Efficacy and Safety of Surgical Decompression in Patients with Cervical Spondylotic Myelopathy

Results of the AOSpine North America Prospective Multi-Center Study

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Background: Cervical spondylotic myelopathy is the leading cause of spinal cord dysfunction worldwide. The objective of this study was to evaluate the impact of surgical decompression on functional, quality-of-life, and disability outcomes at one year after surgery in a large cohort of patients with this condition.

Methods: Adult patients with symptomatic cervical spondylotic myelopathy and magnetic resonance imaging evidence of spinal cord compression were enrolled at twelve North American centers from 2005 to 2007. At enrollment, the myelopathy was categorized as mild (modified Japanese Orthopaedic Association [mJOA] score ≥ 15), moderate (mJOA = 12 to 14), or severe (mJOA < 12). Patients were followed prospectively for one year, at which point the outcomes of interest included the mJOA score, Nurick grade, Neck Disability Index (NDI), and Short Form-36 version 2 (SF-36v2). All outcomes at one year were compared with the preoperative values with use of univariate paired statistics. Outcomes were also compared among the severity classes with use of one-way analysis of variance. Finally, a multivariate analysis that adjusted for baseline differences among the severity groups was performed. Treatment-related complication data were collected and the overall complication rate was calculated.

Results: Eighty-five (30.6%) of the 278 enrolled patients had mild cervical spondylotic myelopathy, 110 (39.6%) had moderate disease, and 83 (29.9%) had severe disease preoperatively. One-year follow-up data were available for 222 (85.4%) of 260 patients. There was a significant improvement from baseline to one year postoperatively ($p < 0.05$) in the mJOA score, Nurick grade, NDI score, and all SF-36v2 health dimensions (including the mental and physical health composite scores) except general health. With the exception of the change in the mJOA, the degree of improvement did not depend on the severity of the preoperative symptoms. These results remained unchanged after adjusting for relevant confounders in the multivariate analysis. Fifty-two patients experienced complications (prevalence, 18.7%), with no significant differences among the severity groups.

Conclusions: Surgical decompression for the treatment of cervical spondylotic myelopathy was associated with improvement in functional, disability-related, and quality-of-life outcomes at one year of follow-up for all disease severity categories. Furthermore, complication rates observed in the study were commensurate with those in previously reported cervical spondylotic myelopathy series.

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

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A commentary by Ronald W. Lindsey, MD, is linked to the online version of this article at jbjs.org.

Cervical spondylotic myelopathy is an often progressive, degenerative disease and is the leading cause of spinal cord dysfunction worldwide[1]. Although the majority of individuals over the age of fifty years exhibit pathological or radiographic evidence of cervical degeneration, only about one-quarter of these develop symptoms of neurological impairment from mechanical neural compression[2-4]. When signs and symptoms of myelopathy are present, the optimal treatment approach, specifically the suitability of surgical spinal cord decompression, remains controversial. This is largely due to mixed reports regarding the natural history of cervical spondylotic myelopathy; although some patients experience progressive disability, others remain static or improve with conservative nonoperative treatment[5].

To date, we are aware of only one randomized controlled trial that has evaluated the efficacy of surgical decompression compared with nonoperative treatment for patients with cervical spondylotic myelopathy[6]. That trial considered only patients with mild myelopathy (modified Japanese Orthopaedic Association [mJOA] score ≥ 12) and failed to detect a difference in functional outcome between those treated conservatively and those treated operatively. However, those findings must be balanced against results obtained from numerous observational studies that indicate that between 30% to 50% of patients with cervical spondylotic myelopathy will experience clinical worsening over the course of follow-up when treated nonoperatively, as summarized in reviews published in 2009[5,7].

Traditionally, surgical decompression has been performed for cervical spondylotic myelopathy to arrest neurological deterioration and prevent further disability. However, several studies have indicated improved clinical outcomes among patients with a major preoperative deficit who were treated surgically[8-10]. To our knowledge, no prospective analysis evaluating surgical outcomes in patients with mild, moderate, or severe cervical spondylotic myelopathy has been published to date.

