrees, and crossed positive if the same experience was noted raising the other leg below 90 degrees.

§ The Roland Disability Questionnaire for Sciatica is a disease specific disability scale that measures functional status in patients with pain in the leg or back. Scores range from 0 to 23, with higher scores indicating worse functional status.

¶ The intensity of pain was indicated on a horizontal 100 mm visual analogue scale, with 0 representing no pain and 100 the worst pain ever experienced.

‖ SF-36 is the abbreviation of Medical Outcomes Study 36-Item Short Form Health Survey (Range 0-100) and is a generic health status questionnaire consisting of 36 items on physical and social functioning delineating 8 domains of quality. Higher score indicates less severe symptoms.

Statistical analysis

The aim of this study was to estimate the difference between the two treatments in disease-specific disability of daily functioning measured with the RDQ. Assuming a mean standard deviation of 10 points[81] over the first year 140 patients were calculated to be required per treatment arm to provide a statistical power of 0.90 with a two-tailed significance level of 0.05 to detect at least three points difference in the RDQ.

Recovery corresponded to "satisfactory outcome" and was defined as complete or nearly complete disappearance of complaints measured by a 7-point Likert scale. The other scores corresponded to "unsatisfactory outcome". The ratio of the respective speeds of recovery was estimated using a Cox Proportional Hazard model, presented as Hazard Ratio with corresponding 95 percent confidence interval. Differences between groups in the Likert-score at two years were evaluated by Fisher's Exact Tests.

Data collection and quality checks were performed with the ProMISe web-based secure data management system of the Department of Medical Statistics & BioInformatics of the LUMC. For all statistical analyses SPSS 14.0 was used[120]. Differences between groups at baseline and after 2 years of follow-up were assessed by comparing means, medians or percentages, depending on the type of variable. Baseline values of variables were used as covariates in the main analyses whenever appropriate to adjust for possible differences between the randomized groups and to increase the power of the analyses. Outcomes of function and pain were analyzed using a repeated measurements analysis of variance with a first order autoregressive covariance matrix. Estimated consecutive scores were expressed as means and 95 % confidence intervals. Point-wise estimates were obtained using models with time as a categorical covariate to allow assessment of systematic patterns. Differences between randomization groups were assessed by estimating either the main effect of the treatment or the interaction between treatment and time. As a second approach to quantification of the differences between the two groups over total follow-up time, "area under the curve" quantities (AUC) were calculated between randomization and week 104 and subsequently compared using Student t-tests. All analyses were performed according to intent-to-treat.

RESULTS

Between November 2002 and February 2005, 599 patients had a surgical indication for treatment of their sciatica according to their family practitioner (Figure 1). After initial consultation with the neurologist, 395 patients met all inclusion criteria and

Table 2. Primary and Secondary Outcomes based on Intent-to-Treat Repeated Measurements Analysis *

	8 weeks			26 weeks		
Primary Outcomes	**Surgery**	**Conservative**	**Treatment effect (95% CI)**	**Surgery**	**Conservative**	**Treatment effect (95% CI)**
Roland Disabilty	6.1 (0.5)	9.2 (0.5)	**3.1 (1.7 to 4.3)**	3.3 (0.5)	3.7 (0.5)	**0.4 (-0.9 to 1.7)**
VAS-Legpain	10.2 (1.9)	27.9 (1.9)	**17.7 (12.3 to 23.1)**	11.0 (1.9)	11.0 (1.9)	**0 (-4.0 to 4.0)**
VAS-Backpain	14.4 (2.1)	25.7 (2.1)	**11.3 (5.6 to 17.4)**	14.2 (2.2)	16.5 (2.1)	**2.3 (-3.6 to 8.2)**
SF-36 bodily pain	62.8 (2.1)	54.4 (2.0)	**-8.4 (-13.5 to -3.2)**	81.2 (2.0)	78.5 (1.9)	**-2.7 (-7.9 to 2.6)**
SF-36 physical functioning	71.2 (1.7)	61.9 (1.9)	**-9.3 (-14.2 to -4.4)**	84.2 (1.8)	82.0 (1.9)	**-2.2 (-7.2 to 2.8)**
Recovered † Patients (%)	36.5	81.2	**44.7**	70.8	77.4	**6.6**

