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Patient-Reported Outcomes and Patient-Reported Satisfaction After Surgical Treatment for Cervical Radiculopathy

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Abstract

Study Design: Retrospective cohort study.

Objectives: It is estimated that 10 000 patients seek medical care due to cervical radiculopathy every year in Denmark. Although the natural course is usually favorable, around 20% undergo surgery for cervical degenerative disease every year in Denmark. We aim to evaluate the patient-reported results and satisfaction of anterior cervical decompression and fusion over a 5-year period from a single Danish center for spine surgery.

Methods: This study is a retrospective study based on prospectively collected data from 318 consecutive patients treated with anterior cervical decompression and fusion over 1 to 3 levels. Data in the DaneSpine registry was collected pre- and postoperatively, and at 1 year after surgery. The outcome measures were Neck Disability Index (NDI), European Quality of Life 5D (EQ-5D), visual analogue score (VAS), and Short Form-36 Physical Component Summary (SF-36 PCS).

Results: Of 318 cases enrolled, 272 (85.5%) had follow-up data available at a minimum 1-year postoperatively. The mean preoperative NDI was 40.0 and improved to 22.7. Mean EQ-5D was 0.50 and improved to 0.70, and mean VAS arm was 60.4 improved to 26.4. All improvements were statistically significant. A total of 74.3% were back to work 1 year after surgery. Achieving minimal clinically important difference (MCID) in VAS neck and SF-36 PCS was strongly correlated to patient satisfaction.

Conclusion: Patients who undergo anterior cervical discectomy and fusion can expect improvement in their pain and disability, with 74.3% of patients reporting a positive change in health status after surgery.

Keywords

cervical, degenerative disc disease, ACDF, radiculopathy, satisfaction, outcome, MCID

Introduction

Cervical radiculopathy is caused by compression or irritation of the nerve root in the foraminal canal, due to a combination of factors, including degeneration of the disc and the uncovertebral joints.[1] The rudimentary uncovertebral joints evolve with age, along with the formation of osteophytes in the processus uncinatus, may compress both the spinal nerve root and the vertebral artery passing through the intervertebral and transverse foramina.[2]

It is estimated that around 50% of the adult Danish population suffer from some degree of neck and/or arm pain.[3] Neck pain and radiculopathy caused by disc herniation is generally a self-limiting condition, and the natural course of cervical radiculopathy is generally favorable, with many patients experiencing relief of symptoms within a period of 4 to 6 months.[4] It is estimated that around 10 000 patients seek medical care due to severe cervical radiculopathy in Denmark every year. These

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patients are primarily treated with analgesics and in some cases physiotherapy.[5]

It is estimated that 2000 of these patients will undergo surgery for cervical degenerative disease every year in Denmark.[6] According to the Danish national spine database (DaneSpine), 4397 anterior cervical decompressions and fusions (ACDF) were performed in Denmark from 2009 to 2015, this may be an underestimation, as several clinics in Denmark did not report data to the national spine database in the beginning of the period.[7] Surgical treatment is reserved for patients suffering from persistent and disabling pain, after 6 to 12 weeks, or patients with progressive neurological deficits.[1]

Clinical presentation depends on the nerve root and disc space involved, and may include pain, sensory or motor deficits, diminished reflexes, or a combination of the above. An epidemiological study, performed from 1976 to 1990, found that monoradiculopathy involving the C7 nerve root to be the most frequent, followed by C6 monoradiculopathy. Disc protrusion, found on magnetic resonance imaging (MRI), was responsible for cervical radiculopathy in 21.9% of patients, and 68.4% were related to a combination of discus protrusion and spondylosis.[8] Earlier studies have reported that, patient satisfaction and patient-reported outcomes (PROs) are fair to good in around 80% of patients undergoing ACDF.[9] The purpose of this study is to present how the clinical outcome data correlates to postoperative satisfaction, and how many of our patients have improved clinically relevant at the 1-year follow-up.

Methods

Our study evaluates results based on PROs of 318 consecutive patients who had primary anterior cervical surgery for degenerative disc disease and/or spondylosis with radicular arm pain. Patients were treated over 1 to 3 levels, at a single institution in Denmark during a 5-year period from 2011 to 2016. Patients were treated with cages with or without anterior plates. Patients with myelopathy, previous surgery or surgery performed on more than 3 levels were excluded. For all questionnaires a minimal clinically important difference (MCID) is applied. The MCID is defined as the smallest meaningful difference in a score that the patients perceive as beneficial.[10]

Baseline patient characteristics and occupational status were collected from the DaneSpine questionnaire. PROs collected preoperatively and 1 year after surgery included the validated Danish versions of the Neck Disability Index (NDI),[11] EuroQoL-5D (EQ-5D),[12-14] visual analogue scale (VAS),[15] and the Short Form 36v1 (SF-36).[16,17]

The NDI is a 10-item self-administered disease-specific questionnaire evaluating the effect of neck pain on a patient's daily life and the corresponding disability. The questionnaire ranges from 0 to 50; the higher the score, the greater the disability. The MCID for this questionnaire is 7.5.[18] In our study, we report the percentage score from 0 to 100, thus an MCID of 15 is used.