The primary aim of the present study was to prospectively evaluate the impact of cervical spine decompressive surgery on functional, quality-of-life, and disability-related outcomes at one year of follow-up in a large cohort of patients with cervical spondylotic myelopathy. We also compared outcomes among patients classified preoperatively as having mild, moderate, or severe myelopathy. Finally, to evaluate the safety of decompressive surgery for patients with cervical spondylotic myelopathy, we prospectively gathered complication data in the immediate postoperative period as well as in the outpatient setting at up to one year of follow-up.

Materials and Methods

Subjects

Patients with clinically and radiographically confirmed cervical spondylotic myelopathy were enrolled in a multicenter, prospective cohort study at twelve North American institutions from December 2005 to September 2007. Participating centers were all contributing members of the AOSpine North America clinical research network SpineNet, which is a North American consortium dedicated to the research of spine-related disorders. The key inclusion criteria were an age of eighteen years or older, symptomatic cervical spondylotic myelopathy, objective cervical cord compression as determined by magnetic resonance imaging (MRI)[11], no prior surgical treatment for myelopathy, and the absence of symptomatic lumbar stenosis. There were no restrictions on the duration of symptoms or prior nonsurgical treatment. The study received approval from the institutional review boards at all participating sites and was registered at ClinicalTrials.gov (NCT00285337).

Enrolled subjects received surgical decompression of the cervical spinal cord combined with an instrumented fusion procedure. Specific surgical details, including the surgical approach (anterior, posterior, or circumferential) and the number of vertebral segments decompressed and fused, were determined by the attending spinal surgeon. Postoperative rehabilitation utilized the standard care at the treating institution and was not prescribed by the protocol.

Outcome Measures and Follow-up

Preoperatively, the baseline status of all patients was assessed with use of a variety of outcome measures including the mJOA scale[12], the Nurick grade[1,13], the Neck Disability Index (NDI)[14,15], and the Short Form-36 version 2 (SF-36v2)[16]. The mJOA and Nurick instruments are investigator-administered cervical spondylotic myelopathy-specific indices measuring the severity of functional and neurological impairment. The mJOA instrument consists of four categories: motor dysfunction in the upper extremity, motor dysfunction in the lower extremity, sensory deficit, and sphincter dysfunction. It evaluates the severity of myelopathy by allocating points according to the degree of dysfunction in each category. The total score is a sum of the scores in the individual categories and can range from 0 (worst) to 18 (best). The Nurick instrument is a six-grade ordinal scale based on an evaluation of gait abnormality. The minimum clinically important difference (MCID) has not been established for the mJOA or Nurick instruments. The NDI evaluates patient self-reported disability related to neck conditions. The NDI score can range from 0 (best) to 100 (worst). The SF-36v2 is a widely used measure of patient generic health status. The SF-36v2 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores were calculated with use of the 1998 U.S. norms and an orthogonal approach to transformation. These SF-36v2 subscores in a standard population have a mean value (and standard deviation) of 50 ± 10. The reported MCID in cervical spine conditions is 7.5 for the NDI and 4.1 for the SF-36v2 PCS[14].

Subjects were classified on the basis of the preoperative mJOA score as having mild (mJOA ≥ 15), moderate (mJOA = 12 to 14), or severe (mJOA < 12) cervical spondylotic myelopathy; this represents a modification of the classification used by Kadanka et al.[6]. The primary follow-up time point was one year after surgery, at which time each of the described outcome assessments was repeated for each patient. In addition, complications were followed prospectively with use of a predetermined list of thirty anticipated complications associated with the surgical treatment of cervical spondylotic myelopathy. Participating investigators prospectively evaluated the entire list of complications at six and twelve months after surgery and at all unplanned visits. External professional monitors further verified the complication information by comparing reported events with patients' medical charts and other available medical documentation. All reported events were categorized as either treatment-related complications or treatment-unrelated events by an independent spine surgeon with expertise in the surgical treatment of cervical spondylotic myelopathy.

