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Surgical Treatment of Spinal Stenosis with and without Degenerative Spondylolisthesis: Cost-Effectiveness after 2 Years

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Background: The SPORT (Spine Patient Outcomes Research Trial) reported favorable surgery outcomes over 2 years among patients with stenosis with and without degenerative spondylolisthesis, but the economic value of these surgeries is uncertain.

Objective: To assess the short-term cost-effectiveness of spine surgery relative to nonoperative care for stenosis alone and for stenosis with spondylolisthesis.

Design: Prospective cohort study.

Data Sources: Resource utilization, productivity, and EuroQol EQ-5D score measured at 6 weeks and at 3, 6, 12, and 24 months after treatment among SPORT participants.

Target Population: Patients with image-confirmed spinal stenosis, with and without degenerative spondylolisthesis.

Time Horizon: 2 years.

Perspective: Societal.

Intervention: Nonoperative care or surgery (primarily decompressive laminectomy for stenosis and decompressive laminectomy with fusion for stenosis associated with degenerative spondylolisthesis).

Outcome Measures: Cost per quality-adjusted life-year (QALY) gained.

Results of Base-Case Analysis: Among 634 patients with stenosis, 394 (62%) had surgery, most often decompressive laminectomy (320 of 394 [81%]). Stenosis surgeries improved health to a greater extent than nonoperative care (QALY gain, 0.17 [95% CI, 0.12 to 0.22]) at a cost of $77 600 (CI, $49 600 to $120 000) per QALY gained. Among 601 patients with degenerative spondylolisthesis, 368 (61%) had surgery, most including fusion (344 of 368 [93%]) and most with instrumentation (269 of 344 [78%]). Degenerative spondylolisthesis surgeries significantly improved health versus nonoperative care (QALY gain, 0.23 [CI, 0.19 to 0.27]), at a cost of $115 600 (CI, $90 800 to $144 900) per QALY gained.

Result of Sensitivity Analysis: Surgery cost markedly affected the value of surgery.

Limitation: The study used self-reported utilization data, 2-year time horizon, and as-treated analysis to address treatment nonadherence among randomly assigned participants.

Conclusion: The economic value of spinal stenosis surgery at 2 years compares favorably with many health interventions. Degenerative spondylolisthesis surgery is not highly cost-effective over 2 years but could show value over a longer time horizon.

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*For a list of the SPORT (Spine Patient Outcomes Research Trial) investigators, see the **Appendix** (available at www.annals.org).

Marked growth in lumbar spine surgery rates over the past 15 years is well documented (1, 2). Although Medicare spent more than $1 billion on spine surgery in 2003, the economic value of these surgeries remains poorly understood. In particular, the value of instrumented lumbar fusion surgery, which increased rapidly in the mid-1990s (3), remains controversial.

Kuntz and colleagues (4) combined published evidence in a model-based analysis of 10-year cost and health outcomes for persons with stenosis, with and without degenerative spondylolisthesis. The analysis showed reasonable value for noninstrumented fusion relative to laminectomy alone, but unfavorable value (costs per quality-adjusted life-year [QALY] gained in excess of $1 million) for instrumented fusion (4). However, the analysis was not based on longitudinal resource utilization or health outcome data appropriate for estimating costs or QALYs and did not consider the value of operative care relative to nonoperative treatment. Other economic analyses have addressed the value of spinal fusion for various populations but have not measured health gains using a QALY scale (5).

The SPORT (Spine Patient Outcomes Research Trial) includes randomized and observational cohorts with confirmed diagnoses of spinal stenosis, with and without degenerative spondylolisthesis (6–8). Primary functional health status outcomes for these participants showed differences in favor of surgery when examined over the first 2 years (7, 8). We report corresponding cost-effectiveness data for each diagnosis—stenosis alone or stenosis with

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Context

A recent large study that examined patient outcomes 2 years after spine surgery for spinal stenosis or degenerative spondylolisthesis suggested that patients who had surgery had better outcomes than patients who did not. However, whether the magnitude of the benefit observed is worth the high cost of surgery remains unclear.

Contribution

This analysis used 2-year follow-up data from the study to estimate the cost-effectiveness of surgery and found that surgery for spinal stenosis costs about $77 000 per quality-adjusted life-year gained and surgery for degenerative spondylolisthesis costs about $115 000 per quality-adjusted life-year gained.

Caution

The data were available for only 2 years; the cost-effectiveness could be better or worse when examined over a longer period.

—The Editors

spondylolisthesis—to compare the value of surgery for diagnoses that have often been combined.

METHODS

More than 70 physicians enrolled study participants from 13 participating U.S. multidisciplinary spine practices in 11 states between March 2000 and March 2005. Participants were enrolled in either a randomized cohort (treatment randomized) or an observational cohort (treatment chosen). Eligible participants were age 18 years or older with symptoms for at least 12 weeks (neurogenic claudication or radicular leg pain with associated neurologic signs) and image-confirmed diagnosis of spinal stenosis on cross-sectional imaging, either alone or associated with degenerative spondylolisthesis. All were judged to be surgical candidates. We excluded patients with stenosis who also had lumbar instability, defined as more than 4 mm or 10 degrees of angular motion between flexion and extension on upright lateral radiographs. For stenosis alone, the protocol surgical intervention was a standard posterior laminectomy. For degenerative spondylolisthesis, the protocol surgery was the same procedure with or without bilateral single-level fusion (iliac crest bone grafting with or without instrumentation). We considered nonoperative treatments, determined by patients' and physicians' choice, to be usual care. A human subjects committee at each institution approved the protocol. An independent data safety and monitoring board oversaw the study. Further details on the design and conduct of SPORT are provided elsewhere (6–10).

