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Surgery versus Prolonged Conservative Treatment for Sciatica

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ABSTRACT

BACKGROUND

Lumbar-disk surgery often is performed in patients who have sciatica that does not resolve within 6 weeks, but the optimal timing of surgery is not known.

METHODS

We randomly assigned 283 patients who had had severe sciatica for 6 to 12 weeks to early surgery or to prolonged conservative treatment with surgery if needed. The primary outcomes were the score on the Roland Disability Questionnaire, the score on the visual-analogue scale for leg pain, and the patient's report of perceived recovery during the first year after randomization. Repeated-measures analysis according to the intention-to-treat principle was used to estimate the outcome curves for both groups.

RESULTS

Of 141 patients assigned to undergo early surgery, 125 (89%) underwent microdiscectomy after a mean of 2.2 weeks. Of 142 patients designated for conservative treatment, 55 (39%) were treated surgically after a mean of 18.7 weeks. There was no significant overall difference in disability scores during the first year ($P=0.13$). Relief of leg pain was faster for patients assigned to early surgery ($P<0.001$). Patients assigned to early surgery also reported a faster rate of perceived recovery (hazard ratio, 1.97; 95% confidence interval, 1.72 to 2.22; $P<0.001$). In both groups, however, the probability of perceived recovery after 1 year of follow-up was 95%.

CONCLUSIONS

The 1-year outcomes were similar for patients assigned to early surgery and those assigned to conservative treatment with eventual surgery if needed, but the rates of pain relief and of perceived recovery were faster for those assigned to early surgery. (Current Controlled Trials number, ISRCTN26872154.)

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SCIATICA IS CHARACTERIZED BY RADIATING pain in an area of the leg typically served by one nerve root in the lumbar or sacral spine; it is sometimes also associated with sensory and motor deficits. The most common cause of sciatica is a herniated disk. The estimated annual incidence of sciatica in Western countries is 5 cases per 1000 adults.¹ The economic effect of lumbar-spine disorders is great. Lumbar-spine disorders rank fifth among disease categories in the cost of hospital care and account for higher costs resulting from absenteeism from work and disability than any other category.² The natural history of sciatica is favorable, with resolution of leg pain within 8 weeks from onset in the majority of patients.³⁻⁵ Since the first successful surgical treatment in 1934,⁶ the international consensus has been that surgery should be offered only if symptoms persist after a period of conservative treatment.⁷ There is, however, no consensus on how long conservative therapy should be tried before surgery is considered.^{8,9} Sociocultural preferences account for a wide variation in the rates of surgery.¹ For example, in the United States and the Netherlands, the rates of surgery are relatively high. Dutch guidelines¹⁰ recommend offering the patient the option of surgery if symptoms do not improve after 6 weeks of conservative treatment. However, the optimal timing of disk surgery has not been established. This report compares the efficacy of early surgical intervention with a strategy of prolonged conservative care and, if needed, subsequent surgery for patients with disabling sciatica.

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 than does a strategy of conservative treatment for an additional 6 months followed by surgery for patients who do not have improvement. The medical ethics committees at the nine participating hospitals approved the protocol. Written informed consent was obtained from all patients. Details of the design and study protocol have been published previously.¹¹

ELIGIBILITY AND RANDOMIZATION

Eligible patients were 18 to 65 years of age, had a radiologically confirmed disk herniation, and had

received a diagnosis from an attending neurologist of an incapacitating lumbosacral radicular syndrome that had lasted for 6 to 12 weeks. Correlation of magnetic resonance imaging (MRI) findings with symptoms was registered by the neurosurgeon. At the time of enrollment, an independent research nurse verified the persistence of symptoms. Patients presenting with cauda equina syndrome, muscle paralysis, or insufficient strength to move against gravity were excluded. Other exclusion criteria were the occurrence of another episode of symptoms similar to those of the current episode during the previous 12 months, previous spine surgery, bony stenosis, spondylolisthesis, pregnancy, or severe coexisting disease.

A computer-generated permuted-block scheme was used for randomization, with patients stratified according to center. One hour before randomization, the patients were evaluated again, and patients who had recovered from their symptoms at that time were excluded from the trial. For patients who were included, the next numbered opaque envelope containing the assigned treatment was opened and the patient was assigned to a treatment group. The patients could not be blinded to treatment group.

TREATMENT

Early surgery was scheduled within 2 weeks after assignment and was canceled only if spontaneous recovery occurred before the date of surgery. The symptomatic disk herniation was removed by a minimal unilateral transflavial approach with magnification, with the patient under general or spinal anesthesia. The goal of surgery was to decompress the nerve root and reduce the risk of recurrent disk herniation by performing an annular fenestration, curettage, and removal of loose degenerated disk material from the disk space with the use of a rongeur, without attempting to perform a subtotal discectomy. The duration of the hospital stay depended on the patient's mobility after surgery. Usual care was provided according to the protocols of the participating surgical departments. Rehabilitation of the patients at home was supervised by physiotherapists using a standardized exercise protocol. The patients were advised to resume their regular jobs when they were able, depending on the nature of their work.

General practitioners provided prolonged conservative treatment to the patients. The patients were informed about their favorable prognosis and

were invited to visit the Web site for our trial, which was designed exclusively to inform patients about the natural course of their illness and the expectation of successful recovery, irrespective of the initial intensity of their pain. Treatment was aimed mainly at enabling the patients to resume daily activities. If necessary, the prescription of pain medication was adjusted according to existing clinical guidelines.¹¹ Patients who were fearful of moving were referred to a physiotherapist. If sciatica persisted for 6 months after the patient underwent randomization, microdiscectomy was offered. Patients who had increasing leg pain not responsive to medication or progressive neurologic deficits were offered surgery earlier than 6 months after randomization.

