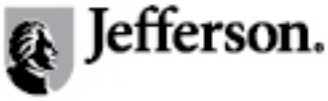

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Effectiveness of Surgery for Lumbar Stenosis and Degenerative Spondylolisthesis in the Octogenarian Population: Analysis of the Spine Patient Outcomes Research Trial (SPORT) Data.

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A commentary by Melvin Helgeson, MD, and Peter Formby, MD, is linked to the online version of this article at jbjs.org.

Effectiveness of Surgery for Lumbar Stenosis and Degenerative Spondylolisthesis in the Octogenarian Population

Analysis of the Spine Patient Outcomes Research Trial (SPORT) Data

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Investigation performed at the Rothman Institute at Thomas Jefferson University, Philadelphia, Pennsylvania, and the Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

Background: The purpose of this study was to determine whether surgery is an effective option for the treatment of stenosis of the lumbar spine and degenerative spondylolisthesis in the octogenarian population.

Methods: An as-treated analysis of patients with lumbar stenosis and degenerative spondylolisthesis enrolled in the Spine Patient Outcomes Research Trial (SPORT) was performed. Patients who were at least eighty years of age (n = 105) were compared with those younger than eighty years (n = 1130). Baseline patient and clinical characteristics were noted, and the difference in improvement from baseline between operative and nonoperative treatment was determined for each group at each follow-up time period up to four years.

Results: There were no significant baseline differences in the primary or secondary patient-reported clinical outcome measures between the two patient age groups. Patients at least eighty years of age had higher prevalences of multilevel stenosis, severe stenosis, and asymmetric motor weakness. Patients at least eighty years of age also had higher prevalences of hypertension, heart disease, osteoporosis, and joint problems at baseline, but they had a lower body mass index and lower prevalences of depression and smoking. Fifty-eight of the 105 patients at least eighty years of age and 749 of the 1130 younger patients underwent operative management. There were no differences in the rates of intraoperative or postoperative complications, reoperation, or postoperative mortality between the older and younger groups. Averaged over a four-year follow-up period, operatively treated patients at least eighty years of age had significantly greater improvement in all primary and secondary outcome measures compared with nonoperatively treated patients. The treatment effects in patients at least eighty years of age were similar to those in younger patients for all primary and secondary measures except the SF-36 (Short Form-36) bodily pain domain and the percentage who self-rated their progress as a major improvement, in both of which the treatment effect was significantly smaller.

Conclusions: Operative treatment of lumbar stenosis and degenerative spondylolisthesis offered a significant benefit over nonoperative treatment in patients at least eighty years of age ($p < 0.05$). There were no significant increases in the complication and mortality rates following surgery in this patient population compared with younger patients ($p > 0.05$).

Level of Evidence: Prognostic Level II. See Instructions for Authors for a complete description of levels of evidence.

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The elderly population in the United States is growing. In 2010, there were over 11.2 million Americans at least eighty years of age, representing a 22% increase compared with 2000[1]. Lumbar stenosis and degenerative spondylolisthesis affect the aging population. A 2009 study using computed tomography found that 47% of individuals at least sixty years of age had lumbar spinal stenosis[2]. The number of surgical procedures for lumbar degenerative disease performed in the elderly, particularly spinal arthrodesis procedures, has increased substantially over the previous decade[3]. As the population ages, the growing demand for treatment of lumbar stenosis and degenerative spondylolisthesis will require a thorough understanding of effective treatment options for this specific group. In the future, limited health-care funds may drive payers to approve payment only for those treatments that are effective for a given patient population.

The operative treatment of lumbar stenosis and degenerative spondylolisthesis provides substantial lasting benefit compared with nonoperative care[4,5]. This is best demonstrated by the four-year follow-up data on stenosis and spondylolisthesis from the Spine Patient Outcomes Research Trial (SPORT)[4,5]. Those reports, however, did not specifically address the effect that patient age has on outcomes. The purpose of the present study was to assess the clinical outcomes of operative and nonoperative treatment of lumbar spinal stenosis and degenerative spondylolisthesis in patients at least eighty years of age.

Materials and Methods

Patient Population and Study Design

The SPORT study design and methods have been published previously. Patients with stenosis of the lumbar spine, alone or combined with degenerative spondylolisthesis, were enrolled at thirteen centers throughout the United States[6,7]. The trial was registered with clinicaltrials.gov (NCT00000411 and NCT00000409). The institutional review board at each participating center approved the SPORT protocol. The criteria for inclusion into the stenosis-only cohort were neurogenic claudication or radicular leg pain with associated neurological signs, spinal stenosis on cross-sectional imaging, symptoms that had persisted for at least twelve weeks, and physician confirmation that the patient was a surgical candidate. The patients who also had degenerative spondylolisthesis on standing lateral radiographs were analyzed separately in the SPORT study. Patients with spondylolysis and isthmic spondylolisthesis were excluded. The cohorts containing patients with stenosis alone and patients with stenosis combined with degenerative spondylolisthesis were combined and included in the present analysis.