Treatment Effectiveness

To measure health outcomes, we used QALYs to account for both quality and length of life (11). We estimated QALYs by using mean health state values at baseline; 6 weeks; and 3, 6, 12, and 24 months with EuroQol EQ-5D (U.S. scoring) (12, 13).

Treatment Cost

Health care diaries helped participants track resource use and work or activities. Total costs included direct medical costs (based on patient-reported utilization and limited to spine-related problems except for physician visits and hospitalizations) and indirect costs (based on patient-reported time away from work or usual activities because of spine-related problems). Information was collected from patients via questionnaires at 6 weeks and 3, 6, 12, and 24 months by using either a 6-week (at 6 weeks and 3 months) or 1-month recall period. Care involving hospitalization, surgery, and devices was not confined to a recall window.

Direct Medical Costs

These costs included any emergency department or outpatient visit (to surgeons, chiropractors, other physicians, physical therapists, acupuncturists, or other health care providers); spine-related diagnostic tests (radiography, computed tomography, magnetic resonance imaging, or electromyography); injections; devices, such as braces, canes, or walkers; medications; and rehabilitation or nursing home days.

To estimate direct medical costs, we assigned unit costs to each visit, test, and procedure on the basis of 2004 Medicare national allowable payment amounts (14) (**Appendix Table**, available at www.annals.org). We based medication costs on 2004 average wholesale prices (15). For each participant, we multiplied medical resource use by unit costs to obtain an estimate of total direct medical cost at each time point. All costs are reported in 2004 U.S. dollars.

Surgery costs depended on the procedure performed and occurrence of complications, which in turn determined the diagnosis-related group. We used the observed 2004 Medicare mean total diagnosis-related group payment to reflect hospital-related surgery costs. We based surgeon costs on 2004 Medicare allowable amounts according to the resource-based relative value scale (16). We estimated anesthesiology costs by using operative time. For hospitalizations not associated with a spine surgery, we based costs on the diagnosis-related group by using mean observed 2004 Medicare payments.

Indirect Costs

At each follow-up, we assessed the effect of spine-related problems on productivity. We asked participants to report missed work days if they were employed outside of the home and missed homemaking days if they designated housekeeping as their primary work activity. We also obtained data on use of unpaid caregivers for spine-related problems, including spousal caregiving. We estimated costs by using the standard human capital approach (17) of multiplying the change in hours worked by the gross of tax wage rate, on the basis of self-reported wages at study entry. We valued costs for missed days of housekeeping and unpaid caregivers on the basis of average wages plus non-health benefits for persons age 35 years or older (18–20).

Statistical Analysis

We pooled data from the SPORT randomized and observational cohorts for this analysis. We analyzed data separately by disease group according to treatment received by using longitudinal regression models fitted with generalized estimating equations (21, 22). We fit separate models for EuroQol EQ-5D and for 30-day costs as measured at 6 weeks and 3, 6, 12, and 24 months after surgery or the beginning of nonoperative therapy. If a visit was missing, all other available visits for that patient were included in the analysis.

The treatment indicator (surgery vs. nonoperative care) was a time-dependent covariate, which allowed for variable surgery times. We assigned outcomes to the surgical group after surgery, with follow-up times measured from the date of surgery. To adjust for potential confounding in each model and the possible effects of missing data, we included baseline variables associated with missing data or treatment received as covariates. All models included a fixed effect for center. To account for correlations among repeated measurements for individuals, including observations before and after surgery, we fit the longitudinal regression models by using the PROC GENMOD function in SAS, version 9.1 (SAS Institute, Cary, North Carolina), specifying a compound symmetry assumption for the working covariance matrix.

Cost-Effectiveness Analysis

The primary cost-effectiveness end point was the cost per QALY gained for surgery relative to nonoperative treatment. We estimated mean total costs and QALYs from baseline to 2 years for each diagnosis and treatment group by using a 3% annualized discount rate for both end points. We used a time-weighted average to estimate the difference in QALYs between the surgical and nonoperative treatments on the basis of adjusted mean differences in EuroQol EQ-5D that we estimated from longitudinal regression models at each follow-up. For costs, we based mean differences on adjusted mean costs summed across time points for each treatment group. Estimates of cost and QALY differences assumed no deaths over 2 years.

To address the economic value of surgery type, we performed incremental analyses to rank interventions by mean costs and compute mean change in cost divided by mean difference in QALYs. To estimate a confidence interval for the cost per QALY gained, we applied a bootstrap method that used 1000 samples taken with replacement from the original sample with the individual as the unit of observation. For each sample, we estimated both costs and QALYs simultaneously. Bootstrapped confidence intervals have nominal coverage probabilities that are robust to deviations from the data covariance structure as long as missing-completely-at-random assumptions are met after adjustment for predictors of missingness.