Data Collection and Quality Assurance

Professional clinical research monitors performed more than eighty site visits to ensure that the data were accurate, reliable, and complete. All data were transcribed into an electronic data capture system and were processed at the AOSpine North America clinical research network data management center.

Statistical Methods

Baseline descriptive statistics were calculated and characteristics were compared among the three severity classes with use of one-way analysis of variance (ANOVA) and the Pearson chi-square test. Missing follow-up scores were assumed to be missing at random, and these scores were accounted for with use of a multiple-imputation procedure involving ten imputation iterations. Such imputation is recommended as being less susceptible to bias and more efficient than performing a completed-case analysis by dropping those cases with incomplete

TABLE I Preoperative Subject Characteristics According to Severity of Cervical Spondylotic Myelopathy (N = 278)

	All	Mild (mJOA ≥ 15) (N = 85)	Moderate (mJOA = 12-14) (N = 110)	Severe (mJOA < 12) (N = 83)	P Value
Age* *(yr)*	56.33 ± 11.71	52.32 ± 9.49	55.43 ± 11.40	61.64 ± 12.31	<0.01
Female sex	113 (40.65%)	33 (38.82%)	44 (40.00%)	36 (43.37%)	0.82
Race					0.61
Caucasian	229 (82.37%)	73 (85.88%)	91 (82.73%)	65 (78.31%)	
African American	28 (10.07%)	5 (5.88%)	13 (11.82%)	10 (12.05%)	
Other	21 (7.55%)	7 (8.24%)	6 (5.45%)	8 (9.64%)	
Current smoker	72 (25.90%)	18 (21.18%)	28 (25.45%)	26 (31.33%)	0.32
Symptom duration* *(mo)*	25.78 ± 45.49	24.48 ± 38.57	26.81 ± 56.34	25.75 ± 35.44	0.94
NDI*	41.76 ± 20.79	33.38 ± 18.93	41.33 ± 19.75	50.70 ± 20.47	<0.01
Nurick grade*	3.14 ± 0.97	2.42 ± 0.75	3.12 ± 0.75	3.89 ± 0.87	<0.01
SF-36v2 PCS score*	36.27 ± 9.63	40.80 ± 8.72	35.58 ± 9.20	32.61 ± 9.32	<0.01
SF-36v2 MCS score*	40.03 ± 10.85	43.32 ± 10.73	40.46 ± 10.16	36.09 ± 10.72	<0.01
No. of levels*	3.86 ± 1.26	3.46 ± 1.17	3.89 ± 1.21	4.23 ± 1.32	<0.01
Surgical approach					<0.01
Anterior	169 (60.79%)	65 (76.5%)	68 (61.8%)	36 (43.4%)	
Posterior	95 (34.17%)	17 (20.0%)	40 (36.4%)	38 (45.8%)	
Circumferential	14 (5.04%)	3 (3.5%)	2 (1.8%)	9 (10.8%)	

*The values are given as the mean and the standard deviation.

variables[17,18]. Utilizing the imputed data sets, paired t tests were used to compare patient outcomes at one year after surgery with preoperative patient status. To evaluate the effects of preoperative disease severity on outcomes, one-way ANOVA with Bonferroni correction was used on the imputed sample to evaluate how the changes in outcome varied among the three severity classes. To adjust for differences in baseline confounders among the severity groups, we utilized a two-step procedure in which we first screened for possible confounders by performing a univariate Pearson linear correlation between each predictor variable and the value of the outcome variable at twelve months and retaining those variables with a correlation coefficient p value of <0.2. The screened variables included demographics, baseline outcome parameters, the duration of symptoms, comorbidities, and the anatomical source of the stenosis. In the second step, we performed multivariate linear regression utilizing the predictors identified during the first step and eliminated those covariates with a partial correlation coefficient of >0.1 in a step-wise fashion. This process was performed separately for each outcome variable. Finally, we performed two-way repeated-measures analysis of covariance (ANCOVA) with time (baseline and twelve months), group (three severity groups), and the time × group interaction adjusted for the confounders identified in the previous step. The study had 80% power to detect a difference of 1.4 in the mJOA score among the groups, based on an observed standard deviation of 2.7.