Study Interventions

Patients with lumbar stenosis combined with degenerative spondylolisthesis were offered participation in either a randomized cohort or a concurrent observational cohort. Participants in the randomized cohort received a computer-generated random treatment assignment (operative or nonoperative treatment) blocked by center; those in the observational cohort chose their treatment with their physician. Patients who were to undergo surgery were designated to receive a lumbar laminectomy if they had stenosis alone or a lumbar laminectomy and arthrodesis if they also had degenerative spondylolisthesis. A set nonoperative treatment program was not specified, but the minimal requirements included active physical therapy, education and counseling with home exercise instruction, and nonsteroidal anti-inflammatory drugs; patients could also receive any additional therapies that their physician recommended. Extensive crossover occurred between the operative and nonoperative arms of the randomized cohort, and baseline characteristics and outcomes of both the patients with stenosis alone and those who also had degenerative spondylolisthesis were similar between the randomized and observational cohorts when analyzed by treatment. Thus, the randomized and observational cohorts were combined into an "as-treated" analysis. The methodology of this as-treated analysis of the combined randomized and observational cohorts has been described in previous publications[4,6-9].

Study Measures

This study included data from patient-reported questionnaires completed at baseline, six weeks, three months, six months, one year, two years, and four years after enrollment or surgery (depending on whether nonoperative or operative treatment was being evaluated). The primary outcome measures were (1) the AAOS (American Academy of Orthopaedic Surgeons) MODEMS (Musculoskeletal Outcomes Data Evaluation and Management System) version of the ODI (Oswestry Disability Index), on which scores can range from 0 to 100, and (2) the physical function and bodily pain domains of the SF-36 (Short Form-36), on which scores can range from 0 to 100[10,11]. The secondary outcome measures were (1) the Stenosis Bothersomeness Index, on which scores can range from 0 to 24; (2) the Low Back Pain Bothersomeness Scale, on which scores can range from 0 to 6; (3) patient satisfaction with current symptoms; and (4) patient self-reported improvement[12,13]. Higher scores on the ODI, Stenosis Bothersomeness Index, and Low Back Pain Bothersomeness Scale are indicative of more severe symptoms. Higher scores on the physical function and bodily pain domains of the SF-36 are indicative of less severe symptoms.

Statistical Analysis

Patients with stenosis with or without degenerative spondylolisthesis were divided into two groups, those who were at least eighty years of age and those who were younger. Baseline characteristics of the two age groups were compared with use of a chi-square test (for categorical variables) or a t test (for continuous variables). Primary analyses compared operative and nonoperative treatments on the basis of changes from baseline to each follow-up time with use of mixed-effects longitudinal regression model; a random individual effect was included to account for correlation between repeated measurements within individuals, and a formal interaction term between treatment and age was included for comparing the treatment effect in subgroups. In this as-treated analysis, the treatment indicator was a time-varying covariate, thus allowing for variable dates of surgery. Time was measured from the beginning of treatment—i.e., the time of surgery for the operative group and the time of enrollment for the nonoperative group. Thus, for operatively treated patients, any changes from baseline that were recorded prior to surgery were included in the estimates of the nonoperative treatment effect, whereas changes from baseline that were recorded after the time of surgery were attributed to the surgery (and analyzed on the basis of the time since the surgery). Repeated measures of outcome were used as the dependent variables, and the treatment received was included as a time-varying covariate.

To adjust for potential confounding variables, baseline variables that were found to be associated with missing data or with the treatment received were included as adjusting covariates in longitudinal regression models. In addition, sex, treatment center, and baseline outcome scores (for the SF-36 and ODI) were included in such models. Secondary and binary outcomes were analyzed with use of generalized estimating equations (GEEs) that assumed a compound symmetry working correlation structure. The outcomes were stratified by age, and outcomes were compared between subgroups at each time point with use of a multiple-degrees-of-freedom Wald test. Overall differences between the subgroups across the four years of follow-up were also assessed with use of the area under the curve and a Wald test.