Sensitivity analyses of analytic assumptions included restricting analyses to the randomized or observational cohort, limiting cost type, increasing surgery costs to 70% of the amount billed to Medicare, using the Short Form-6D (SF-6D) to estimate effectiveness, and accounting for observed mortality. For the most influential factors we plotted cost-effectiveness acceptability curves. These characterize the cumulative distribution function for the bootstrapped cost-effectiveness ratios as the willingness-to-pay per QALY gained is varied.

Role of the Funding Source

The National Institute of Arthritis and Musculoskeletal and Skin Diseases; Office of Research on Women's Health, National Institutes of Health; and the National Institute of Occupational Safety and Health, Centers for Disease Control and Prevention provided funding for the study. The study funding sources had no role in study design or conduct; data collection, management, analysis, or interpretation; or manuscript development or approval.

Results

Our cost-effectiveness analysis included 634 participants with stenosis and 601 participants with degenerative spondylolisthesis with associated stenosis. On the basis of follow-up through 14 May 2007, 394 (62%) participants with stenosis and 368 (61%) participants with degenerative spondylolisthesis had surgery. Disease groups were remarkably similar across most characteristics at baseline, except that the degenerative spondylolisthesis group had more women (69% vs. 39%; $P < 0.001$) and was slightly older (average age, 66.1 vs. 64.6 years; $P = 0.021$). At baseline, patients in each disease group who went on to have surgery had significantly worse self-rated health trends, health status, and stenosis bothersomeness index scores than patients who received nonoperative treatment but were similar for most other characteristics (**Table 1**).

For both disease and treatment groups, mean health state values improved over time (**Figure 1**). Mean discounted QALYs ranged from 1.33 to 1.55 over 2 years of follow-up (**Table 2**).

Total adjusted mean nonoperative care costs were similar across diagnoses (**Table 2**). Health care visits, reported by 97% of participants, did not differ by treatment or disease group. Approximately half of all participants reported physical therapy; chiropractor visits were infrequent (10% in each group), and 6% reported use of acupuncture. Diagnostic tests were reported more frequently among those treated surgically (among patients with stenosis, 71% for surgery recipients vs. 57% for nonoperative management recipients [$P < 0.001$]; among patients with degen-

Table 1. **Baseline Participant Characteristics**

Characteristic	Patients with Spinal Stenosis			Patients with Degenerative Spondylolisthesis with Spinal Stenosis		
	Surgery (*n* = 394)	Nonoperative Management (*n* = 240)	*P* Value	Surgery (*n* = 368)	Nonoperative Management (*n* = 233)	*P* Value
Mean age (SD), *y*	63.6 (12.2)	66.3 (10.5)	0.004	64.7 (10.1)	68.2 (10.3)	<0.001
Women, *n (%)*	152 (39)	97 (40)	0.71	255 (69)	157 (67)	0.69
Non-Hispanic ethnicity, *n (%)*	378 (96)	227 (95)	0.55	359 (98)	228 (98)	0.97
Nonwhite, *n (%)*	332 (84)	201 (84)	0.95	316 (86)	190 (82)	0.19
Mean body mass index (SD), *kg/m²*	29.3 (5.3)	29.9 (6.1)	0.25	29.4 (6.5)	28.8 (5.7)	0.22
Current smoker, *n (%)*	36 (9)	26 (11)	0.58	34 (9)	17 (7)	0.49
At least some college education, *n (%)*	245 (62)	156 (65)	0.53	247 (67)	153 (66)	0.78
Annual income <$50 000, *n (%)*	82 (21)	40 (17)	0.24	82 (22)	55 (24)	0.78
Married, *n (%)*	288 (73)	158 (66)	0.06	249 (68)	147 (63)	0.29
Work status, *n (%)*			0.19			0.93
Full- or part-time	131 (33)	67 (28)		118 (32)	74 (32)	
Disabled	40 (10)	20 (8)		33 (9)	18 (8)	
Homemaker	76 (19)	43 (18)		103 (28)	64 (27)	
Other	147 (37)	110 (46)		114 (31)	77 (33)	
Disability compensation status, *n (%)**	30 (8)	18 (8)	0.92	34 (9)	7 (3)	0.005
Comorbid condition, *n (%)*						
Osteoporosis	30 (8)	30 (12)	0.06	40 (11)	29 (12)	0.65
Heart problem	95 (24)	70 (29)	0.19	65 (18)	57 (24)	0.06
Stomach problem	82 (21)	57 (24)	0.44	79 (21)	54 (23)	0.70
Depression	41 (10)	29 (12)	0.60	63 (17)	35 (15)	0.57
Joint problem	210 (53)	136 (57)	0.46	202 (55)	142 (61)	0.17
Definite surgical treatment preference, *n (%)*	188 (48)	8 (3)	<0.001	162 (44)	5 (2)	<0.001
Perceive problem is getting worse, *n (%)*	265 (67)	113 (47)	<0.001	258 (70)	103 (44)	<0.001
Stenosis location, *n (%)*						
Central	338 (86)	205 (85)	0.99	341 (93)	208 (89)	0.20
Lateral recess	321 (81)	182 (76)	0.11	338 (92)	208 (89)	0.36
Neuroforamen	119 (30)	88 (37)	0.11	152 (41)	91 (39)	0.64
Straight leg raise or femoral tension, *n (%)*	85 (22)	47 (20)	0.62	48 (13)	37 (16)	0.39
Any neurologic deficit, *n (%)*	210 (53)	139 (58)	0.29	203 (55)	124 (53)	0.70
Reflexes—asymmetrically depressed	102 (26)	66 (28)	0.72	98 (27)	52 (22)	0.27
Sensory—asymmetrical decrease	116 (29)	66 (28)	0.66	108 (29)	61 (26)	0.45
Motor—asymmetrical weakness	104 (26)	73 (30)	0.32	87 (24)	59 (25)	0.71
EuroQol EQ-5D U.S. health state value	0.58 (0.2)	0.66 (0.2)	<0.001	0.58 (0.2)	0.65 (0.2)	<0.001
Short Form-6D health state value	0.58 (0.1)	0.62 (0.1)	<0.001	0.58 (0.1)	0.63 (0.1)	<0.001
Short Form-36 subscale scores†						
Bodily pain	28.6 (16.2)	36.6 (18.4)	<0.001	29.2 (16.8)	34.4 (16.7)	<0.001
Physical function	31.7 (21.9)	39.9 (24.5)	<0.001	30.5 (20.5)	40.3 (23.9)	<0.001
Vitality	41.4 (21.8)	44.4 (21.5)	0.09	40.7 (22.4)	47.8 (21.2)	<0.001
Mental health	68.2 (20.3)	71.9 (19.4)	0.02	69.3 (18.8)	71.7 (18.9)	0.13
Social function	52.5 (26.9)	63.5 (27.7)	<0.001	55.3 (27.2)	63.9 (28.3)	<0.001
Role physical	17.1 (30.6)	22 (34.2)	0.06	14.2 (26.8)	24.6 (34.7)	<0.001
Role emotional	55.8 (45.8)	63.7 (43.2)	0.03	57.2 (43.8)	64.4 (41.8)	0.05
General health	66.9 (18.7)	64.7 (20.4)	0.15	68.2 (19.4)	66.8 (19.8)	0.39
Mean Oswestry Disability Index score (SD)‡	46 (17.9)	36.4 (17.9)	<0.001	45 (16.6)	36.2 (18.5)	<0.001
Mean Stenosis Bothersome Index score (SD)§	15.6 (5.4)	12.3 (5.7)	<0.001	15.6 (5.5)	13.3 (5.4)	<0.001

