

Ventral Versus Dorsal Decompression for Cervical Spondylotic Myelopathy: Surgeons' Assessment of Eligibility for Randomization in a Proposed Randomized Controlled Trial

Results of a Survey of the Cervical Spine Research Society

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Study Design. Surgeons attending a Cervical Spine Research Society (CSRS) meeting were surveyed about the surgical approach to cervical spondylotic myelopathy (CSM).

Objective. To elicit spine surgeons' opinions on the suitability of a panel of test cases for randomization in a proposed randomized controlled trial (RCT) of ventral versus dorsal decompression for CSM.

Summary of Background Data. The optimal surgical decompression strategy for CSM has not been defined. Specific eligibility criteria should be defined before a RCT is initiated.

Methods. Twenty actual cases with images were prepared. Surgeons supplied demographic information, preferred surgical approach, and eligibility for randomization for 10 cases.

Results. A total of 91 of 239 (38%) surgeons completed the survey. Of 900 case-strategy responses, 51% recommended ventral surgery, 38% dorsal surgery, and 11% a combined approach. Both overall C2–C7 kyphosis $>5^\circ$ and a segmental kyphotic deformity were inversely correlated with eligibility for randomization ($P < 0.001$ for both). Using these 2 criteria plus age over 85 years, ossification of the posterior longitudinal ligament, and congenital canal stenosis as additional exclusion criteria, 12 of 20 survey cases were considered potentially eligible for randomization. Orthopedic and neurologic surgeons were similar in determining a case's eligibility for randomization.

Conclusions. These results measure surgeons' opinions on the suitability of cases for randomization and help to define entry and exclusion criteria for a RCT comparing ventral to dorsal strategies. Over 50% of CSM cases from a general spinal practice might be eligible for randomization.

Key words: survey, cervical spondylotic myelopathy, clinical trial design. *Spine* 2007;32:429–436

Cervical spondylotic myelopathy (CSM) is a common cause of neurologic morbidity, potentially resulting in a substantial decrease in quality of life as assessed by well-established health outcome instruments.¹ While many authors have advocated surgical decompression for CSM, the optimal surgical strategy remains controversial, and a variety of both ventral and dorsal approaches have been advocated.^{2–4} It is estimated that 30% of patients have an unsatisfactory outcome after surgery for CSM.⁵ Furthermore, the well-known surgical complication rate in multilevel cases underscores the importance of optimizing the operative approach for each patient.⁶ The prevalence of this disease in the elderly, who might be more susceptible to complications, emphasizes the importance of identifying the optimal surgical approach.

There are no established guidelines for the management of patients with CSM. Published series contain heterogeneous patient populations, various approaches, and the reported outcomes differ, rendering comparisons difficult.⁷ The current controversy over the best surgical approach to CSM (ventral *vs.* dorsal) indicates the need for a well-conducted prospective randomized trial. This has been advocated by several authors, implying that participation in a multicenter trial would be of interest to spinal surgeons.⁸ While many clinical variables have been studied in relation to surgical approach and outcome, these factors have not been prospectively analyzed using established outcomes instruments. This has created significant controversy, even among experts, as to the optimal approach.

One crucial item in the design of a randomized controlled trial (RCT) in surgery is to define clearly the circumstances on which clinical uncertainty (equipose) exists between two or more interventions. Clinical equipose was defined by Freedman as “genuine uncertainty within the expert medical community” about the optimal treatment for a specific condition.⁹ The first step toward defining clinical equipose for a randomized study for CSM is to determine which types of cases are controversial among spinal surgeons with an expertise in the cervical spine. In order to define which cases might be appropriate for randomization, we designed a scientific survey which was administered to surgeons attending the Cervical Spine Research Society (CSRS) annual meeting in December 2004. The objective of the survey was to

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elicit spine surgeons' opinions on the suitability of a panel of test cases for randomization, and the results help to define possible entry and exclusion criteria for a randomized trial to determine the optimal surgical strategy for patients with CSM.

Materials and Methods

Respondents. Permission to survey registered meeting attendees at the December 2004 Cervical Spine Research Society was obtained from the CSRS Board. Surveys were provided to surgeons as they registered for the meeting. Completed surveys were collected during all 3 days of the meeting. Each survey included 10 demographic questions followed by 10 cases. The CSRS supplied relevant demographic information on all registered attendees, which allowed population-level comparisons between responding and nonresponding attendees.