Calculations were made with use of SAS (version 9.2 for Windows XP Pro; Cary, North Carolina) procedures PROC MIXED (for continuous data) and PROC GENMOD (for binary and non-normal secondary outcomes). A p value of <0.05 (two-sided) was considered significant. Adjustments for

TABLE I Patient Baseline Demographic Characteristics, Comorbid Conditions, Clinical Findings, and Health Status Measures

Characteristics	Age <80 Yr	Age ≥80 Yr	P Value
No. of patients*	1130	105	
Age† *(yr)*	63.7 ± 10	83.0 ± 2.8	<0.001
Female	612 (54%)	49 (47%)	0.17
Non-Hispanic†	1090 (96%)	102 (97%)	0.93
White†	949 (84%)	90 (86%)	0.75
At least some college education	743 (66%)	58 (55%)	0.04
Income <$50,000	254 (22%)	5 (5%)	<0.001
Married	791 (70%)	51 (49%)	<0.001
Work status			<0.001
Full or part time	423 (37%)	11 (10%)	
Disabled	109 (10%)	2 (2%)	
Retired	471 (42%)	82 (78%)	
Other	127 (11%)	10 (10%)	
Compensation of any form§	88 (8%)	1 (1%)	0.017
BMI† *(kg/m²)*	29.6 ± 6.0	26.6 ± 3.8	<0.001
Smoker	111 (10%)	2 (2%)	0.012
Comorbidities			
Hypertension	505 (45%)	58 (55%)	0.048
Diabetes	160 (14%)	16 (15%)	0.88
Osteoporosis	109 (10%)	20 (19%)	0.004
Heart disease	243 (22%)	44 (42%)	<0.001
Stomach problem	249 (22%)	23 (22%)	0.93
Bowel or intestinal problem	119 (11%)	10 (10%)	0.88
Depression	161 (14%)	7 (7%)	0.044
Joint problem	621 (55%)	69 (66%)	0.043
Other#	423 (37%)	31 (30%)	0.13
Time since most recent episode >6 mo	669 (59%)	60 (57%)	0.76
SF-36†**			
Bodily pain	33.4 ± 19.6	33 ± 17.4	0.82
Physical functioning	34.8 ± 23.0	32.7 ± 21.3	0.37
Mental component summary	49.5 ± 11.8	51.8 ± 11.0	0.061
Physical component summary	29.7 ± 8.6	28.6 ± 7.5	0.19
ODI†,††	42.2 ± 18.3	40.2 ± 17.0	0.28
Stenosis Frequency Index†‡‡	13.9 ± 5.7	14.0 ± 5.5	0.86
Stenosis Bothersome Index†‡‡	14.5 ± 5.7	14.2 ± 5.5	0.61
Low Back Pain Bothersomeness†§§	4.2 ± 1.8	4.1 ± 1.8	0.66
Leg Pain Bothersomeness†§§	4.5 ± 1.7	4.2 ± 1.9	0.091
Very dissatisfied with symptoms	781 (69%)	68 (65%)	0.42
Patient self-assessed health trend			0.70
Getting better	76 (7%)	8 (8%)	
Staying about the same	360 (32%)	37 (35%)	
Getting worse	680 (60%)	59 (56%)	
Treatment preference at baseline			0.74
Preference for nonop.	422 (37%)	42 (40%)	
Not sure	239 (21%)	19 (18%)	
Preference for op.	468 (41%)	43 (41%)	

continued

TABLE I (*continued*)

Characteristics	Age <80 Yr	Age ≥80 Yr	P Value
Pseudoclaudication, any	925 (82%)	94 (90%)	0.065
Straight leg raise or femoral tension	204 (18%)	13 (12%)	0.18
Pain radiation, any	889 (79%)	78 (74%)	0.36
Neurological deficit, any	613 (54%)	63 (60%)	0.30
Reflexes, asymmetric depression	287 (25%)	31 (30%)	0.42
Sensory, symmetric decrease	325 (29%)	26 (25%)	0.45
Motor, asymmetric weakness	284 (25%)	39 (37%)	0.01
Listhesis level			0.83
L3-L4	53 (5%)	4 (4%)	
L4-L5	496 (44%)	48 (46%)	
Stenosis level			
L2-L3	192 (17%)	40 (38%)	<0.001
L3-L4	579 (51%)	77 (73%)	<0.001
L4-L5	1057 (94%)	102 (97%)	0.21
L5-S1	208 (18%)	22 (21%)	0.61
No. of levels with moderate to severe stenosis			<0.001
0	36 (3%)	2 (2%)	
1	573 (51%)	31 (30%)	
2	370 (33%)	43 (41%)	
≥3	151 (13%)	29 (28%)	
Stenosis location			
Central	993 (88%)	99 (94%)	0.071
Lateral recess	956 (85%)	93 (89%)	0.34
Neuroforamen	416 (37%)	34 (32%)	0.43
Stenosis severity			<0.001
Mild	36 (3%)	2 (2%)	
Moderate	475 (42%)	22 (21%)	
Severe	619 (55%)	81 (77%)	
Instability	43 (4%)	4 (4%)	0.79
Diagnosis			0.93
Stenosis alone	581 (51%)	53 (50%)	
Stenosis + DS	549 (49%)	52 (50%)	
Received surgery##	749 (66%)	58 (55%)	0.006

