The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2016 VOL. 374 NO. 15

A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis

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ABSTRACT

BACKGROUND

The efficacy of fusion surgery in addition to decompression surgery in patients who have lumbar spinal stenosis, with or without degenerative spondylolisthesis, has not been substantiated in controlled trials.

METHODS

We randomly assigned 247 patients between 50 and 80 years of age who had lumbar spinal stenosis at one or two adjacent vertebral levels to undergo either decompression surgery plus fusion surgery (fusion group) or decompression surgery alone (decompression-alone group). Randomization was stratified according to the presence of preoperative degenerative spondylolisthesis (in 135 patients) or its absence. Outcomes were assessed with the use of patient-reported outcome measures, a 6-minute walk test, and a health economic evaluation. The primary outcome was the score on the Oswestry Disability Index (ODI; which ranges from 0 to 100, with higher scores indicating more severe disability) 2 years after surgery. The primary analysis, which was a per-protocol analysis, did not include the 14 patients who did not receive the assigned treatment and the 5 who were lost to follow-up.

RESULTS

There was no significant difference between the groups in the mean score on the ODI at 2 years (27 in the fusion group and 24 in the decompression-alone group, P=0.24) or in the results of the 6-minute walk test (397 m in the fusion group and 405 m in the decompression-alone group, P=0.72). Results were similar between patients with and those without spondylolisthesis. Among the patients who had 5 years of follow-up and were eligible for inclusion in the 5-year analysis, there were no significant differences between the groups in clinical outcomes at 5 years. The mean length of hospitalization was 7.4 days in the fusion group and 4.1 days in the decompression-alone group (P<0.001). Operating time was longer, the amount of bleeding was greater, and surgical costs were higher in the fusion group than in the decompression-alone group. During a mean follow-up of 6.5 years, additional lumbar spine surgery was performed in 22% of the patients in the fusion group and in 21% of those in the decompression-alone group.

CONCLUSIONS

Among patients with lumbar spinal stenosis, with or without degenerative spondylolisthesis, decompression surgery plus fusion surgery did not result in better clinical outcomes at 2 years and 5 years than did decompression surgery alone. (Funded by an Uppsala institutional Avtal om Läkarutbildning och Forskning [Agreement concerning Cooperation on Medical Education and Research] and others; Swedish Spinal Stenosis Study ClinicalTrials.gov number, NCT01994512.)

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N Engl J Med 2016;374:1413-23.
DOI: 10.1056/NEJMoa1513721

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Lumbar spinal stenosis is caused by a gradual narrowing of the spinal canal. Patients with lumbar spinal stenosis typically present with low back pain and leg pain, which occur especially when they are walking. This degenerative condition severely restricts function, walking ability, and quality of life. Lumbar spinal stenosis has become the most common indication for spinal surgery,[1-4] and studies have shown that surgical treatment in selected patients is more successful than conservative alternatives.[5-7]

As the use of surgery to treat lumbar spinal stenosis has increased during the past decades, so has the complexity of the surgical procedures.[2] Thus, decompression of the neural structures by means of laminectomy has increasingly been supplemented with lumbar fusion, with the intention of minimizing a potential risk of future instability and deformity. In recent years, approximately half the patients in the United States who have received surgical treatment for lumbar spinal stenosis have undergone fusion surgery.[8]

Degenerative spondylolisthesis, a condition in which one vertebra has shifted forward in relation to the vertebra below it, can be seen on radiographs in some patients who have lumbar spinal stenosis. Many spine surgeons view this sign of instability as a mandatory indication for fusion surgery.[9,10] In the United States, 96% of patients with degenerative spondylolisthesis undergo fusion surgery as an adjunct to decompression surgery.[11] Regardless of the presence of spondylolisthesis,[12] the evidence that suggests an advantage of the more complex decompression surgery plus fusion surgery over decompression surgery alone is weak,[13,14] and a randomized, controlled trial is warranted. The aim of the Swedish Spinal Stenosis Study (SSSS) was to investigate whether fusion surgery as an adjunct to decompression surgery resulted in better clinical outcomes at 2 years than decompression surgery alone among patients who underwent surgery for lumbar spinal stenosis, with or without preoperative degenerative spondylolisthesis.

Table 1. Inclusion and Exclusion Criteria.

