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Surgery versus Conservative Care for Persistent Sciatica Lasting 4 to 12 Months

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ABSTRACT

BACKGROUND

The treatment of chronic sciatica caused by herniation of a lumbar disk has not been well studied in comparison with acute disk herniation. Data are needed on whether diskectomy or a conservative approach is better for sciatica that has persisted for several months.

METHODS

In a single-center trial, we randomly assigned patients with sciatica that had lasted for 4 to 12 months and lumbar disk herniation at the L4–L5 or L5–S1 level in a 1:1 ratio to undergo microdiskectomy or to receive 6 months of standardized nonoperative care followed by surgery if needed. Surgery was performed by spine surgeons who used conventional microdiskectomy techniques. The primary outcome was the intensity of leg pain on a visual analogue scale (ranging from 0 to 10, with higher scores indicating more severe pain) at 6 months after enrollment. Secondary outcomes were the score on the Oswestry Disability Index, back and leg pain, and quality-of-life scores at 6 weeks, 3 months, 6 months, and 1 year.

RESULTS

From 2010 through 2016, a total of 790 patients were screened; of those patients, 128 were enrolled, with 64 in each group. Among the patients assigned to undergo surgery, the median time from randomization to surgery was 3.1 weeks; of the 64 patients in the nonsurgical group, 22 (34%) crossed over to undergo surgery at a median of 11 months after enrollment. At baseline, the mean score for leg-pain intensity was 7.7 in the surgical group and 8.0 in the nonsurgical group. The primary outcome of the leg-pain intensity score at 6 months was 2.8 in the surgical group and 5.2 in the nonsurgical group (adjusted mean difference, 2.4; 95% confidence interval, 1.4 to 3.4; $P<0.001$). Secondary outcomes including the score on the Owestry Disability Index and pain at 12 months were in the same direction as the primary outcome. Nine patients had adverse events associated with surgery, and one patient underwent repeat surgery for recurrent disk herniation.

CONCLUSIONS

In this single-center trial involving patients with sciatica lasting more than 4 months and caused by lumbar disk herniation, microdiskectomy was superior to nonsurgical care with respect to pain intensity at 6 months of follow-up. (Funded by Physicians' Services Incorporated Foundation; ClinicalTrials.gov number, NCT01335646.)

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Sciatica that is caused by acute herniation of a lumbar disk is expected to improve with conservative care in 90% of patients within 4 months after the onset of symptoms.[1] Several randomized trials involving patients with acute sciatica have shown a short-term benefit of surgery over conservative care, but outcomes with these two approaches are similar by 6 to 12 months.[2-5] However, these trials do not address sciatica in patients who have more persistent symptoms, since the majority of patients who were recruited had symptoms with a duration of less than 3 months.[3,4] We performed a single-center trial to determine whether lumbar diskectomy is superior to standardized nonsurgical care in patients with sciatica lasting 4 to 12 months and caused by lumbar disk herniation.

Methods

Trial Design

This investigator-initiated, prospective, randomized, controlled trial was performed at London Health Sciences Centre in London, Ontario, Canada. The research protocol (available with the full text of this article at NEJM.org) was approved by our institutional research ethics board. The trial was funded by the Physicians' Services Incorporated Foundation; there was no industry involvement in the trial. The authors vouch for the completeness and accuracy of the data and for the fidelity of the trial to the protocol.

Enrollment and Randomization

From February 2010 through August 2016, patients were recruited from a consecutive series referred to four orthopedic surgeons and one neurosurgeon at our institution. Trial coordinators performed an initial telephone screening of the referred patients, who were subsequently assessed by a trial spine surgeon for inclusion and exclusion criteria. Eligible patients were between the ages of 18 and 60 years, had a history of unilateral radiculopathy of 4 to 12 months, and had findings on magnetic resonance imaging (MRI) of posterolateral herniation of the disk between the fourth and fifth lumbar vertebrae (L4–L5) or in the lumbosacral junction (L5–S1) on the appropriate side, with compression of the corresponding nerve root. Exclusion criteria were radiculopathy secondary to herniation of a foraminal or far lateral disk, spinal stenosis, deformity at the herniation level, previous lumbar surgery at the involved level, or treatment for the current episode of sciatica with epidural spinal injection or ongoing exercise-based physiotherapy.