* Receiving workers' compensation, Social Security compensation, or other compensation, or application for compensation pending.
† Higher scores indicate less severe symptoms.
‡ Lower scores indicate less severe symptoms.
§ Score range, 0–24.

erative spondylolisthesis, 79% for surgery recipients vs. 56% for nonoperative management recipients [$P < 0.001$]). For both disease groups, injection use (such as epidural or trigger point) was higher among patients treated nonoperatively (among patients with stenosis, 45% for nonoperative management recipients vs. 30% for surgery recipients [$P < 0.001$]; among patients with degenerative spondylolisthesis, 46% for nonoperative management recipients vs. 29% for surgery recipients [$P < 0.001$]). Patterns of medication use showed greater use of nonsteroidal anti-inflammatory medication and cyclooxygenase-2 inhibitors in patients with degenerative spondylolisthesis who received nonoperative management (80%) than in other groups. Narcotic use was higher among those receiving surgery in both groups (among patients with stenosis, 71% of surgery recipients vs. 35% of nonoperative management recipients [$P < 0.001$]; among patients with degenerative spondylolisthesis, 74% of surgery recipients vs. 29% of nonoperative management recipients [$P < 0.001$]), whereas use of muscle relaxants was lowest among nonoperatively treated patients with stenosis (5%). Assistive device use was similar in both groups among patients with stenosis (54%). Among patients with degenerative spondylolisthesis, device use was significantly more common in those undergoing surgery (74% for surgery recipients vs. 46% for nonoperative management recipients; $P < 0.001$), with braces, canes, and walkers reported most commonly.

Total adjusted mean costs for surgical treatment were $26 222 (95% CI, $24 308 to $28 129) for patients with stenosis and $42 081 (CI, $39 800 to $44 373) for patients with degenerative spondylolisthesis (**Table 2**). Most stenosis surgeries (320 of 394 [81%]) were decompressive laminectomies, with mean surgery costs for uncomplicated cases of $7159 (CI, $7133 to $7185). A total of 35 repeated stenosis surgeries were performed on 27 (6.9%) patients, with a mean cost of $19 152 ($10 627 to $27 677) per patient. Fusion was uncommon among patients with stenosis, with only 43 occurrences. Most degenerative spondylolisthesis surgeries (344 of 368 [93%]) involved fusion with instrumentation, with mean costs for uncomplicated cases of $21 489 (CI, $21 318 to $21 660). A total of 48 repeated surgeries were performed on 37 (10.1%) patients, with a mean cost of $17 045 per patient (CI, $13 493 to $20 597).