Source of Funding

This study was sponsored by AOSpine North America, Inc., a non-profit 501(c)(3) corporation.

Results

A total of 278 patients met the eligibility criteria and underwent surgery for symptomatic cervical spondylotic myelopathy. Patients were classified according to disease severity on the basis of the preoperative mJOA score; eighty-five patients (30.6%) had mild cervical spondylotic myelopathy, 110 (39.6%) had moderate myelopathy, and eighty-three (29.9%) had severe myelopathy. Table I provides a summary of baseline characteristics for the entire study population according to preoperative disease severity. Patient age at presentation differed significantly among the severity groups ($p < 0.01$), with the mean age decreasing from severe to moderate to mild disease. Mean preoperative SF-36v2, NDI, and Nurick scores became progressively more favorable from severe to moderate to mild disease. The number of vertebral levels decompressed differed significantly among the groups, with a more extensive decompression performed in patients with severe disease compared with those with moderate or mild disease ($p < 0.01$). There were no significant differences among the severity groups with respect to sex, smoking status, and preoperative symptom duration ($p > 0.05$).

Seventeen of the 278 patients originally enrolled withdrew and one died of an unrelated cause prior to the twelve-month follow-up visit. Of the remaining 260 patients, 222 (85.4%) had follow-up data available at one year after surgery, including seventy-one (91.0%) of seventy-eight with mild myelopathy, eighty-nine (84.8%) of 105 with moderate myelopathy, and sixty-two (80.5%) of seventy-seven with severe myelopathy. All outcome analyses were based on the 260-patient study group, with missing data imputed for the thirty-eight patients without available one-year follow-up.

Table II presents the one-year outcomes in relationship to the preoperative baseline values. Overall, the mJOA score,

TABLE II Patient Outcomes at Baseline and Twelve Months (N = 260)

	Baseline*	Twelve Months*	Difference*	P Value†
mJOA	12.85 (12.53, 13.17)	15.73 (15.40, 16.06)	2.88 (2.52, 3.24)	<0.0001
Nurick grade	3.11 (2.96, 3.26)	1.52 (1.35, 1.69)	−1.59 (−1.77, −1.40)	<0.0001
NDI	42.01 (39.30, 44.47)	30.73 (27.86, 33.60)	−11.28 (−13.77, −8.79)	<0.001
SF-36v2				
Physical functioning	32.64 (31.09, 34.19)	38.56 (36.98, 40.08)	5.92 (4.41, 7.42)	<0.001
Role limitation-physical	31.47 (29.86, 33.08)	38.39 (36.70, 40.08)	6.92 (5.10, 8.74)	<0.001
Bodily pain	35.41 (34.02, 36.81)	41.69 (40.19, 43.19)	6.28 (4.78, 7.77)	<0.001
General health	43.54 (42.16, 44.92)	44.77 (43.35, 46.20)	1.23 (−0.17, 2.63)	NS
Emotional well-being	40.50 (38.83, 42.16)	46.82 (44.99, 48.65)	6.32 (4.51, 8.13)	<0.001
Role limitation-emotional	36.26 (34.23, 38.29)	41.52 (39.41, 43.62)	5.26 (3.10, 7.41)	<0.001
Social functioning	36.36 (34.66, 38.06)	42.55 (40.82, 44.29)	6.19 (4.39, 7.99)	<0.001
Energy/fatigue	40.86 (39.31, 42.40)	46.54 (44.86, 48.22)	5.68 (3.98, 7.39)	<0.001
PCS score	36.01 (34.67, 37.35)	41.61 (40.20, 43.01)	5.60 (4.33, 6.86)	<0.001
MCS score	39.69 (38.27, 41.12)	45.28 (43.76, 46.80)	5.58 (4.20, 6.96)	<0.001

*The values are given as the mean, with the 95% confidence interval in parentheses. †NS = not significant.