Patients were informed that they would be randomly assigned to receive surgery within 3 weeks or standardized nonsurgical care by a trial physician while remaining on the regular waiting list of the surgeon to whom they were initially referred. If required, patients in the nonsurgical cohort could undergo surgery after this standard waiting period, which is typically more than 6 months at our center. Patients who did not provide written informed consent to undergo randomization were recorded in a rejection log.

Patients were randomly assigned in a 1:1 ratio to surgical or nonsurgical treatment with the use of computer-generated permuted blocks[6,7] and were stratified according to the presence or absence of workers' compensation coverage.[6,7]

Trial Interventions

Nonsurgical treatment was standardized to include education of patients regarding day-to-day functioning, activity and exercise, use of oral analgesics, and use of active physiotherapy provided at the discretion of physiotherapists not associated with the trial.[8,9] In addition, patients could receive an epidural glucocorticoid injection administered by a fellowship-trained anesthesiologist. Patients could receive a second or third injection at the discretion of the treating physician on the basis of their response to the previous injection (Table S1 in the Supplementary Appendix, available at NEJM.org). Patients were seen by a physiatrist or trial physician specializing in spinal care to provide medications and education, as well as assessment of the response to nonsurgical treatment on a 6-week basis for a minimum of 6 months.

Patients in the surgical group underwent microdiskectomy performed by a fellowship-trained spine surgeon using an open or minimal-access approach with loupe or microscope assistance. The procedure was performed as day surgery or with a one-night postoperative stay. No patient received instrumentation or fusion.

Outcomes

All outcomes were assessed at baseline, 6 weeks, 3 months, 6 months, and 1 year after enrollment. The primary outcome was the leg-pain

intensity score on the visual analogue scale (ranging from 0 to 10, with higher scores indicating a greater intensity of pain) at 6 months after randomization.Secondary outcomes, which were analyzed at 6 months and 12 months, were a combination of intensity and frequency of leg pain and back pain on the visual analogue scale; scores on the Oswestry Disability Index (ODI, ranging from 0 to 100, with higher scores indicating more severe disability)[10]; scores on the Physical Component Summary (PCS) and Mental Component Summary (MCS) of the 36-Item Short-Form General Health Survey (SF-36) (standardized mean [±SD] of 50±10 determined with the use of norm-based scoring relative to the 2000 Canadian population standardized scores, with higher scores indicating a better quality of life)[11]; employment status; and satisfaction with treatment.[12] For employment status, the "unemployed" category included students and those who were receiving disability payments. Surgery-related adverse events were documented. For patients in the nonsurgical group who crossed over to undergo surgery, outcome measures were obtained at the same predefined time points postoperatively.

STATISTICAL ANALYSIS

The null hypothesis was that there would be no significant between-group difference in the mean score for leg-pain intensity at 6 months. A sample size of 15 patients in each trial group was calculated for the primary outcome on the basis of an alpha level of 0.05, a beta level of 0.80, a standard deviation of 1.9, and a minimal clinically important difference of 2 on the pain scale.[3] Since the score on the ODI was an important secondary outcome measure, we increased the sample size to 64 patients in each group on the basis of a standard deviation of 20 and a minimal clinically important difference of 10.[5] We chose the standard deviations for the sample-size estimate from previous trials of treatments for sciatica with lumbar disk herniation.[3] All the analyses were performed according to the intention-to-treat principle with SPSS software, version 25. A P value of less than 0.05 was considered to indicate statistical significance.

