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Received, February 4, 2010.
Accepted, June 10, 2010.
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 Congress of Neurological Surgeons

Comparative Effectiveness of Ventral vs Dorsal Surgery for Cervical Spondylotic Myelopathy

BACKGROUND: Cervical spondylotic myelopathy (CSM) is the most common cause of spinal cord dysfunction.

OBJECTIVE: To determine the feasibility of a randomized clinical trial comparing the clinical effectiveness and costs of ventral vs dorsal decompression with fusion surgery for treating CSM.

METHODS: A nonrandomized, prospective, clinical pilot trial was conducted. Patients ages 40 to 85 years with degenerative CSM were enrolled at 7 sites over 2 years (2007–2009). Outcome assessments were obtained preoperatively and at 3 months, 6 months, and 1 year postoperatively. A hospital-based economic analysis used costs derived from hospital charges and Medicare cost-to-charge ratios.

RESULTS: The pilot study enrolled 50 patients. Twenty-eight were treated with ventral fusion surgery and 22 with dorsal fusion surgery. The average age was 61.6 years. Baseline demographics and health-related quality of life (HR-QOL) scores were comparable between groups; however, dorsal surgery patients had significantly more severe myelopathy ($P < .01$). Comprehensive 1-year follow-up was obtained in 46 of 50 patients (92%). Greater HR-QOL improvement (Short-Form 36 Physical Component Summary) was observed after ventral surgery ($P = .05$). The complication rate (16.6% overall) was comparable between groups. Significant improvement in the modified Japanese Orthopedic Association scale score was observed in both groups ($P < .01$). Dorsal fusion surgery had significantly greater mean hospital costs (\$29 465 vs \$19 245; $P < .01$) and longer average length of hospital stay (4.0 vs 2.6 days; $P < .01$) compared with ventral fusion surgery.

CONCLUSION: Surgery for treating CSM was followed by significant improvement in disease-specific symptoms and in HR-QOL. Greater improvement in HR-QOL was observed after ventral surgery. Dorsal fusion surgery was associated with longer length of hospital stay and higher hospital costs. The pilot study demonstrated feasibility for a larger randomized clinical trial.

KEY WORDS: Cervical spondylotic myelopathy, Clinical trial, Cost-effectiveness analysis, Outcomes

Neurosurgery 68:622–631, 2011

DOI: 10.1227/NEU.0b013e31820777cf

www.neurosurgery-online.com

Cervical spondylotic myelopathy (CSM) is the most common cause of spinal cord dysfunction.¹ CSM results from degenerative cervical spondylosis, which is one of the most common indications for cervical spine

surgery in the United States (U.S.). More than 112,400 cervical spine operations for degenerative spondylosis are performed annually, representing a 100% increase in use over the past decade, with hospital charges now exceeding \$2 billion per year.² Surgical decompression of the spinal cord and fusion of the spinal column can permit recovery of spinal cord function and limit further injury in many cases. Nearly 20% of all cervical spine operations in the U.S. are performed to treat CSM.³ Recent reports suggest that CSM surgery has a high complication rate (10.3%–16.4%).^{4–6}

ABBREVIATIONS: CSM, cervical spondylotic myelopathy; EQ-5D, EuroQol-5D; HR-QOL, health-related quality of life; mJOA, modified Japanese Orthopedic Association; NDI, Oswestry Neck Disability Index; SF-36 PCS, Short-Form 36 Physical Component Summary

There is significant uncertainty as to the optimal surgical approach (ventral vs dorsal) for treating CSM, especially in older patients.⁷ Both operations are in widespread use in contemporary U.S. surgical practice. Recently, the Institute of Medicine identified CSM as one of the top 100 national health research priorities for comparative effectiveness research.⁸ Our previous work suggests that both orthopedic and neurological cervical spine experts believe that there is sufficient equipoise to justify a comparative trial if the study population is carefully defined.⁹

We report a nonrandomized, prospective, clinical trial comparing ventral and dorsal surgery in a study population defined to reflect equal eligibility for both approaches according to our previous work. This report includes 1-year health-related outcomes of ventral and dorsal surgery for treating CSM and presents a hospital-based economic analysis of a subset of the cohort. Unlike previous comparisons of dorsal and ventral surgery for this condition,^{10,11} clinical equipoise in both the orthopedic and neurosurgical spine communities was a priority in defining the study population. This study was designed as a pilot to demonstrate the feasibility of a prospective, randomized, multicenter clinical trial comparing the clinical outcomes and costs of ventral and dorsal surgery for treating CSM.

PATIENTS AND METHODS

Data Coordination

Institutional review board approval of the clinical protocol was obtained at 7 high-volume clinical centers (3 community hospitals and 4 academic tertiary referral centers). All sites had a dedicated study coordinator for data collection. Patient data were managed at the central coordinating center (Wallace Clinical Trials Center in Greenwich, Connecticut). Patient data were deidentified before transfer from the treating institutions to protect patient confidentiality, in full compliance with the Health Insurance Portability and Accountability Act.

