

Surgery for Degenerative Cervical Myelopathy: A Nationwide Registry-Based Observational Study With Patient-Reported Outcomes

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Received, February 11, 2021.

Accepted, May 16, 2021.

Published Online, July 29, 2021.

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BACKGROUND: Indications and optimal timing for surgical treatment of degenerative cervical myelopathy (DCM) remain unclear, and data from daily clinical practice are warranted.

OBJECTIVE: To investigate clinical outcomes following decompressive surgery for DCM.

METHODS: Data were obtained from the Norwegian Registry for Spine Surgery. The primary outcome was change in the neck disability index (NDI) 1 yr after surgery. Secondary endpoints were the European myelopathy score (EMS), quality of life (EuroQoL 5D [EQ-5D]), numeric rating scales (NRS) for headache, neck pain, and arm pain, complications, and perceived benefit of surgery assessed by the Global Perceived Effect (GPE) scale.

RESULTS: We included 905 patients operated between January 2012 and June 2018. There were significant improvements in all patient-reported outcome measures (PROMs) including NDI (mean -10.0 , 95% CI -11.5 to -8.4 , $P < .001$), EMS (mean 1.0 , 95% CI 0.8 - 1.1 , $P < .001$), EQ-5D index score (mean 0.16 , 95% CI 0.13 - 0.19 , $P < .001$), EQ-5D visual analogue scale (mean 13.8 , 95% CI 11.7 - 15.9 , $P < .001$), headache NRS (mean -1.1 , 95% CI -1.4 to -0.8 , $P < .001$), neck pain NRS (mean -1.8 , 95% CI -2.0 to -1.5 , $P < .001$), and arm pain NRS (mean -1.7 , 95% CI -1.9 to -1.4 , $P < .001$). According to GPE scale assessments, 229/513 patients (44.6%) experienced “complete recovery” or felt “much better” at 1 yr. There were significant improvements in all PROMs for both mild and moderate-to-severe DCM. A total of 251 patients (27.7%) experienced adverse effects within 3 mo.

CONCLUSION: Surgery for DCM is associated with significant and clinically meaningful improvement across a wide range of PROMs.

KEY WORDS: Cervical spine, Decompressive surgery, Degenerative, Degenerative cervical myelopathy, Observational study, Spine disorder, Spine surgery

Neurosurgery 89:704–711, 2021

<https://doi.org/10.1093/neuros/nyab259>

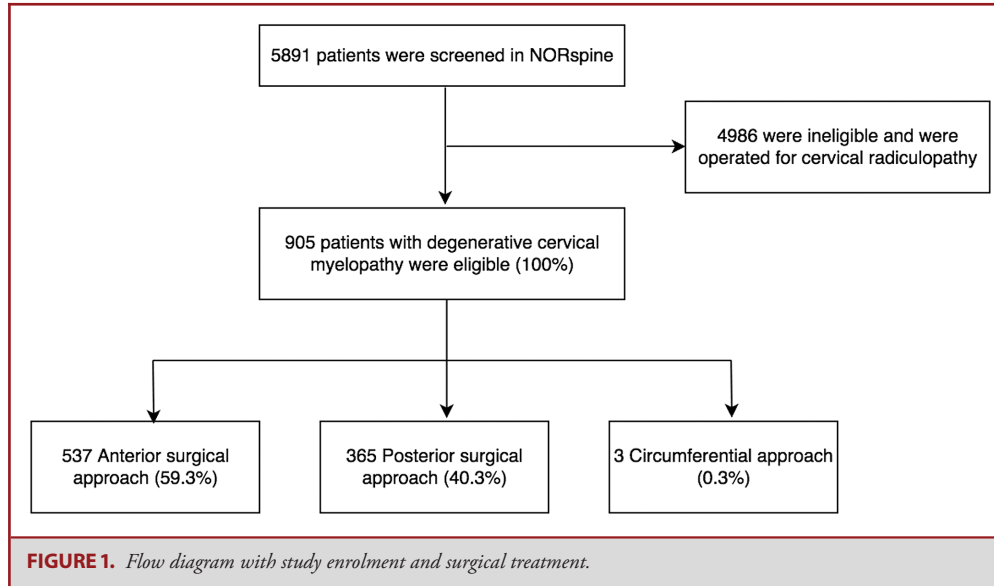
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Degenerative cervical myelopathy (DCM) is a progressive spine disorder and the most common cause of spinal cord impairment in adults over 55 yr.^{1–4} The cervical spine is prone to degenerative changes such as disk herniation, ligament hypertrophy or