The primary outcome analysis used a mixed model of longitudinal regression for repeated measures that accounted for the correlation (on the assumption of compound symmetry) among the outcome scores for the same patient. The adjusted mean difference in the primary outcome was tested at the 6-month follow-up. Fixed effects were the trial group, the postoperative visit as a categorical variable, and the interaction between trial group and visit. The leg-pain score at baseline was included as a covariate. Similar analyses were applied to the secondary outcomes with pairwise comparisons between groups at 6 months and 12 months. For binary outcomes, generalized estimating equations were used to fit repeated-measures logistic-regression models. There was no adjustment for multiple testing of secondary outcomes, and these results are presented only as point estimates with unadjusted confidence intervals, from which no definite clinical inferences can be made. An interim analysis was conducted when 50% of the patients had been enrolled to ensure safety and no protocol violations. No statistical adjustment was made for this analysis.

We performed post hoc sensitivity analyses for missing data using multiple imputation and inclusion of covariates associated with baseline and missing values at 6 months with the same mixed-model approach. (Details are provided in the Supplementary Appendix.)

RESULTS

PATIENTS

A total of 790 patients were screened, and 376 met the eligibility criteria as determined by the initial telephone interview (Fig. 1). An additional 208 patients were determined to be ineligible at the screening visit. The majority of the patients who were excluded no longer had radicular symptoms (53%) or did not have an L4–L5 or L5–S1 posterolateral disk herniation on MRI (34%). Forty eligible patients declined to participate in the trial at the screening visit. Thus, 128 patients underwent randomization, with 64 assigned to the surgical group and 64 to the nonsurgical group. For the primary outcome assessment at 6 months, the follow-up rate was 80% in the surgical group and 84% in the nonsurgical group; at 12 months, the corresponding rates of follow-up were 80% and 73%.

The baseline demographic and preoperative data are shown in Table 1 and Table S2. The mean age of the study population was 38 years, 41% were female, and the disk herniation was

