

Prolonged conservative care versus early surgery in patients with sciatica caused by lumbar disc herniation: two year results of a randomised controlled trial

Wilco C Peul,^{1,2} Wilbert B van den Hout,³ Ronald Brand,⁴ Ralph T W M Thomeer,¹ Bart W Koes,⁵ for the Leiden-The Hague Spine Intervention Prognostic Study Group

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¹Department of Neurosurgery, Leiden University Medical Centre, PO Box 9600, 2300 RC Leiden, Netherlands

²Department of Neurosurgery, Medical Centre Haaglanden, The Hague, Netherlands

³Department of Medical Decision Making, Leiden University Medical Centre

⁴Department of Medical Statistics, Leiden University Medical Centre

⁵Research Department of General Practice, Erasmus Medical Centre, 3000 CA Rotterdam, the Netherlands

Correspondence to: W C Peul
w.c.peul@lumc.nl

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ABSTRACT

Objectives To evaluate the effects of early lumbar disc surgery compared with prolonged conservative care for patients with sciatica over two years of follow-up.

Design Randomised controlled trial.

Setting Nine Dutch hospitals.

Participants 283 patients with 6-12 weeks of sciatica.

Interventions Early surgery or an intended six months of continued conservative treatment, with delayed surgery if needed.

Main outcome measures Scores from Roland disability questionnaire for sciatica, visual analogue scale for leg pain, and Likert self rating scale of global perceived recovery.

Results Of the 141 patients assigned to undergo early surgery, 125 (89%) underwent microdiscectomy. Of the 142 patients assigned to conservative treatment, 62 (44%) eventually required surgery, seven doing so in the second year of follow-up. There was no significant overall difference between treatment arms in disability scores during the first two years ($P=0.25$). Improvement in leg pain was faster for patients randomised to early surgery, with a significant difference between "areas under the curves" over two years ($P=0.05$). This short term benefit of early surgery was no longer significant by six months and continued to narrow between six months and 24 months. Patient satisfaction decreased slightly between one and two years for both groups. At two years 20% of all patients reported an unsatisfactory outcome.

Conclusions Early surgery achieved more rapid relief of sciatica than conservative care, but outcomes were similar by one year and these did not change during the second year.

Trial Registry ISRCT No 26872154.

INTRODUCTION

Some 5-10 of every 1000 inhabitants in Western countries develop sciatica each year,¹ and during the first six weeks the leg pain diminishes in 70% of patients.² Most guidelines recommend considering surgery for the remainder of patients.³ The time needed for spontaneous recovery from sciatica caused by a disc herniation is not known with certainty. Until a few years ago, the one randomised trial on the subject showed that conservative treatment and surgery had similar results after four years of follow-up among patients with moderate pain intensities.⁴

We previously reported the results of a randomised controlled trial comparing early surgery with prolonged conservative care for patients with sciatica over one year's follow-up.⁵ In the current analysis we provide results for an additional year of follow-up and describe the pain and disability status of patients at two years.

MATERIAL AND METHODS

We conducted a multicentre prospective randomised trial among patients with 6-12 weeks of persistent sciatica to determine whether early surgery leads to better outcomes than conservative treatment for six months and delayed surgery for patients with persistent pain.⁶

Eligibility and randomisation

Eligible patients were aged 18-65 years with sciatica and a disc herniation. Patients were included only if they had a dermatomal pattern of pain distribution with concomitant neurological disturbances that correlated to the same nerve root being affected. Before randomisation, participating neurosurgeons verified the indication for surgery and independently confirmed the presence of nerve root compression by a herniated disc by means of magnetic resonance imaging. Patients presenting with a cauda equina syndrome or severe paresis were excluded, as were those who had had identical complaints in the previous 12 months or a history of spinal surgery, spinal stenosis, deformity, or severe comorbidity.

One hour before randomisation, patients were again evaluated by independent research nurses, and any patients who no longer met the eligibility criteria because of recovery were excluded. See bmj.com for details of randomisation.

Treatment

Early surgery was preferably scheduled within two weeks of assignment and cancelled only if spontaneous recovery occurred before the date of surgery. The duration of hospital stay depended on each patient's functional ability to mobilise. After discharge, the rehabilitation process was supervised by the patient's physiotherapist. Depending on the nature of their work, patients were advised to resume their regular jobs after six weeks onwards.