ossification, and osteophyte formation that may lead to spinal cord compression and dysfunction.^{4,5} DCM should be considered in patients >50 yr with progressive neurological symptoms, such as pain and stiffness in the neck, pain and numbness in limbs, poor coordination, imbalance, loss of dexterity, frequent falls, and bowel and/or urinary incontinence.^{6,7} As nonspecific and subtle initial early features of DCM overlap with other neurological conditions, it is frequently challenging to catch the diagnosis early. Lack of awareness and incomplete neurological assessments can also delay diagnosis,⁸ and this may also increase patients’ risk of developing life-long disability and impaired quality of life.^{9,10} Magnetic resonance imaging (MRI) is the investigation of choice to detect spinal cord compression with

ABBREVIATIONS: DCM, degenerative cervical myelopathy; EMS, European myelopathy score; EQ-5D, EuroQoL-5D; GPE, Global Perceived Effect; MCIC, minimal clinically important change; mJOA, modified Japanese Orthopedic Association; NDI, neck disability index; NORspine, Norwegian Registry for Spine Surgery; NRS, numeric rating scales; PROM, patient-reported outcome measure

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or without intramedullary signal abnormalities and electrophysiologic testing can sometimes help exclude alternative diagnoses.^{7,11} Incidental degenerative changes in the cervical spine with spinal cord compression are commonly encountered on MRI and do not correlate well with the severity of symptoms.⁴ As the oldest sector of the population continues to grow and wishes to remain active, physicians will be required to manage an increasing number of patients with degenerative changes in the spine and DCM.^{4,12}

Indications and optimal timing for surgical treatment of DCM remain unclear, and additional high-quality data from daily clinical practice including all disease severities are warranted. According to current guidelines, surgery is recommended for moderate-to-severe or progressive DCM to prevent further deterioration.⁵ Two prospective multicenter AOSpine studies showed that decompressive surgery in selected patients can halt disease progression and achieve meaningful, albeit limited, recovery in pain, function, and quality of life.^{13,14} These 2 large studies were instrumental in driving the development of the 2017 AOSpine and Cervical Spine Research Society guidelines for management of DCM.⁵ Still, it is a common perception among health-care providers that chances of clinically relevant improvement following surgery for DCM are slim.

In this nationwide study with prospectively collected data from the Norwegian Registry for Spine Surgery (NORspine), we investigated clinical outcomes in patients undergoing decompressive surgery for DCM.

METHODS

Reporting is consistent with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement.¹⁵ The

TABLE 1. Personal Characteristics, Coexisting Illnesses, and Measures of Health

Variables	
Age, years (standard deviation [SD])	57.5 (+/-12.4)
Female	365 (40.3)
Married or partner	627 (69.3)
Current tobacco user	324 (35.8)
College education	281 (31.0)
Prior cervical spine surgery	102 (11.3%)
Body mass index (SD)	27.2 (+/-4.8)
Comorbidity	508 (56.1)
American Society of Anesthesiologists grade > 2	190 (21.0)
Ranawat grade 3A or 3B	339 (37.5)
Symptoms >1 yr	183 (20.2)
Preoperative EMS (SD)	14.3 (+/-2.4)
Preoperative NDI (SD)	34.9 (+/-16.8)
Preoperative EQ-5D (SD)	0.45 (+/-0.33)
Preoperative diagnostic imaging:	
MRI	885 (97.8)
Computed tomography	112 (13.5)
Myelography	2 (0.2)
Electrophysiologic testing	5 (0.6)

Values are numbers (percentages) unless stated otherwise.