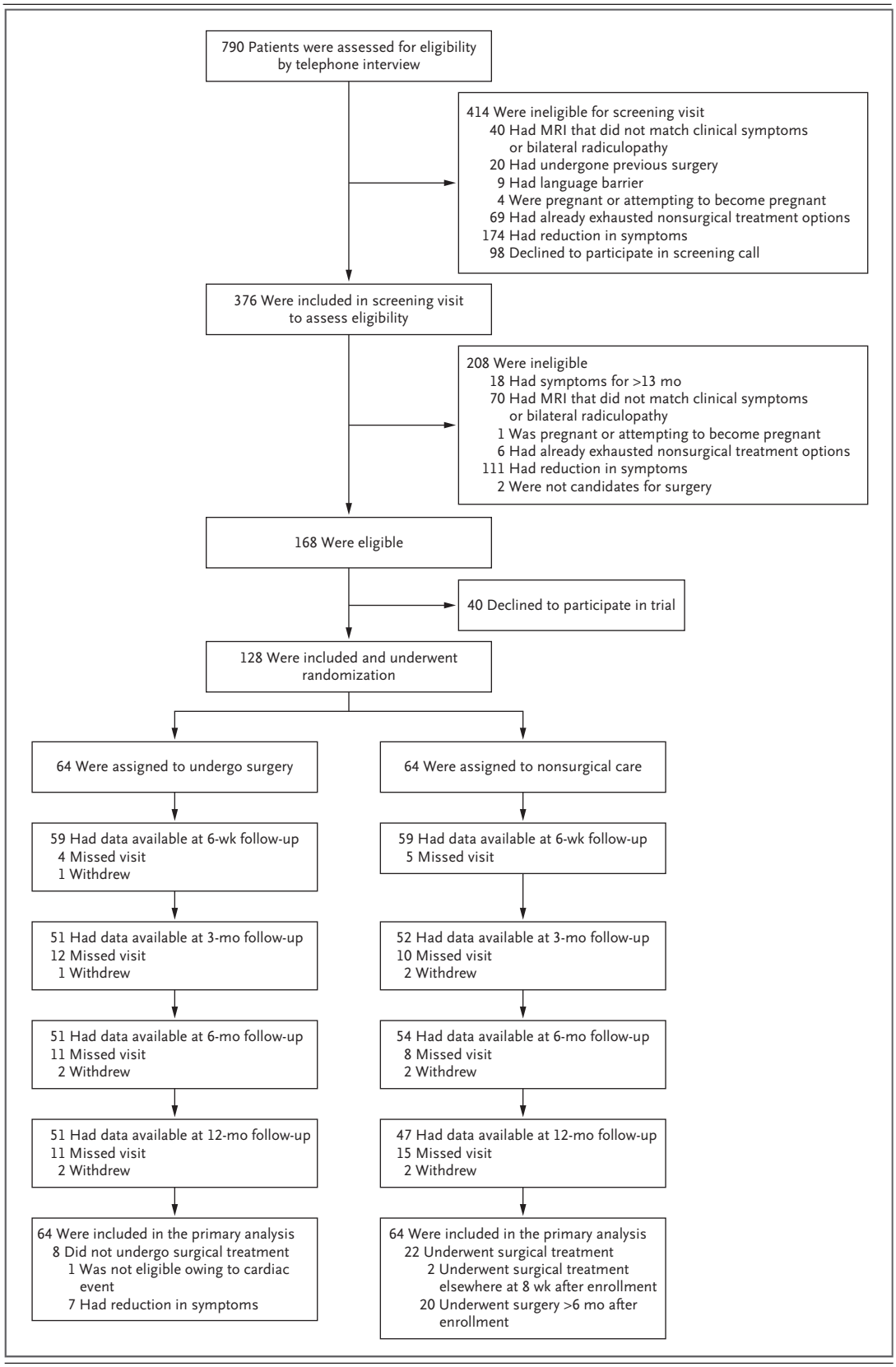

Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.*

Characteristic	Surgical Group (N=64)	Nonsurgical Group (N=64)
Age — yr	38.0±8.3	37.1±11.9
Body-mass index†	27.1±5.6	27.4±10.5
Female sex — no. (%)	27 (42)	25 (39)
Receipt of workers' compensation — no. (%)	4 (6)	2 (3)
Primary symptom — no. (%)		
Leg pain	49 (77)	55 (86)
Back pain	3 (5)	3 (5)
Both	12 (19)	6 (9)
Neurologic symptom — no. (%)		
Numbness	48 (75)	45 (70)
Tingling	32 (50)	30 (47)
Weakness	15 (23)	13 (20)
Any neurologic deficit — no. (%)		
Asymmetric decrease in reflexes	36 (56)	27 (42)
Asymmetric decrease in sensory response	41 (64)	37 (58)
Asymmetric weakness in motor response	20 (31)	19 (30)
Type of disk herniation — no. (%)		
Protruding	14 (22)	9 (14)
Extruded	46 (72)	47 (73)
Sequestered	6 (9)	10 (16)
Disk herniation level — no. (%)		
L4–L5	17 (27)	20 (31)
L5–S1	47 (73)	44 (69)
Pain-intensity score‡		
Leg	7.7±2.0	8.0±1.8
Back	6.7±2.6	6.5±2.8
Oswestry Disability Index§	49.7±15.8	50.2±15.9
SF-36 score¶		
Physical Component Summary	26.4±7.6	25.3±6.7
Mental Component Summary	36.0±13.8	36.2±12.4

* Plus–minus values are means ±SD. Patients could have more than one herniation type or neurologic symptom.
† The body-mass index is the weight in kilograms divided by the square of the height in meters.
‡ Scores for the intensity of leg and back pain range from 0 to 10, with higher scores indicating more severe symptoms.
§ Scores on the Oswestry Disability Index range from 0 to 100, with higher scores indicating worse disability and pain.
¶ Scores on the components of the 36-Item Short-Form General Health Survey (SF-36) are based on normative data and have a mean (±SD) of 50±10, with higher scores indicating a better quality of life.

most common at the L5–S1 level. The only significant between-group difference was a higher rate of antidepressant use in the surgical group.

Figure 1 (facing page). Enrollment, Randomization, and Follow-up.