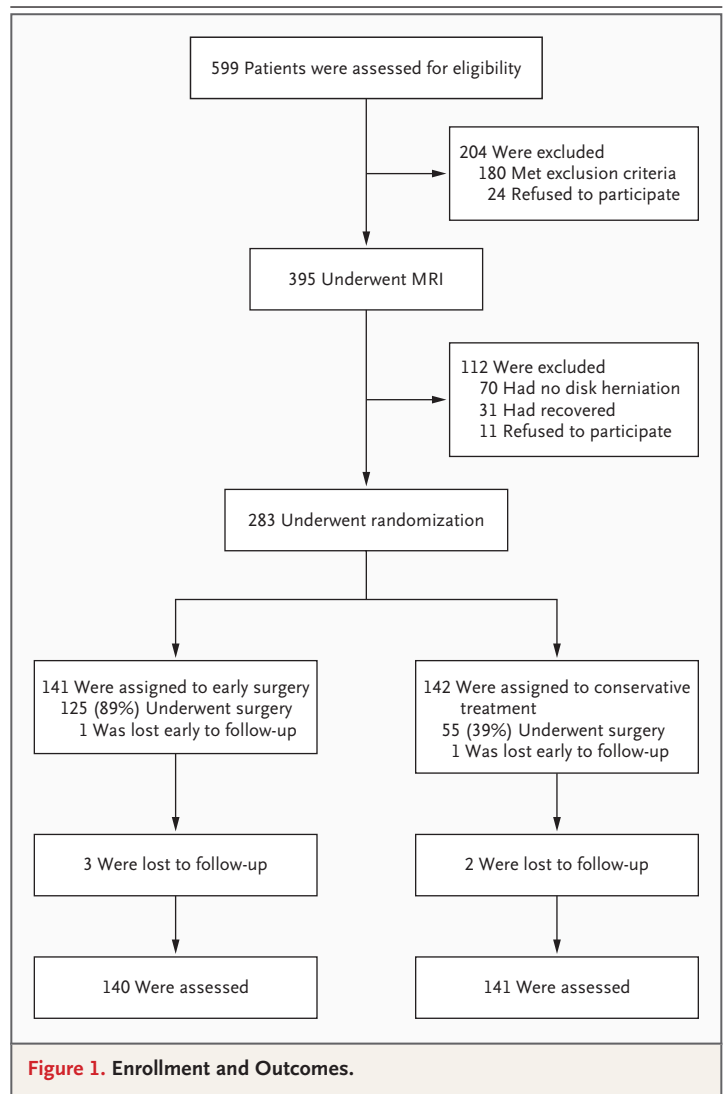
OUTCOMES

The patients were assessed by means of the Roland Disability Questionnaire for Sciatica,¹² the 100-mm visual-analogue scale for leg pain,¹³ and a 7-point Likert self-rating scale of global perceived recovery. Functional disability, intensity of leg pain, and global perceived recovery were the primary outcomes and were assessed at 2, 4, 8, 12, 26, 38, and 52 weeks.

Secondary outcomes were recorded at monitoring visits scheduled at 8, 26, and 52 weeks. At these visits the patients underwent a repeated neurologic examination; functional and economic observational assessments¹⁴ were performed by the independent research nurse; and scores on the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) scale,¹⁵ the Sciatica Frequency and Bothersomeness Index,^{12,16} and a 100-mm visual-analogue scale for health perception¹¹ were obtained. Research nurses observed their own patients at the planned follow-up times and were not blinded to the patients' treatment assignments.

STATISTICAL ANALYSIS

The aims of this study were to determine the difference between the two treatment groups in disease-specific disability with respect to daily functioning, as measured by the score on the Roland Disability Questionnaire and the visual-analogue scale for leg pain, and to determine the difference in median time to recovery, measured by dichotomized self-assessment on the Likert scale as a function of time since randomization. On the assumption of a mean standard deviation of 10



points¹⁶ during the first year, we calculated that a sample of 140 patients per treatment group would be required to provide a statistical power of 0.90 with a two-tailed significance level of 0.05 to detect a difference of at least 3 points in the score on the Roland Disability Questionnaire.

Recovery was defined as complete or nearly complete disappearance of symptoms as measured on a 7-point Likert scale. Although this trial was designed primarily to determine average differences in functional outcome, it was initially estimated that this sample size would also have a statistical power of 90% to detect a difference of 2 months in the median time to recovery with the use of estimates from survival models.

Data collection and checking for quality were

Table 1. Characteristics of the Patients.*

Characteristic	Early-Surgery Group (N=141)	Conservative-Treatment Group (N=142)
Age — yr	41.7±9.9	43.4±9.6
Male sex — no. (%)	89 (63)	97 (68)
Body-mass index†	25.9±4.1	25.8±4.0
Duration of sciatica — wk	9.43±2.37	9.48±2.11
Took sick leave from work — no. (%)	107 (76)	116 (82)
Duration of sick leave — wk	5.32±2.78	5.28±2.62
Radiating pain in left leg — no. (%)	67 (48)	73 (51)
Pain on straight-leg raising — no. (%)‡	100 (71)	104 (73)
Pain on crossed straight-leg raising — no. (%)‡	71 (50)	70 (49)
Sensory loss — no. (%)	123 (87)	128 (90)
Dermatome anesthesia — no. (%)	31 (22)	33 (23)
Muscle weakness — no. (%)	93 (66)	99 (70)
Difference in deep-tendon reflexes in the knees — no. (%)	54 (38)	51 (36)
Difference in deep-tendon reflexes in the ankles — no. (%)	75 (53)	107 (75)
Clinically suspected level of herniated disk — no. (%)		
L3–L4	6 (4)	5 (4)
L4–L5	69 (49)	57 (40)
L5–S1	66 (47)	83 (58)
Roland Disability Questionnaire score§	16.5±4.4	16.3±3.9
Score on the visual-analogue scale of pain¶		
Leg	67.2±27.7	64.4±21.2
Back	33.8±29.6	30.8±27.7
Leg and back	61.0±22.3	58.2±20.0
Score on the visual-analogue scale of general health	47.8±24.5	46.0±24.5
SF-36 score**		
Bodily pain	21.9±16.6	23.9±18.1
Physical functioning	33.9±19.6	34.6±19.0
Social functioning	44.6±30.1	43.3±27.1
Physical role	8.2±20.7	8.3±21.0
Emotional role	51.0±46.0	52.4±46.0
Mental health index	67.8±19.7	67.7±19.5
Vitality	47.5±21.3	47.9±21.3
General health perception	64.6±20.3	64.1±20.3

performed with the ProMISE data management system of the Department of Medical Statistics and BioInformatics¹⁷ of the Leiden University Medical Center. SPSS software, version 12.0,¹⁸ was used for all statistical analyses.