* Results are described by their mean (SE)
† Likert global perceived recovery is defined by a 7-point scale "Worse" to "Complete" recovery. Recovery is

were examined by MRI. At the second visit 283 patients continued to suffer from sciatica and the disk herniation had been visualized; they were allocated to one of two treatment strategies. No significant differences in baseline characteristics between patients were noted for the two study groups (Table 1). Twenty-three patients (8 %) were lost to follow-up. Of 141 patients assigned to receive early surgical treatment, 16 patients recovered before surgery was actually performed. Median time to early surgery for the remaining 125 patients was 1.9 weeks (Table 1) after randomization. Of the 142 patients assigned to the conservative treatment group 55 underwent surgery during the first year (Table 2) after a median period of 14.6 weeks, because of intractable pain expressed by a mean 54 mm VAS-leg score and RDQ of 15.0, measured shortly before deciding to surgery. During the second year after randomization another 7 patients received delayed surgical care because of persistent or intermittent pain, resulting in 62 surgically treated patients in the conservative treatment arm. In both groups 6 percent of operated patients suffered recurrent sciatica leading to a second surgical intervention during the 2 years of follow-up. Complications occurred in 1.6 percent of all surgical patients, involving 2 dural tears and 1 wound haematoma. All complications disappeared spontaneously. None of the patients developed neurological deficit as a result of surgery.

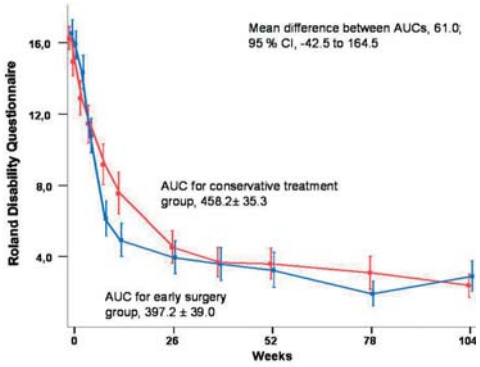
Table 2. Continued

	52 weeks			104 weeks		
Primary Outcomes	**Surgery**	**Conservative**	**Treatment effect (95% CI)**	**Surgery**	**Conservative**	**Treatment effect (95% CI)**
Roland Disabilty	4.0 (0.5)	4.8 (0.5)	**0.8 (-0.5 to 2.1)**	3.1 (0.5)	2.6 (0.5)	**0.5 (-0.8 to 1.8)**
VAS-Legpain	8.4 (1.9)	14.5 (1.9)	**6.1 (2.2 to 10.0)**	11.0 (1.9)	9.0 (1.9)	**-2 (-6.0 to 2.0)**
	15.5 (2.2)	17.8 (2.1)	**2.3 (-3.6 to 8.2)**	15.9 (2.2)	17.3 (2.1)	**1.4 (-4.5 to 6.3)**
SF-36 bodily pain	76.1 (1.1)	72.8 (1.9)	**-3.3 (-8.4 to 1.8)**	78.4 (1.9)	80.7 (1.8)	**2.3 (-2.7 to 7.3**
SF-36 physical functioning	79.1 (1.9)	77.6 (1.7)	**-1.5 (-6.4 to 3.4)**	82.3 (1.9)	83.6 (1.8)	**1.3 (-3.7 to 6.3)**
Recovered † Patients (%)	82.5	85.7	**3.2**	81.3	78.9	**2.4**

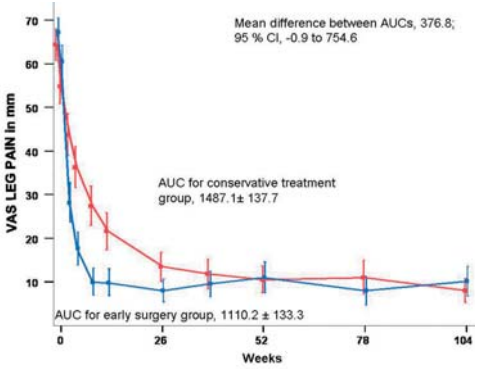
defined as complete or nearly complete recovery using the Likert 7-point scale. Proportions recovered patients between groups at 2 years was not different (p=0.66)

The speed of recovery was statistically different between the groups (Cox model, p<0.001) resulting in an unadjusted hazard ratio of 1.97 (95 % CI 1.72-2.22): recovery was nearly twice as fast for early surgery[129]. Ultimately 95 % of patients of both groups experienced satisfactory recovery by the end of the first year of follow-up. It thus appeared that a slower rate of recovery did not result in a difference in outcome at one year and this lack of a difference between groups was maintained for up to two years. Some patients, however, experienced recurrent low back related complaints after the first year, which resulted in 81.3 % satisfactory results at 2 years for the early surgery group and 78.9 % for the prolonged conservative care group (p=0.66) (Table 2).