Study Population

Patients were prospectively enrolled at participating sites over a 2-year period (November 2006-January 2009). The average period of enrollment at each site was 15 months. Patients, ages 40 to 85 years, with CSM (defined as 2 or more of the following symptoms/signs: clumsy hands, gait disturbance, hyperreflexia, Babinski reflexes, bladder dysfunction) and cervical spinal cord compression at 2 or more levels (confirmed by advanced neuroimaging studies) from degenerative spondylosis were eligible. Patients were excluded if they had any of the following criteria: (1) C2-7 kyphosis more than 5 degrees (measured on a plain film radiograph in extension); (2) segmental kyphotic deformity (defined as ≥ 3 osteophytes extending dorsal to a C2-7 dorsal-caudal line [Figure 1]); (3) ossification of the posterior longitudinal ligament; (4) developmental narrow canal (12-mm anteroposterior canal diameter measured at the base of C2); (5) previous cervical spine surgery; (6) significant active health-related comorbidity (American Society of Anesthesiology class III or higher).

Imaging Review and Assessment of Clinical Equipoise

All patients underwent preoperative cervical spine magnetic resonance imaging and computed tomography scans, and flexion-extension lateral radiographs were obtained. The images were electronically uploaded to



FIGURE 1. Sagittal computed tomography reconstructed image demonstrating a segmental kyphotic deformity. Segmental kyphotic deformity was defined as 3 or more levels of disc osteophyte extending dorsal to a line drawn from the dorsal caudal point of C2 to the dorsal caudal point of C7.⁹

a Web-based platform (www.csm-study.org) for a central imaging review to confirm each patient's eligibility. All images were then reviewed by a panel of spinal experts (composed of 12 study investigators plus 2 other senior spine surgeons). Surgeon-reviewers then individually confirmed or rejected each patient's eligibility for either a ventral or dorsal approach (equipoise). A simple majority vote from the panel members finding equipoise for either a ventral or dorsal approach was used to define a case as potentially eligible for randomization. The treating surgeon then discussed the results of the panel review with the patient before an operative approach was selected. The panel review was used for educational purposes and did not affect eligibility in the study.

Covariates

We collected patient demographic characteristics including sex and age as well as baseline health status measures to control for baseline differences in the treatment groups.

Outcomes Assessment

Two disease-specific outcome measures—the modified Japanese Orthopedic Association (mJOA) scale¹² and the Oswestry Neck Disability Index (NDI)¹³—and 2 general health-related quality of life (HR-QOL) measures—the norm-based Short-Form 36 Physical Component Summary (SF-36 PCS) and the EuroQol-5D (EQ-5D)—were obtained preoperatively, and at 3, 6, and 12 months postoperatively. Scoring of the SF-36 PCS¹⁴ and the EQ-5D^{15,16} were performed centrally using published guidelines.

Surgical Treatment

All patients underwent surgery at the discretion of the surgeon and the patient. No patients underwent both ventral and dorsal surgery to treat CSM. Ventral surgery was performed in all cases using a multilevel discectomy with fusion and plating according to the study protocol.¹⁷ All surgeons used structural allograft or autograft at each disc space and removed compressive osteophytes using the operating microscope. Semiconstrained or dynamic plates were used at the discretion of the operating surgeon. Dorsal surgery was performed using a midline cervical laminectomy with the application of lateral mass screws and rods for rigid fixation.¹⁸ All dorsal decompressions included lateral mass fusion using allograft, autograft, or both.

Complications

Study site coordinators met with patients at 30 days postoperatively and at 1 year postoperatively to determine whether any surgical complications had occurred. Major adverse events (death, myocardial infarction, pulmonary embolus, readmission, recurrent laryngeal nerve injury, new hoarseness, new neurological deficit [eg, C5 palsy], infection, dysphagia resulting in weight loss and/or formal swallowing evaluation and therapy, esophageal perforation, and reoperation) within 30 days were recorded. Delayed complications (reoperation, fusion complication including nonunion, problems with instrumentation, deformity) were recorded at 1 year.

Economic Data

An economic analysis was conducted on a subset of patients ($n = 41$) for whom both baseline and 1-year EQ-5D were available, along with hospital charge data. We performed an economic analysis from a hospital-based perspective to compare the 2 surgical approaches. The economic analysis did not include postoperative care, productivity loss, or costs associated with subsequent hospitalizations. Total hospital charges were obtained for each patient. In addition, CSM-related International Classification of Diseases, 9th Revision, Clinical Modification ICD-9-CM diagnosis and procedure codes, Diagnosis-Related Group codes, and Current Procedural Terminology codes were obtained.

Statistical Analysis

Baseline demographics and health outcome data before and after surgery were analyzed using commercially available software (Stata version 10; StataCorp, College Station, Texas). The Fisher exact test was used for categorical variables and the Mann-Whitney U test was used for continuous variables. Repeated-measures covariance pattern models were used to evaluate changes in outcomes after surgery and to compare the outcomes of the 2 surgical approaches.¹⁹ The models included fixed effects for surgical approach, time (baseline and 3, 6, and 12 months) and the interaction between approach and time, and modeled correlation of repeated measures using an unstructured covariance pattern. These models were also adjusted for age and sex. Comparisons of outcomes were made using linear contrasts, and data are presented as least squares means. No adjustments were made for multiple comparisons.

Hospital charges for each patient were converted into costs by applying Medicare cost-to-charge ratios from each of the participating centers.²⁰ Costs were initially examined as unadjusted means between ventral and dorsal surgery for 41 patients who had valid economic data available. We did not calculate an incremental cost effectiveness ratio because ventral surgery was followed by both larger improvements in mean HR-QOL and lower mean costs and thus seemed to dominate the dorsal approach.