Nurick grade, and NDI score improved significantly from baseline to one year postoperatively ($p < 0.05$). Significant improvements in health-related quality-of-life were observed for nine of the ten components of the SF-36v2 ($p < 0.05$), with a trend toward improvement for the remaining general health component. Table III compares outcomes among patients according to preoperative disease severity. Patients with mild disease preoperatively experienced the smallest improvement in the mJOA score and those with severe disease experienced the largest ($p < 0.01$). No differences in improvement among the severity groups were observed for the remaining functional, disability-related, and quality-of-life outcome measures that were assessed.

The Appendix presents a comparison of outcomes among patients according to preoperative disease severity after adjustment for baseline covariates. Again, patients with mild disease preoperatively experienced the smallest improvement in the mJOA score and those with severe disease experienced the largest (time × severity interaction [the interaction between improvement over time and preoperative disease severity], $p < 0.01$). No differences in improvement among the severity groups were observed for the remaining functional, disability-related, and quality-of-life outcome measures at the time of follow-up. A complete list of the covariates included in each multivariate model is presented in the Appendix.

TABLE III Change in Outcome at Twelve Months According to Severity Group (N = 260)

	Mild*	Moderate*	Severe*	P Value†
mJOA	1.29 (0.70, 1.87)	2.58 (2.07, 3.09)	4.91 (4.34, 5.49)	<0.0001
Nurick grade	−1.54 (−1.86, −1.22)	−1.51 (−1.81, −1.22)	−1.74 (−2.08, −1.41)	NS
NDI	−12.05 (−16.34, −7.76)	−9.79 (−13.68, −5.90)	−12.53 (−17.02, −8.05)	NS
SF-36v2				
Physical functioning	5.64 (2.88, 8.39)	6.68 (4.23, 9.13)	5.16 (2.36, 7.97)	NS
Role limitation-physical	7.32 (4.27, 10.38)	7.78 (5.07, 10.49)	5.35 (2.18, 8.51)	NS
Bodily pain	7.95 (5.42, 10.48)	5.29 (2.99, 7.59)	5.94 (3.18, 8.70)	NS
General health	1.89 (−0.58, 4.37)	1.10 (−1.12, 3.32)	0.73 (−1.96, 3.43)	NS
Emotional well-being	7.25 (4.25, 10.25)	3.98 (1.15, 6.82)	8.57 (5.31, 11.83)	NS
Role limitation-emotional	5.49 (1.78, 9.21)	4.27 (0.82, 7.73)	6.35 (2.55, 10.16)	NS
Social functioning	7.14 (4.08, 10.19)	5.32 (2.29, 8.35)	6.42 (3.35, 9.49)	NS
Energy/fatigue	5.78 (2.83, 8.72)	5.04 (2.41, 7.67)	6.45 (3.53, 9.38)	NS
PCS score	6.36 (4.15, 8.57)	5.64 (3.67, 7.61)	4.77 (2.36, 7.17)	NS
MCS score	6.52 (4.24, 8.81)	4.26 (2.19, 6.34)	6.43 (3.98, 8.88)	NS

*The values are given as the mean, with the 95% confidence interval in parentheses. †NS = not significant.

TABLE IV Treatment-Related Complications According to Disease Severity at Baseline