Regional Committee for Medical Research Ethics approved the study (2016/840), and all participants provided written informed consent.

Study Population

NORspine is a comprehensive registry for quality control and research and includes all eight centers performing cervical spine surgery in Norway.^{16,17} Currently, approximately 81% of patients who undergo

surgery in the cervical spine in Norway are included in NORspine. The inclusion rate for DCM surgery is probably higher as these procedures typically are scheduled. NORspine participation was not a requirement for patients to gain access to treatment or for a provider to be eligible for reimbursement and payment. Patients were eligible if they were ≥ 18 yr, underwent decompressive surgery for DCM between January 1, 2012 and June 15, 2018, had a preoperative European myelopathy score (EMS) < 18 points, and were registered in NORspine.

Surgical Procedures

All patients underwent decompressive surgery of the cervical spine. The surgical approach, the number of operated levels, and the use and type of instrumentation were performed at the surgeons' discretion.

Outcome Measures

The primary outcome was change in the neck disability index (NDI) between baseline and 1 yr. Secondary outcome measures were changes at 1 yr in EMS, EuroQoL-5D (EQ-5D), and numeric rating scales (NRS) for headache, neck pain, and arm pain. In addition, we report complications occurring within 3 mo and patients' perceived benefit of surgery assessed by the Global Perceived Effect (GPE) scale at 1 yr.

The NDI is a self-rated questionnaire developed for patients with neck disability.¹⁸ The questionnaire is composed of 10 items: 7 related to activities of daily living, 2 to pain, and 1 to concentration. The sum of the 10 items is recalculated into a percentage NDI score from 0 to 100 (no to maximum disability). The minimal clinically important change (MCIC) is approximately 7.5 percentage points.^{19,20}

The EMS has 5 subscores obtained by patient questionnaires to evaluate the 4 major neural systems, the impairment of which contributes to the clinical picture of DCM: (a) the upper motor neuron with signs of spasticity as well as bladder and bowel disturbances; (b) the lower motor neuron with impairment of hand function; (c) the posterior roots with upper limb radicular deficits and paresthesias; and (d) the posterior columns with proprioceptive sensory loss, disturbed coordination, and ataxia.^{21,22} The total score ranges between 5 and 18, and the lower the score, the more severe the deficits. Scores ≥ 13 were classified as mild DCM and scores between 5 and 12 points were classified as moderate-to-severe DCM.²¹ There is no consensus of the MCIC for EMS, but even a small change in severe DCM might be considered important in daily function.

Changes in health-related quality of life were measured with EQ-5D.²³ An index value for health status is generated for each patient. Scores range from -0.6 to 1, in which 1 corresponds to perfect health. Effect size estimations were used to evaluate the magnitude of changes.²⁴ EQ-5D also contains a vertical visual analogue scale, ranging from 0 to 100 (lower scores indicate poorer health).

Intensities of headache, neck pain, and arm pain were assessed on 0 to 10 NRS, with response options ranging from 0 (no pain) to 10 (worst imaginable pain). The MCIC for NRS is approximately 1.5 points.²⁵

The GPE has 7 response categories: (1) complete recovery, (2) much better, (3) slightly better, (4) unchanged, (5) slightly worse, (6) much worse, and (7) worse than ever.²⁶

Surgeons provided the following data on perioperative complications: unintentional durotomy, nerve root injury, wrong level surgery, misplacement of implant, intraoperative hemorrhage requiring blood replacement, respiratory complications, anaphylactic reaction, spinal cord injury, esophageal injury, major vessel injury, cardiovascular complications, and other nerve injury. Patients reported the following complications if occurring within 3 mo: wound infection, urinary tract infection,

pneumonia, pulmonary embolism, deep vein thrombosis, dysphagia, dysphonia, and new-onset arm or leg weakness.