The mean baseline score for leg-pain intensity was 7.7±2.0 in the surgical group and 8.0±1.8 in the nonsurgical group. The characteristics of the patients who missed the 6-month visit were similar to the characteristics of the rest of the cohort except that they were more likely to be smokers (61% vs. 39%).

Of the 64 patients in the surgical group, 56 underwent the procedure a median of 3.1 weeks after enrollment. Seven patients cancelled surgery because of a reduction in symptoms. One patient had cardiac arrhythmia and was unable to have surgery. As compared with the patients who underwent surgery, these 8 patients had baseline symptoms for a shorter duration (5.8±1.5 months vs. 8.0±2.7 months), had better physical functioning (PCS score, 31.6±8.4 vs. 25.6±7.2), and had less disability (ODI score, 39.3±16.7 vs. 51.2±15.2) (Table S3).

Of the 64 patients who received nonsurgical care, 22 (34%) crossed over to undergo surgery at a median of 11 months (range, 2 to 25) after enrollment. Two of these patients underwent surgery at another facility 2 months after enrollment and were lost to follow-up thereafter. Hence, 62 patients (97%) in the nonsurgical group were continuing to receive nonsurgical care at 6 months. At baseline, the 22 patients who underwent surgery after the failure of nonsurgical treatment were younger than those who underwent the assigned surgery (33.1±10.5 years of age vs. 37.7±8.0 years of age) and were less likely to have an asymmetrical decrease in reflexes (27% vs. 57%) (Table S3).

OUTCOMES

At 6 months, the score for leg-pain intensity was 2.8±0.4 in the surgical group and 5.2±0.4 in the nonsurgical group (difference, 2.4; 95% confidence interval [CI], 1.4 to 3.4; P<0.001) (Table 2). Secondary outcomes were generally in the same direction as the primary outcome. At 1 year, the leg-pain intensity score was 2.6±0.4 in the surgical group and 4.7±0.4 in the nonsurgical group; the ODI score was 22.9±2.3 and 34.7±2.4, respectively. The absence of a prespecified plan for adjustment for multiple comparisons does not allow for clinical inferences from secondary outcomes (Table S4).

Patients in the two groups had a reduction in symptoms at the 6-month follow-up visit (Fig. 2 and Fig. S1). Sensitivity analyses for missing data were similar in direction to the results of the primary analysis (Tables S5 and S6).

ADVERSE EVENTS

In the intention-to-treat analysis, the percentage of patients who reported one or more adverse events related to surgery was similar in the two groups: 6% in the surgical group and 8% in the nonsurgical group who crossed over to undergo surgery (Table 3). Superficial wound infection and postoperative new-onset neuropathic pain were the most common adverse events. One patient in the surgical group underwent a repeat procedure for recurrent disk herniation 250 days after the index procedure.

DISCUSSION

In our single-center trial involving patients with sciatica lasting 4 to 12 months caused by lumbar disk herniation at the L4–L5 or L5–S1 level, surgery resulted in less leg pain at 6 months than nonsurgical treatment. Randomized trials have shown a beneficial treatment effect for surgery over conservative care in the first 6 months among patients with lumbar disk herniation. However, in some randomized trials, the patients had symptoms for a shorter duration than the minimum of 4 months required for entry in our trial.[2-5,13,14]

One trial, which included only patients with a history of 6 to 12 weeks of severe sciatica, showed that the benefit of early surgery was no longer different between the surgical group and the nonsurgical group by 6 months.[2,3] Another trial involving patients with radicular pain lasting 6 to 12 weeks showed no difference in outcomes between the surgical group and the nonsurgical group at 6 weeks.[4] In SPORT (Spine Patient Outcomes Research Trial),[5] which recruited a majority of patients who had symptoms lasting less than 6 months, investigators found a significant advantage of surgery over nonsurgical care in the as-treated analysis. In our trial, we found that the treatment effect for secondary outcome measures (e.g., back pain and physical functioning) at both 6 months and 12 months were in the same direction as the primary outcome, but a formal analysis was not possible because the original statistical plan made no accommodation for multiple comparisons.