*SPORT patients in the randomized and observational cohorts with spinal stenosis (alone or with degenerative spondylolisthesis [DS]). †The values are given as the mean and the standard deviation. ‡Race or ethnic group was self-assessed. Whites and blacks could be either Hispanic or non-Hispanic. §Patients who were receiving or had applications pending for Workers' Compensation, Social Security compensation, or other compensation. #Problems related to stroke, cancer, fibromyalgia, chronic fatigue syndrome, posttraumatic stress disorder, alcohol use, drug dependency, lung, liver, kidney, blood vessel, nervous system, migraine, or anxiety. **SF-36 scores can range from 0 to 100, with higher values indicating less severe symptoms. ††ODI scores can range from 0 to 100, with lower values indicating less severe symptoms. ‡‡The Stenosis Frequency Index and Stenosis Bothersomeness Index can range from 0 to 24, with lower values indicating less severe symptoms. §§The Low Back Pain Bothersomeness Scale and Leg Pain Bothersomeness Scale can range from 0 to 6, with lower values indicating less severe symptoms. ##Operatively treated patients were classified according to whether they received such treatment during the first 4 yr of enrollment.

multiple comparisons were not made because the analyses in the present study do not represent multiple independent comparisons from which one is seeking a single significant result, but rather the longitudinal assessment over time of various aspects of the patient outcome (e.g., symptoms, function, and disability)[14].

Source of Funding

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TABLE II Operative Treatments, Complications, and Other Events

Characteristic	Age <80 Yr	Age ≥80 Yr	P Value
No. of operatively treated patients*	742	58	
Procedure†			0.002
Decompression only	341 (47%)	39 (68%)	
Noninstrumented single arthrodesis	95 (13%)	8 (14%)	
Instrumented single arthrodesis	292 (40%)	10 (18%)	
Arthrodesis of ≥2 levels	103 (14%)	4 (7%)	0.19
Laminectomy level‡			
L2-L3	162 (22%)	30 (52%)	<0.001
L3-L4	421 (58%)	50 (86%)	<0.001
L4-L5	690 (95%)	57 (98%)	0.35
L5-S1	241 (33%)	25 (43%)	0.16
No. of levels decompressed			<0.001
0	12 (2%)	0	
1	247 (33%)	5 (9%)	
2	248 (33%)	18 (31%)	
≥3	235 (32%)	35 (60%)	
Operative time§ *(min)*	167.2 ± 85.9	157.5 ± 61.9	0.41
Blood loss§ *(mL)*	445.7 ± 459.5	413.4 ± 430.7	0.60
Blood replacement			
Intraop.	164 (22%)	7 (12%)	0.095
Postop.	93 (13%)	8 (14%)	0.97
Length of hospital stay§ *(d)*	3.9 ± 2.9	4.1 ± 2	0.60
Postop. mortality			
Within 6 wk of surgery	1 (0.1%)	1 (1.7%)	0.33
Within 3 mo of surgery	2 (0.3%)	1 (1.7%)	0.52
Intraop. complications#			
Dural tear/spinal fluid leak	71 (10%)	8 (14%)	0.42
Vascular injury	1 (0%)	0	0.10
Other	11 (1%)	1 (2%)	0.68
None	659 (89%)	49 (84%)	0.40
Postop. complications and other events**			
Nerve root injury	1 (0%)	0	0.10
Wound dehiscence	1 (0%)	0	0.10
Wound hematoma	5 (1%)	0	0.82
Wound infection	18 (2%)	2 (3%)	0.98
Other	59 (8%)	2 (3%)	0.31
None	574 (78%)	47 (81%)	0.76
Additional surgical procedures††			
Within 1 yr	44 (6%)	3 (5%)	0.85
Within 2 yr	77 (10%)	3 (5%)	0.23
Within 3 yr	97 (13%)	3 (5%)	0.10
Within 4 yr	109 (14%)	4 (7%)	0.12
Recurrent stenosis or progressive spondylolisthesis	44 (6%)	0	
Pseudarthrosis or fusion exploration	4 (0.5%)	0	
Complication or other event	41 (5.6%)	2 (3.6%)	
New condition	17 (2.3%)	0	

*SPORT patients in the randomized and observational cohorts with spinal stenosis (alone or with degenerative spondylolisthesis). Surgical information was available for 742 patients younger than 80 yr and fifty-eight at least 80 yr of age. †Specific procedure data were available for 728 patients younger than 80 yr and fifty-seven at least 80 yr of age. ‡L4-L5 and L5-S1 data were available for 730 and 727 patients younger than 80 yr, respectively. §The values are given as the mean and the standard deviation. #No cases were reported of aspiration into the respiratory tract, nerve-root injury, or operation at the wrong level. **Any reported complications up to 8 wk after surgery. None of the following were reported: bone graft complication, cerebrospinal fluid leak, paralysis, cauda equina injury, and pseudarthrosis. ††1, 2, 3, and 4-yr post-surgery re-operation rates are Kaplan-Meier estimates, and p values are based on the log-rank test. Numbers and percentages are based on the first additional surgery if a patient had more than one additional surgery.