Inclusion Criteria
Pseudoclaudication in one or both legs and back pain (score on visual-analogue scale >30)*
1 or 2 adjacent stenotic segments (cross-section area of the dural sac ≤75 mm^2) between L2 and the sacrum on magnetic resonance imaging
Duration of symptoms >6 mo
Written informed consent
Exclusion Criteria
Spondylolysis
Degenerative lumbar scoliosis (Cobb angle >20 degrees)
History of lumbar spinal surgery for spinal stenosis or instability
Stenosis not caused by degenerative changes
Stenosis caused by a herniated disk
Other specific spinal conditions (e.g., ankylosing spondylitis, cancer, or neurologic disorders)
History of vertebral compression fractures in affected segments
Psychological disorders (e.g., dementia or drug abuse) that caused the surgeon to consider participation to be inappropriate

* Scores on the visual-analogue scale range from 0 to 100, with higher scores indicating more severe pain.

METHODS

TRIAL DESIGN

We conducted a multicenter, open-label, clinical superiority trial in which patients who had lumbar spinal stenosis, with or without degenerative spondylolisthesis, were randomly assigned, in a 1:1 ratio, to undergo either decompression surgery plus fusion surgery (fusion group) or decompression surgery alone (decompression-alone group). We enrolled patients between 50 and 80 years of age who had received a diagnosis of lumbar spinal stenosis and who met the inclusion criteria (Table 1). The diagnosis of lumbar spinal stenosis was based on the presence of typical symptoms and the finding on magnetic resonance imaging (MRI) of a stenotic segment at one or two adjacent lumbar vertebral levels with a cross-section area of the dural sac measuring 75 mm^2 or less.

Patients were assessed for degenerative spondylolisthesis before they underwent randomization. Assessment for preoperative degenerative spondylolisthesis was performed with the use of conventional lateral radiography[15]; flexion–extension radiographs were not obtained. Degenerative spondylolisthesis was defined as the presence of a vertebra that had slipped forward at least 3 mm in relation to the vertebra below it.

Simple randomization was performed with the use of a Web-based system that enabled computer-generated random treatment assignment. Randomization was stratified according

