

Nonoperative Care Versus Surgery for Degenerative Cervical Myelopathy

An Application of a Health Economic Technique to Simulate Head-to-Head Comparisons

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Background: Degenerative cervical myelopathy (DCM) occurs when spondylotic changes compress the spinal cord and cause neurologic dysfunction. Because of a lack of comparative data on nonoperative care versus surgery for DCM, it has been difficult to support patients through the shared decision-making process regarding treatment options. Our objective was to synthesize the best available data in a manner that helps clinicians and patients to weigh the differences between nonoperative care and surgery at different ages and disease severity. The 2 patient-centered questions we sought to answer were (1) “am I more likely to experience worsening myelopathy with nonoperative care, or need more surgery if I have my myelopathy treated operatively?” and (2) “how much better will my quality of life be with nonoperative care versus surgery?”

Methods: We used a health economic technique, microsimulation, to model head-to-head comparisons of nonoperative care versus surgery for DCM. We incorporated the best available data, modeled patients over a lifetime horizon, used direct comparators, and incorporated uncertainty in both natural history and treatment effect.

Results: Patients with mild DCM at baseline who were ≥ 75 years of age were less likely to neurologically decline under nonoperative care than to undergo a second surgery if the index surgery was an anterior cervical discectomy and fusion (ACDF), cervical disc arthroplasty (ADR), or posterior cervical decompression and instrumented fusion (PDIF). Using quality-adjusted life-years (QALYs), our results suggest that surgery for DCM may be superior to nonoperative care. However, for all patients except those with severe DCM who are of middle age or younger (depending on the procedure, ≤ 50 to ≤ 60 years of age), the lower bound of the 95% confidence interval for the estimated difference in QALYs was < 0 .

Conclusions: In most patient groups, neurologic progression with nonoperative management is more likely than the need for additional cervical surgery following operative management, with the exception of patients 75 to 80 years of age and older with mild DCM. Furthermore, on average, surgery for DCM tends to improve quality of life. However, patients with DCM who are older than middle age should be aware that the estimates of the quality-of-life benefit are highly uncertain, with a lower bound of < 0 .

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

Cervical spondylosis is a common condition, with a prevalence that varies according to patient age (e.g., 70% of 70-year-old patients)¹. Progressive neurologic dysfunction may develop in the form of radiculopathy and/or myelopathy. A previous study found that approximately 1 in 4 nonmyelopathic patients with spondylotic cord compression developed clinical myelopathy at a median of 44 months of follow-up². Degenerative

cervical myelopathy (DCM) occurs when spondylotic changes compress the spinal cord^{3,4} and is characterized by fine-motor dysfunction of the hands, upper-extremity sensory changes, gait dysfunction, and/or bladder/bowel incontinence.

To protect against progressive neurologic dysfunction as well as catastrophic spinal cord injury, current clinical practice guidelines recommend surgical decompression for patients

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with moderate-to-severe symptomatic DCM, the consideration of surgery in addition to structured rehabilitation for mildly symptomatic patients, and close observation for patients with asymptomatic spinal cord compression^{5,6}. Unadjusted cervical surgery rates, for all diagnoses, are accelerating in the United States, and increased 206% between 1992 and 2005⁷.

Cervical spine surgery is primarily offered to halt the progression of DCM and has been shown to improve neurologic deficits as measured by the modified Japanese Orthopaedic Association (mJOA) scale⁸⁻¹¹. Although surgery is often effective, 1 in 4 patients will not achieve the minimally important difference (MID) on the mJOA, and approximately 15% of surgical patients will experience a major complication¹⁰⁻¹². Moreover, some studies have found that the risk of worsening myelopathy following surgery is nearly equivalent to the annual probability of acute spinal cord injury in nonoperatively treated patients with DCM (see Appendix 1 Table A1). Given that surgery is primarily offered to arrest, and not ameliorate, myelopathy, operative management should be reserved for patients in whom the risk of DCM progression is greater than the risks of surgery.