Study Survey. Each survey included 10 cases randomly drawn from a panel of 20 consecutively treated cases pooled from 2 investigators' practices (Z.G., private community hospital practice, and J.-V.C., academic hospital practice, surgically treated patients over 2 years). Each case included a brief clinical vignette, sagittal MR and CT images, flexion-extension images (if available), and MR axial views of each region of stenosis. If present, spinal cord T2 signal abnormality was noted. The C2–C7 Cobb angle was recorded, and the number of stenosis levels was indicated for each case. In addition, any motion on flexion-extension images of the cervical spine was recorded. Each case presentation was followed by two questions. First, the respondent was asked to circle "Randomize" or "Do Not Randomize," indicating whether or not the surgeon would feel comfortable randomizing the patient to either a ventral or dorsal surgical strategy if he or she were participating in a randomized study. Second, each surgeon was asked to characterize his or her surgical approach to each case (ventral *vs.* dorsal *vs.* both), number of levels to be decompressed, fusion or not, and levels of screw fixation, if any.

Statistical Methods. Although surveys were distributed to all CSRS meeting attendees, only responses from physicians practicing in the United States were included in the analyses because demographic information on non-U.S. residents was not available.

Demographic information supplied by individual respondents was cross-referenced with aggregate demographic information (on all meeting attendees) to generate aggregate-level information on the nonresponding population. Fisher exact test and the Jonckheere-Terpstra test (for age and case volume) were then used to relate demographic and practice characteristics to responder status. Because individual-level information on nonrespondents was not available, only univariate analyses were possible. Respondents with missing practice or demographic information were omitted from analyses.

Individual Cases. Univariate analyses and multivariate logistic regression analyses were used to determine the characteristics predicting eligibility for randomization as well as preferred surgical approach for each case. Where appropriate, the regression analyses were adjusted for clustering of responses by case or surgeon using sandwich variance-covariance matrices.¹⁰

To compare eligibility for randomization according to surgeons' specialty (orthopedic surgery or neurosurgery), odds ra-

Table 1. Demographics and Practice Characteristics of Survey Respondents

Characteristic	Respondents (%)	Nonrespondents (%)
Specialty		
Orthopedics	64	76
Neurosurgery	35	24
Not known	1	0
Spinal fellowship	73	NA
Years in practice		
0–10	45	22
11–20	33	46
>20	20	19
Not known	2	13
Region		
Midwest	21	24
Mountain	4	4
Northeast	44	34
South	21	26
West Coast	8	11
Not known	2	0
No. of operative CSM cases/year		
0–5	8	NA
6–10	24	NA
11–20	31	NA
>20	37	NA
Not known		

NA indicates data not available.

tios for individual cases were calculated and combined using random-effects meta-analysis technique and RevMan Version 4.1 software (Update Software, Oxford, UK).

The data were analyzed using commercially available software (StatXact for Windows, Cytel, Cambridge, MA; Stata for Windows, Stata Corp., College Station, TX; S-PLUS Version 3.3 for Windows, Insightful, Seattle, WA; RevMan 4.1, Update Software, Oxford, UK).

Results

Characteristics of Survey Respondents and Comparison With Nonrespondents

Of the 239 CSRS meeting attendees who practiced in the United States, 91 completed and returned the survey (respondents). Demographic and practice characteristics of the respondents are summarized in Table 1. A total of 64% of respondents were orthopedic surgeons and 35% were neurosurgeons. Respondents and nonrespondents were similar in specialty ($P = 0.07$) and geographic location ($P = 0.6$); however, respondents were younger than nonrespondents ($P = 0.003$).

Characteristics of Respondents Willing to Serve as Investigators

A total of 52% (47 of 91) of respondents expressed interest in joining an RCT. Demographic and practice characteristics of respondents willing to serve as investigators are summarized in Table 2. Univariate analysis identified younger age ($P = 0.006$) and spinal fellowship training ($P = 0.007$) as predictors of willingness to serve as an investigator. In multivariate analysis adjusted for specialty, case volume, geographic region, both younger age ($P = 0.047$), and spinal fellowship training ($P =$

Table 2. Demographic and Practice Characteristics of Respondents Willing to Serve as Investigators*

Characteristic	%
Specialty	
Orthopedics	66
Neurosurgery	32
Not known	2
Spinal fellowship	85
Years in Practice	
0–10	57
11–20	30
>20	13
Region	
Midwest	21
Mountain	4
Northeast	40
South	28
West Coast	4
Unknown	2
No. of operative CSM cases/year	
0–5	2
6–10	21
11–20	38
>20	38

*A total of 47 of 91 (52%) survey respondents stated willingness to serve as investigators in a RCT.