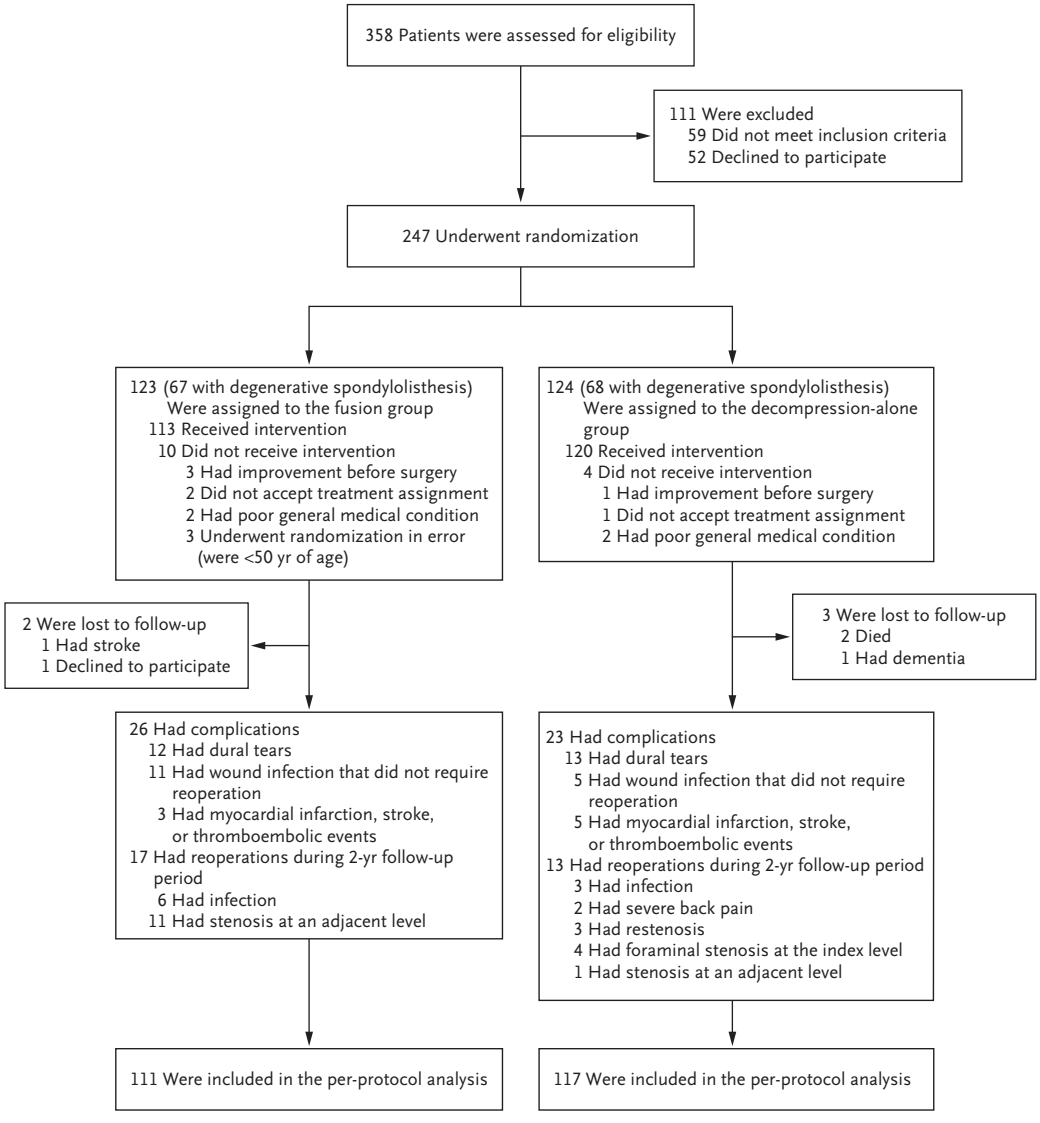

Figure 1. Enrollment, Randomization, Treatment, and 2-Year Follow-up.

to the presence or absence of degenerative spondylolisthesis (Fig. 1).

All the trial surgeons were senior consultants and were highly experienced in performing the two trial interventions. The method used for decompression surgery or fusion surgery was determined solely by the surgeon.

DATA COLLECTION AND OUTCOMES

Outcomes of this trial were measured with the use of patient-reported data obtained from validated questionnaires (which are provided in the Supplementary Appendix, available with the full text of this article at NEJM.org), including the National Swedish Register for Spine Surgery (Swespine) questionnaire[16] and the Zurich Claudication Questionnaire (ZCQ).[17] The Swespine has data on more than 80% of all spinal surgery procedures that have been performed in Sweden since 1998, including preoperative, perioperative, and postoperative protocols. The Swespine staff collects patient information by means of postal questionnaires that are sent before surgery and 1, 2, and 5 years after surgery. For the trial, we

confirmed that the Swespine questionnaires were answered before surgery and 2 and 5 years after surgery, and we reminded the patients to answer the questionnaires, if necessary. In addition, we sent the ZCQ before surgery and 2 years after surgery. The questionnaires, which were sent to the patients along with a prepaid envelope, were unrelated to any hospital visit and were completed without the assistance of the surgeon or any other person involved in the trial.

The primary outcome was the score on the Oswestry Disability Index (ODI; which ranges from 0 to 100, with higher scores indicating more severe disability)[18]; the ODI is a standard for measuring degree of disability and estimating quality of life in persons with low back pain. Secondary outcomes were scores on the European Quality of Life–5 Dimensions (EQ-5D; which range from 0 to 1, with higher scores indicating better quality of life),[18] visual-analogue scales for back pain and leg pain[18] (which range from 0 to 100, with higher scores indicating more severe pain), and the ZCQ (which ranges from 1 to 4, with higher scores indicating more severe disability). In addition, the patients responded to questions (which are described in the Supplementary Appendix) related to overall satisfaction, a global assessment of back and leg pain, and walking ability.[18] In addition to the patient-reported outcome measures, the 6-minute walk test (which measures the distance in meters that a person is able to walk in 6 minutes)[19] was administered by a physiotherapist or a trial nurse at baseline and at a 2-year follow-up visit.

Except for the results of the ZCQ and the 6-minute walk test, the data for analysis were collected from the Swespine. In addition to performing an analysis of data obtained at the 2-year follow-up, we used the Swespine to conduct a prespecified analysis of data obtained at the 5-year follow-up. Information about complications and reoperations was collected from patients' medical files and from the Swespine.