RESULTS

Patient Population

Fifty eligible patients who met inclusion criteria were enrolled from 7 sites comprising academic and community practice in urban and rural locations. The average period of enrollment at each site was 15 months. The median enrollment per site was 7 (range, 1-13 patients). Spinal expert's review confirmed that 89% of these patients would be eligible for a future RCT comparing ventral and dorsal fusion surgery. Twenty-eight patients (56%) underwent ventral fusion surgery and 22 (44%) underwent dorsal surgery with fusion (Figure 2). Table 1 summarizes the demographic and baseline HR-QOL and disability assessments for both ventral and dorsal surgery patients. The ventral and dorsal surgery cohorts had similar age, sex, and baseline HR-QOL measures. Patients undergoing dorsal surgery had significantly lower baseline mJOA scores (11.6 vs 13.4 (of a total maximum score of 17; $P = .03$), suggesting a greater degree of clinical myelopathy in the dorsal surgery group.

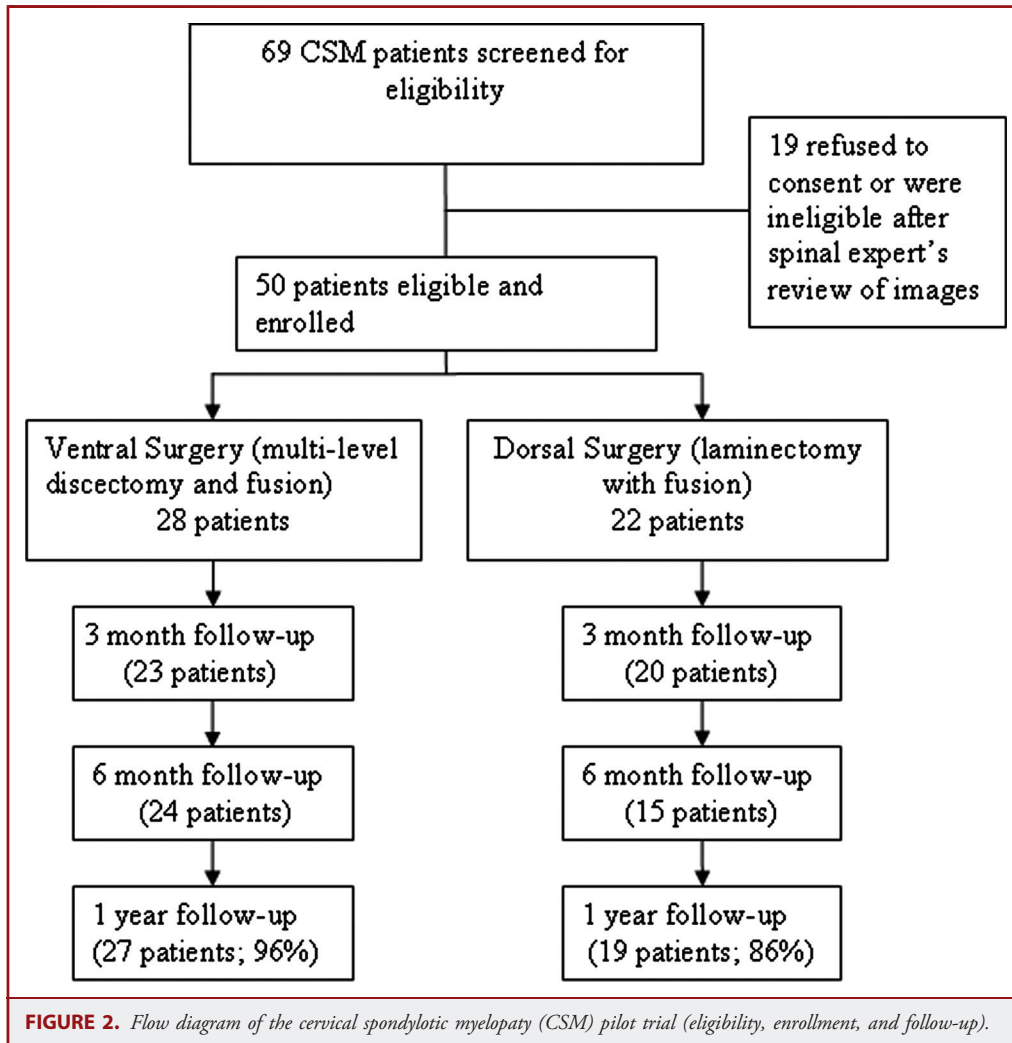
Surgical Management and Complications

Table 2 shows length of hospital stay and complications of surgery for ventral and dorsal surgery patients. Dorsal surgery was associated with longer lengths of hospital stay (4.0 vs 2.6 days; $P < .01$) compared with ventral surgery. Despite clinical equipoise of the surgical approach at baseline, dorsal surgery was performed at an average of 3.1 levels compared with 2.1 levels for ventral fusion surgery ($P < .001$). In addition, dorsal surgery was used more frequently when spondylosis was treated at the upper cervical (C2-3 and C3-4) levels ($P < .001$). Older age was associated with more rostral (C2-3 and C3-4) spondylosis ($P < .05$). Overall, CSM surgery patients had a relatively high complication rate (16.6%). In the ventral cohort, the 30-day complication rate was 17.9% (5/28), of which 80% were swallowing difficulties. In the dorsal cohort, the 30-day complication rate was 13.6% (3/22), all related to postoperative C5 palsies. No early or delayed reoperations were performed in either group.