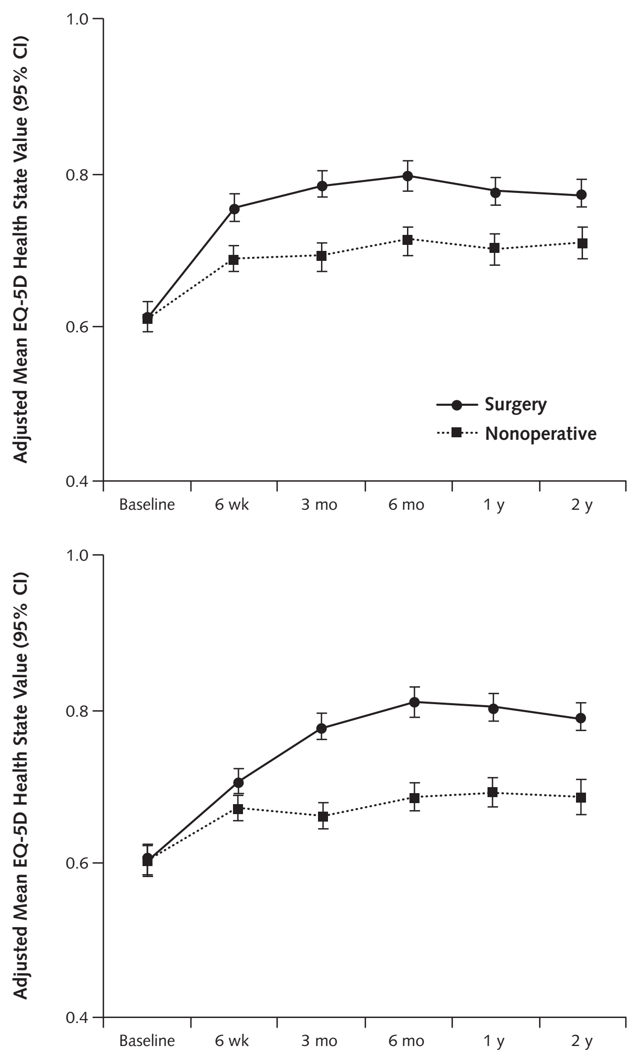
Work loss costs tended to be higher for surgically treated patients (**Table 2**), with a higher proportion of surgically treated patients reporting any missed work days (among patients with stenosis, 25% of surgery recipients vs. 17% of nonoperative management recipients [$P = 0.024$]; among patients with degenerative spondylolisthesis, 26% of surgery recipients vs. 10% of nonoperative management recipients [$P < 0.001$]). Although unpaid caregiver costs were minimal, missed homemaking costs were substantial for both treatment groups and diagnoses.

Incremental cost per QALY gained for surgical treatment relative to nonoperative care was $77 600 for stenosis and $115 600 for degenerative spondylolisthesis (**Table 3**). Study cohort, cost type, and mortality made little difference to the value of surgical intervention (**Table 4**). In contrast, changing surgery cost or estimating effectiveness with the SF-6D led to less favorable cost-effectiveness estimates (**Figure 2**).

Examining cost-effectiveness by surgery type, decompression without fusion had the most favorable value among patients with stenosis (**Table 3**). Although fusion surgery was significantly more costly than decompression alone (cost difference, $17 545 [CI, $11 074 to $24 090]), it resulted in no QALY gain over 2 years (QALY difference, −0.01 [CI, −0.14 to 0.11]). In the 48% of bootstrapped samples in which a QALY gain was observed for fusion relative to decompression alone, the mean cost-effectiveness ratio exceeded $4 million.

Fusion with instrumentation surgery in patients with degenerative spondylolisthesis was more costly than laminectomy alone (mean cost difference, $21 266 [CI, $7854 to $32 631), but health outcome did not significantly differ by surgery type (mean QALY difference, 0.01 [CI, −0.21 to 0.24]). In the 66% of samples in which fusion resulted in a QALY gain, it did so at a mean cost per QALY gained of $997 400 (CI, $48 300 to $4 672 000). Relative to nonoperative treatment, instrumented fusion had slightly more favorable economic value than noninstrumented fusion and circumferential fusion seems most efficient, but these differences were not statistically significant (**Table 3**). Comparing instrumented with noninstrumented fusion, costs (difference, $2258 [CI, −$3812 to $7826]) and QALYs (difference, 0.02 [CI, −0.07 to 0.09) did not significantly differ. In the 68% of bootstrapped samples in which instrumentation was associated with a QALY gain, the mean cost was $448 600 per QALY gained (CI, −$177 200 to $1 691 000).

Figure 1. **Adjusted mean EuroQol EQ-5D health state values and 95% CIs over time, by treatment received.**



Top. Spinal stenosis group. **Bottom.** Degenerative spondylolisthesis with spinal stenosis group.