Computed tomography (CT) was performed directly after the surgical procedures, and MRI, CT, and conventional lateral radiography were performed at the 2-year follow-up visit. The results of these imaging studies have yet to be evaluated and are therefore not discussed in this report.

Data for the health economic evaluation were collected by means of special questionnaires that were unrelated to the Swespine (see the Supplementary Appendix for details). The questionnaires were sent before surgery and 6 months, 1 year, and 2 years after surgery. Data on direct operation costs were obtained from one clinic (Stockholm Spine Center) that was used as a proxy for all participating clinics. The EQ-5D score was used to assess quality of life at baseline and at 1 and 2 years after surgery. Data on direct and indirect patient costs included the number of visits to health care personnel, use of sick leave, participation in the work force, use of pharmaceutical agents, length of hospitalizations, personal out-of-pocket expenses, and number of days that family members assisted the patient. In accordance with the trial protocol, data on patient costs were not collected after 2 years.

TRIAL OVERSIGHT

The SSSS trial was approved by the local Swedish ethics review boards, and all participants provided oral and written informed consent. The trial was conducted and the data were reported in accordance with the trial protocol, which is available at NEJM.org. The authors designed the trial, analyzed the data, wrote the manuscript (with the first draft written by the first author), made the decision to submit the manuscript for publication, and vouch for the completeness and accuracy of the data and analysis and for the fidelity of this report to the trial protocol. No institution or company had a role in the data analysis, the preparation of the manuscript, or the decision to submit the manuscript for publication.

STATISTICAL ANALYSIS

We calculated that a minimum of 40 patients in each of the four strata — fusion group with spondylolisthesis, fusion group without spondylolisthesis, decompression-alone group with spondylolisthesis, and decompression-alone group without spondylolisthesis — would be required for the trial to have 80% power to detect a difference in the ODI score of at least 12 between the treatment groups at a significance level of 0.05. We chose a difference of 12 conservatively, since a decrease in the ODI score of 15 had been suggested by the Food and Drug Administration to indicate minimally important improvement after spinal fusion surgery.[20] We estimated a dropout rate of 10% and a distribution of patients with and patients without spondylolisthesis

of 25% versus 75%, and therefore we estimated that the trial would need to include 320 patients. However, we noted a more even distribution of spondylolisthesis among the trial participants than we had expected, and the sample size was revised so that randomization was stopped at 247 patients, since more than 40 patients had been included in each stratum.

Our primary analysis, which was a per-protocol analysis, included patients who underwent the assigned surgery and completed the 2-year follow-up. Differences between the two treatment groups were analyzed with the use of Student's t-test. The ordinal variables were tabulated descriptively but were also dichotomized and analyzed with the use of standard summary measures that were based on two-by-two contingency tables. In addition, we calculated relative risks and 95% confidence intervals by comparing outcomes in the fusion group with those in the decompression-alone group. The analysis was performed both with and without stratification according to the presence or absence of preoperative degenerative spondylolisthesis. Less than 2% of patients had missing outcome data for any of the variables. We used multiple imputation[21-23] to create five estimates of missing data in the health economic evaluation, including values for age, sex, and scores on the visual-analogue scales for back pain and leg pain, the ODI, and the EQ-5D. Values for the health economic evaluation were imputed for 30% of patients at the 6-month follow-up, 33% at the 1-year follow-up, and 14% at the 2-year follow-up. Calculations of standard deviation and error were adjusted to account for the increased size of the data set.

RESULTS

PARTICIPANTS

From October 2006 through June 2012, a total of 247 patients from seven Swedish hospitals were enrolled in the SSSS trial (see Table S1 in the Supplementary Appendix). The baseline characteristics of the patients are shown in Table 2. There were no significant differences between the two treatment groups in any of the preoperative variables, including general health. Among patients with preoperative degenerative spondylolisthesis, the mean degree of vertebral slip was 7.4 mm (range, 3.0 to 14.3).

A total of 123 patients were assigned to the fusion group, and 10 of those patients did not receive the assigned treatment (Fig. 1); 124 patients were assigned to the decompression-alone group, and 4 of those patients did not receive the assigned treatment. Therefore, 113 patients underwent decompression surgery plus fusion surgery and 120 underwent decompression surgery alone. Five patients were lost to follow-up. Therefore, the per-protocol analysis included 228 patients (111 in the fusion group and 117 in the decompression-alone group) (Fig. 1). The different approaches to the surgical interventions that were used in each treatment group are described in the Supplementary Appendix.