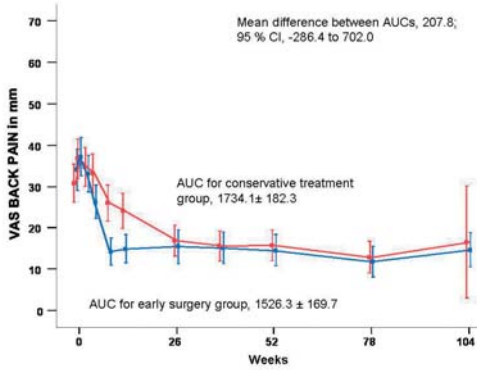
Repeated measurement analysis of continuous outcomes resulted in different courses over time for disability and pain (Table 2; Figure 2). A separation of mean scores exists in favor of early surgery during the first half year after randomization, followed by converging scores. Areas under the curves (AUC) were significantly different over 2 years for VAS leg pain (p=0.05) but without an overall significant difference between AUC's for the RDQ (p=0.25) and VAS back pain (p=0.41). Between 12 and 104 weeks no statistically significant differences were found between randomized groups for any of the primary outcomes at the consecutive fixed follow-up moments.



Panel A



Panel B



Panel C

Figure 2. Repeated Measurement Analysis Curves of Mean scores for Roland Disabilty Questionnaire (Panel A), Leg Pain (Panel B) and Back Pain (Panel C) on a Visual-Analogue Scale.
All three panels show the 2-year curves with 95 percent confidence intervals represented by vertical bars at consecutive moments of measurement. Red lines represent the conservative treatment group, while the blue lines represent early surgery.
Panel A** represents the mean disability scores at consecutive moments of measurement. Although the curves differ, and the short term mean results at 8 and 12 weeks show significantly non-overlapping confidence intervals the overall difference between the areas under the curves (AUC) over 12 months is not significant **(p=0.25).
***Panel B** represents mean visual analogue scores for intensity of leg pain in mm, showing an early effect for leg pain in favour of the surgical group from 2 to 26 weeks, but with near equal scores at one year. The difference between the mean AUC's is significantly different **(p<0.05)**.*
Panel C** represents mean visual analogue scores for intensity of low back pain in mm. Starting with a lower intensity score when compared to leg pain, the mean AUC's exhibit a less strong and not significant difference **(p=0.41)
** Area's under the curve are expressed by their means ± SE, while the mean difference is expressed by the corresponding 95 percent confidence interval*

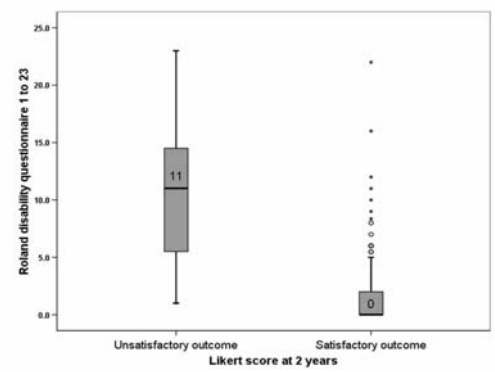
Irrespective of assigned treatment those 56 patients (20 %), who had unsatisfactory results according to the global perceived recovery score at two years, had statistically different RDQ, VAS leg pain, and VAS back pain scores (Table 3) as compared to those with a satisfactory outcome (Mann-Whitney; $p<0.001$). Since these outcome scores had skewed distributions and large standard deviations, box-plots visualizing median, percentiles and outliers are presented instead of 95 % confidence intervals (Figure 3).

Discussion

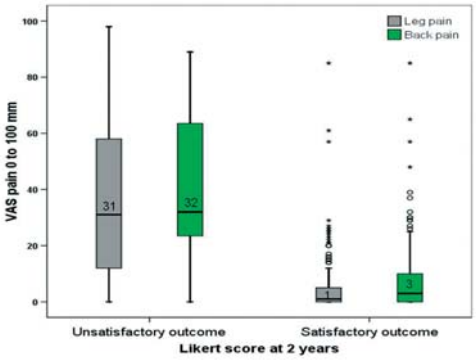
Although early surgery compared to prolonged conservative care resulted in twice as fast recovery from severe sciatica after a period of six to twelve weeks, one and two year outcome scores for both groups were rather similar. The major advantage of early surgery for patients is rapid relief of leg pain, reassurance of recovery and earlier return to normal activities including work. While a strategy of delayed surgery may cause some additional weeks of suffering, up to 56 % of patients obviated surgery. Remarkably, early surgery did not decrease the risk of an unsatisfactory outcome at 1 or 2 years. Although the risk is relatively low, still 20 % of the patients suffered from recurrent or chronic pain and disability after 1 and 2 years of follow-up. Since 8 % of patients were lost to follow-up for various reasons the study lost some power. Analyses without or including last scores carried forward provided similar results. Furthermore baseline characteristics among drop-outs were comparable to all those providing the 2 year follow-up data. Nevertheless, it remains possible that selective lost-to-follow-up has occurred.