Data Collection

On admission for surgery, the patients completed a self-administered questionnaire, which included questions about demographics, personal characteristics, and patient-reported outcome measures (PROMs). Using a standard registration form, surgeons recorded data on diagnosis, severity of DCM according to the Ranawat²⁷ classification of myelopathy, comorbidity, American Society of Anesthesiologists grade, image findings, and surgical procedure. NORspine distributed self-administered questionnaires to the patients by mail 3 and 12 mo after surgery. Nonresponders received 1 reminder with a new copy of the questionnaire.

Statistical Analysis

Statistical analyses were performed with SPSS (IBM Corp) version 26.0 and Software R (R Foundation for Statistical Computing) version 3.6.3. For statistical comparison tests, we defined the significance level as $P \leq .05$. Frequencies were used for demographic variables at baseline, and changes in PROMs were compared with paired-sample *T*-test.

Missing data were managed with mixed linear model analyses. Previous studies have shown that imputations are not required before performing a mixed model analysis on longitudinal data.^{28,29} Patients were not excluded from mixed model analyses if a variable was missing at some, but not all, time points following baseline.

Patient and Public Involvement

A member from The Norwegian Back Pain Association reviewed the study protocol and provided feedback concerning the study design.

RESULTS

Figure 1 shows the inclusion and exclusion process leading to 905 eligible patients. Baseline characteristics are presented in Table 1. Participants underwent surgery at 8 neurosurgical departments. The mean age was 57.5 \pm 12.4 yr, 365 (40.3%) were female, and 163 patients (18.0%) had moderate-to-severe DCM at baseline. In total, 697 participants (77%) provided patient reported outcome measures at 3 and/or 12 mo. The only differences in baseline characteristics between responders and non-responders were tobacco use (32.1% vs 47.6%, $P < .001$), age (58.3 vs 54.9 yr, $P < .001$), and life partner (73.1% vs 59.1%, $P < .001$). Preoperative EMS was missing in 89 patients (9.8%).

Primary Outcome

The mean NDI score at baseline was 35.1 and at 1-yr follow-up was 25.1 (difference -10.0 , 95% CI -11.5 to -8.4 , $P < .001$). In patients with mild DCM, the mean NDI score at baseline was 32.2 and at 1-yr follow-up was 22.7 (difference -9.5 , 95% CI -11.7 to -7.9 , $P < .001$). In patients with moderate-to-severe DCM, the mean NDI score at baseline was 48.7 and at 1-yr follow-up was 34.9 (difference -13.8 , 95% CI -19.0 to -8.6 , $P < .001$). The mean change in NDI exceeded the MCIC of 7.5 points for all DCM severities.

TABLE 2. Complete Case Analysis and Mixed Linear Model Analysis for Outcomes at 1 yr in Patients With DCM