Prolonged conservative management was provided by each patient's family practitioner. Ample information

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was supplied about the favourable prognosis. Treatment comprised 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. If patients had considerable fear of movement, guidance from a physiotherapist was recommended. If sciatica persisted six months after randomisation, microdiscectomy was considered. Increasing leg pain not responsive to drugs and progressive neurological deficit were indications to perform surgery earlier, within six months.

Outcomes

Primary outcomes were measured by means of the Roland disability questionnaire for sciatica,⁷ a 100 mm visual analogue scale for leg pain,⁸ and a 7-point Likert self rating scale of global perceived recovery. The outcomes were assessed at 2, 4, 8, 12, 26, 38, 52, 78, and 104 weeks. Secondary outcomes (see table) were measured at monitoring visits scheduled at 8, 26, 52, 78, and 104 weeks. Research nurses observed their own patients at the planned follow-up visits and were aware of the patients' treatment assignments.

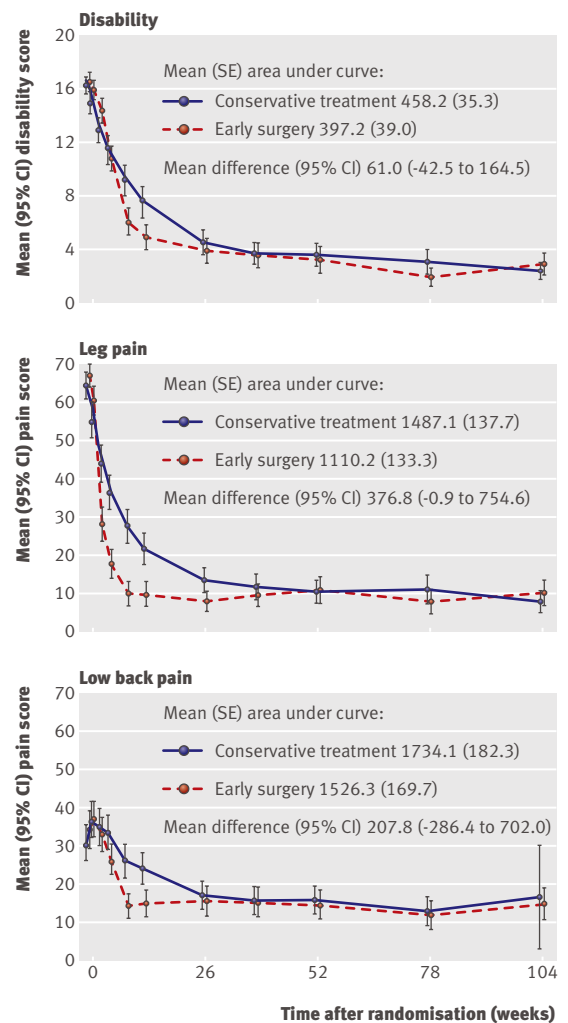
Statistical analysis

The aim of this study was to estimate the difference between the two treatments in disease-specific disability of daily functioning measured with the Roland disability questionnaire. We calculated 140 patients would be required per treatment arm to provide sufficient statistical power. Recovery corresponded to "satisfactory outcome" and was defined as complete or almost complete disappearance of complaints measured by a 7-point Likert scale. The ratio of the respective speeds of recovery was estimated using a Cox proportional hazard model. Differences between groups in the Likert score at two years were evaluated with Fisher's exact test.

Outcomes of function and pain were analysed using a repeated measurements analysis of variance with a first order autoregressive covariance matrix. Pointwise estimates were obtained using models with time as a categorical covariate to allow assessment of systematic patterns. Differences between randomisation 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 were calculated between randomisation and week 104 and subsequently compared using Student's *t* tests. All analyses were performed according to intention to treat.

RESULTS

Between November 2002 and February 2005, 599 patients had a surgical indication for treatment of sciatica according to their family practitioner, and the 283 patients who continued to have sciatica and in



Repeated measurement analysis curves of mean scores for Roland disability questionnaire (top panel) and visual-analogue scales for leg pain and back pain (lower panels)

whom a disc herniation had been visualised were allocated to one of the two treatment strategies. Baseline characteristics were similar in the two study groups (see bmj.com).

Twenty three (8%) of the patients were lost to follow-up. Analyses with or without their last scores carried forward provided similar results, and baseline characteristics among dropouts were similar to those of the patients providing the two year follow-up data.