Comparative 1-Year Surgical Outcome Assessments

One-year surgical outcomes assessments were available for 46 of 50 patients (92%). At 1 year, data for 4 patients were not available for follow-up analysis because 2 patients were not compliant with study questionnaires and 2 patients were lost to follow-up. Compared with baseline scores, 1-year disease-specific and overall HR-QOL significantly improved in both study cohorts (Table 3).

Two disease-specific outcomes instruments were used: the mJOA (to assess myelopathy) and the NDI (to assess neck disability). Those undergoing the ventral procedures had significantly higher mJOA scores (less myelopathy) at baseline and at 1 year. After controlling for baseline differences in mJOA scores, group differences in mJOA at 1 year were no longer significant (-0.74 ; 95% confidence interval, -1.78 to 0.31 ; $P = .16$). The postoperative mJOA scores in both groups were nearly 2 points



better (out of 17) compared with the preoperative mJOA scores ($P < .001$ for both dorsal and ventral approaches). Figure 3 shows the preoperative and postoperative NDI scores over 1 year. Compared with patients treated with ventral surgery, those receiving dorsal surgery demonstrated a trend toward higher NDI scores (ie, greater amount of pain and disability) 1 year after surgery ($P = .07$).

To assess HR-QOL, both the EQ-5D and the SF-36 PCS instruments were used. At 1 year, HR-QOL (both EQ-5D and SF-36 PCS) significantly improved in those undergoing ventral surgery, and a trend toward improvement was observed in those undergoing dorsal surgery (Table 3). Higher SF-36 PCS scores were observed 1 year after ventral compared with dorsal surgery ($P = .05$). After controlling for age, sex, preoperative SF-36 PCS score, preoperative mJOA score, and preoperative NDI, the ventral surgery group still had superior improvements in SF-36 PCS outcome at 1 year compared

TABLE 1. Patient Demographic and Baseline Health Measures of 50 Cervical Spondylotic Myelopathy Patients^a

Characteristic	Ventral Surgery (n = 28)	Dorsal Surgery (n = 22)	P Value
Mean age, y	60	64	.21
Sex, % female	43	27	.25
mJOA score, 0-17	13.4	11.6	<.01
Neck Disability Index, 1-100	36.3	35.6	.91
EuroQol-5D, 0-1	0.64	0.61	.63
SF-36 PCS, population mean 50, SD 10	35.6	32.4	.27

^amJOA, modified Japanese Orthopedic Association (scale); SF-36 PCS, Short-Form 36 Physical Component Summary.

TABLE 2. Length of Stay, Operated Levels, and Complications for Ventral vs Dorsal Surgery^a

	Ventral Surgery (n = 28)	Dorsal Surgery (n = 22)	P Value
Length of stay, mean days (median; IQR)	2.6 (2; 2-3)	4.0 (3; 3-5)	.002
C2-3 stenosis, ^b %	0 (0)	3 (13.6)	.079
C3-4 stenosis, %	8 (28.6)	17 (77.3)	.001
C4-5 stenosis, %	19 (67.9)	17 (77.3)	.537
C5-6 stenosis, %	23 (82.1)	16 (72.3)	.503
C6-7 stenosis, %	13 (46.4)	12 (54.5)	.776
C7-T1 stenosis, %	0 (0)	2 (9)	.189
Levels operated on, mean (median; IQR)	2.1 (2; 2-2)	3.1 (3; 3-4)	<.001
Complications, %	5 (17.9)	3 (13.6)	1.000

^aIQR, interquartile range (25th-75th percentile).^bLevel was decompressed at surgery.

with dorsal surgery patients ($P = .027$). Ventral surgery patients did not have significantly greater improvements in EQ-5D outcomes at 1 year compared with dorsal surgery patients ($P = .13$).

Economic Analysis of Ventral and Dorsal Surgery

Data from 41 patients were available for the economic analysis (ie, baseline and 12-months EQ-5D data as well as hospital charge data). The mean unadjusted hospital cost for an initial dorsal fusion surgery was \$29465 (95% confidence interval, \$21914-\$37106), which was significantly higher than the mean hospital cost for an initial ventral surgery with fusion (\$19245; 95% confidence interval, \$15983-\$22506; $P = .005$ [Figure 4]). There was significant variation in mean hospital costs across recruitment sites varying from a low of \$3270 to a high of \$33324 (by institution). In this small sample, there was no