OUTCOMES AT 2 YEARS

Per-Protocol Analysis

There was no significant difference between the two treatment groups in the primary outcome; the mean score on the ODI at 2 years was 27 in the fusion group and 24 in the decompression-alone group (P=0.24). The ODI score had decreased from baseline by 15 in the fusion group and by 17 in the decompression-alone group (difference in change between the fusion group and the decompression-alone group, –2; 95% confidence interval [CI], –7 to 3; P=0.36). Analyses performed with stratification according to the presence or absence of degenerative spondylolisthesis at baseline resulted in outcomes that were similar to the outcomes in the overall analysis (Table 3). For the primary outcome, we found no significant interaction between type of treatment and presence of spondylolisthesis (P=0.33 for interaction). An exploratory post hoc analysis of the subgroup of patients with spondylolisthesis involving a vertebral slip of 7.4 mm or greater (range, 7.4–14.3) showed no difference in ODI score between the two treatment groups at baseline or at 2 years. In this patient subgroup, the mean score on the ODI at 2 years was 25 in both the fusion group (35 patients) and the decompression-alone group (34 patients) (P=0.98), and the score on the visual-analogue scale for back pain was 36 in the fusion group and 32 in the decompression-alone group (P=0.55).

There was no significant difference between treatment groups in the results of the 6-minute walk test at 2 years (397 m in the fusion group and 405 m in the decompression-alone group, P=0.72). Among patients with spondylolisthesis, the walking distance increased by 73 m (to 382 m)

Table 2. Baseline Characteristics of the Patients.*

Characteristic	Absence of Degenerative Spondylolisthesis		Presence of Degenerative Spondylolisthesis	
	Fusion Group (N=46)	Decompression-Alone Group (N=52)	Fusion Group (N=67)	Decompression-Alone Group (N=68)
Age — yr	66±9	66±8	68±7	67±7
Female sex — no. (%)	19 (41)	29 (56)	51 (76)	56 (82)
Smoker — no. (%)	7 (15)	9 (17)	9 (13)	10 (15)
Degree of vertebral slip — mm	—	—	7.4±2.6	7.4±2.8
ASA score — no. (%)†				
1 or 2	38 (83)	46 (88)	57 (85)	53 (78)
3	8 (17)	6 (12)	10 (15)	15 (22)
ODI score‡	43±15	41±15	41±13	41±14
EQ-5D score§	0.40±0.31	0.37±0.31	0.39±0.31	0.36±0.30
VAS score for back pain¶	59±24	61±25	64±20	63±24
VAS score for leg pain¶	65±19	61±24	64±21	65±22
ZCQ score‖				
Symptom severity	3.4±0.72	3.5±0.69	3.4±0.6	3.5±0.5
Physical function	2.4±0.63	2.5±0.55	2.6±0.5	2.5±0.5
Result of 6-minute walk test — m**	312±155	331±129	309±117	313±110

* Plus–minus values are means ±SD. The data do not include the 14 patients who did not receive the assigned treatment.
† An American Society of Anesthesiologists (ASA) score of 1 indicates the presence of no disease, 2 the presence of mild systemic disease, and 3 the presence of severe systemic disease.
‡ Scores on the Oswestry Disability Index (ODI) range from 0 to 100, with higher scores indicating more severe disability.
§ Scores on the European Quality of Life–5 Dimensions (EQ-5D) range from 0 to 1, with higher scores indicating better quality of life.
¶ Scores on the visual-analogue scales (VASs) for back pain and leg pain range from 0 to 100, with higher scores indicating more severe pain.
‖ Scores on the Zurich Claudication Questionnaire (ZCQ) range from 1 to 4, with higher scores indicating more severe disability.
** The 6-minute walk test measures the distance in meters that a person is able to walk in 6 minutes.

in the fusion group and by 83 m (to 396 m) in the decompression-alone group (P=0.60) (Table 3). Subjective patient assessments of improvement in walking ability at the 2-year follow-up did not differ between the treatment groups (Table 3).