Of the 141 patients assigned to receive early surgical treatment, 16 (11%) recovered before surgery was actually performed. They did not receive conservative care. Median time to early surgery for the remaining 125 patients was 1.9 weeks after randomisation. Of the 142 patients assigned to conservative treatment, 55 underwent surgery during the first year after a median of 14.6 weeks because of intractable pain. During the second year after randomisation, another seven patients received delayed surgical care because of persistent or intermittent pain, resulting in 62 surgically

treated patients (44%) in the conservative treatment arm.

In both treatment groups 6% of surgically treated patients had recurrent sciatica that led to a second surgical intervention during the two years of follow-up, representing 3% of the total conservative treatment cohort and 5% of the early surgery cohort. Complications occurred in 1.6% of all surgical patients, and none required an intervention. None of the patients developed neurological deficit.

During the first 12 weeks after randomisation, mean disability and pain scores improved significantly faster in the early surgery group, but they then converged over the next 3-6 months (table, fig). The areas under the curves in the figure were significantly different between the two groups over the two years' follow-up for leg pain scores ($P=0.05$) but were not significant for the disability scores ($P=0.25$) and back pain ($P=0.41$). After the 12 week outcome assessment, no significant differences were found between the treatment groups for any of the primary outcomes at any of the remaining assessments.

During the first year, early surgery achieved a faster rate of perceived recovery with a hazard ratio of 1.97 (95% CI 1.72 to 2.22, $P<0.001$). By the end of the first year of follow-up, however, 95% of patients in both treatment groups had experienced satisfactory recovery, and this lack of a difference between groups was maintained for the following year. Some patients, however, did experience a recurrence of problems after the first year, which resulted in 81.3% of patients in the early surgery group and 78.9% in the prolonged conservative care group having satisfactory results at two years ($P=0.66$) (table).

DISCUSSION

The major advantages of early surgery compared with prolonged conservative care for patients with sciatica are more rapid relief of leg pain, reassurance about

recovery, and earlier return to normal activities. These benefits, however, were no longer significant by six months' follow-up, and, even at eight weeks, the statistically significant difference between treatment groups in primary outcome scores was not sufficient to be clinically meaningful. Although a strategy of delayed surgery might result in some extra weeks of discomfort, up to 56% of our patients did not require surgery for recovery. It might therefore be time to shift from the current situation of physicians' recommendations about the need for surgery (often based on their personal preferences) to patients deciding, with the help of their physician, which treatment strategy is best for them.

Early surgery did not decrease the risk of an unsatisfactory outcome at one or two years' follow-up. Longer term follow-up for 5-10 years is needed to obtain reliable data about what proportion of patients become chronically disabled and to detect a possible difference between treatments in the risk of unsatisfactory outcome.

Limitations of study

Research nurses provided information and counselling for conservative care. It was obviously impossible to blind patients to this, and practical limitations prevented blinding of the nurses. Obviously, research nurses are not usually available for patient care, which might hamper the implementation of a strategy of delayed surgery in routine care.

In both randomisation arms, 95% of patients had reported satisfactory recovery by the end of the first year's follow-up, but at the two year assessment only 80% of all patients reported that they had recovered. Some patients who had reported complete recovery within a year of randomisation later apparently had recurrent symptoms of leg or back pain. To solve this problem of relapse, it may be necessary to redefine

Primary and secondary outcomes from early surgery (ES) versus prolonged conservative treatment (PCT) for patients with sciatica. Values are means (SE) unless stated otherwise and are based on intention to treat, repeated measurements analysis