There is limited evidence to inform the effectiveness of surgery versus nonoperative care for DCM. A widely cited guideline from the AO Spine North America and the Cervical Spine Research Society (AO/CSRS) found only 1 comparative study on surgery versus nonoperative care for DCM⁶. Given the low-quality evidence on treatment for DCM, shared decision-making should be used to ensure that patients' decisions reflect their values and preferences¹³.

Shared decision-making is a process by which clinicians and patients jointly deliberate treatment options and related risks^{14,15}. Although considered a key element of high-quality care, shared decision-making has been shown to be underutilized in surgical practice¹⁶. A potential barrier to the implementation of shared decision-making in DCM is the paucity of comparative studies and relevant data on the (un)certainty around relative benefits and risks of treatment options.

In this study, we used a microsimulation strategy to simulate head-to-head comparisons of nonoperative care versus surgery for DCM. Microsimulation is an established health

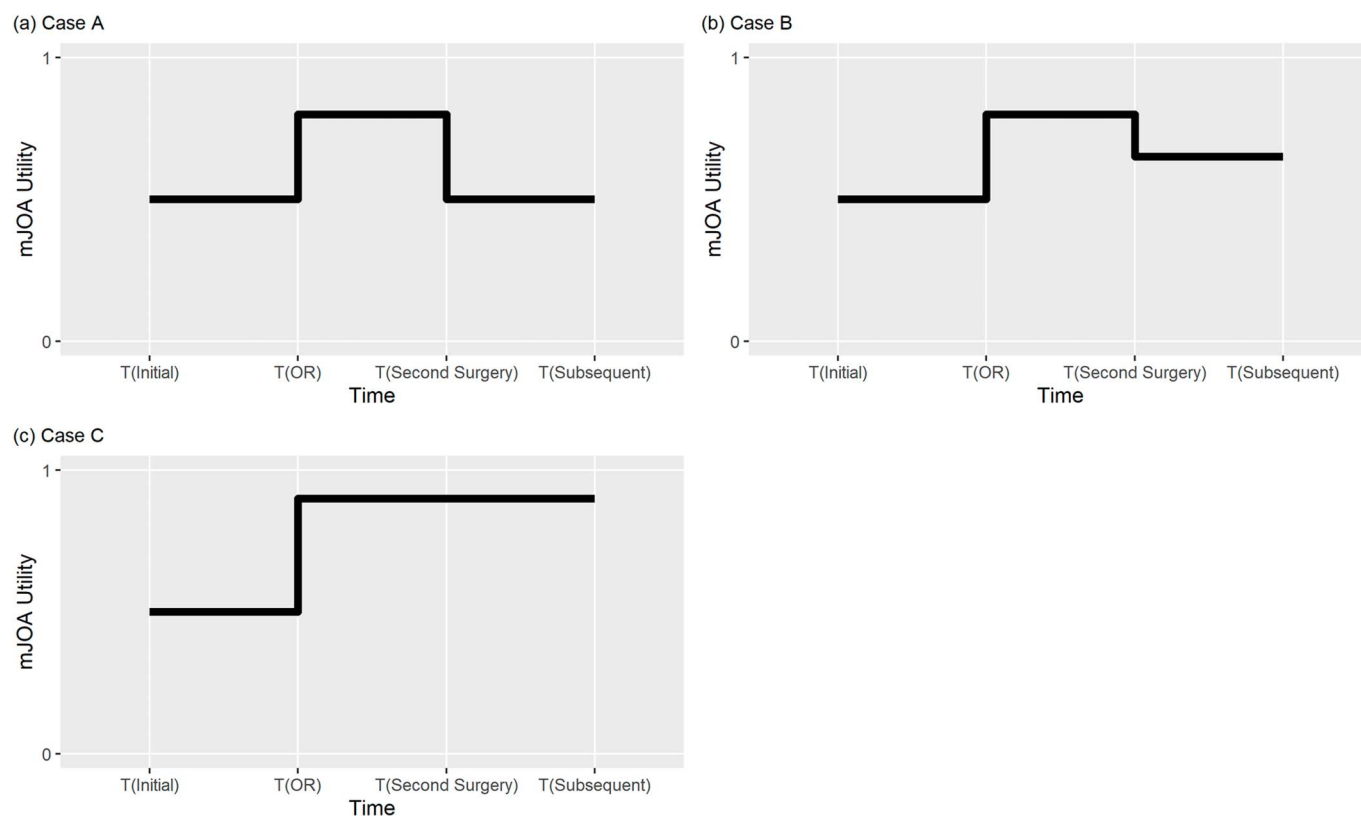


Fig. 1 Modeling of quality of life for surgically treated patients. In all cases, surgical patients immediately experienced a neurologic improvement in the mJOA score after the first surgery (OR). The magnitude of change was drawn from a probability distribution for change scores obtained from the pooled published data (Appendix 2). In Case A, at the time to second surgery (TTSS), patients reverted to their baseline mJOA health state; for example, this corresponds to patients with adjacent-segment disease developing worsening myelopathy without neurologic improvement following the second surgery. In Case B, at TTSS, patients were assigned a utility between the baseline mJOA health state and neurologically improved mJOA health state; for example, this corresponds to patients with adjacent-segment disease developing worsening myelopathy, with neurologic improvement following the second surgery. In Case C, at TTSS, patients did not experience a decline in mJOA health state; for example, this corresponds to patients undergoing a second surgery for pseudarthrosis.

TABLE I Life Expectancy of the Simulated Cohort

Baseline Age (yr)	Life Expectancy (yr)
40	83.9
45	84.3
50	84.6
55	85.1
60	85.6
65	86.4
70	87.4
75	88.8
80	90.5
85	92.8

economic technique that is particularly useful when controlled experiments are rare or unethical, as it allows investigators to leverage existing data to draw unique conclusions¹⁷. This technique is now widely used to study chronic diseases, infectious diseases, and cancer, and to guide public-policy decisions¹⁸⁻²². Results are presented in a manner that helps clinicians and patients weigh the differences between nonoperative care and surgery, including the associated uncertainties, as part of the shared decision-making process. This approach empowers patients to make decisions in line with their values and preferences.