Variable	Baseline	1 yr	Mean change	95% CI	P-value
Complete case analyses:					
<i>All categories</i>					
NDI (N = 385)	35.1	25.1	-10.0	-11.5 to -8.4	<.001
EMS (N = 416)	14.3	15.2	1.0	0.8 to 1.1	<.001
EQ-5D summary score (N = 453)	0.45	0.61	0.16	0.13 to 0.19	<.001
EQ-5D VAS (N = 470)	49.1	62.9	13.8	11.7 to 15.9	<.001
Headache NRS (N = 435)	3.3	2.2	-1.1	-1.4 to -0.8	<.001
Neck pain NRS (N = 457)	4.8	3.0	-1.8	-2.0 to -1.5	<.001
Arm pain NRS (N = 459)	5.1	3.5	-1.7	-1.9 to -1.4	<.001
<i>Mild myelopathy</i>					
NDI (N = 298)	32.2	22.7	-9.5	-11.7 to -7.9	<.001
EMS (N = 330)	15.3	15.8	0.5	0.4 to 0.7	<.001
EQ-5D summary score (N = 338)	0.52	0.66	0.14	0.11 to 0.18	<.001
EQ-5D VAS (N = 345)	52.8	65.5	12.7	10.3 to 15.1	<.001
Headache NRS (N = 314)	3.1	2.1	-1.0	-1.4 to -0.7	<.001
Neck pain NRS (N = 332)	4.6	2.9	-1.7	-2.0 to -1.4	<.001
Arm pain NRS (N = 336)	4.8	3.2	-1.6	-1.9 to -1.3	<.001
<i>Moderate-to-severemyelopathy</i>					
NDI (N = 64)	48.7	34.9	-13.8	-19.0 to -8.6	<.001
EMS (N = 86)	10.4	13.0	2.6	2.0 to 3.2	<.001
EQ-5D summary score (N = 83)	0.18	0.44	0.26	0.16 to 0.36	<.001
EQ-5D VAS (N = 86)	35.3	53.1	17.8	12.0 to 23.5	<.001
Headache NRS (N = 83)	3.7	2.8	-0.9	-1.6 to -0.2	.009
Neck pain NRS (N = 83)	5.3	3.4	-1.9	-2.6 to -1.3	<.001
Arm pain NRS (N = 82)	5.8	4.1	-1.7	-2.5 to -0.9	<.001
Mixed linear model analyses					
<i>All categories</i>					
NDI (N = 854)	35.1	25.8	-9.4	-10.6 to -8.1	<.001
EMS (N = 880)	14.3	15.2	0.9	0.7 to 1.0	<.001
EQ-5D summary score (N = 887)	0.44	0.60	0.16	0.14 to 0.19	<.001
EQ-5D VAS (N = 884)	49.1	62.5	13.4	11.6 to 15.2	<.001
Headache NRS (N = 870)	3.2	2.1	-1.0	-1.3 to -0.8	<.001
Neck pain NRS (N = 882)	4.8	3.0	-1.7	-2.0 to -1.5	<.001
Arm pain NRS (N = 882)	5.0	3.4	-1.6	-1.9 to -1.4	<.001
<i>Mild myelopathy</i>					
NDI (N = 633)	32.3	23.1	-9.2	-10.6 to -7.8	<.001
EMS (N = 653)	15.3	15.8	0.5	0.3 to 0.6	<.001
EQ-5D Summary score (N = 647)	0.52	0.66	0.14	0.11 to 0.17	<.001
EQ-5D VAS (N = 645)	52.8	65.5	12.7	10.7 to 14.8	<.001
Headache NRS (N = 633)	3.0	2.0	-1.0	-1.3 to -0.7	<.001
Neck pain NRS (N = 642)	4.6	2.9	-1.7	-2.0 to -1.4	<.001
Arm pain NRS (N = 642)	4.8	3.2	-1.6	-1.9 to -1.3	<.001
<i>Moderate-to-severe myelopathy</i>					
NDI (N = 144)	48.8	35.3	-13.5	-17.3 to -9.7	<.001
EMS (N = 163)	10.4	13.0	-2.6	-2.1 to -3.0	<.001
EQ-5D Summary score (N = 162)	0.14	0.43	0.29	0.21 to 0.36	<.001
EQ-5D VAS (N = 159)	36.0	53.6	17.6	12.8 to 22.3	<.001
Headache NRS (N = 156)	3.5	2.6	-0.9	-1.5 to -0.4	<.001
Neck pain NRS (N = 158)	5.5	3.4	-2.1	-2.6 to -1.5	<.001
Arm pain NRS (N = 157)	5.8	4.0	-1.8	-2.4 to -1.1	<.001

Secondary Outcomes

PROMs are presented in Table 2. There were significant improvements in all PROMs at 1 yr including EMS (mean 1.0, 95% CI 0.8–1.1, $P < .001$), EQ-5D index score (mean 0.16, 95% CI 0.13–0.19, $P < .001$), EQ-5D visual analogue scale (mean 13.8, 95% CI 11.7–15.9, $P < .001$), headache NRS (mean –1.1, 95% CI –1.4 to –0.8, $P < .001$), neck pain NRS (mean –1.8, 95% CI –2.0 to –1.5, $P < .001$), and arm pain NRS (mean –1.7, 95% CI –1.9 to –1.4, $P < .001$).