Differences between groups at baseline were assessed by comparing means, medians, or per-

centages, depending on the type of variable. The 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. The outcomes of function and pain were analyzed with a repeated-measures analysis of

Table 1. (Continued.)

Characteristic	Early-Surgery Group (N=141)	Conservative-Treatment Group (N=142)
Sciatica Frequency and Bothersomeness Index ^{††}		
Frequency	16.0±4.6	16.2±4.2
Bothersomeness	14.6±5.1	14.5±4.1
Preference for conservative treatment — no. (%)	42 (30)	43 (30)
Surgical treatment during follow-up — no. of patients (%)	125 (89)	55 (39)
Time to surgery — wk		
Mean (95% CI)	2.2 (1.9–2.5)	18.7 (14.3–23.0)
Median	1.9	14.6
Interquartile range	1.1–2.4	6.4–26.0
Repeated surgery — no. (%)	4 (3.2)	1 (1.8)

* Plus-minus values are means ±SD. There were no significant differences between the two groups in any of the baseline characteristics. CI denotes confidence interval.

[†] Body-mass index is the weight in kilograms divided by the square of the height in meters.

[‡] The examiner observed the production of pain with a typically dermatomal pattern of distribution and pelvic-muscle resistance during unilateral provocative straight-leg raising below an angle of 60 degrees and during crossed straight-leg raising (i.e., when the other leg was raised) 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 measured by a horizontal 100-mm visual-analogue scale, with 0 representing no pain and 100 the worst pain ever experienced.

^{||} The perception of general health was measured by a horizontal 100-mm visual-analogue scale, with 0 representing the worst and 100 the best perception of health a patient could imagine.

** The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) is a generic health-status questionnaire consisting of 36 questions on physical and social functioning delineating eight domains of quality. The scale ranges from 0 to 100, with higher scores indicating less severe symptoms.

^{††} The Sciatica Frequency and Bothersomeness Index assesses the frequency (from 0 [not at all] to 6 [always]) and bothersomeness (from 0 [not bothersome] to 6 [extremely bothersome]) of back and leg symptoms. The sum of the results of the questions yields indexes ranging from 0 to 24 for frequency and bothersomeness of leg pain; numbness, tingling, or both in the leg; weakness in the leg or foot; and pain in the back or leg while sitting.

variance using a first-order autoregressive covariance matrix. The estimated consecutive scores were expressed as means and 95% confidence intervals. Pointwise estimates were obtained by using models with time as a categorical covariate to allow assessment of systematic patterns.

Differences between treatment groups were assessed by estimating either the main effect of the treatment or the interaction between treatment and time. As a second approach to quantifying the differences between the two groups over total follow-up time, the areas under the curve between the time of randomization and week 52 were calculated and compared by Student's t-test. Finally, a Kaplan-Meier survival analysis was used to estimate the time elapsed from randomization until recovery, and the curves were compared with the use of a log-rank test.

A Cox model was used to compare speeds of recovery by calculation of a hazard ratio. Whether the speed of recovery differed among subgroups of patients with different characteristics¹¹ was assessed by testing the interaction between each subgroup variable and the randomization variable, with a cutoff value of 0.10 for significance because of the lower power of the interaction test. All analyses were performed according to the intention-to-treat principle.

RESULTS

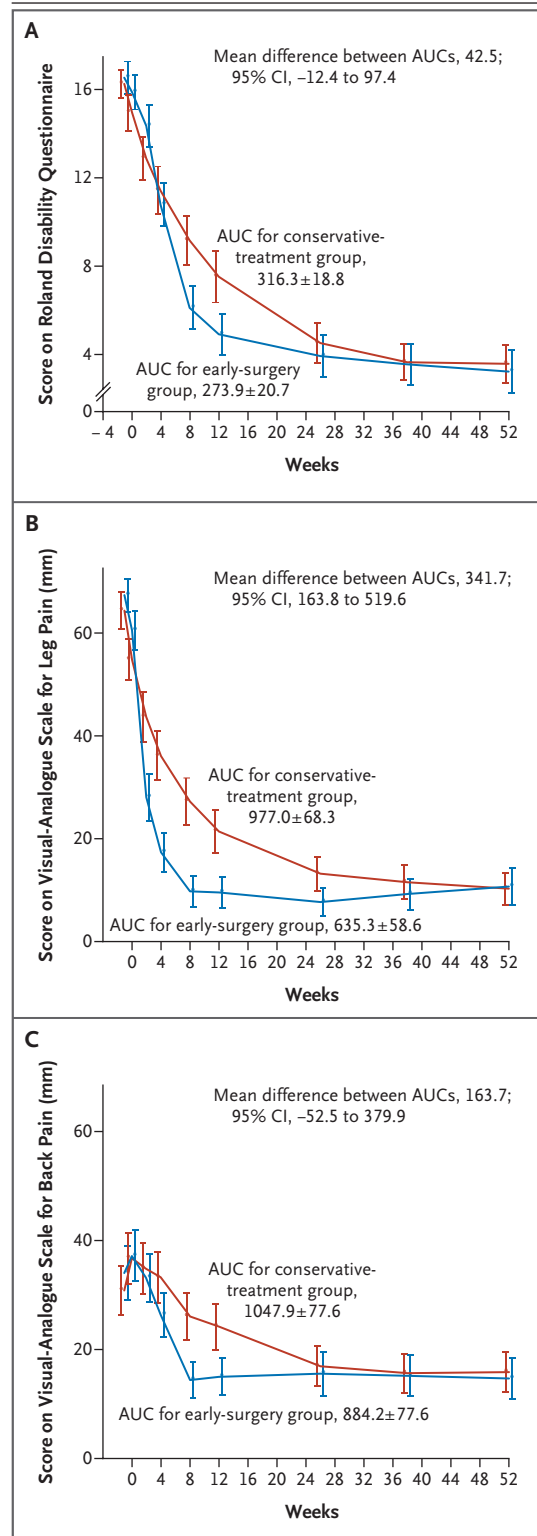
Between November 2002 and February 2005, 599 patients meeting the criteria for surgery, as determined by their general practitioners, were contacted (Fig. 1). After initial consultation with a neurologist, 395 patients who met the inclusion criteria

Figure 2. Curves of Mean (\pm SE) Scores on the Roland Disability Questionnaire (Panel A), the Visual-Analogue Scale for Leg Pain (Panel B), and the Visual-Analogue Scale for Back Pain (Panel C).