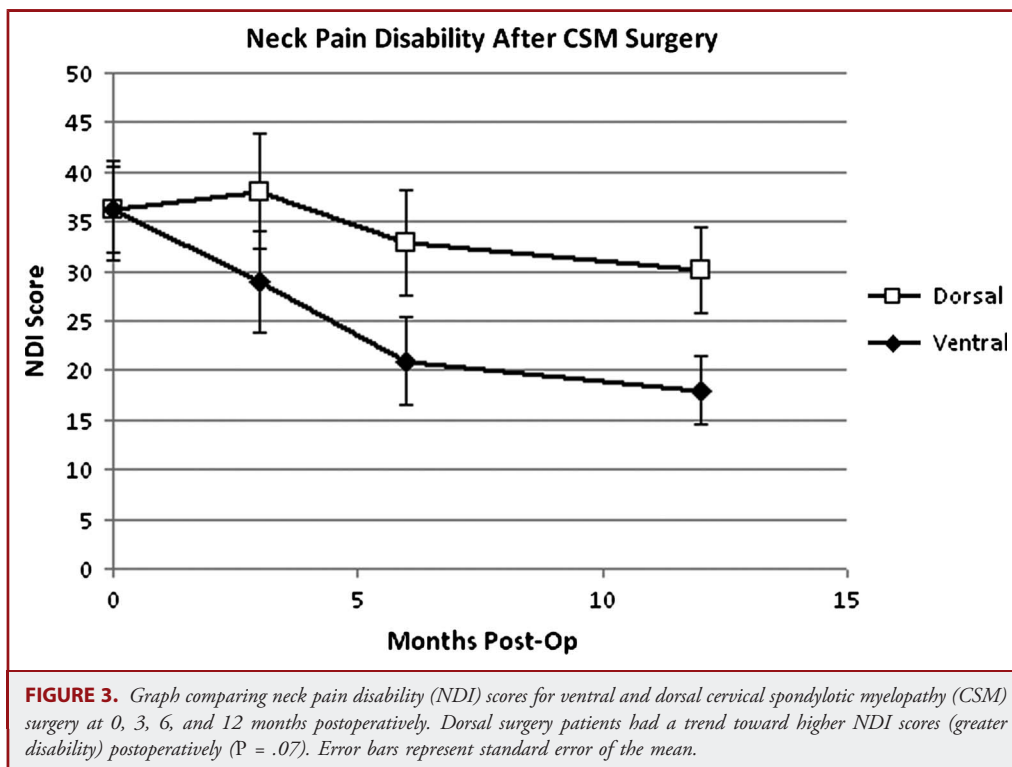
TABLE 3. Outcome Assessments for Dorsal and Ventral Surgical Approaches Over 12 Months^a

Outcome Measure	Follow-up	Dorsal (n = 22)		Ventral (n = 28)		Difference Between 2 Approaches (95% CI)	P Value ^b
		Mean	SE	Mean	SE		
EQ-5D							
	Presurgery	0.60	0.05	0.64	0.04	-0.05 (-0.18 to 0.09)	.49
	3 mo	0.66	0.05	0.76	0.04	-0.09 (-0.22 to 0.03)	.13
	6 mo	0.59	0.07	0.77	0.05	-0.18 (-0.35 to 0.01)	.04
	12 mo	0.73	0.03	0.81	0.03	-0.08 (-0.16 to 0.004)	.06
	0-12 mo change (95% CI)	0.13 (0.01-0.26) $P = .04^c$		0.16 (0.09-0.23) $P < .001^c$			
SF-36 PCS							
	Presurgery	32.72	2.20	35.32	1.91	-2.60 (-8.41 to 3.22)	.37
	3 mo	35.24	2.28	39.20	2.03	-3.96 (10.05 to 2.12)	.20
	6 mo	38.31	2.51	45.00	2.04	-6.70 (-13.16 to -0.24)	.04
	12 mo	38.53	2.51	45.23	2.11	-6.70 (-13.30 to -0.16)	.05
	0-12 mo change (95% CI)	5.74 (0.56-10.92) $P = .03^c$		9.92 (6.7-13.1) $P < .001^c$			
NDI							
	Presurgery	36.20	5.02	36.21	4.38	-0.01 (-13.79 to 3.29)	.99
	3 mo	37.97	5.75	28.86	5.07	9.11 (-6.23 to 24.45)	.23
	6 mo	32.86	5.33	20.91	4.43	11.95 (-1.89 to 5.79)	.09
	12 mo	30.13	4.26	17.96	3.54	12.17 (1.15-23.20)	.03
	0-12 mo change (95% CI)	-5.89 (-15.6 to 3.8) $P = .22^c$		-18.4 (-25.5 to -11.2) $P < .001^c$			
mJOA							
	Pre-surgery	11.60	0.50	13.40	0.44	-1.80 (-3.13 to -0.47)	.009
	3 mo	13.20	0.58	14.75	0.51	-1.55 (-3.10 to -0.01)	.05
	6 mo	13.44	0.63	15.31	0.52	-1.87 (-3.50 to -0.23)	.03
	12 mo	13.54	0.45	15.44	0.39	-1.91 (-3.10 to -0.70)	.003
	0-12 mo change (95% CI)	1.94 (0.76-3.12) $P = .0028^c$		2.04 (1.23-2.86) $P < .001^c$			

^aSE, standard error; CI, confidence interval; EQ-5D, EuroQol-5D; SF-36 PCS, Short-Form 36 Physical Component Summary; NDI, Neck Disability Index; mJOA, modified Japanese Orthopedic Association (scale).

^bP values compare the difference between surgical approaches at a given time point.

^cP values compare the change from baseline to 1 year within the surgical approach.