0.048) remained independent and significant predictors of interest in joining a proposed randomized trial.

Preferred Ventral and Dorsal Surgical Approaches Among Respondents

Surgeons were asked to select their preferred operative strategy in the treatment of CSM. In Figure 1, surgeon responses specifying their preferred operative strategies for both ventral and dorsal approaches are shown. For a ventral approach, respondents were nearly equally divided between preference for multilevel discectomy (51%) or for corpectomy (49%). For a dorsal procedure, surgeons most commonly preferred laminectomy with fusion (51%), followed by laminoplasty (30%), or laminectomy alone (19%).

Demographic and Radiographic Characteristics of Survey Cases

The 91 respondents completed a survey that each contained 10 cases. These cases were randomly drawn from a group of 20 cases that represented consecutively treated cases from 2 of the investigators' practices (Z.G. and J.-V.C.). The cases were presented within each survey in random order.

Demographic and radiographic characteristics for each case are listed in Table 3. The mean age of the patients was 58 years (range, 18–87 years); 50% of the cases were male. Kyphosis (C2–C7 Cobb angle) was present in 6 (30%) of the cases. A segmental kyphotic deformity (defined in Figure 2) was present in 6 (30%) cases.

Case-Strategy Responses

There were 91 completed surveys containing 900 individual case-strategy responses; 85 surgeons responded to all 10 cases, 4 to 9 cases, 1 to 8 cases, and 1 to 6 cases; 51% of cases-strategy responses specified a ventral approach, 38% a dorsal approach, and 10% a combined ventral and dorsal approach. Fusion was recommended in 99% of cases when either a ventral or combined surgical approach was selected. In contrast, fusion was recommended in only 41% of cases when a dorsal approach was chosen ($P < 0.001$).

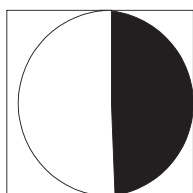
Eligibility of Individual Cases for Randomization

There were 898 case-responses that specified whether the surgeon considered the case eligible for randomization. Eligibility for randomization was defined as the percentage of respondents who selected "Randomize" after reviewing a particular case. Eligibility for randomization ranged from 23% of respondents (Case 11) to 78% of respondents (Case 16). Eligibility for randomization for all 20 cases is shown in Table 3. The order of case presentation within the survey did not affect eligibility for randomization ($P = 0.8$, logistic regression).

Specification of ventral or a combined approach *versus* a dorsal surgical approach affected eligibility for randomization. 65% of cases in which a dorsal surgical strategy was specified were considered eligible for randomization, compared with only 51% of cases for which a ventral or combined approach was specified ($P = 0.002$). Overall C2–C7 kyphosis with a Cobb angle $>5^\circ$ was associated with the choice of a ventral strategy ($P = 0.10$). Both overall cervical kyphosis and a segmental kyphotic deformity (defined in Figure 2) were inversely correlated with eligibility for randomization ($P < 0.001$ for both, Table 4).

Of the 91 respondents, 5 (5%) were not willing to randomize any cases; none of these 5 surgeons expressed willingness to be an investigator in a RCT. Ten respondents (9%), of whom 5 expressed willingness to join an RCT, were willing to randomize all survey cases examined. Overall, 57% of case-responses indicated willingness to ran-

Ventral Approaches



Dorsal Approaches



Figure 1. Surgeon-stated preferred approach for ventral and dorsal cases.