Complication	Mild (N = 85) *(no.)*	Moderate (N = 110) *(no.)*	Severe (N = 83) *(no.)*	All (N = 278)	
				No.	%
Altered mental status		1	1	2	0.7
C5 radiculopathy	2		3	5	1.8
Cardiopulmonary event	1	2	4	7	2.5
Deep infection			1	1	0.4
Durotomy	1	1	1	3	1.1
Dysphagia	3	4	3	10	3.6
Dysphonia		1		1	0.4
Epidural/wound hematoma	2			2	0.7
Facial swelling	1			1	0.4
Gastrointestinal	1		1	2	0.7
Iatrogenic fracture during the operation		1		1	0.4
Instrumentation failure	1			1	0.4
Instrumentation or graft malposition/migration	2	1	2	5	1.8
Mental health complication			1	1	0.4
New neurological deficit (other)	1			1	0.4
New radiculopathy (not C5)	2	1		3	1.1
Numbness and tingling in hands		1		1	0.4
Pneumonia	1			1	0.4
Postoperative deformity		2		2	0.7
Pseudarthrosis	2	1	2	5	1.8
Renal complication			1	1	0.4
Reoperation, not otherwise specified		1		1	0.4
Serious bleeding			1	1	0.4
Sore throat	1			1	0.4
Stroke	1			1	0.4
Superficial infection	3	2	3	8	2.9
Symptomatic adjacent segment disease		1	1	2	0.7
Throat spasm	1			1	0.4
Thromboembolism			1	1	0.4
Worsening of axial neck pain	2			2	0.7
Worsening of myelopathy	2	1		3	1.1
Wound hematoma		1		1	0.4
Any	17	17	18	52	18.7

Fifty-two patients (18.7%) had a total of seventy-eight postoperative complications by the one-year follow-up visit (Table IV). The complication rate did not differ among the severity groups ($p > 0.05$). The most common complication experienced was dysphagia in the early postoperative setting in 3.6% of patients, followed by superficial infection in 2.9%. Six patients (2.2%) required revision surgery during the study period; indications for revision included neck hematoma, deep

wound infection, and graft malposition. Three patients had worsening myelopathy in the immediate postoperative setting, and two of these had improved to the baseline functional status at the one-year follow-up visit.

Discussion

We believe that this study represents the largest and most comprehensive evaluation of surgical outcomes in a prospective cohort of patients with symptomatic cervical spondylotic myelopathy reported to date. The broad eligibility criteria and prospective design indicate that the surgical outcomes described should be generally applicable to the majority of patients who present with mild, moderate, or severe symptoms of cervical spondylotic myelopathy and a compatible diagnosis on imaging studies. The overall finding was that surgical intervention resulted in improvement in functional, disability-related, and quality-of-life outcomes at one year of follow-up. Furthermore, the degree of improvement observed at the time of follow-up did not depend on the severity of preoperative symptoms and was not affected by adjustment for baseline confounders. The one exception to this observation was the mJOA score, for which improvement was directly related to preoperative disease severity, with patients with severe myelopathy improving the most and patients with mild myelopathy improving the least. This finding is likely attributable to a ceiling effect for this outcome measure: patients with mild disease are expected to experience smaller increments of improvement as they cannot improve past a perfect score.

The complication rate of 18.7% observed in this cohort was commensurate with documented rates ranging from 11% to 38% in comparable series of patients treated surgically for cervical spondylotic myelopathy[19,20]. Moreover, the reporting of complications in our study was done in a rigorous, prospective manner with external monitoring. Hence, the rates of adverse events reported in our study would be expected to be higher than those reported in retrospective studies in the literature. The fact that the complication rates in the present study were in keeping with those in the literature is noteworthy, as is the fact that most complications were transient and without long-term functional impact. The most common complication was postoperative dysphagia in a total of ten patients. Although three patients had worsening of the myelopathy in the initial postoperative period, two of these patients improved to at least the baseline functional level at one year of follow-up.

In the present study, we grouped patients into three different categories according to the preoperative disease severity: mild (mJOA ≥ 15), moderate (mJOA = 12 to 14), and severe (mJOA < 12). This is at variance with the approach used by Kadanka et al., who dichotomized the mJOA score at 12 to distinguish mild to moderate cervical spondylotic myelopathy (mJOA ≥ 12) from severe myelopathy (mJOA < 12)[21]. We incorporated the separate moderate level on the basis of a consensus among the study authors that an mJOA score of 12 to 14 reflects a substantial level of disability not compatible with a mild designation.