TABLE III Adjusted As-Treated Analysis of Improvement from Baseline Averaged Over Four Years of Follow-up*

Outcome Measure		Mean Improvement (Std. Error)		Treatment Effect (95% CI)†
		Operative	Nonoperative	
SF-36 bodily pain†	<80 yr	28 (0.6)	13.4 (0.7)	14.6 (13.1 to 16.2)
	≥80 yr	21.3 (2.2)	13.8 (2.3)	7.5 (2.3 to 12.8)
	P value	0.004	0.85	0.01
SF-36 physical function†	<80 yr	24.4 (0.6)	11.1 (0.7)	13.3 (11.7 to 14.8)
	≥80 yr	13.4 (2.3)	3.8 (2.4)	9.6 (4.2 to 15)
	P value	<0.001	0.004	0.20
ODI§	<80 yr	−21.3 (0.5)	−8.9 (0.6)	−12.4 (−13.6 to −11.2)
	≥80 yr	−18.5 (1.8)	−5.2 (1.9)	−13.3 (−17.6 to −9)
	P value	0.14	0.06	0.69
Stenosis Bothersomeness Index#	<80 yr	−7.8 (0.2)	−3.6 (0.2)	−4.3 (−4.7 to −3.8)
	≥80 yr	−6.6 (0.6)	−3.8 (0.7)	−2.8 (−4.4 to −1.2)
	P value	0.07	0.74	0.093
Low Back Pain Bothersomeness Scale**	<80 yr	−1.9 (0)	−1 (0.1)	−0.9 (−1 to −0.8)
	≥80 yr	−1.8 (0.2)	−1 (0.2)	−0.8 (−1.2 to −0.3)
	P value	0.51	0.89	0.55
Very or somewhat satisfied with symptoms *(%)*	<80 yr	65.9	31.8	34.1 (30.7 to 37.6)
	≥80 yr	55.2	30	25.3 (13.6 to 37)
	P value	0.029	0.70	0.15
Self-rated progress as major improvement *(%)*	<80 yr	66.4	24.9	41.5 (38.3 to 44.7)
	≥80 yr	54.6	31.1	23.5 (11.6 to 35.4)
	P value	0.016	0.22	0.004

*Scores are adjusted for sex, education, income, work status, compensation, BMI, smoking status, hypertension, osteoporosis, heart problem, depression, joint problems, no. of moderate to severe stenotic levels, diagnosis, baseline score (for SF-36, ODI, and Stenosis Bothersomeness), and center. The area under the curve was used to calculate the average result over the four-year follow-up period. †The treatment effect is the difference between the operative and nonoperative mean change from baseline. ‡The SF-36 score can range from 0 to 100, with a higher score indicating less severe symptoms. §The ODI can range from 0 to 100, with a lower score indicating less severe symptoms. #The Stenosis Bothersomeness Index can range from 0 to 24, with a lower score indicating less severe symptoms. **The Low Back Pain Bothersomeness Scale can range from 0 to 6, with a lower score indicating less severe symptoms.

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Results

Of the patients with lumbar stenosis (alone or combined with degenerative spondylolisthesis), 105 patients were at least eighty years of age (mean age [and standard deviation], 83.0 ± 2.8 years) and 1130 were younger (mean age, 63.7 ± 10 years). The baseline demographic characteristics, comorbid conditions, clinical findings, and health status measures of these two age groups are compared in Table I. At baseline, patients at least eighty years of age had higher prevalences of hypertension, heart disease, osteoporosis, and joint problems, but they had a lower BMI (body mass index) and lower prevalences of depression and smoking ($p < 0.05$). There were no baseline differences in the primary (ODI and SF-36 physical function and bodily pain scores) or secondary patient-reported clinical outcome measures ($p > 0.05$). Patients at least eighty years of age had greater prevalences of multilevel stenosis (involving three or more levels), severe stenosis, and asymmetric motor weakness.

Operative details, complications, and other events in the two age groups are compared in Table II. Fifty-eight (55.2%) of the patients who were at least eighty years of age underwent surgery (which involved decompression alone in 68% of these, noninstrumented arthrodesis in 14%, and instrumented arthrodesis in 18%). In contrast, 749 (66.3%) of the patients who were less than eighty years of age underwent surgery (which involved decompression alone in 47% of the 742 with available clinical follow-up data, noninstrumented arthrodesis in 13%, and instrumented arthrodesis in 40%). Patients at least eighty years of age had a significantly greater proportion of multilevel lumbar laminectomies (those involving three or more levels) compared with younger patients (60% compared with 32%, $p < 0.001$). The two age groups did not differ with respect to the rates of intraoperative and postoperative complications, reoperations, and postoperative mortality ($p > 0.05$).