Modified Intention-to-Treat Analysis

We used the Swespine to obtain 2-year follow-up data for the 9 patients who did not initially receive the assigned treatment but did undergo subsequent surgery; 6 underwent decompression surgery alone, and 3 underwent decompression surgery plus fusion surgery. In a modified intention-to-treat analysis that included these 9 patients, outcomes were similar to the outcomes in the per-protocol analysis (Table S4 in the Supplementary Appendix).

OUTCOMES AT 5 YEARS

Among the 153 patients who were enrolled early enough in the trial to have potentially completed 5 years of follow-up, 7 had died, 1 had had a major stroke, and 1 had severe dementia; the remaining 144 patients were eligible for the 5-year follow-up assessment. Of those patients, 138 (96%) provided information on outcomes.

There were no significant differences between the fusion group and the decompression-alone group in any of the seven patient-reported outcome measures, and the results were similar among patients with and those without spondylolisthesis (Table S2 in the Supplementary Appendix). The mean score on the ODI at 5 years was 27 in the fusion group and 28 in the decompression-alone group (P=0.86); the ODI score had decreased from baseline by 14 (95% CI, 9 to 19)

Table 3. Outcomes in the Per-Protocol Population.*

Outcome	Absence of Degenerative Spondylolisthesis				Presence of Degenerative Spondylolisthesis			
	Fusion Group (N=44)	Decompression-Alone Group (N=51)	P Value	Relative Risk (95% CI)	Fusion Group (N=67)	Decompression-Alone Group (N=66)	P Value	Relative Risk (95% CI)
During the procedure								
Operating time — min	150±47	80±28	<0.01		149±44	95±40	<0.01	
Amount of bleeding — ml	648±498	288±319	<0.01		686±434	311±314	<0.01	
At 2 yr								
ODI score	29±20	27±18	0.70		25±19	21±18	0.11	
EQ-5D score	0.62±0.31	0.59±0.35	0.85		0.63±0.31	0.69±0.28	0.20	
VAS score for back pain	41±32	45±31	0.66		36±29	26±25	0.15	
VAS score for leg pain	35±31	34±33	0.46		32±30	29±31	0.60	
ZCQ score								
Symptom severity	2.6±1.0	2.5±1.1	0.41		2.4±0.9	2.4±1.0	0.56	
Physical function	1.9±0.7	1.8±0.8	0.20		1.8±0.8	1.7±0.7	0.53	
Patient satisfaction	2.2±0.9	2.1±0.9	0.65		2.1±0.9	1.9±0.8	0.22	
Result of 6-minute walk test — m	417±163	416±130	0.38		382±152	396±144	0.60	
Reporting satisfaction with the surgery — no. (%)†	23 (52)	27 (53)		0.99 (0.67–1.45)	43 (64)	45 (68)		0.94 (0.74–1.20)
Reporting decrease in back pain — no. (%)‡	33 (75)	33 (65)		1.16 (0.89–1.51)	53 (79)	54 (82)		0.97 (0.82–1.14)
Reporting decrease in leg pain — no. (%)§	36 (82)	35 (69)		1.19 (0.94–1.50)	52 (78)	48 (73)		1.07 (0.88–1.30)
Reporting increase in walking distance — no. (%)¶	40 (91)	41 (80)		1.13 (0.96–1.33)	59 (88)	57 (86)		1.02 (0.90–1.16)

* Plus–minus values are means ±SD. The per-protocol analysis did not include the 14 patients who did not receive the assigned treatment and the 5 who were lost to follow-up. CI denotes confidence interval.

† In an assessment of overall satisfaction, patients responded to the following question: How do you feel about the results of your back surgery? The answer choices were "I'm satisfied," "I'm doubtful," and "I'm dissatisfied." The data reflect the number of patients who answered "I'm satisfied."

‡ In a global assessment of back pain, patients responded to the following question: How is your back pain today compared with before the operation? The data reflect the number of patients who answered "completely gone," "greatly improved," or "somewhat improved."

§ In a global assessment of leg pain, patients responded to the following question: How is your leg or sciatic pain today compared with before the operation? The data reflect the number of patients who answered "completely gone," "greatly improved," or "somewhat improved."

¶ In an assessment of walking ability, patients responded to the following question: How far can you walk at a normal pace? The answer choices were "less than 100 m," "100 to 500 m," "0.5 to 1 km," and "more than 1 km." The data reflect the number of patients whose answers indicated an increase in walking distance from baseline.