The decision about whether to recommend diskectomy or nonsurgical treatment in this population is controversial because a longer duration of symptoms has been correlated with a poorer outcome associated with lumbar diskectomy in some studies.[15-19] However, patients may

Table 2. Primary and Secondary Outcomes.*

Outcome	Surgical Group		Nonsurgical Group		Difference (95% CI)
	No. of Patients	Value	No. of Patients	Value	
Primary outcome					
Intensity score for leg pain at 6 mo†	51	2.8±0.4	54	5.2±0.4	2.4 (1.4 to 3.4)
Secondary outcomes‡					
Intensity score for leg pain at 12 mo	51	2.6±0.4	54	4.7±0.4	2.1 (1.1 to 3.2)
Oswestry Disability Index					
At 6 mo	51	22.8±2.3	54	33.7±2.3	10.9 (4.5 to 17.2)
At 12 mo	51	22.9±2.3	47	34.7±2.4	11.8 (5.3 to 18.3)
Score on SF-36 Physical Component Summary					
At 6 mo	51	40.6±1.3	54	35.1±1.2	−5.5 (−8.9 to −2.0)
At 12 mo	51	42.8±1.3	47	34.1±1.3	−8.7 (−12.2 to −5.1)
Score on SF-36 Mental Component Summary					
At 6 mo	51	48.6±1.6	54	42.2±1.6	−6.4 (−10.8 to −1.9)
At 12 mo	51	48.1±1.6	47	42.3±1.6	−5.7 (−10.3 to −1.2)
Intensity score for back pain					
At 6 mo	51	3.0±0.3	54	4.9±0.3	1.9 (1.0 to 2.9)
At 12 mo	51	3.2±0.3	47	5.1±0.3	1.9 (0.9 to 2.8)
Satisfaction with treatment (%)					
At 6 mo	51	92.0±3.9	52	71.4±6.3	−20.6 (−43.4 to 2.2)
At 12 mo	51	89.9±4.3	47	71.4±6.6	−18.5 (−43.0 to 6.0)
Employed (%)					
At 6 mo	51	80.0±5.8	53	64.2±7.5	−15.8 (−45.4 to 13.8)
At 12 mo	51	78.7±6.0	46	62.0±7.9	−16.7 (−47.7 to 14.3)

* Plus–minus values are means ±SE. Means are derived from mixed-model repeated-measures analysis. The dependent variable was the score at each predetermined time point. Fixed effects included the baseline score, treatment, and time. Time was treated as a categorical variable. The patient was included in the model as a random effect. A compound symmetry covariance matrix was used to model the within-patient variance–covariance errors. Percentages are derived from longitudinal logistic-regression models fitted with the use of generalized estimating equations. CI denotes confidence interval.

† $P<0.001$ for the between-group difference in the primary outcome.

‡ Because of the lack of a plan for adjustment for multiple comparisons, the secondary outcomes are presented as point estimates with unadjusted 95% confidence intervals and cannot be used for clinical inferences.

prefer to avoid surgery if they think that nonsurgical treatment could be successful or if they anticipate a risk from surgery.[20] In a post hoc analysis of SPORT data, a symptom duration of 6 months or more was associated with a worse outcome than a shorter duration after either surgical or nonsurgical treatment.[19] Other studies have shown that patients who were waiting to undergo surgery for 12 weeks or more had worse pain 6 months after surgery than those who had a shorter waiting period.[16]

The prolonged waiting time to see a surgeon in the Canadian health care system was an opportunity to minimize the crossover effect, since only 2 patients underwent surgery within 6 months after enrollment in our trial. By design, the patients in the nonsurgical group received standardized treatment by a designated separate trial physician who would not provide surgical care. Such patients remained on the surgeon's waiting list for surgical consultation, which occurred approximately 6 months after enrollment. A strength of this trial is that the nonsurgical cohort received standardized treatment. Patients were ex-