The change in EQ-5D index score represents a moderate clinical change, with an effect size of 0.51. Further, there were significant improvements in all PROMs for both mild and moderate-to-severe DCM. The mean changes in neck and arm pain NRS exceeded the MCIC of 1.5 points. Mixed linear model analyses showed similar results for all PROMs

Patients' perceived benefit of surgery assessed by the GPE at 3 mo and 1 yr is presented in Figure 2A and 2B, respectively. According to GPE assessments, 229 out of 513 patients (44.6%) reported complete recovery or feeling much better at 1 yr. In total, 81 out of 513 patients (15.8%) reported feeling "slightly worse," "much worse," or "worse than ever" at 1 yr.

Table 3 provides details of surgical treatments and complications. There were no deaths within 30 d of surgery. In total, 251 patients (27.7%) experienced complications or adverse effects within 3 mo.

DISCUSSION

This nationwide study shows that surgery for DCM is associated with significant and clinically relevant improvements across the whole range of PROMs at 1 yr. Favorable outcomes were observed for both mild and moderate-to-severe DCM, with the largest effects observed in the latter more severely disabled group. Our study adds to the evidence from previous observational studies that surgical treatment cannot only arrest further progression of myelopathy, but also improve functional status, neurological outcomes, and quality of life.^{13,14,30} Although >70% of responders perceived a benefit from surgery, a substantial placebo effect cannot be ruled out following such complex treatment.³¹ Risk associated with surgery for DCM is not negligible and should be clearly communicated to patients prior to surgery. Patients should also be informed that complete resolution of symptoms is unlikely following surgery. Life-threatening complications and early reoperations are fortunately rare. In our study, 27.7% of responders experienced adverse effects or complications within 3 mo and 15.8% perceived a clinical worsening.

The epidemiology of DCM is poorly understood, and exact numbers of prevalence or incidence are not known. The prevalence of surgically treated DCM in Europe has been estimated between 1.6 and 4.7 per 100 000 inhabitants.^{32,33} It is important to refer patients with suspected DCM promptly to MRI and a specialist for consideration of decompressive surgery,