Materials and Methods

Overview of Decision Model

We used microsimulation to build realistic models of both operative and nonoperative care for DCM that account for risk factors and changing event rates over time^{18,23}. Reporting was conducted in accordance with Consolidated Health Economic Evaluation Reporting Standards 2022²⁴.

Health Economic Analysis Plan and Rationale and Description of Model

Analyses were planned a priori to support shared-decision-making conversations. It has been shown that patients have difficulty understanding probabilities and uncertainty around outcomes²⁵. Therefore, our analyses were designed to answer 2 clear questions: (1) Am I more likely to experience worsening myelopathy with nonoperative care, or need more surgery if I have my myelopathy treated operatively? (2) How much better will my quality of life be with nonoperative care versus surgery?

The first question was structured to address the U.S. Food and Drug Administration (FDA) definition of “success” for the evaluation of total artificial disc Investigational Device Exemption (IDE) applications²⁶. Many of these IDE applications included patients with DCM, and therefore, we felt these criteria to be relevant. The FDA instructs that “success” be based on improvement in pain, improvement in function, the absence of a new neurologic deficit, the absence of a secondary

surgical intervention, and the absence of a serious adverse event. We sought to simulate this composite end point using the best available data. Comprehensive data were only available for neurologic deficits and secondary surgical interventions.

We implemented a probabilistic microsimulation model, through Monte Carlo sampling of the Bayesian posterior distributions for model parameters estimated by the meta-analyses, on the risks of neurologic progression and second surgery using R (R Foundation for Statistical Computing)²⁷. Since Bayesian analysis yields probability distributions jointly for all parameters²⁸, it was not necessary to directly specify covariance.

In Analysis 1, we computed the time to neurologic progression (TTNP) for patients undergoing nonoperative care, and the time to second surgery (TTSS) for patients undergoing initial surgery. No event occurred if that time (TTNP or TTSS) was greater than the predicted survival.

In Analysis 2, we computed the difference in predicted quality-adjusted life-years (QALYs).

Study Population

The simulation was run with different baseline ages (40, 45, 50, 55, 60, 65, 70, 75, 80, and 85 years) and baseline DCM severity (mild, with an mJOA of 15 to 17; moderate, with an mJOA of 12 to 14; and severe, with an mJOA of ≤ 11). In total, we simulated 3,000,000 patients undergoing nonoperative care, and 12,000,000 patients undergoing surgical treatment.