All three panels show curves for the 52 weeks after randomization, with 95% confidence intervals (CIs) represented by vertical bars and determined with the use of repeated-measures analysis. In Panel A, although the curves differ for the mean scores on the Roland Disability Questionnaire (scores range from 0 to 23, with higher scores indicating worse functional status) and the short-term results at 8 and 12 weeks have nonoverlapping confidence intervals, the overall difference between the areas under the curve (AUCs) during the 52 weeks is not significant ($P=0.13$). Panel B shows the mean scores on the visual-analogue scale for intensity of leg pain. The scale ranges from 0 to 100 mm, with higher scores indicating more intense pain. There was an early effect on leg pain in favor of the surgical group from 2 to 26 weeks, but the scores were nearly equal at 1 year. The difference between the AUCs was significant ($P<0.001$). Panel C shows the mean scores on the visual-analogue scale for intensity of low back pain. The initial intensity of low back pain was less than that of leg pain. The difference between the AUCs for low back pain was not as large as the difference between the AUCs for leg pain and was not significant ($P=0.14$).

were referred for MRI. At the second visit, 283 patients continued to have symptoms of sciatica, and disk herniation responsible for the symptoms had been observed by means of MRI. These patients were randomly assigned to one of the two treatment strategies. No significant differences were noted in baseline characteristics between patients in the two study groups (Table 1). Of 141 patients assigned to receive early surgical treatment, 16 recovered before surgery could be performed. The median time from randomization to surgery for the remaining 125 patients was 1.9 weeks (Table 1). Of the 142 patients assigned to conservative treatment, 55 underwent surgery during the first year after a median period of 14.6 weeks because of intractable pain, as measured by a mean score on the visual-analogue scale of 54 mm for leg pain and a score on the Roland Disability Questionnaire of 15.0. In the early-surgery group, 3.2% of patients had recurrent sciatica leading to a second surgical intervention, as compared with 1.8% of patients in the conservative-treatment group who underwent surgery. Complications occurred in 1.6% of all surgical patients, consisting of two dural tears and one wound hematoma. All complications resolved spontaneously. None of the patients had neurologic signs after surgery.

The curves for the scores on the Roland Dis-



ability Questionnaire show a separation in favor of conservative treatment in the first 4 weeks after randomization (Fig. 2). The curves cross at 4 weeks, indicating the moment when a better

outcome was noted in the early-surgery group. The greatest difference in function occurred between 8 and 12 weeks. The areas under the curve for mean score on the Roland Disability Questionnaire did not differ significantly between the groups over the 52-week follow-up period ($P=0.13$). However, there was a significant difference ($P<0.001$) between the areas under the curve for the mean visual analogue scale for leg pain in favor of early surgery. After surgery, leg and concomitant back pain diminished quickly, whereas a slower and linear recovery from pain was noted in the group receiving prolonged conservative treatment. One year after randomization, however, the scores on the Roland Disability Questionnaire, the Likert scale, and the visual-analogue scale for leg pain had nearly equal recovery rates in the two groups (Table 2). The subgroup of 55 patients with persistent sciatica and conservative treatment followed by surgery had a similar improvement in these scores at 1 year as compared with patients allocated to early surgery. The survival analysis (Fig. 3) showed an effect of early surgery on the speed of recovery during the first 36 weeks ($P<0.001$ by the log-rank test), but the difference in cumulative incidence of recovery decreased over time, with similar recovery rates of about 95% for both groups after 52 weeks. The median time to recovery was 4.0 weeks (95% confidence interval [CI], 3.7 to 4.4) for early surgery and 12.1 weeks (95% CI, 9.5 to 14.9) for prolonged conservative treatment.

The hazard ratio, as estimated in a univariable Cox model with recovery as an end point, was 1.97 (95% CI, 1.72 to 2.22) in favor of early surgery. Analysis of treatment groups according to predefined baseline characteristics showed that surgery was beneficial in all subgroups assessed, with the possible exception of patients in whom sciatica was not provoked by sitting (Fig. 4).

DISCUSSION

Although relief of symptoms was twice as fast among patients with sciatica who were treated with early surgery as among those who were treated conservatively, this multicenter, randomized trial demonstrated that this strategy did not result in a better overall 1-year functional recovery rate than did a policy of prolonged conservative treatment with an offer of subsequent surgery. During the 12 months after randomization, 89% of patients in the early-surgery group and 39% of those in the conservative-treatment group underwent mi-

crodiscectomy. At 1 year of follow-up, there were no significant differences between the groups in the mean scores for any outcome measurement, including leg pain. Thus, the major advantage of early surgical treatment is faster relief of sciatica.

The slow rate of recovery of daily functioning in the first 2 weeks after early surgery may have been due to the use of standard microdiscectomy techniques rather than modern microendoscopic or sequestrectomy methods.¹⁹⁻²¹ Recovery was faster during the following weeks, but there was no significant difference between the groups in the overall rate of recovery during the first year. The scores on the Roland Disability Questionnaire did not reach the minimal clinically important difference of 4 points required to conclude that early surgery results in clinically superior outcomes.^{11,12} Relief from leg pain occurred significantly faster in the early-surgery group, but the maximum differences between the groups in the mean scores on the visual-analogue scale for leg pain were less than 20 mm on a 100-mm scale, and at 1 year the scores were nearly equal.

The benefits of surgery for speed of recovery and relief of pain were consistent among patients in all predefined subgroups, except for patients whose sciatica was not provoked by sitting. However, the beneficial effect was marginally significant, and the majority of patients (76%) did have provocation of sciatica by sitting. It is reasonable to assume, however, that daily functioning is highly influenced by the inability to sit without pain. The absence of interactions between the assigned treatment and Lasègue's sign, intensity of pain, disk sequestrations detected by MRI, and the preference of the patient for the type of treatment was remarkable and unexpected.