Table 2. **Adjusted Mean Quality-Adjusted Life-Years (*QALYs*) and Costs (95% CIs) over 2 Years***

Outcome	Patients with Spinal Stenosis		Patients with Degenerative Spondylolisthesis with Spinal Stenosis	
	Surgery (*n* = 394)	Nonoperative Management (*n* = 240)	Surgery (*n* = 368)	Nonoperative Management (*n* = 233)
Cost-effectiveness				
QALYs†	1.54 (1.51 to 1.56)	1.37 (1.33 to 1.40)	1.55 (1.53 to 1.58)	1.33 (1.30 to 1.36)
Direct costs, $				
Surgery mean cost‡	10 635 (9798 to 11 472)	–	23 087 (22 415 to 23 759)	–
Health care visits§	2262 (1986 to 2538)	2176 (1886 to 2466)	2407 (2124 to 2690)	2169 (1884 to 2453)
Diagnostic tests‖	976 (678 to 1273)	1376 (1064 to 1688)	967 (724 to 1211)	975 (732 to 1218)
Medications‖	1972 (1711 to 2232)	2273 (1998 to 2548)	2070 (1796 to 2344)	2503 (2227 to 2779)
Other health care services¶	2188 (1458 to 2918)	1416 (650 to 2181)	3378 (2829 to 3926)	1057 (506 to 1608)
Total direct costs**	17 688 (16 465 to 18 912)	7161 (5871 to 8450)	31 938 (30 806 to 33 070)	6906 (5765 to 8048)
Indirect costs, $				
Work loss‖	2276 (1705 to 2847)	1585 (985 to 2185)	2208 (1698 to 2719)	993 (482 to 1504)
Unpaid caregivers‖	281 (111 to 452)	268 (90 to 447)	610 (431 to 788)	71 (−108 to 250)
Missed homemaking‖	4668 (3323 to 6012)	5681 (4268 to 7094)	7706 (6117 to 9295)	7794 (6198 to 9390)
Total indirect costs**	7056 (5604 to 8509)	7401 (5874 to 8928)	10 472 (8803 to 12 140)	8942 (7267 to 10 617)
Total costs, $†**	26 222 (24 308 to 28 129)	13 519 (10 921 to 15 796)	42 081 (39 800 to 44 373)	16 046 (13 862 to 18 234)

* Baseline covariates used for spinal stenosis models were age, sex, comorbid stomach conditions, straight leg raise or femoral tension sign, smoking status, comorbid joint conditions, patient self-assessed health trend, annual income, compensation, body mass index, baseline EuroQol EQ-5D score, and center. Baseline covariates used for degenerative spondylolisthesis models were age, sex, work status, depression, osteoporosis, joint problems, current symptom duration, reflex deficit, number of moderate or severe stenotic levels, baseline EuroQol EQ-5D score, baseline stenosis bothersomeness, and center.
† Means and CIs are based on longitudinal models with bootstrap sampling.
‡ Includes surgeon costs, anesthesiology costs, and hospitalization costs, which were estimated for both the Medicare and general adult populations.
§ Includes all health care visits within the recall period.
‖ Limited to spine problem–related use or work/homemaking loss.
¶ Includes all emergency department visits or hospitalizations and spine-related use of medical devices, injections, paid caregivers, and rehabilitation.
** The sum of the components does not equal the total cost because the estimate is based on data aggregated at the level of the individual in adjusted, as-treated analyses.

DISCUSSION

We used longitudinally collected, patient-reported data on resource utilization, work loss, and health-related quality of life to estimate cost per QALY gained for surgical treatment relative to nonoperative care for patient populations with persistent back and leg symptoms due to stenosis alone or degenerative spondylolisthesis with stenosis. Given the eligibility criteria for these 2 disease groups, it is not surprising that surgical procedures differed between groups, with fusion being common only among those with degenerative spondylolisthesis. As a result, the economic value of surgery differed between diagnoses, something that previous research studies with pooled diagnoses could not highlight. Although surgery was more costly than nonoperative treatment, health outcomes over 2 years were significantly better among those treated surgically. Although the ratios we report for spine surgery ($77 600 for stenosis and $115 600 for degenerative spondylolisthesis) are high compared with those for well-accepted elective orthopedic procedures, such as total hip replacement for osteoarthritis (costs <$10 000 per QALY gained over a lifetime [23]), it is important to emphasize that our analysis, with its limited 2-year time horizon, did not address lifetime QALY gains. Nonetheless, the value of stenosis surgery was below the $100 000 per QALY limit sometimes used to deem interventions as "costly" (24). In contrast, surgery for stenosis secondary to degenerative spondylolisthesis, which involved fusion in most cases, exceeded $100 000 over the first 2 years. If the difference in health state values observed at 2 years between those treated surgically and those treated nonoperatively was maintained over the longer term, this would improve the value of surgery—unless higher ongoing costs also incurred.

Our findings regarding cost-effectiveness of surgery for stenosis at 2 years are consistent with the favorable value suggested by Katz and colleagues (25), who examined laminectomy and noninstrumented fusion among patients with degenerative spinal stenosis. An important distinction, however, is our access to primary patient-reported data and use of the validated EuroQol instrument to obtain the societal health state values we used to estimate QALYs (26). Consistent with a cost-effectiveness study of surgery for lumbar disc herniation (27), which estimated effectiveness with both EuroQol EQ-5D and SF-6D, we found that QALY gains were somewhat lower when estimated with SF-6D.