Table 3. Eligibility for Randomization and Characteristics of 20 Unselected Survey Cases of Cervical Spondylotic Myelopathy From 2 Surgeons' Practices

Subject No.	Age (yr)	Stenosis	C2-C7 Curvature*		T2 Signal†	SKD‡	Ventral§ (%)	Eligible (%)
1	67	3	6	L	No	Yes	44	44
2	61	4	2	K	No	Yes	12	45
3	64	2	29	L	Yes	No	34	64
4	72	3	20	L	No	No	32	77
5	42	3	4	K	Yes	No	75	42
6	64	2	1	K	No	Yes	72	57
7	66	4	11	L	No	No	8	62
8	77	4	22	L	Yes	No	17	57
9	42	3	7	L	No	No	89	62
10	53	3	6	K	No	No	83	34
11	59	2	10	K	Yes	Yes	80	23
12	61	3	5	K	Yes	Yes	37	51
13	47	3	10	L	Yes	No	38	74
14	51	2	18	L	No	No	70	66
15	58	2	32	L	No	No	26	56
16	49	2	15	L	Yes	No	65	78
17	87	4	10	L	Yes	No	6	47
18	18	3	15	L	Yes	No	50	74
19	32	3	4	L	Yes	Yes	84	48
20	52	2	5	L	No	No	83	76

*C2-C7 curvature is expressed as the Cobb angle (in degrees) followed by K (kyphosis) or L (lordosis).

†T2 intramedullary signal abnormality on cervical spine MR imaging.

‡Segmental kyphotic deformity as defined in Figure 2.

§Percentage of surgeons who selected a ventral strategy for the case.

||Percentage of surgeons who selected "randomize" after reviewing the case.

domize. Level of experience did predict willingness to randomize, but not for particular cases. "Younger" surgeons (those with less than 10 years experience) were more willing to randomize in general than "older" surgeons ($P = 0.04$), but a heterogeneity analysis (Figure 3) showed remarkable agreement in each case's "randomizability" between younger and older surgeons (P for heterogeneity = 0.88).

Orthopedic Versus Neurologic Surgeons

Of the 898 case-responses indicating eligibility for randomization or not, there were 888 case-responses, which allowed comparison between the tendency to randomize for neurologic and orthopedic surgeon respondents. One com-

pleted survey did not indicate neurosurgical *versus* orthopedic training. Figure 4 shows eligibility for randomization of individual cases according to surgeon specialty. Orthopedic surgeons selected randomization in 57% of the case-responses and neurologic surgeons selected randomization in 56% ($P = 0.89$). There was no significant difference in tendency to consider individual cases eligible for randomization between specialties (P for heterogeneity = 0.06).

Entry and Exclusion Criteria for Future Prospective Surgical Trial of CSM

This survey was designed to provide a basis for defining the entry and exclusion criteria for a prospective surgical

Figure 2. Two cases with sagittal CT reconstructed images are depicted. A line is drawn from the dorsal caudal point of C2 to the dorsal caudal point of C7. If 3 or more levels of disc-osteophyte extend dorsal to the line, then the case has a segmental-cervical kyphotic deformity (SKD). **A**, Example of a case with SKD. C2-C7 Cobb angle is 6°. Eligibility for randomization was 44%. **B**, Case with no SKD. C2-C7 Cobb angle is 5°. Eligibility for randomization was 76%. Eligibility for randomization = percent of respondents selecting randomization to either a ventral or dorsal surgical strategy.



Table 4. Factors Associated With Eligibility for Randomization

Characteristic	P
Age	NS
Levels of stenosis	NS
T2 signal abnormality	NS
Presence of kyphosis	0.001
Segmental-kyphotic deformity	0.001
Ventral strategy	NS

NS indicates not significant.

trial of CSM. Using the factors defined as significant predictors of ineligibility for randomization (*i.e.*, overall cervical kyphosis or presence of a midcervical kyphotic deformity as defined in Figure 2) as exclusion criteria and adding age over 85 years, developmental narrow canal, and ossification of the posterior longitudinal ligament as additional exclusion criteria, we have formulated possible eligibility criteria for a future RCT comparing ventral to dorsal surgical approaches (Table 5). Using these criteria, 12 of the 20 survey cases would be defined as eligible for randomization. Among the respondents, eligibility for randomization among these 12 cases defined as “eligible” was 65% compared with 46% in the 8 cases defined as “ineligible” ($P < 0.001$, Figure 5). Eligibility for randomization was comparable for orthopedic (69%) and neurologic surgeons (63%) for these 12 cases ($P = 0.14$).