Since 1934, many studies have demonstrated the success of surgical treatment of sciatica. In Weber's landmark study comparing surgery with conservative care in a randomized clinical trial, which excluded patients with "intolerable" pain, the outcome of surgery was superior at 1-year follow-up, whereas after 4 years the results of surgery and conservative treatment no longer differed.²²⁻²⁴ Surgery had some early advantages in a randomized study comparing surgery with the use of corticosteroids.²⁵

Weinstein et al. recently reported the results of the Spine Patient Outcomes Research Trial (SPORT) comparing surgery with conservative treatment but failed to show any advantage of surgery for primary outcomes in their intention-to-treat anal-

Table 2. Primary and Secondary Outcomes According to Treatment and Timing of Treatment after Randomization.*

Variable	2 Wk			8 Wk		
	Early Surgery	Conservative Treatment	Difference between Conservative Treatment and Early Surgery (95% CI)	Early Surgery	Conservative Treatment	Difference between Conservative Treatment and Early Surgery (95% CI)
Primary outcome						
Roland Disability Questionnaire score†	14.4±0.5	13.0±0.5	-1.6 (-2.8 to -0.3)	6.1±0.5	9.2±0.5	3.1 (1.7 to 4.3)
VAS score for leg pain‡	28.5±1.9	44.2±1.9	15.7 (11.7 to 19.7)	10.2±1.9	27.9±1.9	17.7 (12.3 to 23.1)
VAS score for back pain§	33.3±2.1	34.9±2.1	1.5 (-4.5 to 7.4)	14.4±2.1	25.7±2.1	11.3 (5.6 to 17.4)
Likert score for global perception of recovery‡¶	3.1±0.1	3.5±0.1	0.4 (0.1 to 0.6)	2.2±0.1	3.1±0.1	0.9 (0.6 to 1.2)
Secondary outcome						
Prolo functional observational assessment score	1.1±0.1	1.1±0.1	0.04 (-0.2 to 0.3)	2.8±0.1	2.0±0.1	-0.8 (-1.1 to 0.6)
Prolo economic observational assessment score	1.2±0.1	1.3±0.1	0.2 (-0.2 to 0.6)	1.8±0.1	2.3±0.1	0.5 (0.1 to 0.8)
SF-36 score						
Bodily pain	—	—	—	62.8±2.1	54.4±2.0	-8.4 (-13.5 to -3.2)
Physical functioning	—	—	—	71.2±1.7	61.9±1.9	-9.3 (-14.2 to -4.4)
Social functioning	—	—	—	69.9±2.3	67.6±2.3	-2.3 (-8.3 to 3.7)
Physical role	—	—	—	29.5±3.1	29.3±3.2	-0.2 (-5.9 to 5.5)
Emotional role	—	—	—	69.3±3.5	66.2±3.7	-3.1 (-9.3 to 3.0)
Mental health index	—	—	—	82.1±1.3	73.0±1.7	-9.1 (-13.4 to -4.8)
Vitality	—	—	—	67.5±1.7	57.1±1.7	-10.4 (-15.1 to -5.7)
General health perception	—	—	—	75.7±1.5	65.2±1.6	-10.5 (-15.2 to -5.8)
SFBI frequency	—	—	—	5.3±0.4	9.3±0.5	4.0 (2.7 to 5.3)
SFBI bothersomeness	—	—	—	4.0±0.4	7.6±0.5	3.6 (2.3 to 4.9)
VAS score for general health	59.8±1.9	55.2±2.2	-4.6 (-10.4 to 1.2)	74.7±2.3	62.7±2.4	-12.0 (-18.8 to 5.3)
Total no. of surgeries performed**	87	2	85	123	16	107

* The outcomes were analyzed with repeated-measures analyses according to the intention-to-treat principle. Plus-minus values are means ±SE. CI denotes confidence interval, VAS visual-analogue scale, SF-36 the Medical Outcomes Study 36-Item Short-Form General Health Survey, and SFBI the Sciatica Frequency and Bothersomeness Index. Dashes denote tests not administered.

† The overall difference between scores is not significant ($P=0.12$).

‡ Fixed effects are significantly different in favor of early surgery ($P<0.001$).

§ The scores are significantly different in favor of early surgery ($P=0.045$).

yses.²⁶ Substantial crossover, however, occurred in both treatment groups, resulting in a difference in surgery rates of only 14% at 6 weeks. Furthermore, only 59% of patients assigned to surgery actually underwent surgery, which apparently was scheduled at highly variable times during the first year instead of being performed early. Another difference between our study and that by Weinstein et al. is that we enrolled patients who had had sciatica for 6 to 12 weeks, whereas at least 20%

of the patients in the study by Weinstein et al. had had symptoms for at least 6 months.²⁶

The primary outcomes of our study were also strongly influenced by a substantial crossover of patients assigned to conservative treatment, but the effects of crossover on the differences between the groups were mitigated by early performance of surgery in the group assigned to surgery. Although 61% of patients recovered quickly without surgery, the remaining 39% continued to register relatively

26 Wk			52 Wk		
Early Surgery	Conservative Treatment	Difference between Conservative Treatment and Early Surgery (95% CI)	Early Surgery	Conservative Treatment	Difference between Conservative Treatment and Early Surgery (95% CI)
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)
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)
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)
2.1±0.1	2.3±0.1	0.2 (-0.1 to 0.5)	1.9±0.1	2.1±0.1	0.2 (-0.1 to 0.4)
3.4±0.1	2.9±0.1	-0.5 (-0.7 to -0.2)	3.3±0.1	3.3±0.1	0.04 (-0.2 to 0.3)
3.0±0.1	2.9±0.1	-0.1 (-0.5 to 0.3)	3.2±0.1	3.4±0.1	0.2 (-0.2 to 0.6)
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)
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)
86.9±1.8	82.4±1.9	-4.5 (-10.6 to 1.4)	89.4±1.6	88.1±1.7	-1.3 (-7.3 to 4.7)
69.1±3.5	61.9±3.6	-7.2 (-13.0 to -1.4)	78.4±3.2	74.5±3.3	-3.9 (-9.7 to 1.9)
84.9±2.7	81.0±3.0	-3.9 (-10.1 to 2.3)	87.2±2.6	88.6±2.5	1.4 (-4.8 to 7.6)
83.2±1.3	80.5±1.5	-2.7 (-7.0 to 1.6)	83.0±1.3	81.1±1.4	-1.9 (-6.2 to 2.4)
71.7±1.5	68.5±1.6	-3.2 (-7.9 to 1.3)	72.2±1.7	69.9±1.5	-2.3 (-7.1 to 2.5)
74.1±1.7	71.6±1.6	-2.5 (-7.2 to 2.2)	74.2±1.8	74.3±1.7	-0.1 (-4.8 to 4.7)
4.8±0.4	6.6±0.4	1.8 (0.7 to 1.9)	4.8±0.5	5.3±0.4	0.5 (-0.8 to 1.8)
3.2±0.4	4.4±0.4	1.2 (0.1 to 1.3)	3.1±0.4	3.5±0.4	0.4 (-0.7 to 1.5)
76.2±2.2	71.7±2.4	-4.5 (-11.0 to 2.0)	79.3±2.2	77.9±2.2	-1.4 (-7.9 to 5.1)
125	42	83	125	55	70