To compare our findings with those of other reports, we must consider the type of surgery within each cohort. However, caution must be used in interpreting cost-effectiveness by surgery type because relatively few patients with stenosis had fusion (43 of 394 [11%]), relatively few patients with degenerative spondylolisthesis had noninstru-

Table 3. **Adjusted Mean 2-Year Costs, Quality-Adjusted Life-Years *(QALYs)*, and Cost per QALY Gained Relative to Nonoperative Treatment***

Patient Group	Patients, *n*	Mean Cost (95% CI), $	QALY (95% CI)	Cost <$100 000 per QALY Gained, %†	Cost per QALY Gained (95% CI), $‡
Spinal stenosis					
Nonoperative	240	13 519 (10 921 to 15 796)	1.37 (1.33 to 1.40)	–	–
All surgery	394	26 222 (24 308 to 28 129)	1.54 (1.51 to 1.56)	89	77 600 (49 600 to 120 000)
Type of surgery					
Decompression	320	22 404 (21 132 to 23 709)	1.54 (1.51 to 1.57)	100	47 900 (28 200 to 73 600)
Fusion	43	39 949 (33 626 to 46 292)	1.53 (1.41 to 1.64)	17	258 200 (70 700 to 710 700)
Degenerative spondylolisthesis with spinal stenosis					
Nonoperative	233	16 046 (13 862 to 18 234)	1.33 (1.30 to 1.36)	–	–
All surgery	368	42 081 (39 800 to 44 373)	1.55 (1.53 to 1.58)	14	115 600 (90 800 to 144 900)
Type of surgery					
Decompression	19	22 012 (10 860 to 34 647)	1.53 (1.31 to 1.75)	92	38 900 (−39 000 to 174 409)
Fusion	344	42 979 (40 574 to 45 354)	1.55 (1.53 to 1.58)	8	120 200 (94 100 to 153 400)
Type of fusion surgery					
Noninstrumented fusion	75	40 858 (36 004 to 45 651)	1.54 (1.48 to 1.61)	27	119 900 (72 200 to 192 000)
Instrumented fusion	269	43 116 (40 343 to 46 018)	1.56 (1.53 to 1.59)	12	118 100 (91 200 to 153 100)
Type of instrumentation					
Posterolateral fusion (pedicle screws)	209	42 562 (39 263 to 45 893)	1.54 (1.50 to 1.58)	10	121 400 (92 000 to 159 700)
Circumferential (360°) fusion§	60	46 970 (39 511 to 55 414)	1.62 (1.54 to 1.70)	43	107 000 (65 100 to 166 700)

* Baseline covariates used for spinal stenosis models were age, sex, comorbid stomach conditions, straight leg raise or femoral tension sign, smoking status, comorbid joint conditions, patient self-assessed health trend, annual income, compensation, body mass index, baseline EuroQol EQ-5D score, and center. Baseline covariates used for degenerative spondylolisthesis models were age, sex, work status, depression, osteoporosis, joint problems, current symptom duration, reflex deficit, number of moderate or severe stenotic levels, baseline EuroQol EQ-5D score, baseline stenosis bothersomeness, and center.
† Percentage of bootstrapped samples in which estimated cost per QALY gained was less than $100 000.
‡ Versus nonoperative management.
§ Circumferential fusions included anterior, posterior, and transforaminal lumbar interbody fusions.

mented fusion (75 of 368 [20%]), and few patients with degenerative spondylolisthesis had decompression alone (19 of 368 [5%]). Kuntz and colleagues (4) used Markov modeling to project cost-effectiveness over a 10-year period for mixed groups of patients with stenosis with and without degenerative spondylolisthesis and reported costs per QALY gained of $56 500 for noninstrumented fusion relative to laminectomy alone ($74 700 in 2004 U.S. dollars). We report higher ratios for fusion relative to decompression alone (mean costs per QALY gained >$300 000 in each group), but because only 19 patients with degenerative spondylolisthesis in SPORT had laminectomy without fusion, it is difficult to draw definitive conclusions. In addition, we do not know all the clinical factors that led to the decision to perform decompression alone or how such factors may have affected outcomes.

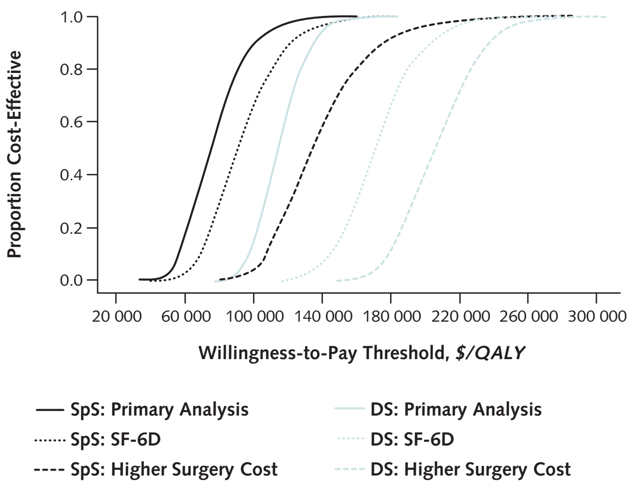
Although our analysis was not powered to detect differences by fusion type, we found some evidence that instrumented fusion may be more efficient than noninstrumented fusion and that circumferential (anterior–posterior) fusion may be most efficient. Although our findings differ from those of Kuntz and colleagues (4), who reported costs greater than $2 million per QALY gained for instrumented fusion relative to noninstrumented fusion, we found no statistically significant differences in either costs or QALYs by type of fusion surgery over 2 years. A previous clinical study of instrumented