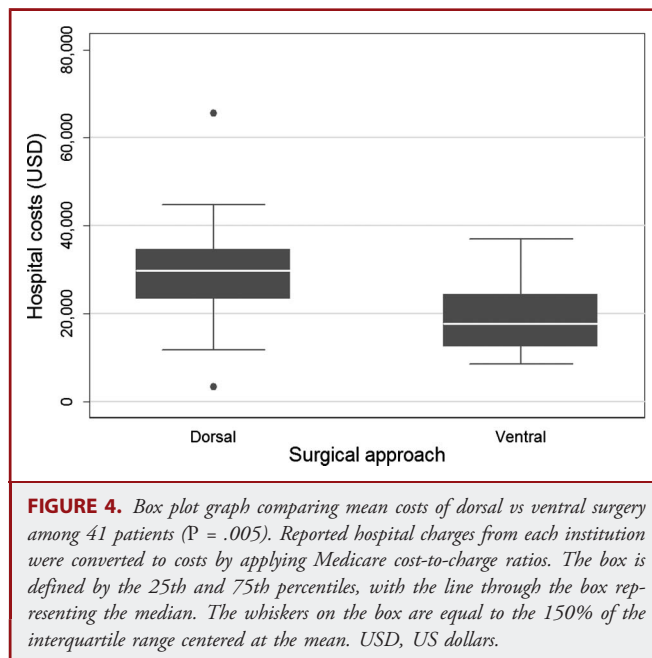


significant difference in the 1-year EQ-5D between the ventral and dorsal surgery groups.

DISCUSSION

Comparative-effectiveness research has gained increasing attention since passage of the American Recovery and Reinvestment Act of 2009. This Act allocated \$1.1 billion for new research projects aimed at understanding the differences between established medical treatments.²¹ In this report, 2 well-established surgical strategies for treating CSM are compared directly by measuring disease-specific and overall HR-QOL outcomes during a 1-year postoperative period. In addition, an economic analysis was performed using a hospital perspective. The study population was carefully selected to produce a homogeneous group of patients for whom clinical equipoise between the ventral and dorsal surgical approaches was expected to exist in the broader spine surgery community. Patients in both surgical cohorts had an improvement in their myelopathic symptoms as measured using the mJOA scale, although patients in the dorsal cohort also had lower mJOA scores preoperatively. Dorsal surgery was more complex (3.1 vs 2.4 operated-on levels), associated with greater postoperative pain and disability, and associated with longer hospital stay and had greater unadjusted hospital costs compared with ventral surgery. Overall complication rates were similar between the 2 groups. Compared with their baseline

scores, both groups had significant improvement in HR-QOL scores at 1 year, but ventral surgery had greater improvements in SF-36 PCS scores at 1 year compared with dorsal surgery. The



small sample size limited our ability to conclude that ventral surgery had significantly greater EQ-5D at 1 year compared with dorsal fusion surgery. As a result, we could not, from the pilot study, generate any definitive conclusion regarding cost-effectiveness. Ventral fusion surgery did have lower unadjusted hospital costs compared with dorsal surgery, suggesting that ventral surgery might be a more cost-effective approach.

Pathophysiology

CSM is caused by dynamic repeated compression of the spinal cord from degenerative arthritis of the cervical spine.²² Axonal stretch-associated injury appears to be the main factor causing myelopathy in animal models of CSM.²² Spinal cord ischemia from compression of larger vessels and impaired microcirculation is another proposed mechanism for CSM.^{23,24} Surgery to decompress and fuse the stenotic portion of the cervical spine is often advocated for severe or progressive CSM symptoms. Although two thirds of patients improve with surgery, it is not successful in 15% to 30% of cases.²⁵ Numerous series have reported that 10% to 20% of patients worsen clinically after surgery.²⁵⁻²⁸ In the current study, fusion was performed in all cases, and comparable improvement in myelopathic symptoms was seen in both ventral and dorsal surgery cohorts.

Comparative Effectiveness

Earlier studies examining the outcomes of ventral vs dorsal surgery for CSM have had mixed findings. Ventral decompression might be more effective in relieving the symptoms of myelopathy in 2 specific clinical circumstances. Patients with preoperative kyphosis (>13 degrees) have poorer disease-specific outcomes (measured using mJOA) after dorsal surgery (laminoplasty) according to 1 prospective study.²⁹ Another recent study concluded that for patients with preoperative intramedullary signal changes on magnetic resonance imaging, ventral decompression was associated with a significantly greater improvement in motor function compared with dorsal approaches.³⁰ In the current study, we excluded patients with kyphosis greater than 5 degrees in an effort to define a patient population in whom clinical equipoise exists between ventral and dorsal approaches. Despite our efforts to create a homogeneous study population, the patients in the dorsal group had more severe myelopathy preoperatively as reflected by lower mJOA scores, had more levels operated on, and were more likely to have more rostral cervical spondylosis. Further refinement of the eligibility criteria will still be necessary before conducting a randomized trial to reduce heterogeneity within the treatment groups.

In this study, the dorsal surgery group had higher measures of postoperative neck pain. It is possible that the larger extent of muscle dissection required for lateral mass fixation and dorsal fusion resulted in the higher postoperative pain scores seen in the dorsal surgery cohort in this study. Future comparative-effectiveness research studies could explore this in greater detail by comparing dorsal cervical fusion procedures with laminectomy alone or laminoplasty procedures to determine whether postoperative pain scores and HR-QOL scores differ between dorsal fusion and dorsal motion-preservation techniques.