¶ Likert global perceived recovery is defined by a 7-point scale from “worse” to “complete” recovery. Lower scores represent recovery.

|| The Prolo scale is a four-point qualitative scale completed by the observer. A lower value represents poorer functioning and decreased ability to work. Functional observation scores showed a difference in favor of surgery ($P<0.001$), whereas the overall economic scores were not significantly different.

** Just before crossing over to surgery, 55 patients assigned to conservative treatment had a mean VAS leg-pain score of 54.0 mm (95% CI, 46.2 to 61.8) and a score on the Roland Disability Questionnaire of 15.0 (95% CI, 13.3 to 16.8).

high pain and disability scores, concordant with physical suffering for a prolonged period until surgery was performed. Österman et al. recently reported the results of a trial similar to ours showing the same trend, with earlier recovery of those assigned to surgery and nearly 40% of patients undergoing seemingly “inevitable” surgery during conservative management; however, this study did not accrue enough patients to gain adequate statistical power.²⁷

Sciatica has high direct and indirect costs.² Most of these costs are not generated by medical treatment but are attributed to loss of productivity. More than 1.5 million disk surgeries are performed annually worldwide, with various strategies for the timing of surgery.²⁸ We are not aware of earlier studies that have evaluated how the timing of surgery affects outcome. Patients need a thorough understanding of the course of symptoms to inform their decisions about surgery. The

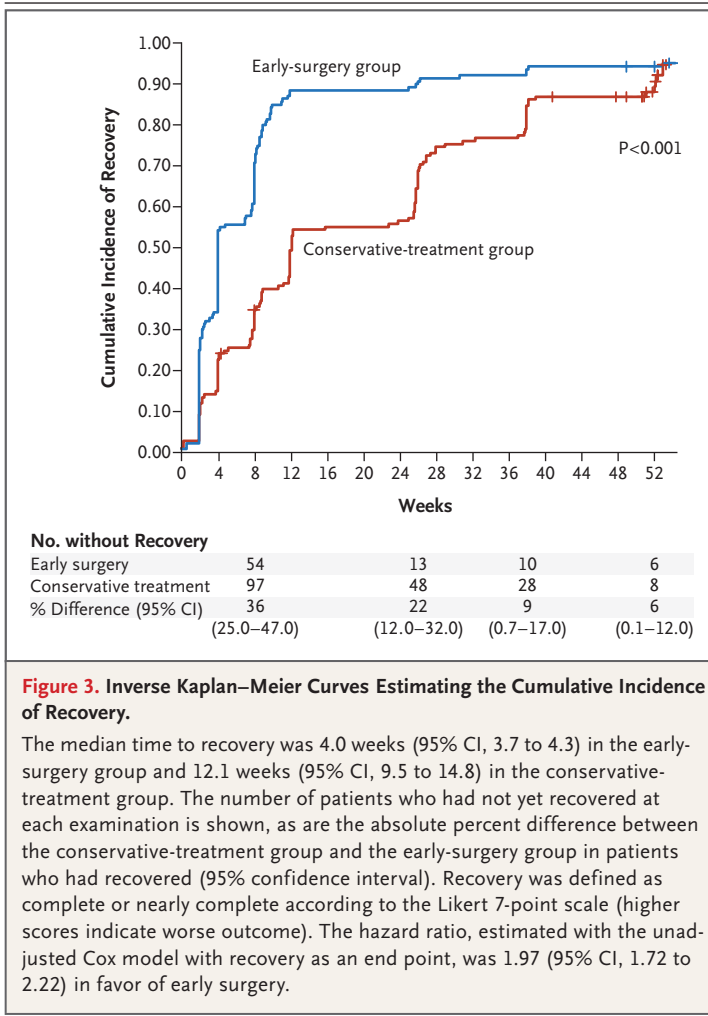


Figure 3. Inverse Kaplan–Meier Curves Estimating the Cumulative Incidence of Recovery.

The median time to recovery was 4.0 weeks (95% CI, 3.7 to 4.3) in the early-surgery group and 12.1 weeks (95% CI, 9.5 to 14.8) in the conservative-treatment group. The number of patients who had not yet recovered at each examination is shown, as are the absolute percent difference between the conservative-treatment group and the early-surgery group in patients who had recovered (95% confidence interval). Recovery was defined as complete or nearly complete according to the Likert 7-point scale (higher scores indicate worse outcome). The hazard ratio, estimated with the unadjusted Cox model with recovery as an end point, was 1.97 (95% CI, 1.72 to 2.22) in favor of early surgery.

results of this study will help in the decision-making process.

This study had several features that may limit the generalizability of its findings. First, patients assigned to conservative therapy were guided by research nurses who participated in pain management. Although this additional support did not prevent surgery in 39% of patients with severe sciatica, it does not reflect usual care. This must be kept in mind when a strategy of prolonged conservative treatment is implemented for wider populations. Second, it was clearly impossible for the patients and the nurses to be blinded to the treatment assignment. Finally, the time until recovery was determined on the basis of examinations performed only at predefined times during follow-up. The exact date of recovery was not determined, resulting in an underestimation of the speed of recovery in the interval between the sampling time

Figure 4 (facing page). Time to Complete Recovery According to Baseline Characteristics of the Patients.