Table 4. **Sensitivity Analysis Results**

Analytic Assumptions	Mean Cost per QALY Gained (95% CI), $: Spinal Stenosis	Mean Cost per QALY Gained (95% CI), $: Degenerative Spondylolisthesis with Spinal Stenosis
Primary analysis*	77 600 (49 564–120 042)	115 600 (90 839–144 863)
Observational cohort only	81 000 (42 344–143 525)	121 500 (81 873–179 537)
Randomized cohort only	82 800 (43 378–151 807)	107 800 (77 553–145 773)
Direct medical costs only	70 900 (49 964–104 601)	111 800 (90 761–138 806)
Direct medical and worker productivity costs only	81 700 (55 734–121 751)	118 100 (95 705–146 669)
Adjusted for observed mortality	76 910 (49 041–119 553)	114 600 (89 965–143 603)
QALY estimation with Short Form-6D	93 400 (59 205–143 660)	172 500 (132 178–221 930)
Higher surgery cost	139 000 (96 243–206 501)	206 600 (167 434–253 298)

QALY = quality-adjusted life-year.
* Combined randomized and observational cohorts, all costs, Medicare surgery costs, no mortality, and EuroQol EQ-5D score.

Figure 2. **Cost-effectiveness acceptability curves, by disease group and analytic assumption.**



The primary analysis used total costs based on Medicare payment amounts and the EuroQol EQ-5D to estimate QALYs. The SF-6D analyses estimated QALYs based on this form. Higher surgery costs were based on 70% of the amount billed to Medicare. DS = degenerative spondylolisthesis; QALY = quality-adjusted life-year; SF-6D = Short Form-6D; SpS = spinal stenosis.

versus noninstrumented fusion (28) also showed no outcome differences at 2 years. However, a recent case series reporting on the long-term outcomes of patients with degenerative spondylolisthesis who had noninstrumentated fusion (29) found inferior results in patients with pseudoarthrosis compared with patients with a solid fusion. This suggests that the higher rate of fusion obtained with instrumentation may lead to improved outcomes over a longer time. Nonetheless, in the absence of definitive findings regarding health gains, the economic value of such surgeries should not be viewed as favorable.

Our analysis has several limitations. First, because of the high degree of crossover in both the observational and randomized cohorts, we present a pooled analysis that utilized longitudinal modeling to evaluate costs and outcomes of participants as they were treated. Thus, although we carefully adjusted for baseline differences between treatment groups, our analysis does not fully benefit from the protection against bias offered by randomized designs. Of note, a recent systematic review of treatment effects in low back pain studies (30), which included some patients similar to those in SPORT, reported that clinical and social factors (such as pain duration, presence of spondylolisthesis, or involvement with worker's compensation) may affect estimated treatment effects more than study design (such as randomized vs. observational).

Second, we used patient-reported resource utilization and productivity losses to estimate total costs. Although more complete capture of resource use may have been possible through linkage with electronic billing records, such an approach may have resulted in biased cost ascertainment with near complete capture of some treatments (such as surgery) and less complete capture of other, less traditional treatments (such as acupuncture). In addition, the limited recall windows for most non–hospital-based care (6 weeks and 1 month) may have underestimated costs associated with ongoing nonoperative care.

Finally, we relied on Medicare payment schedules to estimate costs. Although these regulated payments may more accurately represent the resources necessary to produce a service than charges, they do not reflect actual costs and do not allow us to differentiate between costs of different types of instrumentation. The latter was the focus of a recent United Kingdom study (31), which showed that circumferential fusion with titanium cages is cost-ineffective compared with femoral ring allograft but did not consider uninstrumented fusion or nonoperative care. We characterized the substantial effect that higher costs associated with surgery would have on the value of surgical intervention in sensitivity analyses. However, the Medicare costing perspective has policy relevance because most persons studied were age 65 years or older.

Current trends in spine surgery in the United States, combined with continued escalation in health care expenditures, highlight the importance of understanding the economic value of common surgical interventions. Our comprehensive analysis suggests that surgical treatment of spinal stenosis with laminectomy provides reasonable value even over a limited 2-year time frame. By contrast, surgery for stenosis associated with degenerative spondylolisthesis is much more costly and will need to show continued health benefit without ongoing costs before it could be characterized as being cost-effective.

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Appendix Table. **Unit Costs for Specific Items, in 2004 U.S. Dollars**

Type of Cost	Unit Cost, $
Direct	
Any health care visit	
Surgeon	37.88
Physician	41.07
Chiropractor	21.11
Physical therapy	45.68
Acupuncture	65.05
Other	38.89
Any diagnostic tests	
Magnetic resonance imaging without contrast	566.54
Magnetic resonance imaging with contrast	622.93
Radiography	66.10
Computed tomography	292.78
Electromyography	103.64
Other health care services	
Injection	122.84
Emergency department visit	87.10
Rehabilitation or nursing home stay (per day)	255.27
Paid caregiver (per hour)	29.87
Medication costs (per day)	
NSAID/COX-2 inhibitor	4.26
Oral steroids	10.18
Narcotics	5.24
Muscle relaxants	5.08
Antidepressants	2.59
Other	5.10
Over-the-counter medications	0.73
Alternative medications	0.57
Indirect	
Work loss (per hour)	28.42
Unpaid caregiver (per hour)	16.29
Missed homemaking (per hour)	15.00

COX-2 = cyclooxygenase-2; NSAID = nonsteroidal anti-inflammatory drug.