Complications

Enthusiasm for multilevel ventral surgery has been tempered by the high complication rates in the past. The complication rate for ventral corpectomy (29.3%) seemed to be higher than that for dorsal surgical approaches (7.1%) in 1 study.¹¹ Early experience with multilevel corpectomy was associated with high rates of graft dislodgment and fusion failures.^{31,32} This has led many spine surgeons to adopt a multilevel discectomy and instrumented fusion with lower observed complication rates.¹⁷ In our study population, the multilevel discectomy and fusion were selected as the ventral procedure in an attempt to reduce complications. No case of graft migration was identified in this study at 1 year. Longer follow-up (for at least 2 years) will be required to determine whether pseudarthrosis or deformity is more prevalent in ventral vs dorsal fusion patients.

In a large retrospective cohort review of U.S. hospital admissions for cervical spine surgery using the Nationwide Inpatient Sample from 1992 to 2001, Wang et al³ found that surgery for cervical spondylosis with myelopathy (19% of 932,009 admissions) was associated with higher complication rates compared with other types of cervical spine surgery. Dorsal surgery was used more frequently in older patients and was independently associated with higher complication rates. Age older than 74 years was also an independent predictor for the development of complications. Similarly, another recent study found the complication rate after CSM surgery in patients older than 75 years was 38% compared with 6% in younger patients.³³ This particular analysis, however, did not directly compare ventral and dorsal surgery complication rates and was not limited to CSM patients. Another study also used the Nationwide Inpatient Sample (from 1993 to 2002; 58,115 admissions) to compare complication rates between ventral and dorsal fusion procedures for CSM. This retrospective analysis identified a complication rate of 11.9% for ventral surgery and 16.4% for dorsal fusion surgery.⁶ In the current prospective clinical study, complication rates were found to be higher than the rates recorded from an administrative database. Our study confirms that both ventral surgery and dorsal surgery for CSM are associated with a significant complication rate (16.6% overall).

Economic Analysis

Health cost analysis is challenging for a number of reasons. There is a lack of professional consensus on the methodology.³⁴ We have chosen to focus the economic analysis on hospital-based costs derived by combining Medicare cost-to-charge ratios with actual hospital charges. This preliminary analysis does not include other significant costs such as physician fees, outpatient imaging technical fees, laboratory fees, physical therapy and rehabilitation fees, and possible subsequent hospital admissions. In addition, nonmedical costs such as loss of productivity (specifically loss of work income) are major drivers of health care costs not included in this analysis.³⁵ Our economic analysis focused on hospital-based costs, which can be used as a reasonable proxy for comparative analysis of interventions, assuming that they are

proportional to the costs of 2 treatment approaches.^{36,37} We observed that unadjusted hospital costs for dorsal fusion surgery were significantly higher than those observed for ventral surgery with fusion. Our findings are consistent with those of a recently published retrospective longitudinal review of the Washington State Inpatient Database (1998-2002) that used a published algorithm for identifying cervical spine surgery admissions related to degenerative spine disease.³ Median hospital charges for dorsal decompression with fusion adjusted to 2007 U.S. dollars were 62% greater than hospital charges for ventral fusion admissions compared with dorsal surgery (\$23 300 vs \$14 400; $P < .001$).³⁸

Quality-of-Life Outcomes

Ventral surgery in this study was associated with a trend toward significantly better HR-QOL outcome measured with the SF-36 PCS instrument. This observation might have important implications for patients and surgeons in whom clinical equipoise seems to exist between the 2 approaches. Both ventral and dorsal surgical approaches have been used in the United States for nearly 50 years. To date, no RCT has been performed to compare the effectiveness of these competing procedures. If a future RCT comparing ventral surgery and dorsal surgery definitively identified 1 strategy as superior (ie, better HR-QOL outcomes), the results could potentially influence the treatment of many thousands of CSM patients who require surgical treatment. Even if ventral and dorsal surgery were followed by equal improvement in HR-QOL in an RCT, the economic analysis presented here would suggest that ventral surgery might be less costly and hence could be more cost-effective.

Limitations

Our study's eligibility criteria defined a population designed to reflect clinical equipoise between ventral and dorsal surgery; this population represents nearly 50% of CSM patients treated surgically in the United States.⁹ Although the eligibility criteria suggest generalizability of the results, only 50 patients were enrolled from 7 sites during an average enrollment period of 15 months per site. Each site investigator performed an average of 37 operations for CSM during the study period, suggesting that 20% (not 50%) of the actual cases were enrolled. There are several possible explanations for this finding. First, the majority of CSM operations are performed in the community setting, whereas many of the investigators included in the pilot study are senior spine surgeons who treat more complex revision cases that were not eligible for study inclusion. Second, many of the sites did not have adequate screening procedures in place early in the study period so some potential study candidates were invariably missed. Third, patients treated with ventral corpectomy, laminectomy without fusion, and laminoplasty procedures were not included, further limiting the numbers accrued in the study.

The current study cannot be used to definitively compare ventral and dorsal surgery because the observed differences might be explained by confounding variables. The dorsal surgery group

might have represented a more complex group of patients because the operations in this group involved a significantly higher number of levels operated on and the baseline myelopathy scores were worse in the dorsal cohort.