Table 4. Resource Use.*

Variable	Fusion Group	Decompression-Alone Group	P Value
During the procedure	**(N=113)**	**(N=119)**	
Length of hospital stay (days)	7.4±8.4	4.1±6.1	<0.001
Mean operation costs (U.S. $)†	12,200	5,400	
At 2 yr	**(N=104)**	**(N=109)**	
No. of visits to doctors	1.3±3.3	1.8±5.3	0.49
No. of visits to other health care professionals	13±32	22±45	0.13
Total no. of days receiving benefits of any kind	61±172	41±117	0.35
No. of patients using analgesics for back problems at 2 yr (%)	42 (40)	40 (37)	0.57

* Plus–minus values are means ±SD. Of the 233 patients who received the assigned treatment, all but 1 consented to participate in the health economic evaluation. Data related to resource use at 2 years were available for 213 patients.
† Because operation costs were extrapolated from only one hospital (Stockholm Spine Center), no standard deviation is presented for this variable (see the Supplementary Appendix). The costs were estimated in 2014.

in the fusion group and by 15 (95% CI, 11 to 19) in the decompression-alone group.

COMPLICATIONS AND REOPERATIONS

Dural tears occurred in 12 patients (11%) in the fusion group and in 13 patients (11%) in the decompression-alone group (Fig. 1). Postoperative wound infection that required treatment with antibiotic agents but not reoperation with wound débridement occurred in 11 patients (10%) in the fusion group and in 5 patients (4%) in the decompression-alone group. Myocardial infarction, stroke, or thromboembolic events occurred in 3 patients (3%) in the fusion group and in 5 patients (4%) in the decompression-alone group. The percentage of patients who underwent additional lumbar-spine surgery before the end of October 2015 (within a mean follow-up period of 6.5 years) was 22% in the fusion group and 21% in the decompression-alone group (Table S3 and the figure in the Supplementary Appendix).

HEALTH ECONOMIC EVALUATION

Of the 233 patients who received the assigned treatment, all but 1 consented to participate in the health economic evaluation. Data related to resource use at 2 years were available for 213 patients (92%) and are shown in Table 4. The mean direct costs of each procedure (mainly hospital costs, including surgery) were $6,800 higher in the fusion group than in the decompression-alone group because of the additional operating time, extended hospitalization, and cost of the implant. However, indirect costs were similar in the two treatment groups. Analyses performed with stratification according to the presence or absence of degenerative spondylolisthesis at baseline resulted in outcomes that were similar to the outcomes in the overall analysis (data not shown).

DISCUSSION

This randomized, controlled trial, which included 247 patients with lumbar spinal stenosis, with or without degenerative spondylolisthesis, revealed no clinical benefit 2 years after surgery of adding fusion surgery to decompression surgery. As compared with decompression surgery alone, the more technically advanced procedure of decompression plus fusion was associated with higher costs but not with greater clinical benefits at 2 years. Approximately two thirds of the patients involved in the trial had a follow-up longer than 5 years, and the lack of superiority of decompression plus fusion seemed to persist at 5 years among those patients.

The presence of degenerative spondylolisthesis has often been considered to be a sign of instability, although there is no consensus on the definition of that term. Some studies have suggested that there may be a risk of iatrogenic slip or an increased degree of spondylolisthesis after decompression surgery in patients with degenerative spondylolisthesis.[24,25] However, the possible clinical consequences of a slipped vertebra have been under debate for decades.[24,26] The

natural course of untreated degenerative spondylolisthesis has been reported to be benign and has not been correlated with progression of slip or clinical symptoms.[27] Furthermore, few studies support the widespread use of fusion surgery in patients with lumbar spinal stenosis, regardless of the presence of spondylolisthesis.[13,14] Despite this lack of evidence, surgeons often use a combination of decompression surgery and fusion surgery as a means of avoiding possible postoperative instability and restenosis. Two studies[9,10] have served as the main foundation for this combined procedure, but their validity has been questioned.[13,14] Other observational studies promoting fusion surgery have been limited by small sample size.[14,28,29] Despite weak evidence, degenerative spondylolisthesis has nonetheless been regarded as such a strong indication for fusion surgery that it was an exclusion criterion in a randomized, controlled trial of nonsurgical treatment for lumbar spinal stenosis.[30] In our trial, we found that there was no significant difference between the two treatment groups in amelioration of back pain, regardless of the presence of preoperative degenerative spondylolisthesis. Moreover, previous studies have shown that the presence of preoperative spondylolisthesis was not associated with an increased level of back pain.[26,31] Several recent cohort studies have not shown any substantial benefit from the addition of fusion surgery to decompression surgery for lumbar spinal stenosis, even in the presence of spondylolisthesis.[32-35]