Comparators

In each simulation, we followed 100,000 patients with DCM undergoing each of the following methods of care: (1) nonoperative care, (2) anterior cervical discectomy and fusion (ACDF), (3) cervical disc arthroplasty (ADR), (4) cervical laminoplasty (LAMP), and (5) posterior cervical decompression and instrumented fusion (PDIF).

Time Horizon

Life expectancy was predicted using 2017 to 2019 Canadian life tables²⁹. The simulation was run until patient death.

TABLE II Distribution of mJOA Scores

mJOA Score	Mild DCM Cohort	Moderate DCM Cohort	Severe DCM Cohort
17	11.8%		
16	29.4%		
15	58.8%		
14		22.9%	
13		33.3%	
12		43.8%	
11			30.5%
10			34.1%
9			35.4%

Selection and Measurement of Outcomes

For patients undergoing nonoperative care, we simulated the time to neurologic progression, TTNP. For patients undergoing surgical treatment, we simulated the time to second surgery, TTSS.

Valuation of Outcomes

Utilities for the QALY calculation were obtained from a general-population direct utility valuation study³⁰.

Analytics and Assumptions

In Analysis 1, we computed the TTNP with nonoperative care, and the TTSS for patients undergoing initial surgery. No event occurred if that time (TTNP or TTSS) was greater than the predicted survival.

In Analysis 2, we computed the difference in predicted QALYs.

mJOA scores were stochastically generated for each simulated patient. Nonoperatively treated patients remained in their baseline mJOA health state until the TTNP, when they experienced a stochastic neurologic decline. Neurologic decline was implemented as an mJOA change corresponding to the MID for disease severity: (1) 1-point decline for baseline mild DCM, (2) 2-point decline for baseline moderate DCM, and (3) 3-point decline for baseline severe DCM¹². Change scores for the mJOA were implemented using a multinomial distribution as shown in Appendix 2 Table A2b.

Characterizing Heterogeneity and Distributional Effects

A meta-analysis of the natural history of DCM was used to populate our decision model³¹. A Bayesian Gompertz survival regression model was used to simulate the TTNP for each simulated patient, one-by-one.

A meta-analysis of the TTSS for patients undergoing ACDF, ADR, LAMP, and PDIF was also used to populate our model³². The log-normal survival regression model was used to simulate the TTSS for each simulated patient, one-by-one.

Characterizing Uncertainty

Modeling for surgically treated patients was run using 3 separate patterns of neurologic change affected by surgery (Fig. 1). In all cases, surgical patients immediately experienced a neurologic improvement in mJOA score after the first surgery. The magnitude of change was drawn from a probability distribution for change scores obtained from the pooled published data (see Appendix 2 Tables A2a and A2b). Our model permitted an immediate change in the mJOA to a perfect score of 18 (for example, the maximum allowable change was 9 points for a severely myelopathic patient with a baseline mJOA score of 9). In Case A, at TTSS, patients reverted to their baseline mJOA health state; for example, this corresponds to patients with adjacent-segment disease developing worsening myelopathy without neurologic improvement following the second surgery. In Case B, at TTSS, patients were assigned a utility between the baseline mJOA health state and a neurologically improved mJOA health state; for example, this corresponds to patients with adjacent-segment disease developing worsening myelopathy, with neurologic improvement following the second surgery. In Case C, at TTSS, patients did not experience a decline in mJOA health state; for example, this corresponds to patients undergoing a second surgery for pseudarthrosis.