Hazard ratios (black squares) and 95% confidence intervals (horizontal lines) show the effect within each subgroup. P values are for the interaction between treatment effect and the predefined subgroup variables for the group receiving prolonged conservative treatment as compared with the early-surgery group. Age, Lasègue’s sign, crossed straight-leg raising, score on the visual-analogue scale of leg pain, and McGill affective score were dichotomized before being entered into the Cox proportional-hazards model. Similar results were obtained when analyses of continuous variables were performed. Lasègue’s sign was defined as positive if the examiner observed production of pain with a typically dermatomal pattern of distribution and pelvic-muscle resistance during unilateral provocative straight-leg raising below an angle of 60 degrees, and crossed straight-leg raising was defined as positive if the examiner observed production of pain with a typically dermatomal pattern of distribution and pelvic-muscle resistance when the other leg was raised below 90 degrees. The McGill affective score (range, 0 to 5) measures the qualitative perception of pain by the patient. High affective dimensional scores correlate with a more depressed and anxious mood. Sequestered disk herniations are characterized by a defect in the anulus fibrosus and loose disk fragments in the epidural space as visualized by MRI.

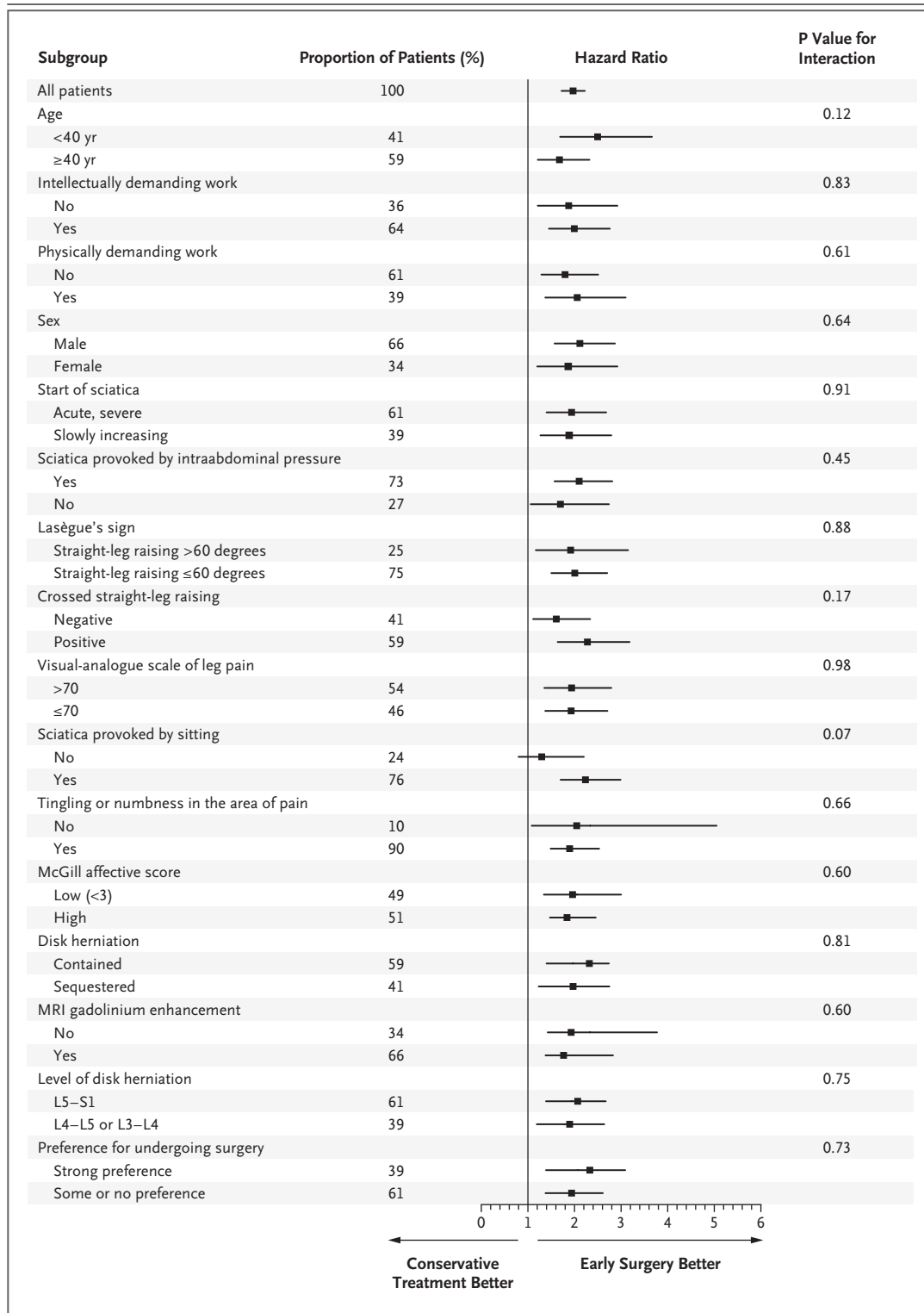
points; however, both treatment groups were affected in the same way.

In the present study, patients with sciatica who were considering disk surgery were provided information about how early surgery and conservative treatment affect three outcome measures: disease-specific disability, intensity of leg pain, and time to recovery. Our findings suggest that patients are more likely to choose surgery if they are not able to cope with leg pain, find the natural course of recovery from sciatica unacceptably slow, and want to minimize the time to recovery from pain. Patients whose pain is controlled in a manner that is acceptable to them may decide to postpone surgery in the hope that it will not be needed, without reducing their chances for complete recovery at 12 months. Although both strategies have similar outcomes after 1 year, early surgery remains a valid treatment option for well-informed patients.