The results of our trial might at first seem to contrast with the findings of Ghogawala et al.,[36] which are presented in this issue of the *Journal.* In their trial, the addition of fusion surgery to decompression surgery resulted in moderately superior scores on the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) physical-component summary but not on the ODI. However, the comparison of results between the two trials is hampered, because the trial by Ghogawala et al. had a higher dropout rate and a substantially higher reoperation rate during follow-up in the decompression-alone group than in the fusion group (34% vs. 14%), which could have negatively affected the results of the SF-36 assessment of overall well-being during the recovery period. Moreover, reoperation is not solely the choice of the patient and is more likely to be performed at the discretion of the surgeon. The threshold for performing a reoperation in an unsatisfied patient is probably lower when one treatment option remains (i.e., fusion surgery), especially when clinical instability is considered to be an important indication for surgery.

The yearly loss in walking speed among elderly persons has been estimated to be 1.6%.[37] The walking test performed in our trial revealed an improvement in walking performance after surgery that was well above the minimal clinically relevant difference of 18 m for this test.[38] Improvement was unrelated to type of surgery.

Fusion surgery is associated with an increased risk of severe complications in elderly patients. A large analysis of registry data showed that the addition of fusion surgery to decompression surgery doubled the risk of severe adverse events and was associated with an absolute risk difference that corresponded to a number needed to harm of 30 treated patients.[2,39] Our trial was not powered to analyze differences in complication rates.

The addition of fusion surgery to decompression surgery significantly increased direct hospital costs, including the costs of surgery and the in-hospital stay, but did not increase indirect costs at 2 years. Although economic data at 5 years were not collected, the clinical results and, in particular, the similar rates of reoperation in the two treatment groups indicate that the outcomes at 2 years are robust. As compared with decompression plus fusion, the use of decompression surgery alone not only is associated with a lower treatment cost per patient but also can save resources by releasing surgical capacity as a consequence of shorter operating time and hospitalization.

Both the patients and the surgeons were aware of the treatment assignments, but none of the surgeons were involved in the outcome assessment. The results of the trial are valid only for patients who have spinal stenosis at one or two adjacent lumbar vertebral levels, with or without degenerative spondylolisthesis; this is the case for most patients with lumbar spinal stenosis and constitutes the most common indication for spine surgery. The per-protocol analysis and the modified intention-to-treat analysis (with only five patients who received an intervention missing from the analysis) revealed only minor differences between groups in overall results.

Validated and reliable imaging studies to

identify signs of instability are lacking. To establish the diagnosis of degenerative spondylolisthesis, we used conventional lateral radiography as a complement to the preoperative MRI. Another available diagnostic tool is flexion–extension radiography, but this method has been questioned because of measurement errors, lack of definition of normal movements,[40] and low repeatability[41] unless the observed vertebral slip exceeds 5 mm.[41] Nonetheless, outcomes among the patients with spondylolisthesis involving a slip of 7.4 mm or greater did not differ from the outcomes among all the patients with degenerative spondylolisthesis or the outcomes among all the patients, with or without spondylolisthesis; this strongly indicates that the use of conventional lateral radiography without the use of flexion–extension radiography did not bias our findings.

In summary, in this randomized trial of Swedish patients with lumbar spinal stenosis involving one or two adjacent vertebral levels, with or without degenerative spondylolisthesis, decompression with fusion did not result in clinical outcomes that were superior to those with decompression surgery alone.

Supported by the Avtal om Läkarutbildning och Forskning (Agreement concerning Cooperation on Medical Education and Research) between Uppsala University and Uppsala County Council and by the Stockholm Spine Center. Johnson & Johnson provided financial support for the health economic analysis. The National Swedish Register for Spine Surgery (Swespine) is supported by the Swedish Association of Local Authorities and Regions; all of Sweden's municipalities, county councils, and regions are members of the association.

Mr. Ólafsson reports receiving grant support from Medtronic. Dr. Borgström is an employee of and holds stock in Quantify Research. No other potential conflict of interest relevant to this article was reported.

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

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