The results of the current study with respect to treatment options for cervical spondylotic myelopathy must be considered in the context of the existing literature. To date, the only randomized controlled trial comparing surgical with conservative treatment that we are aware of revealed no difference between these therapies with respect to long-term functional outcomes in patients with mild cervical spondylotic myelopathy[6,21]. However, the conclusions of that study must be tempered by its notable methodological weaknesses, including unbalanced treatment groups, an underpowered analysis, and a substantial loss-to-follow-up rate[22,23]. Second, the natural history of patients with symptomatic cervical spondylotic myelopathy is unpredictable, with a large percentage of patients known to experience a progressive functional deterioration when followed prospectively over time[24-27]. At present, there are no reliable means to determine which patients will improve or remain stable and which will deteriorate. Third, there is convincing neuroanatomical evidence that prolonged periods of spinal cord compression, as is seen in cervical spondylotic myelopathy, are associated with irreversible, detrimental pathological processes[28,29].

We have shown that surgery for cervical spondylotic myelopathy was associated with improvement in functional, disability-related, and quality-of-life outcomes over time, regardless of baseline disease severity. We did not incorporate a randomized controlled design as this was considered logistically and ethically unfeasible. From an ethical standpoint, there was consensus among the authors that there was no treatment equipoise and that it would therefore be inappropriate to withhold surgery from a patient with symptomatic myelopathy and radiographic evidence of spinal cord compression. Furthermore, from a logistical standpoint, if a randomized trial had been undertaken, the crossover rate from the nonoperative arm would likely have undermined the randomized study design, as has been observed in other recent clinical trials of surgical intervention for spinal disorders[30]. Our design, in spite of its limitations, was deemed by the study investigators to be the most practical and ethical approach available to evaluate the impact of surgical treatment on cervical spondylotic myelopathy.

Because patients were prospectively enrolled at twelve different centers throughout North America, the findings of the current study have a greater degree of external validity than findings of single-center studies. The use of many recruitment sites allowed the accrual of almost 300 patients with cervical spondylotic myelopathy, which is a substantially larger sample size than any other study performed to date. In addition, our use of four different outcome measures allowed a comprehensive evaluation of the impact of surgery on patient outcomes. Lastly, the presence of ongoing external data monitoring helped to ensure the collection of high-quality data including treatment-related complications.

In addition to the lack of a nonsurgical control group, the study has several other limitations. First, a 15% attrition rate was observed at the one-year time point. We compensated for these missing data through the use of a multiple-imputation procedure, as is the recommended practice. A standardized surgical protocol was not utilized and different investigators might have opted to treat the same patient differently. However, in all cases the same goals of spinal cord decompression and subsequent stabilization were achieved regardless of the specific approach employed. Furthermore, this treatment heterogeneity is more reflective of current surgical practice, adding to

the generalizability of the study findings. We have not explored the relative effectiveness of different surgical approaches on surgical outcomes; this question will form the basis of future analyses utilizing this data set. We compensated for the possible differences among the severity groups by performing adjusted analyses. Although such analyses have limitations, they represent the best possible approach to dealing with the confounding influence of extraneous variables in nonexperimental data. Finally, data regarding the patients who were screened for study eligibility but not enrolled were not retained throughout the study period. In spite of this, our decision to incorporate very broad enrollment criteria helps to ensure the external validity of the study findings. It is noteworthy that the prospective data collection at the lead center in the study included over 90% of the patients screened for enrollment, which speaks to the generalizability of the data analysis.

Overall, this large prospective multicenter analysis demonstrated that surgery for patients with cervical spondylotic myelopathy resulted in improved functional, disability-related, and quality-of-life outcomes at one year of follow-up compared with the preoperative status. Future studies will be required to more accurately define which patients stand to benefit the most from surgical intervention for cervical spondylotic myelopathy and to determine the optimal surgical techniques used in a given patient.

Appendix

eA Tables showing patient outcomes at baseline and twelve months, adjusted for preoperative characteristics, according to severity group as well as the baseline covariates used in the adjusted analysis for each outcome variable are available with the online version of this article as a data supplement at jbjs.org. ■

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