CONCLUSION

Surgery for treating CSM, from both dorsal and ventral approaches, was followed by significant improvements in disease-specific symptoms and in HR-QOL measured 1 year post-operatively. Greater improvement in HR-QOL was observed after ventral surgery, although dorsal surgery patients had a greater degree of myelopathy preoperatively. Dorsal fusion surgery was associated with more levels operated on, longer hospital stay, and more hospital costs. This pilot study demonstrated both the feasibility and importance of an RCT to examine this clinically relevant topic.

Disclosure

The study was supported by a research grant (GH-382) from the Jean and David Wallace Foundation (to Z.G., Greenwich Hospital). This study was additionally supported by Clinical and Translational Science Award grant number UL1 RR024146 (to Z.G., Yale University) from the National Center for Research Resources, a component of the National Institutes of Health (NIH), and the NIH Roadmap for Medical Research. The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

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Acknowledgments

We thank Andrea Douglas, MD, and Robert Whitmore, MD, for critical review of the manuscript. We thank Ronald I. Apfelbaum, MD, and Paul R. Cooper, MD, for participating in the spinal experts' review of patient images.

COMMENT

Ghogawala et al present the results of a nonrandomized, prospective study comparing ventral and dorsal surgery for cervical spondylotic myelopathy (CSM). The study was performed as a pilot study for a proposed randomized, clinical trial (RCT). In the current investigation, 50 patients with were enrolled at 7 sites over a 2-year period. A panel of 14 surgeons assessed each patient's suitability for randomization in the proposed RCT. If a majority of surgeons indicated that either an anterior or a posterior approach would be appropriate (not necessarily ideal), equipoise was said to exist for the surgical approach. The treating physician, in consultation with the patient, made the decision regarding the approach in each individual patient.

Of the 50 patients enrolled in the study, the panel's responses indicated that 89% would be eligible for an RCT. Patients in the 2 groups differed significantly in their baseline modified Japanese Orthopedic Association (mJOA) scale score, a measure of myelopathy. Differences in age and sex between the 2 groups did not reach statistical significance, likely because of the relatively small sample size. Twenty-eight patients underwent ventral fusion surgery and 22 underwent dorsal decompression and arthrodesis.

Patients were operated on at a mean of 2.1 levels in the ventral group and 3.1 levels in the dorsal group ($P < .001$). A significantly greater proportion of patients in the dorsal surgery group had surgery including upper cervical levels (C2-4) compared with the ventral group. The length of stay (LOS) was significantly greater for the dorsal group (mean 4.0 days) compared with the ventral group (2.6 days). A similar proportion of patients in each group had a complication. Four of the 5 ventral complications were related to dysphagia; all the dorsal complications were C5 palsies. Both groups showed improvement on the mJOA score; adjusting for the baseline scores, the difference between the groups was not significant. There was a trend toward greater improvement in neck pain with ventral surgery. General health-related quality of life improved significantly in the ventral compared with the dorsal group on one measure but not on another. The mean unadjusted costs associated with ventral surgery were significantly lower compared with those for dorsal surgery (\$19,245 vs \$29,465, $P = .005$).

The differences in the patient populations in each treatment subgroup make it impossible to know whether the noted differences in outcomes are attributed to the procedure or to the differences in the cohorts. If, for example, the ventral group had undergone surgery at a mean of 3, rather than 2, levels we would expect higher costs and longer hospital stays and possibly a greater proportion of patients with complications. The only way to fairly compare treatments is to have completely similar, or exchangeable, patient populations in the 2 groups.

Comparative-effectiveness research is based on the implicit assumption that there is a "best" treatment for a given condition. One of the difficulties of conducting studies of degenerative spinal disorders is the heterogeneity of patients even within a single diagnostic category such as CSM. This well-conducted study demonstrates how difficult it is to develop criteria that define a homogeneous patient population for patients with this diagnosis. Additionally, it provides evidence of the complexity of surgical decision making. Not surprisingly, the treating

surgeon considered factors such as patient age, severity of myelopathy, and the number of involved segments in recommending a surgical approach. This resulted in important differences between the treatment groups. Refining the inclusion and exclusion criteria of the study for an RCT may improve the homogeneity of the study population, but doing so would further reduce the study's generalizability.

As the authors discuss, this study does not include all variations on ventral and dorsal surgery. Commonly performed procedures such as corpectomy, discectomy and fusion without plating, laminectomy, and laminoplasty might, in fact, be better options than the study procedures in certain patients. Determining a "best" operation or approach in a head-to-head, comparative manner would be a difficult, possibly unfeasible, task. Furthermore, important differences in outcome between subgroups may be obscured in the overall analysis and are likely to be discarded unless the subgroups are identified a priori for separate analysis. If one procedure is found to have better outcomes than another for a small subset of patients, it is possible that those findings may be

incorrectly generalized to other patient groups and patient and physician choice inappropriately restricted.

Most likely, there is not a single "best" approach to cervical spondylotic myelopathy. The different operations are tools that must be appropriately selected for specific situations. A practicing neurosurgeon needs to know not what is, on average, the best operation but rather what procedure is most likely to produce the best outcome in an individual patient. This pilot study and the proposed RCT are designed to answer the first question. Data to answer the second would most efficiently be obtained from a prospective registry designed by neurosurgeons and analyzed with statistical techniques that allow ongoing model updating and improvement. As organized neurosurgery develops clinical databases we should be able to refine our recommendations regarding treatment to individual patients, our fundamental common responsibility.

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