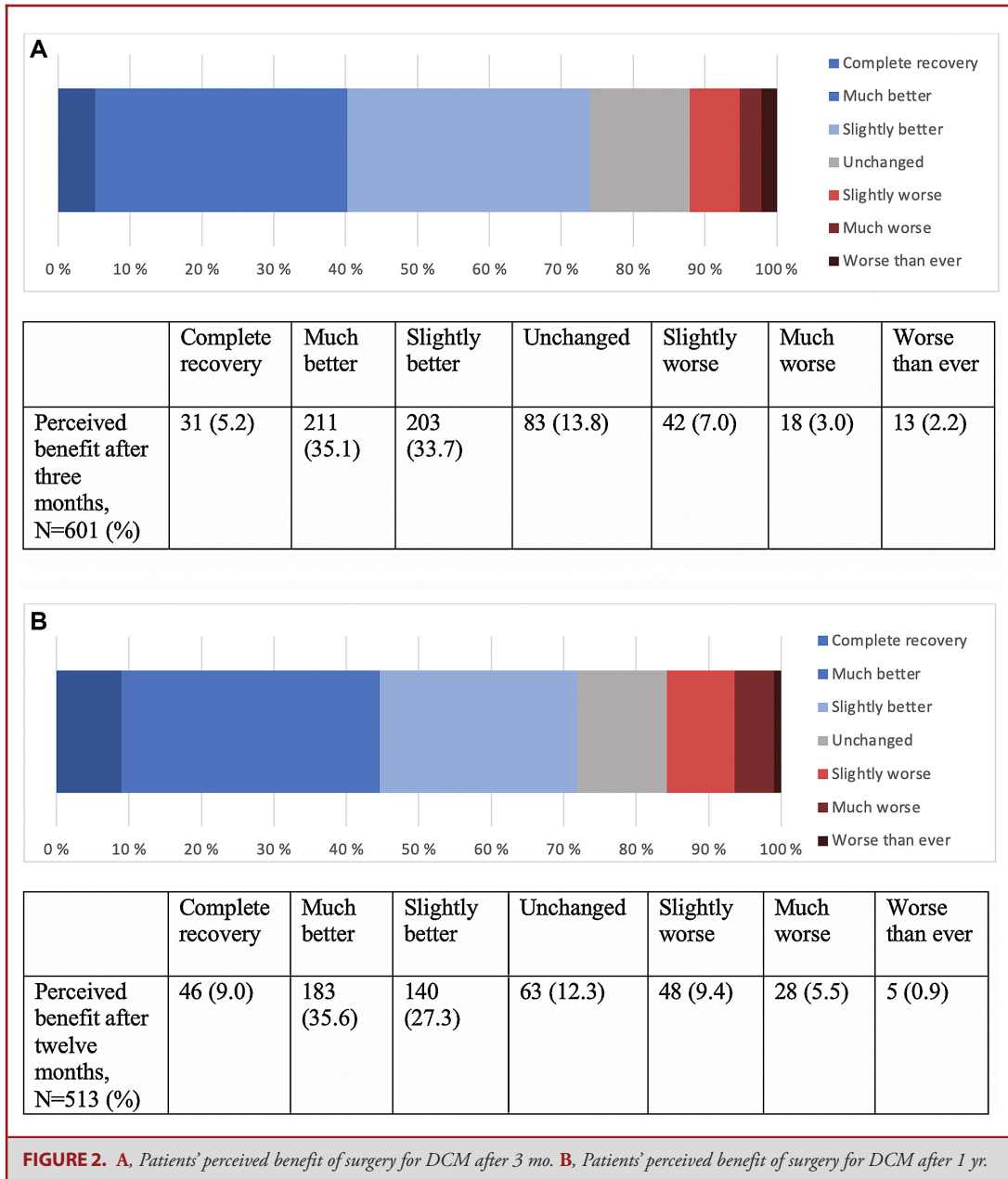
as delayed diagnosis and treatment can lead to unnecessary residual symptoms and worsening of disability. For nonmyelopathic patients without radiculopathy and only radiological evidence of cervical cord compression, prophylactic surgery is not recommended.^{5,6} These patients should be followed clinically if feasible and counseled as to potential risks of progression and advised to seek medical attention if symptoms should develop.

Until recently, there has been limited evidence to guide clinical management of mild DCM.⁵ In a large and recent prospective study on mild DCM with 2 yr follow-up, significant gains in a wide range of PROMs were observed following surgery.³⁴ Two small randomized trials in patients with mild-to-moderate DCM found no differences in neurological outcomes at 2 yr between those who received conservative vs surgical treatment.^{35,36} Still, the majority of patients in our study had mild DCM and significant improvements were observed for all PROMs. However, these improvements were smaller compared to patients with moderate-to-severe DCM. Although we have detailed clinical data at the time of surgery, little is known about the dynamics of symptoms, disability, and neurological functioning preceding surgery. A recent study showed that machine learning algorithms might become useful to identify patients with mild DCM that will benefit from surgery.³⁷ The phenotype of mild DCM needs to be acknowledged, and a recent study reported that neck pain, motor symptoms, and female gender were associated with greater impairment of quality of life and greater response to surgery.³⁸ Additional observational studies or clinical trials should be encouraged to clarify the natural course of the disease and evaluate surgery and structured rehabilitation for patients with mild DCM.