Discussion

Ninety-one CSRS meeting attendees completed a survey consisting of 10 cases randomly drawn from a panel of

20 consecutively treated actual cases of multilevel cervical spondylotic myelopathy. For each case, respondents indicated eligibility for randomization to either a ventral or dorsal surgery if he or she were participating in a RCT. In addition, each respondent was asked to characterize his or her surgical approach. Respondents and nonrespondents were similar in specialty and geographic location; 51% of respondents expressed an interest in joining a RCT. Younger respondents and those with spinal fellowship training were more likely to express interest in being an investigator. The current study identified 2 simple exclusionary criteria, C2–C7 kyphosis and segmental kyphotic deformity, that might be applied in a RCT comparing 2 types of surgical procedures for CSM. Using these criteria and adding age greater than 85 years, developmental narrow canal (12 mm), and ossification of the posterior longitudinal ligament as additional exclusionary criteria, 12 of 20 of the survey cases would be eligible for randomization. There was no apparent difference between orthopedic and neurologic surgeons in expressed willingness to randomize individual cases.

Prospective surgical trials comparing different procedures for a particular disease are rare in part because of the difficulty of recruiting patients to these trials. One of the major barriers to participation in a surgical trial is the “willingness to randomize” a patient. This is an altruistic act on the part of patients but requires individual physicians and patients to be convinced that there is a clinical equivalence (or equipoise) between different interventions.^{11–13} Clinical equipoise has been defined as “genuine uncertainty within the expert medical community” between different treatment options. The current study

Figure 3. Eligibility for randomization for the 20 individual cases comparing surgeons with 0 to 10 years experience (“younger”) to those with greater than 10 years experience (“older”). Each horizontal line represents an individual survey case. The central square marks the odds ratio estimate for eligibility for randomization compared between “younger” and “older” surgeons. Where the square is to the left of the central vertical line, “older” surgeons were more likely to randomize the case; and where it is to the right of the vertical line, “younger” surgeons were more likely to randomize the case. The length of each horizontal line represents the 95% confidence interval for the odds ratio estimate. Where the confidence interval includes 1 (the horizontal lines overlap the central vertical line), there was no significant difference between eligibility for “older” and “younger” surgeons (19 of 20 cases). The diamond (bottom line) indicates the pooled estimate of eligibility for randomization for all cases between the 2 groups (“older” vs. “younger”); the diamond is to the right of the central line, indicating “younger” surgeons were significantly more likely to randomize, in general, than “older” surgeons.