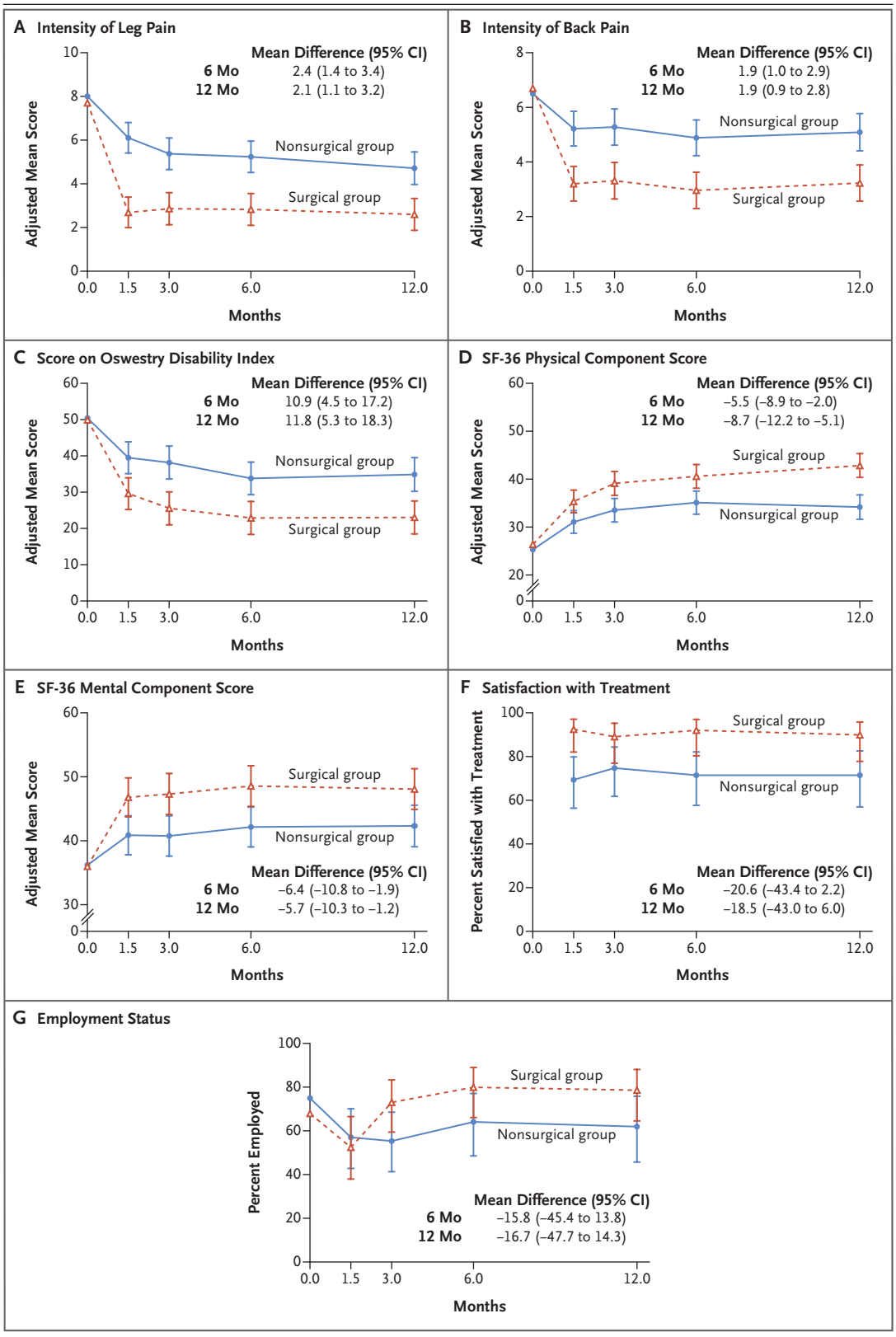

Figure 2 (facing page). Primary and Secondary Outcomes at Each Follow-up Visit through 1 Year.