Patients randomized to conservative care were guided by research nurses who supported patients with information and counselling. It is obviously impossible to blind patients and practical limitations prevented the randomization result to be concealed from the independent research nurses. Although this additional support did not prevent the operations of 39 % of patients during the first year it does not reflect usual care. However, this guidance by research nurses has occurred in all cases and therefore may have affected the results in both groups. Obviously research nurses are not present in usual care situations hampering implementation of a strategy of delayed surgery. However, their counselling function may be performed by the recent introduction of nurse-practitioners or physician-assistants, who are quite able to support patients with information and guidance.

The finding that ultimately prolonged conservative care results in outcomes similar to those of early surgery is not new and had already been reported by Weber in 1983[40]. In the latter study, however, patients with severe sciatica were excluded.



Panel A



Panel B

*Figure 3. Boxplots; primary outcome scores according to perceived recovery at 12 months * †*
** These scores are defined as outliers*
† Medians are presented in interquartile boxes. Mann-Whitney statistics p<0.001

Table 3. Primary outcome scores according to dichotomized perceived recovery at 2 years *

Outcome †	RDQ	VAS leg pain	VAS back pain
Unsatisfactory recovery ‡ (n=56/20 %)	10.8 (5.6)	35.5 (27.0)	**53.3 (106.2)**
Satisfactory recovery ‡ (n=225/80%)	1.5 (2.8)	5.1 (10.3)	**7.4 (11.5)**
Total (n=281)	**3.4 (5.2)**	**11.1 (19.3)**	**16.8 (52.2)**

* Scores of primary outcomes are described by their mean (SD)
† Mann-Whitney nonparametric two-sided test for all three outcome differences between groups (p<0.001)
‡ The 7-point Likert scale was dichotomized. Complete and nearly complete recovery represent "satisfactory" outcome, while the other 5 scores ranging from some recovery to severe worsening of complaints were "unsatisfactory".

Since this landmark randomized trial showed outcome scores to converge after only 4 years, patients with severe sciatica were not easy to convince that postponement of surgery might be effective in the short term for at least some of them and would not be harmful. After the Weber study several high quality observational cohort series presented significantly worse results after prolonged conservative care as compared to surgery. Two studies[163;184] found a threshold of two months of sciatica, after which the risk of an unsatisfactory outcome increases. The present study presents more insight into this topic. Since these otherwise nicely performed studies were not based on randomized cohorts, baseline factors of patients may not be completely comparable and therefore interpretation of the results is hazardous. It may be concluded

that advising early surgery to all patients with the goal to minimize the chance of long-term disability is not justified. Nygaard[185] as well as Ng[186] pointed out in comparable observational studies that delayed surgery after 8 and 12 months of sciatica respectively produced worse results compared to timing of surgery before these limits. These studies do not per se contradict the present trial, but our data do not support their conclusions either. Indeed it is difficult to keep patients with persistent sciatica on a conservative treatment plan for longer than 8-12 months. However, the substructure of a strategy of surgery before 8 months should be base on a randomized controlled trial considering different time windows of complaints. The trend in the studies by Weinstein[49], Osterman[66] and Butterman[126], however, does not point to an unsatisfactory outcome of prolonged conservative care. Because these trials as well as the present study had a randomized design we conclude that early surgery in patients, with 6-12 weeks sciatica, does not lead to markedly improved functioning over the first year. The therapeutic role of surgery is restricted to faster recovery and relief of leg pain, which, however, may yield a valuable gain for a large proportion of patients in Western society, who are not able or willing to await the natural course with possibly delayed surgery. A second conclusion is that prolonged conservative care does not result in an increase in unsatisfactory outcomes at 2 years and disk operations may be reduced by at least 50 % with similar outcomes after 1-2 years of follow-up.

Notwithstanding similar long-term treatment effects presented by four roughly comparable randomized controlled trials, our data unequivocally show that prolonged conservative care with possibly delayed surgery resulted in a significantly slower rate of recovery. If the purpose is to gain fast pain relief, early surgery remains a valuable treatment option for well-informed patients after at least 6 weeks of sciatica.