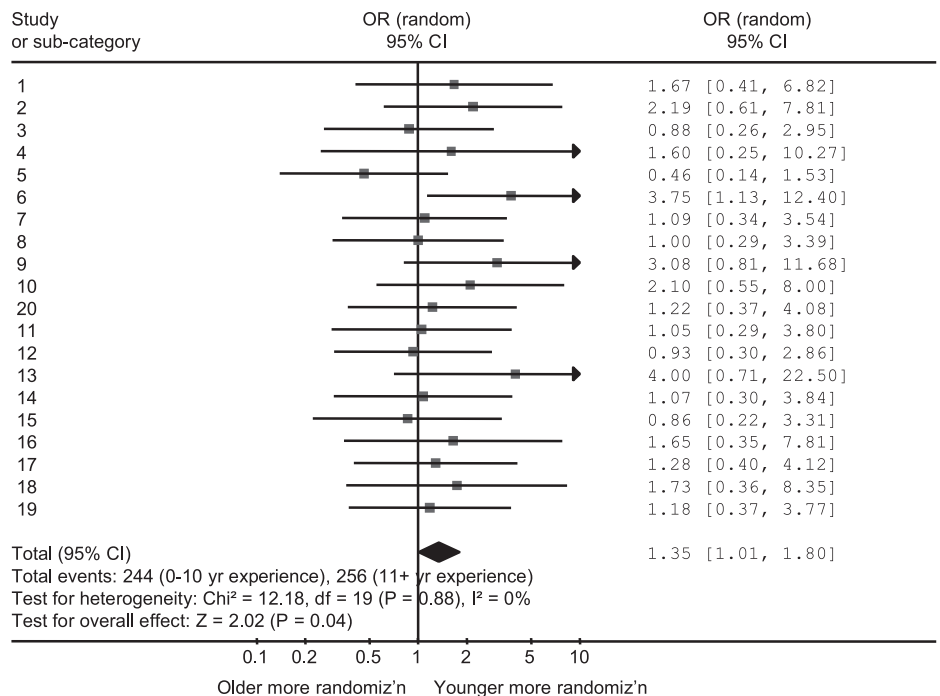
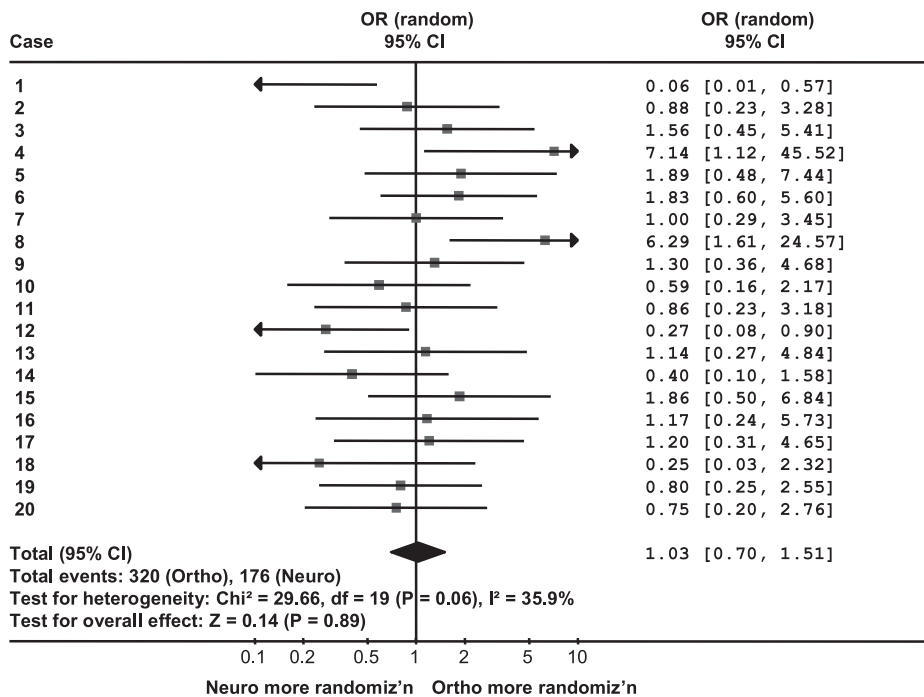


Figure 4. Eligibility for randomization for the 20 individual cases compared between orthopedic and neurologic surgeons. Each horizontal line represents an individual survey case. The central square marks the odds ratio estimate for eligibility for randomization compared between orthopedic and neurologic surgeons. The length of the line represents the 95% confidence interval for the odds ratio estimate. Where the confidence interval includes 1 (the horizontal lines overlap the central vertical line), there was no significant difference between eligibility according to orthopedic and neurologic surgeons (16 of 20 cases). The diamond (bottom line) indicates the pooled estimate of eligibility for randomization for all cases between the 2 specialties; it overlaps the central vertical line, indicating no significant specialty-related difference in eligibility for randomization.



demonstrates that clinical equipoise exists between ventral and dorsal procedures in a significant number of surgical cases of CSM. One possible effect of this type of study might be to encourage the participation of patients and clinicians in a randomized clinical trial comparing ventral and dorsal procedures. Importantly, since not all cases were equivalent in their suitability for randomization, analysis of the survey results allowed the definition of entry and exclusion criteria. The current study demonstrates that orthopedic and neurologic surgeons (attending a cervical spine meeting), regardless of the surgeon's years of experience, show remarkable agreement when reviewing a cases' eligibility for randomization. To our knowledge, the use of a survey of clinical experts to establish clinical equipoise between 2 spinal surgical procedures and to help clarify eligibility criteria for a planned RCT has not been reported previously.