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APPENDIX

The participants in the Leiden–The Hague Spine Intervention Prognostic Study Group were as follows: *Protocol Committee* — W.C. Peul, B.W. Koes, and R.T.W.M. Thomeer; *Steering Committee* — B.W. Koes, R.T.W.M. Thomeer, J.A.H. Bekhof, J.T.J. Tans, W.B. van den Hout, W.C. Peul (principal investigator), R. Brand, and H.C. van Houwelingen; *Statistical Analysis* — R. Brand, W.C. Peul, and H.C. van Houwelingen; *Manuscript Preparation* — W.C. Peul, B.W. Koes, and R.T.W.M. Thomeer; *Research Nurses and Data Collection and Management* — M. Nuyten, P. Bergman, G. Holtkamp, S. Dukker, A. Mast, L. Smakman, C. Waanders, L. Polak, and A. Nieborg; *Participating Hospitals and Coordinating Physicians* — *Medical Center Haaglanden, The Hague* — J.T.J. Tans and R. Walchenbach; *Diaconessen Hospital, Leiden* — J. van Rossum, P. Schutte, and R.T.W.M. Thomeer; *Groene Hart Hospital, Gouda* — G.A.M. Verheul, J.E. Dalman, and J.A.L. Wurzer; *Reinier de Graaf Hospital, Delft/Voorburg* — J.W.A. Sven and A. Kloet; *Spaarne Hospital, Heemstede/Haarlem* — I.S.J. Merkies and H. van Dulken; *Bronovo Hospital, The Hague* — P.C.L.A. Lambrechts and J.A.L. Wurzer; *Haga Hospital, The Hague* — R.W.M. Keunen and C.F.E. Hoffmann; *Rijnland Hospital, Leiderdorp/Alphen ad Rijn* — J. Haan and H. van Dulken; *Lange Land Hospital, Zoetermeer* — R. Groen and R.R.F. Kuiters; *Leiden University Medical Center, Leiden* — R.A.C. Roos and J.H.C. Voormolen; *Public Health and Primary Care, Leiden University, Leiden* — J.A.H. Bekhof.

REFERENCES

1. Cherkin DC, Deyo RA, Loeser JD, Bush T, Waddell G. An international comparison of back surgery rates. *Spine* 1994; 19:1201-6.
2. van Tulder MW, Koes BW, Bouter LM. A cost-of-illness study of back pain in The Netherlands. *Pain* 1995;62:233-40.
3. Vroomen PC, de Krom MC, Wilmlink JT, Kester AD, Knottnerus JA. Lack of effectiveness of bed rest for sciatica. *N Engl J Med* 1999;340:418-23.
4. Hofstee DJ, Gijtenbeek JM, Hoogland PH, et al. Westeinde sciatica trial: randomized controlled study of bed rest and physiotherapy for acute sciatica. *J Neurosurg* 2002;96:Suppl 1:45-9.
5. Awad JN, Moskovich R. Lumbar disc herniations: surgical versus nonsurgical treatment. *Clin Orthop Relat Res* 2006; 443:183-97.
6. Mixer WJ, Barr J. Rupture of the intervertebral disc with involvement of the spinal canal. *N Engl J Med* 1934;211:210-5.
7. Andersson GB, Brown MD, Dvorak J, et al. Consensus summary of the diagnosis and treatment of lumbar disc herniation. *Spine* 1996;21:Suppl:75S-78S.
8. Luijsterburg PA, Verhagen AP, Braak S, Avezaat CJ, Koes BW. Do neurosurgeons subscribe to the guideline lumbosacral radicular syndrome? *Clin Neurol Neurosurg* 2004;106:313-7.
9. Vader JP, Porchet F, Larequi-Lauber T, Dubois RW, Burnand B. Appropriateness of surgery for sciatica: reliability of guidelines from expert panels. *Spine* 2000;25: 1831-6.
10. Stam J. Consensus on diagnosis and treatment of the lumbosacral radicular syndrome. *Ned Tijdschr Geneesk* 1996; 140:2621-7. (In Dutch.)
11. Peul WC, van Houwelingen HC, van der Hout WB, et al. Prolonged conservative treatment or 'early' surgery in sciatica caused by a lumbar disc herniation: rationale and design of a randomized trial. *BMC Musculoskelet Disord* 2005;6:8.
12. Patrick DL, Deyo RA, Atlas SJ, Singer DE, Chapin A, Keller RB. Assessing health-related quality of life in patients with sciatica. *Spine* 1995;20:1899-908.
13. Collins SL, Moore RA, McQuay HJ. The visual analogue pain intensity scale: what is moderate pain in millimetres? *Pain* 1997;72:95-7.
14. Prolo DJ, Oklund SA, Butcher M. Toward uniformity in evaluating results of lumbar spine operations: a paradigm applied to posterior lumbar interbody fusions. *Spine* 1986;11:601-6.
15. Brazier JE, Harper R, Jones NM, et al. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ* 1992;305:160-4.
16. Atlas SJ, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part II: 1-year outcomes of surgical and nonsurgical management of sciatica. *Spine* 1996; 21:1777-86.
17. ProMISE, version 2: Project Manager Internet Server. Leiden, the Netherlands: Department of Medical Statistics and Bio-Informatics, Section of Advanced Data Management, Leiden University Medical Center.
18. SPSS software, version 12.0. Chicago: SPSS.
19. Balderston RA, Gilyard GG, Jones AA, et al. The treatment of lumbar disc herniation: simple fragment excision versus disc space curettage. *J Spinal Disord* 1991; 4:22-5.
20. Carragee EJ, Spinnickie AO, Alamin TF, Paragioudakis S. A prospective controlled study of limited versus subtotal posterior discectomy: short-term outcomes in patients with herniated lumbar intervertebral discs and large posterior annular defect. *Spine* 2006;31:653-7.
21. Thome C, Barth M, Scharf J, Schmiedek P. Outcome after lumbar sequestrectomy compared with microdiscectomy: a prospective randomized study. *J Neurosurg Spine* 2005;2:271-8.
22. Weber H. Lumbar disc herniation: a controlled, prospective study with ten years of observation. *Spine* 1983;8:131-40.
23. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;357:1191-4.
24. Weber H. The effect of delayed disc surgery on muscular paresis. *Acta Orthop Scand* 1975;46:631-42.
25. Buttermann GR. Treatment of lumbar disc herniation: epidural steroid injection compared with discectomy: a prospective, randomized study. *J Bone Joint Surg Am* 2004;86:670-9.
26. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT): a randomized trial. *JAMA* 2006;296:2441-50.
27. Osterman H, Seitsalo S, Karppinen J, Malmivaara A. Effectiveness of microdiscectomy for lumbar disc herniation: a randomized controlled trial with 2 years of follow-up. *Spine* 2006;31:2409-14.
28. Frymoyer JW. Back pain and sciatica. *N Engl J Med* 1988;318:291-300.

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