Results

Study Parameters

The 10-year neurologic progression-free survival for patients with mild and moderate-to-severe DCM was 68% and

TABLE III Percentage of Patients with TTNP Less Than TTSS or Death for Surgery Versus Nonoperative Care*

Cohort Age (yr)	Mild DCM (%)				Moderate-to-Severe DCM (%)			
	ACDF	ADR	LAMP	PDIF	ACDF	ADR	LAMP	PDIF
40	54.51	53.35	57.00	53.85	93.98	91.75	98.90	93.11
45	54.37	53.23	56.88	53.75	93.76	91.53	98.64	92.87
50	54.19	53.05	56.67	53.60	93.36	91.18	98.25	92.48
55	53.89	52.78	56.35	53.35	92.82	90.65	97.61	91.97
60	53.41	52.36	55.82	52.80	91.85	89.74	96.55	91.09
65	52.76	51.66	55.06	52.23	90.39	88.38	95.03	89.74
70	51.62	50.59	53.83	51.11	88.18	86.27	92.61	87.59
75	49.79	48.96	51.98	49.55	84.82	83.11	88.94	84.28
80	47.31	46.51	49.26	47.04	79.97	78.29	83.56	79.59
85	43.94	43.20	45.58	43.67	73.53	72.03	76.40	73.15

*A proportion of <50% indicates that nonoperative care is superior; a proportion of >50% indicates that surgery is superior. TTNP = time to neurologic progression, TTSS = time to second surgery, DCM = degenerative cervical myelopathy, ACDF = anterior cervical discectomy and fusion, ADR = cervical disc arthroplasty, LAMP = laminoplasty, and PDIF = posterior cervical decompression and instrumented fusion.