At baseline, the data points represent the observed means or percentages of patients in the surgical group and the nonsurgical group, whereas the data points on the plot lines represent the estimated means based on a mixed-effects model after adjustment for the baseline value. The I bars denote 95% confidence intervals. Because of the lack of a plan for adjustment for multiple comparisons, the secondary outcomes are presented as point estimates with unadjusted 95% confidence intervals and cannot be used for clinical inferences. Panel A shows the leg-pain intensity scores over time, with the 6-month visit as the primary outcome. Secondary outcomes were scores on the visual analogue scale for back-pain intensity (Panel B), the score on the Oswestry Disability Index (Panel C), scores on the 36-Item Short-Form General Health Survey (SF-36) Physical Component Summary (Panel D) and Mental Component Summary (Panel E), the percentage of patients satisfied with treatment (Panel F), and the percentage of patients who were employed (Panel G). Scores for the intensity of leg and back pain range from 0 to 10, with higher scores indicating more severe symptoms. Scores on the Oswestry Disability Index range from 0 to 100, with higher scores indicating worse disability and pain. Mean summary scores on the SF-36 components are based on normative data and have a mean (±SD) of 50±10, with higher scores indicating a better quality of life.

Table 3. Surgery-Related Adverse Events at 1 Year.*

Adverse Events	Surgical Group	Nonsurgical Group
Intention-to-treat analysis		
No. of patients	64	64
No. of patients with at least 1 event (%)	4 (6)	5 (8)
No. of events (event rate)	5 (0.08)	6 (0.09)
As-treated analysis		
No. of patients	56	22
No. of patients with at least 1 event (%)	4 (7)	5 (23)
No. of events (event rate)	5 (0.09)	6 (0.27)
Adverse events — no.		
Dural tear	0	1
Superficial wound infection	2	1
Nerve-root injury	0	1
Postoperative adjacent level condition	0	1
New-onset postoperative neuropathic pain	1	2
Recurrent herniation after surgery†		
No further surgery performed	1	0
Revision surgery performed	1	0

* A total of 56 of 64 patients in the surgical group actually underwent surgery, and 22 of 64 patients in the nonsurgical group crossed over to undergo surgery. Of these 22 patients, 20 underwent surgery more than 6 months after enrollment and so were included in the primary analysis.

† Recurrent herniation refers to a herniation on the same side and level as the primary herniation.

cluded if they had already been treated with epidural spinal injections or active exercise-based physiotherapy, since these treatments were components of the treatment provided to the nonsurgical group (Table S1).

Our trial had crossovers between the two treatment groups. Although the trial was designed to minimize the delay in surgery, 7 patients in the surgical group had a reduction in symptoms and thus did not undergo the procedure, and surgery was contraindicated in 1 patient. These patients had symptoms for a shorter duration, better physical functioning, and less disability than others in the surgical group. In the nonsurgical group, 2 of 22 patients who ultimately crossed over underwent surgery before the 6-month trial visit because of intractable sciatic pain. These patients were lost to follow-up, so 62 patients (97%) actually had nonsurgical care for 6 months. In SPORT, 30% of the patients in the nonsurgical group crossed over to undergo surgery 3 months into the trial,[5] and 64% of the patients crossing over to surgery in another trial[14] did so within 3 months.

Our trial has several limitations. First, there was a potential for selection bias, since both the trial surgeons and patients might have been less inclined to pursue nonsurgical care if they had severe sciatica.[20] This bias was minimized by the fact that patients did not have the option of undergoing surgery outside of this trial at our center, a factor that may explain why only a few patients declined to participate in the trial at the time of recruitment. Second, our trial was conducted in a single center, which limits its generalizability. Third, up to 20% of the data for the primary outcome assessment were missing. Thus, multiple imputation was used, and the main results were in the same direction as the primary outcome analysis.

We found that patients who underwent surgery for sciatica lasting 4 to 12 months caused by lumbar disk herniation had a greater reduction in pain at 6 months than those who received conservative treatment. Nine patients had

adverse events associated with surgery, and one patient underwent repeat surgery for recurrent disk herniation.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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