Primary and secondary outcome measures averaged over a four-year follow-up period are presented in Table III according to age group and treatment. For patients at least eighty years of age, improvement in all primary outcome measures from baseline was significantly greater in the operatively treated group. Specifically, the difference in improvement between operative and nonoperative treatment in the octogenarian age group was significant in favor of operative treatment for the SF-36 bodily pain score (7.5; 95% confidence interval [CI], 2.3 to 12.8), the SF-36 physical function score (9.6; 95% CI, 4.2 to 15.0), and the ODI (−13.3; 95% CI, −17.6 to −9.0) ($p < 0.05$). The treatment effect in this age group compared with patients less than eighty years of age was significantly smaller for the SF-36 bodily pain score (7.5 [95% CI, 2.3 to 12.8] compared with 14.6 [95% CI, 13.1 to 16.2] in the younger patients, $p < 0.01$]), and it was statistically similar for the SF-36 physical function score (9.6 [95% CI, 4.2 to 15.0] compared with 13.3 [95% CI, 11.7 to 14.8], $p = 0.2$) and the ODI (−13.3 [95% CI, −17.6 to −9.0] compared with −12.4 [95% CI, −13.6 to −11.2], $p = 0.69$).

Secondary outcome measures averaged over a four-year follow-up period are also presented in Table III. For patients at least eighty years of age, improvement in all secondary outcome measures from baseline was significantly greater in the operatively treated group. Specifically, the treatment effect in this age group was significant in favor of operative treatment for the Stenosis Bothersomeness Index (−2.8; 95% CI, −4.4 to −1.2), the Low Back Pain Bothersomeness Scale (−0.8; 95% CI, −1.2 to −0.3), the percentage of patients satisfied with symptoms (25.3%; 95% CI, 13.6% to 37%), and the percentage that self-rated progress as a major improvement (23.5%; 95% CI, 11.6% to 35.4%) ($p < 0.05$). The treatment effect in this age group compared with patients less than eighty years of age was significantly smaller for the percentage that self-rated progress as a major improvement (23.5% [95% CI, 11.6% to 35.4%] compared with 41.5% [95% CI, 38.3% to 44.7%] in the younger patients, $p = 0.004$) and statistically similar for the remaining secondary measures.

Discussion

As the elderly population grows and health-care resources are limited, it is increasingly important to identify interventions that are effective at improving the quality of life of elderly patients with spinal disorders. Lumbar stenosis and degenerative spondylolisthesis are common and debilitating conditions in this patient population. Although operative treatment of these conditions has been shown to be effective for patients in general, few studies have addressed the effectiveness of operative treatment in patients who are eighty years of age or older[15,16]. The SPORT data, with follow-up to four years, allows the assessment of the effects of nonoperative and operative management in this patient population. The present study specifically examined the octogenarian population with lumbar stenosis, some of whom also had degenerative spondylolisthesis. The results revealed that the operative treatment of lumbar stenosis with or without degenerative spondylolisthesis offers patients who are eighty years of age or older a substantial benefit over nonoperative treatment. After surgery, octogenarian patients had significant improvements in all recorded patient-reported health measures from baseline. Compared with patients less than eighty years of age, these patients had similar rates of intraoperative and postoperative complications and mortality. However, operative treatment may be more effective in patients less than eighty years of age, as indicated by the significantly greater treatment effect for the SF-36 bodily pain score in the younger patient group.

Some previous studies have assessed the affect of age on the outcome of lumbar spine decompression for stenosis. Jakola et al.[15] reported baseline, three-month, and twelve-month outcomes in a cohort of 101 patients at least seventy years of age who underwent lumbar decompression surgery for stenosis. There was no comparison group. Those authors reported significant improvements in the EQ-5D (EuroQol-5D) and ODI from baseline measurements at three and twelve months postoperatively. They reported an 18% overall complication rate and a 6% major complication rate, and they found that increased age did not predict a worse outcome following laminectomy. Nanjo et al.[16] recently performed a retrospective study comparing the outcomes of lumbar decompression surgery in patients at least eighty years of age and in younger patients. Of 702 consecutive patients treated with this surgery, only 241 (forty-six at least eighty years old and 195 younger) were included in the analysis and had adequate follow-up data at baseline and at least six months after surgery. The mean duration of follow-up was 14.4 months. The authors reported no significant difference in the JOA (Japanese Orthopaedic Association) scores preoperatively, at six months postoperatively, and at the time of the final follow-up[16]. Similar to our findings, there was no significant difference in complication rates between the two groups.