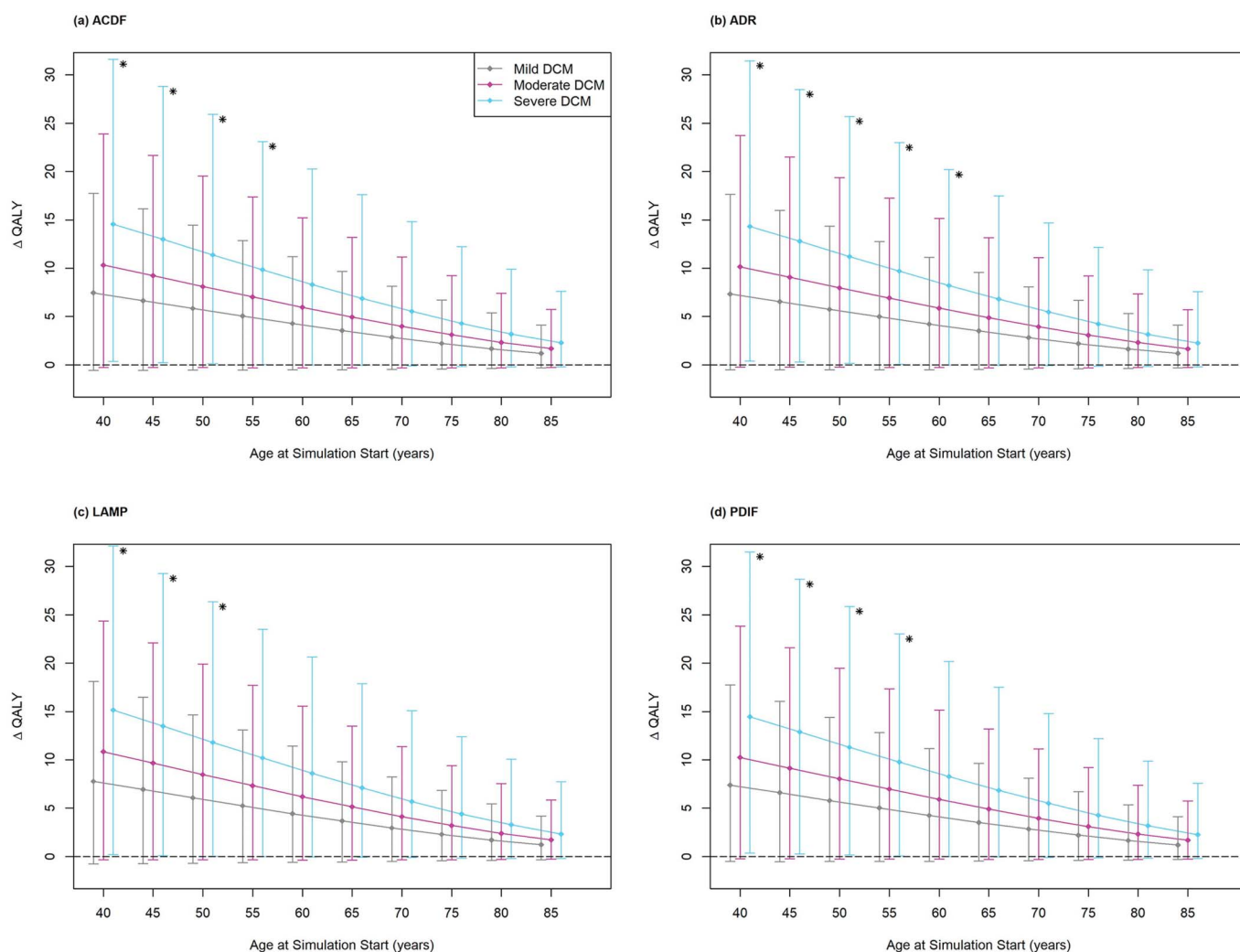


Fig. 2
Difference in quality-adjusted life-years (Δ QALYs) for surgery versus nonoperative care among simulated patients undergoing anterior cervical discectomy and fusion (ACDF) (Fig. 2-A), cervical disc arthroplasty (ADR) (Fig. 2-B), cervical laminoplasty (LAMP) (Fig. 2-C), or posterior cervical decompression and instrumented fusion (PDIF) (Fig. 2-D). Asterisks indicate that the lower bound of the 95% confidence interval for the estimated Δ QALY was >0 (indicating surgery was superior). The lower bound was >0 only for patients with severe DCM undergoing ACDF at an age of ≤ 55 years, ADR at an age of ≤ 60 years, LAMP at an age of ≤ 50 years, and PDIF at an age of ≤ 55 years. Whiskers indicate the 95% confidence interval.

46%, respectively. The 10-year second-surgery-free survival for ACDF, ADR, LAMP, and PDIF was 88%, 84%, 99%, and 86%, respectively. Life expectancy for the simulated cohort is shown in Table I. The distribution of mJOA scores for simulated patients with mild, moderate, and severe DCM is shown in Table II.

Neurological Progression and Second Surgeries

The percentage of nonoperatively treated patients expected to neurologically decline before those treated operatively required a second surgery (TTNP $<$ TTSS or death) is shown in Table III. Patients with mild DCM at baseline who were ≥ 75 years of age were less likely to neurologically decline under nonoperative care than to undergo a second surgery if the index surgery was an ACDF, ADR, or PDIF. Once ≥ 80 years of age, patients with mild

DCM at baseline were also more likely to undergo a second surgery after LAMP. For patients with moderate-to-severe DCM at baseline, neurologic progression after nonoperative care was more likely than second surgery for all age groups.

QALYs

The differences in QALYs between nonoperative care and surgery for patients with baseline mild, moderate, and severe myelopathy are shown in Figure 2 and Appendix Tables A3, A4, and A5. Under all simulation conditions, for all baseline DCM severities, the mean point estimates of the QALY difference (Δ QALY) were positive, indicating that surgery was favored over nonoperative care. Δ QALYs increased with baseline DCM severity. Δ QALYs were also inversely related to baseline cohort age.

However, there was high uncertainty in the QALY estimates. For the majority of simulations, the lower bound of the 95% confidence interval for the estimated Δ QALY was <0 (indicating nonoperative care was superior). The lower bound was >0 only for patients with severe DCM undergoing ACDF at an age of ≤ 55 years, ADR at an age of ≤ 60 years, LAMP at an age of ≤ 50 years, and PDIF at an age of ≤ 55 years (Fig. 2).

Discussion

Because of a lack of comparative data on nonoperative care versus surgery for DCM, it has been difficult to support patients through the shared decision-making process regarding treatment options. When the quality of evidence is low, it is also important to articulate the (un)certainly around the relative benefits and harms of treatment options so that patients can make decisions that align with their values and preferences. In this study, we synthesized the best available evidence to simulate head-to-head comparisons of nonoperative care versus surgery for DCM.