There are no randomized trials comparing surgical and nonsurgical management of patients with moderate-to-severe DCM. In a recent trial, adjuvant treatment perioperatively with riluzole (Aventis Pharma) did not improve functional recovery beyond decompressive surgery in patients with moderate-to-severe DCM.³⁹ Age-related degeneration of the cervical spine encompasses a complex set of anatomical changes that can result in DCM.⁴ Spine surgeons can draw from a repertoire of different operations to treat DCM, and the surgical strategy is typically based on patient specific factors and preferences of the surgeon. An interesting topic is the comparative efficacy and effectiveness of different surgical treatments.^{30,40-42} Unfortunately, this is beyond the scope of our study as we did not have detailed enough information in order to compare the effectiveness of different surgical procedures. Interestingly, a recent trial showed that an anterior surgical approach did not significantly improve outcomes compared with a posterior surgical approach.⁴³

Limitations

The modified Japanese Orthopedic Association (mJOA) scale is currently the recommended disease-specific PROM. The use



of the EMS might make it more challenging to compare results across more recent studies. This is to some extent alleviated by the use of the NDI and EQ-5D, which are included in recent studies on DCM. NORspine started including patients several years prior to the current practice guidelines.⁵ Solely assessing the myelopathy is likely insufficient to fully understand clinical outcome in its totality, and combinations of questionnaires are recommended.^{38,44,45} A study comparing 7 different scales, including mJOA and EMS, found that all of them detected

significant improvement following surgery.⁴⁶ Still, each scale had differing qualities of reliability, validity, and responsiveness. Lack of randomization is an obvious limitation. Loss to follow-up is another concern, but a previous NORspine study showed no difference in outcomes between responders and nonresponders.⁴⁷ Follow-up exceeding 1 yr may be warranted to detect the effect of surgery on progression of symptoms. Some patients may have received physical therapy, but our study cannot assess the impact of such interventions.

TABLE 3. Surgical Treatment, Complications, and Events

Variables	
Emergency surgery	137 (15.1)
Surgical approach	
Anterior	537 (59.3)
Posterior	365 (40.3)
Instrumented fusion	17 (1.9)
Circumferential	3 (0.3)
Number of levels decompressed, median (range)	2 (1-6)
Spine level of surgery	
C0-C1	3 (0.3)
C1-C2	4 (0.4)
C2-C3	54 (6.0)
C3-C4	258 (28.5)
C4-C5	389 (43.0)
C5-C6	580 (64.1)
C6-C7	327 (36.1)
C7-TH1	35 (3.9)
Operation time, min (SD)	92.5 (+/-42.7)
Number of days in hospital (SD)	1.7 (+/-1.8)
Reoperation within 90 d	5 (0.6)
Patients with complications	251 (27.7)
Perioperative complications	
Unintentional durotomy	4 (0.4)
Nerve root injury	0
Iatrogenic spinal cord injury	2 (0.2)
Wrong level surgery	0
Postoperative hematoma	2 (0.2)
Misplacement of implant	0
Esophageal injury	0
Major blood vessel injury	0
Cardiovascular complications	1 (0.1%)
Respiratory complications	1 (0.1)
Anaphylactic reaction	0
Other complications	5 (0.6%)
Complications within 3 mo	
Deep wound infection	9 (1.0%)
Superficial wound infection	35 (3.9%)
Urinary tract infection	41 (4.5%)
Pneumonia	12 (1.3%)
Pulmonary embolism	5 (0.6%)
Deep venous thrombosis	7 (0.8%)
New-onset arm or leg weakness	120 (13.3%)
Dysphagia	72 (8.0%)
Dysphonia	62 (6.9%)

Values are numbers (percentages) of participants unless stated otherwise.

CONCLUSION

Surgery for DCM is associated with significant improvements across the whole range of PROMs. Favorable outcomes were observed at 1 yr for both mild and moderate-to-severe DCM. Surgical treatment cannot only arrest further progression of myelopathy but also improve functional status, neurological outcomes, and quality of life.

Funding

This study did not receive any funding or financial support.

Disclosures

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

This work is in memory of Stein Andresen, former user representative in NORspine. The authors thank NORspine and are greatly indebted to all patients and spine surgeons who participated in NORspine registration.

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