Although not directly relevant to the present study because they address revision surgery, Adogwa et al.[17,18] reported the results of revision decompression and arthrodesis surgery in patients with lumbar pseudarthrosis (n = 17), adjacent-level disease (n = 28), and same-level recurrent stenosis (n = 24) who were at least sixty-five years of age. The authors found that patients who underwent such surgery for those disorders had significant improvement from baseline in the ODI score and the VAS (visual analog scale) score for back pain at two years of follow-up.

As with any study of clinical outcomes, there is the potential for both type-1 and type-2 error. When multiple comparisons are made, there is a risk of identifying a difference between groups that is the result of random chance rather than a true difference (a type-1 error). The analysis in the present study consisted of longitudinal assessments over time of various dimensions of the patient outcome (e.g., symptoms, function, and disability). Those were not multiple independent comparisons from which we were seeking a single significant result, and it is for this reason that we did not use a Bonferroni or similar correction for multiple comparisons. The various time points were not independently assessed but rather compared within the overall context of a longitudinal regression

model across three complementary domains of the patient outcome. If there are conflicting findings regarding these domains of outcome, then one should be hesitant to accept the findings regardless of the p value or the level of significance, whereas consistent findings across the complementary dimensions of outcome should improve one's confidence that the findings are not due to chance. In the present study, the differences in outcome between operative and nonoperative treatment in patients at least eighty years of age were consistent in direction and significant across measures of symptoms, function, and disability.

There were confounding baseline variables that differed between patients at least eighty years of age and younger patients; these included underlying medical comorbidities, the severity and number of levels of stenosis, BMI, and smoking history. Furthermore, there were significant differences in the nature of surgery in the older and younger patient groups. Approximately 50% of patients in each age group had degenerative spondylolisthesis, but only 32% of patients at least eighty years of age (eighteen of fifty-eight) compared with 53% of younger patients (387 of 742) underwent arthrodesis. Although no significant differences in complications between age groups were seen in the study, the complication rate in the octogenarian age group would potentially have been higher if a similar proportion had undergone arthrodesis. Finally, the initial SPORT study was designed to compare operative with nonoperative treatment of lumbar stenosis and degenerative spondylolisthesis, and it was not powered to detect differences in outcomes according to patient age. The number of patients at least eighty years of age who underwent arthrodesis was relatively low, and it is possible that the study was underpowered to detect an actual difference in complication rates between age groups (a type-2 error). The differences in patient and surgical factors as well as the number of study patients must be considered when interpreting the results comparing patients at least eighty years of age with younger patients. Those differences in patient and surgical factors should not, however, affect the validity of the within-group comparison of preoperative and postoperative measures in the octogenarian patients.

The within-group comparison of preoperative and postoperative data in patients at least eighty years of age demonstrated significant improvements in patient-reported pain and function from baseline to four years of follow-up, with surgery offering significant benefit over nonoperative care in this patient population. The substantial treatment effect that surgery has been shown to have in prior SPORT studies of patients with stenosis and degenerative spondylolisthesis appears to have been maintained even among this octogenarian population[4-7]. Although the cost-effectiveness of surgery for stenosis and degenerative spondylolisthesis has been established for the general patient population[19,20], further studies specifically analyzing cost data and improvement in quality of life will be needed to determine whether such procedures are also truly cost-effective in this elderly and retired population. ■

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References

1. Administration on Aging, Department of Health & Human Services. U.S. population by age: July 1, 2010. 2010. http://www.aoa.gov/Aging_Statistics/Census_Population/census2010/Index.aspx. Accessed 2013 Aug 21.

2. Kalichman L, Cole R, Kim DH, Li L, Suri P, Guermazi A, Hunter DJ. Spinal stenosis prevalence and association with symptoms: the Framingham Study. Spine J. 2009 Jul;9(7):545-50. Epub 2009 Apr 23.

3. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. JAMA. 2010 Apr 7;303(13):1259-65.

4. Weinstein JN, Lurie JD, Tosteson TD, Zhao W, Blood EA, Tosteson AN, Birkmeyer N, Herkowitz H, Longley M, Lenke L, Emery S, Hu SS. Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis. Four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. J Bone Joint Surg Am. 2009 Jun;91(6):1295-304.

5. Weinstein JN, Tosteson TD, Lurie JD, Tosteson A, Blood E, Herkowitz H, Cammisa F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H. Surgical versus nonoperative treatment for lumbar spinal stenosis four-year results of the Spine Patient Outcomes Research Trial. Spine (Phila Pa 1976). 2010 Jun 15;35(14):1329-38.

6. Weinstein JN, Lurie JD, Tosteson TD, Hanscom B, Tosteson AN, Blood EA, Birkmeyer NJ, Hilibrand AS, Herkowitz H, Cammisa FP, Albert TJ, Emery SE, Lenke LG, Abdu WA, Longley M, Errico TJ, Hu SS. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. N Engl J Med. 2007 May 31;356(22):2257-70.