The first question we sought to answer was “am I more likely to experience worsening myelopathy with nonoperative care, or need more surgery if I have my myelopathy treated operatively?” Our findings suggest that worsening myelopathy is less likely than second surgery following ACDF, ADR, or PDIF for patients ≥ 75 years of age with mild DCM, and following LAMP for patients ≥ 80 years of age with mild DCM. Patients with moderate-to-severe myelopathy, and younger patients with mild myelopathy, are more likely to experience worsening myelopathy than to need a second surgery.

The second question we sought to answer was “how much better will my quality of life be with nonoperative care versus surgery?” Using QALYs, our results suggest that, for patients overall, surgery for DCM may be superior to nonoperative care. However, for all patients except those with severe DCM who are of middle age or younger (depending on the procedure, ≤ 50 to ≤ 60 years of age), the lower bound of the 95% confidence interval for the estimated Δ QALY was negative, which indicates that nonoperative care would be superior.

Reconciling Our Findings with Current Guidelines

Using the GRADE approach³⁷, the AO/CSRS DCM guideline makes a “strong” recommendation in favor of surgery for patients with moderate-to-severe DCM⁶. When assessing the effectiveness of interventional procedures with the GRADE approach, randomized trials are initially classified as high-certainty evidence and observational studies, as low-certainty evidence; however, both may be further downgraded because of the risk of bias, imprecision, indirectness, inconsistency, and small study effects³³. The AO/CSRS guideline identified only 1 randomized trial exploring surgery versus nonoperative care for moderate DCM and only observational data for severe DCM³⁴. The GRADE approach typically does not allow for strong recommendations when the supporting evidence is only low or very low in certainty, and no exceptions were met for the

DCM guidelines³⁵. Thus, by the GRADE approach, the AO/CSRS guidelines should, at most, have suggested a weak recommendation for surgery over nonoperative care. This conclusion is consistent with our findings of high uncertainty regarding the benefit of surgery among all DCM severities.

Strengths

Our QALY estimates align with those reported in a previous decision analysis on DCM³⁶. However, in addition to stratifying results on the basis of age and procedure, our decision analysis incorporated 2 methodologic improvements that increase the fidelity and granularity of our model. We derived transition probabilities for neurologic deterioration and reoperation from meta-analyses. These studies incorporated data from 529 patients regarding natural history and 73,811 patients regarding second surgeries. Such extensive data input offers a more comprehensive and widely applicable perspective than prior studies. Additionally, the use of parametric survival curves allowed us to incorporate time-dependency in our decision model. Furthermore, in our decision analysis, the utility of neurologic deterioration was obtained from a direct general population utility valuation study for the mJOA³⁰. In contrast, previous work used a fixed value of 0.045, on the utility scale, for neurologic deterioration. Our approach allowed modeling of the differential impact of components of the mJOA on quality of life, and the differential marginal utility of change as related to DCM severity.


Limitations

Our analysis was constrained by the available data. In the natural history meta-analysis used to populate our decision model³¹, only 63 (12%) of the patients had baseline severe DCM. In the second-surgery meta-analysis used to populate our model, we were unable to control for surgical indications (DCM versus radiculopathy versus neck pain versus deformity). As a consequence of using a lifetime horizon, the survival curves for TTNP and TTSS were extrapolated beyond the observed data. However, these model inputs were of high quality; it is important to note that of the 13 primary studies incorporated in the meta-analyses used to populate this model, only 1 study had elements at high risk for bias. Limited available data also did not allow us to incorporate demographic variables such as level of education, activity, or work status.

Conclusions

Our health economic simulation comparing the effectiveness of nonoperative care versus surgery for DCM provides data that can be used in conversations of shared decision-making between patients and physicians. In most patient groups, neurologic progression is more likely than the need for additional cervical surgery, with the exception of patients 75 to 80 years of age and older with mild DCM. Furthermore, on average, surgery for DCM tends to improve quality of life. However, patients with DCM who are older than middle age should be aware of high uncertainty in the estimates of the quality-of-life benefit.

Appendix

 Supporting material provided by the authors is posted with the online version of this article as a data supplement at [jbjs.org \(http://links.lww.com/JBJSOA/A696\)](http://links.lww.com/JBJSOA/A696). ■

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