A survey of surgeons attending a busy academic meeting to establish clinical equipoise between 2 alternative treatment options for the management of a specific dis-

ease is not a substitute for a systematic review.¹⁴ Recent Cochrane reviews have addressed the comparison of surgery *versus* conservative care for CSM; however, a systematic review of surgical approaches for CSM has not been yet published.¹⁵ The controversy between anterior *versus* posterior decompression in patients with myelopathy dates at least to 1952.¹⁶ In that year, Allen described results in a series of 8 patients and concluded that "when the distorting abnormality is placed in front of the cord it is futile to expect permanent relief from posterior decompression."¹⁶ Since then, numerous retrospective series have described the clinical and radiographic results of surgery for the treatment of CSM. In most cases, the patient characteristics determining the choice of one approach over another are not apparent, and good results

Table 5. Proposed Entry and Exclusion Criteria for a Prospective, Randomized Clinical Trial Comparing Ventral *Versus* Dorsal Decompression for Cervical Spondylotic Myelopathy (CSM)

Entry Criteria	Exclusion Criteria
Cervical cord compression (2 or more levels) from degenerative spondylosis with clinical myelopathy	1. C2-C7 kyphosis >5° 2. Segmental kyphotic deformity (as defined in Figure 2) 3. Ossification of posterior longitudinal ligament (OPLL) 4. Developmental narrow canal* 5. Age >85 yr

*Defined as an anteroposterior canal diameter less than 12 mm on lateral cervical spine radiograph.

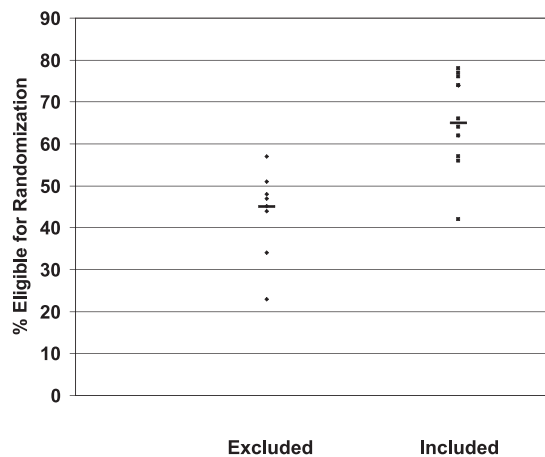


Figure 5. Eligibility for randomization of cases included and excluded by the criteria shown in Table 5. Median values are represented by horizontal bars. Cases defined as eligible by these criteria had significantly higher rates of eligibility for randomization according to survey results ($P < 0.001$).

have been reported with either approach.⁸ Some authors have advocated the use of flexion-extension MRI scans to influence the choice of approach.¹⁷ Others have chosen to approach CSM that is limited to 2 levels anteriorly, but favor a posterior approach in cases involving 3 or more levels unless there is loss of lordosis.⁸ Results from the current study suggest that most surgeons (two thirds or more) would not randomize a case if there was 5° cervical kyphosis or a segmental cervical kyphotic deformity. In these cases, a dorsal strategy is considered unsuitable by most surgeons. In other cases, greater than 40% of respondents would agree to randomize the case to either a ventral or dorsal strategy. These results, however, represent the ad hoc opinions of 91 surgeons who attended a cervical spine meeting. These results can serve as one piece of data that a panel of clinical researchers might consider in creating a set entry and exclusion criteria (Table 5) for an actual RCT comparing ventral and dorsal surgery for CSM.

Many surgeons expressed a preference for a particular type of ventral or dorsal approach. For example, surgeons were equally divided between corpectomy as opposed to multilevel discectomy in performing ventral decompression and fusion for CSM. One of the potential design goals of an RCT comparing surgical procedures would be to standardize the surgical approach.¹⁸ If a randomized clinical trial design called for ventral approaches to be done using multilevel discectomy with fusion, for example, participating surgeons who prefer (and therefore routinely perform) corpectomy might be less skilled in removing osteophyte and obtaining a satisfactory decompression using a multilevel discectomy approach. Devereaux *et al* have proposed expertise-based RCTs as a method for overcoming this particular problem in trials comparing surgical procedures where significant training and expertise (*i.e.*, volume) is required.¹⁹

There are no established guidelines for the surgical management of patients with CSM. Several studies have attempted to identify patient characteristics that might be associated with benefit from decompressive surgery.^{8,20–30} Factors examined have included the presence of T2 signal hyperintensity before and after surgery,^{27,30} the degree of spinal cord compression,^{20–23} the clinical severity of myelopathy,^{8,21,27} the duration of the disease,^{8,27} the degree of obstruction of cerebrospinal fluid flow past the region of stenosis,²⁹ and patient age.⁸ The significance of many of these variables as they relate to outcome, not to mention the choice of approach, remains controversial. With so many potentially confounding clinical variables, it is likely that only a randomized clinical trial would provide definitive data for comparing outcomes after ventral *versus* dorsal procedures, because of the biases that these variables would introduce in an observational trial.^{31,32}