7. Weinstein JN, Tosteson TD, Lurie JD, Tosteson AN, Blood E, Hanscom B, Herkowitz H, Cammisa F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H; SPORT Investigators. Surgical versus nonsurgical therapy for lumbar spinal stenosis. N Engl J Med. 2008 Feb 21;358(8):794-810.

8. Lurie JD, Faucett SC, Hanscom B, Tosteson TD, Ball PA, Abdu WA, Frymoyer JW, Weinstein JN. Lumbar discectomy outcomes vary by herniation level in the Spine Patient Outcomes Research Trial. J Bone Joint Surg Am. 2008 Sep;90(9):1811-9.

9. Radcliff KE, Rihn J, Hilibrand A, Dilorio T, Tosteson T, Lurie JD, Zhao W, Vaccaro AR, Albert TJ, Weinstein JN. Does the duration of symptoms in patients with spinal stenosis and degenerative spondylolisthesis affect outcomes?: analysis of the Spine Outcomes Research Trial. Spine (Phila Pa 1976). 2011 Dec 1;36(25):2197-210.

10. McHorney CA, Ware JE Jr, Lu JF, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. Med Care. 1994 Jan;32(1):40-66.

11. Daltroy LH, Cats-Baril WL, Katz JN, Fossel AH, Liang MH. The North American Spine Society Lumbar Spine Outcome Assessment Instrument: reliability and validity tests. Spine (Phila Pa 1976). 1996 Mar 15;21(6):741-9.

12. Atlas SJ, Singer DE, Keller RB, Patrick DL, Deyo RA. Application of outcomes research in occupational low back pain: the Maine Lumbar Spine Study. Am J Ind Med. 1996 Jun;29(6):584-9.

13. Deyo RA, Diehl AK. Patient satisfaction with medical care for low-back pain. Spine (Phila Pa 1976). 1986 Jan-Feb;11(1):28-30.

14. Rihn JA, Hilibrand AS, Radcliff K, Kurd M, Lurie J, Blood E, Albert TJ, Weinstein JN. Duration of symptoms resulting from lumbar disc herniation: effect on treatment outcomes: analysis of the Spine Patient Outcomes Research Trial (SPORT). J Bone Joint Surg Am. 2011 Oct 19;93(20):1906-14.

15. Jakola AS, Sørlie A, Gulati S, Nygaard OP, Lydersen S, Solberg T. Clinical outcomes and safety assessment in elderly patients undergoing decompressive laminectomy for lumbar spinal stenosis: a prospective study. BMC Surg. 2010;10:34. Epub 2010 Nov 22.

16. Nanjo Y, Nagashima H, Dokai T, Hamamoto Y, Hashiguchi H, Ishii H, Kameyama Y, Morio Y, Murata M, Tanida A, Tanishima S, Teshima R. Clinical features and surgical outcomes of lumbar spinal stenosis in patients aged 80 years or older: a multi-center retrospective study. Arch Orthop Trauma Surg. 2013 Sep;133(9):1243-8. Epub 2013 Jul 14.

17. Adogwa O, Owens R, Karikari I, Agarwal V, Gottfried ON, Bagley CA, Isaacs RE, Cheng JS. Revision lumbar surgery in elderly patients with symptomatic pseudarthrosis, adjacent-segment disease, or same-level recurrent stenosis. Part 2. A cost-effectiveness analysis: clinical article. J Neurosurg Spine. 2013 Feb;18(2):147-53. Epub 2012 Dec 11.

18. Adogwa O, Carr RK, Kudyba K, Karikari I, Bagley CA, Gokaslan ZL, Theodore N, Cheng JS. Revision lumbar surgery in elderly patients with symptomatic pseudarthrosis, adjacent-segment disease, or same-level recurrent stenosis. Part 1. Two-year outcomes and clinical efficacy: clinical article. J Neurosurg Spine. 2013 Feb; 18(2):139-46. Epub 2012 Dec 11.

19. Tosteson AN, Skinner JS, Tosteson TD, Lurie JD, Andersson GB, Berven S, Grove MR, Hanscom B, Blood EA, Weinstein JN. The cost effectiveness of surgical versus nonoperative treatment for lumbar disc herniation over two years: evidence from the Spine Patient Outcomes Research Trial (SPORT). Spine (Phila Pa 1976). 2008 Sep 1;33(19):2108-15.

20. Tosteson AN, Tosteson TD, Lurie JD, Abdu W, Herkowitz H, Andersson G, Albert T, Bridwell K, Zhao W, Grove MR, Weinstein MC, Weinstein JN. Comparative effectiveness evidence from the spine patient outcomes research trial: surgical versus nonoperative care for spinal stenosis, degenerative spondylolisthesis, and intervertebral disc herniation. Spine (Phila Pa 1976). 2011 Nov 15;36(24): 2061-8.