Outcomes	8 weeks			26 weeks			52 weeks			104 weeks		
	ES	PCT	Difference (95% CI)	ES	PCT	Difference (95% CI)	ES	PCT	Difference (95% CI)	ES	PCT	Difference (95% CI)
Disability*	6.1 (0.5)	9.2 (0.5)	3.1 (1.7 to 4.3)	4.0 (0.5)	4.8 (0.5)	0.8 (-0.5 to 2.1)	3.3 (0.5)	3.7 (0.5)	0.4 (-0.9 to 1.7)	3.1 (0.5)	2.6 (0.5)	0.5 (-0.8 to 1.8)
Leg pain†	10.2 (1.9)	27.9 (1.9)	17.7 (12.3 to 23.1)	8.4 (1.9)	14.5 (1.9)	6.1 (2.2 to 10.0)	11.0 (1.9)	11.0 (1.9)	0 (-4.0 to 4.0)	11.0 (1.9)	9.0 (1.9)	-2 (-6.0 to 2.0)
Back pain†	14.4 (2.1)	25.7 (2.1)	11.3 (5.6 to 17.4)	15.5 (2.2)	17.8 (2.1)	2.3 (-3.6 to 8.2)	14.2 (2.2)	16.5 (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	62.8 (2.1)	54.4 (2.0)	-8.4 (-13.5 to -3.2)	76.1 (1.1)	72.8 (1.9)	-3.3 (-8.4 to 1.8)	81.2 (2.0)	78.5 (1.9)	-2.7 (-7.9 to 2.6)	78.4 (1.9)	80.7 (1.8)	2.3 (-2.7 to 7.3)
SF-36 physical functioning	71.2 (1.7)	61.9 (1.9)	-9.3 (-14.2 to -4.4)	79.1 (1.9)	77.6 (1.7)	-1.5 (-6.4 to 3.4)	84.2 (1.8)	82.0 (1.9)	-2.2 (-7.2 to 2.8)	82.3 (1.9)	83.6 (1.8)	1.3 (-3.7 to 6.3)
Patients with satisfactory recovery (%)‡	81.2	36.5	44.7 (34.2 to 55.0)	77.4	70.8	6.6 (-3.7 to 17.0)	85.7	82.5	3.2 (-5.4 to 11.9)	81.3	78.9	2.4 (-7.2 to 12.0)

*Roland disability questionnaire for sciatica. Scores range from 0 to 23, with higher scores representing worse disability.

†Measured on 100 mm visual analogue scale, with 0 representing no pain and 100 the worst pain ever experienced.

‡"Complete" and "nearly complete" scores on 7-point Likert scale of global perceived recovery.

WHAT IS ALREADY KNOWN ON THIS TOPIC

For patients who have had sciatica for 6-12 weeks, early surgery provides faster recovery than prolonged conservative care

After a year, however, results are similar for early surgery and conservative care

WHAT THIS STUDY ADDS

The absence of outcome differences between groups given early surgery and conservative care after a year remains up to two years

The proportion of patients with unsatisfactory outcomes rises by two years to 20%, and early surgery failed to reduce this proportion

Of those patients randomised to prolonged conservative care, 40% eventually required delayed surgery for relief of symptoms

Since the treatment effects of early surgery are gone after six months, well informed patients, rather than physicians, should decide whether and when to have surgery

“recovery” as the absence of symptoms for a certain minimum period of time.

Comparison with other studies

Our finding that prolonged conservative care ultimately resulted in outcomes similar to those achieved with early surgery had already been reported by Weber in 1983.⁴ Since he reported that outcome scores converged only after four years, his study did little to reassure patients with severe sciatica that postponement of surgery might be effective in the short term and would not be harmful.

Several high quality observational cohort series presented significantly worse results after prolonged conservative care compared with surgery. Two studies found a threshold of two months of sciatica, after which the risk of an unsatisfactory outcome with prolonged conservative care increased.^{9,10} Since these studies were not based on randomised cohorts, interpretation of the results should be cautious. From our results, it may be concluded that advising early surgery to all patients with the aim of minimising the risk of long term disability is not justified.

Two comparable observational studies reported that delayed surgery after eight and 12 months of sciatica respectively produced worse results than earlier surgery.^{11,12} These results do not per se contradict those from our trial, but our data do not support the studies' 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 general conclusions from the randomised trials by Weinstein et al,¹³ Osterman et al,¹⁴ and Buttermann¹⁵ do not point to an unsatisfactory outcome of prolonged conservative care. From these results in

conjunction with our own, we conclude that early surgery in patients with 6-12 weeks of sciatica does not lead to markedly improved functioning over the first two years. Besides an early gain in recovery in Ostermann's and our study, surgery did not reduce the chances of unsatisfactory outcomes compared with non-surgical care.

This conclusion raises doubts about whether there is an optimal timing for surgery applicable to all patients with sciatica and, indeed, whether surgery has any effect at all on the natural course of sciatica.

Conclusions

The therapeutic role of surgery for sciatica is restricted to faster recovery and relief of leg pain. This, however, may still be considered a valuable gain by a large proportion of patients who are not able or willing to await the natural course of their condition, with possibly delayed surgery.

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