Critics of the randomized clinical trial point to high costs, difficulties in obtaining funding, and lack of relevance of the results if no difference is found. In addition, there are significant barriers to recruiting both patients and busy cli-

nicians to participate. The SPORT trial, for example, funded by the National Institutes of Health is projected to cost 13.5 million dollars and plans to recruit about 1200 patients in its randomized study arms. This study randomizes patients to surgical *versus* nonsurgical therapy for 3 different types of lumbar spinal conditions for which surgery is often performed. The National Emphysema Treatment Trial enrolled 1200 patients, comparing medical and surgical treatments and cost more than 35 million dollars to complete over 6 years.³³ Simpler trial protocols with limited exclusion criteria and simple data collection instruments can sometimes reduce costs substantially, as demonstrated by Baigent *et al*.³⁴ Careful planning is mandatory both to reduce costs and to determine the feasibility of performing a randomized trial, once a relevant clinical question regarding the comparison of 2 or more established surgical procedures has been established.

One of the limitations of this type of study is that survey responses may not accurately predict the behavior of physicians participating in an actual RCT. Survey participants have less incentive to express a sincere opinion on a survey than they might in actual clinical practice. Insincere voting might tend to exaggerate or minimize eligibility for randomization depending on other agendas, such as the desire to participate in a trial, or to scuttle it. Within the respondents, there was a range of responses. Five respondents were unwilling to randomize any cases and 10 respondents (9%) were willing to randomize all survey cases. Furthermore, since the analysis was performed on only American surgeons attending the CSRS meeting, these data might not necessarily represent the views of all American surgeons, or more broadly, the global community of spine surgeons. Even if clinical equipoise for many types of cases of CSM is accepted by surgeons attending a scientific meeting (as our data suggest), an individual clinician involved in a RCT might feel that his experience or interpretation of the literature indicates a particular strategy might be superior for a specific patient. This problem, reviewed by Chard and Lilford,³⁵ can serve as a barrier to recruitment of patients into RCTs. Moreover, many patients when presented with 2 options will express a preference even if a surgeon has no preference and is willing to randomize. A pilot study would be essential in planning a RCT to establish preliminary outcomes data¹ (using the SF-36, the modified Japanese Orthopedic Association (mJOA) myelopathy scale, the Nurick scale, and a dysphagia complications assessment, *etc.*) in order to estimate the sample size necessary to conduct a RCT. In addition to a pilot study, a systematic review of the literature on ventral *versus* dorsal surgery for CSM by experts would provide surgeons with further data to support a RCT or not. Clarification of the degree of clinical uncertainty between ventral and dorsal surgery using a scientific review of the literature would also be important before proceeding with a RCT in order to convince surgeon investigators, who might otherwise be reluctant to randomize patients.

■ Conclusion

The present survey study, based on 20 actual clinical cases, has drawn from the expertise of 91 registered attendees of a recent CSRS meeting to elicit surgeons' opinions on the characteristics of patients with CSM requiring surgical decompression, which would be eligible for participation in a planned RCT. This study, based on surgeons' responses to a survey, demonstrates that more than 50% of cases of CSM seen in routine spinal surgical practice might be eligible for a randomized clinical trial comparing ventral and dorsal surgical approaches. Further work by clinical researchers with expertise in trial design and a systematic review of the literature will also be important to refine eligibility criteria for and determine feasibility of a RCT comparing ventral and dorsal surgery for CSM.

■ Key Points

- There is significant interest among spinal surgeons for a randomized controlled trial comparing ventral and dorsal procedures for CSM.
- Surgeons surveyed identified 5 simple exclusion criteria (kyphosis, a segmental kyphotic deformity, ossification of the posterior longitudinal ligament, developmental narrow canal [12 mm], or age greater than 85 years) that could be applied in a future randomized controlled trial.
- Greater than 50% of CSM cases from a general spine practice might be eligible for randomization according to survey results.

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