The EQ-5D is a standardized generic questionnaire evaluating health state value on a scale between 0 and 1 where 0 equals death and 1 equals perfect health. As it is not disease specific, it is difficult to establish a true value of MCID. MCID for this questionnaire is highly dependent on the method of calculation and thus the threshold for EQ-5D ranges from 0.05 to 0.24.[19] For this study we used a MCID of 0.24 as suggested by a previous study on ACDF.[19]

The SF-36 is also a generic questionnaire consisting of 36 questions evaluating health status on multiple domains. The health transition item (HTI), is derived from the SF-36, and refers to how the patient feels at the time of the questionnaire compared with 1-year prior. One domain was used for evaluation of physical health, the Physical Component Summary (PCS) score. MCID for the PCS is 4.1.[18]

VAS is a linear scale of pain measurement, where 0 equals no pain and 100 equals extreme pain. VAS was obtained on a 10-cm line and response was converted to a 0 to 100 scale. VAS was obtained for both neck and arm pain. MCID for VAS is considered 25 for both arm and neck pain.[18]

Patient satisfaction was registered at 1-year follow-up and categorized as satisfied, uncertain or dissatisfied. Results were divided into 3 different patient-reported satisfaction grades, to present PRO data in each satisfaction group.

Patients were considered as lost to follow-up if all the PROs were missing at 1 year.

Paired t-tests were used to compare baseline and one-year outcomes. Categorical data is presented by frequencies and related percentages; continuous data is displayed by means and standard deviation. Continuous variables were analyzed for significant difference between the 3 groups using analysis of variance, categorical variables using chi-square test. To evaluate associations between achieving MCID for PRO data and satisfaction, logistic regression model was performed and data is presented as odds ratio and confidence intervals. All statistical analyses were performed using STATA (version 14.1) with the *P* value threshold for significance set at .01. Approval was obtained from the Danish Data Protection Agency. As this study was a retrospective review of data collected prospectively, and patients had already given consent to research being performed on their questionnaires, no approval from the National Committee on Health Research Ethics was needed.

Results

Among the 318 cases enrolled, a total of 272 (85.5%) had complete data after at a minimum of 1-year follow-up. Most patients had surgery over a single-level (53.6%), followed by 2 levels (41.8%). C5/C6 was the most common level of surgery (52.6%) followed by C6/C7 (41.0%). Among the surgical candidates; mean age was 49.9 years and 24.6% were smokers, baseline characteristics are reported in Table 1.

Patient-Reported Outcomes

At 1-year follow-up, there was a statistically significant reduction in NDI from 40.0 points preoperatively to 22.7 points at ($P < .001$). The mean EQ-5D score improved from 0.50 to 0.70

Table 1. Summary of Baseline Demographics and Patient-Reported Outcomes for Respondents.

Patients with follow-up, n (%)	272 (85.5)
Age, years, mean (SD)	49.9 (9.2)
Males, n (%)	140 (51.5)
Smokers, n (%)	67 (24.6)
BMI, kg/m^2, mean (SD)	26.5 (4.1)
Levels (%)	
1	53.6
2	41.8
3	4.6
Patient-reported outcomes, mean (SD)	
Neck Disability Index	40.0 (16.2)
EuroQoL-5D	0.50 (0.29)
Short Form 36 PCS	35.5 (7.9)
VAS neck pain	52.8 (27.9)
VAS arm pain	60.4 (25.1)

Abbreviations: BMI, body mass index; PCS, Physical Component summary; SD, standard deviation; VAS, visual analogue scale.

postoperative ($P < .001$). The mean preoperative SF-36 PCS was 35.5 and at 1-year follow-up the mean SF-36 PCS was 42.5($P < .001$). Both neck and arm pain were reduced at the time of follow-up. The mean improvement in VAS arm was 34.0 mm, compared to a baseline VAS arm of 60.4 mm ($P < .001$). Neck pain measured by VAS was reduced from 52.8 mm preoperatively, to 30.0 mm postoperatively, a reduction of 22.8 mm ($P < .001$) (Table 2).

Patient Satisfaction

When analyzed for patient satisfaction we found that 65.9% of the patients were satisfied, 28.2% were uncertain, and 5.9% were dissatisfied with the surgical result at 1-year follow-up. Patients, who were satisfied or uncertain of the outcome of surgery, had statistically significant improvement on all PROs. The improvements in the uncertain group were all significantly lower than for the satisfied group. The group of dissatisfied patients reported worsening in all parameters, compared to baseline (Table 2). When evaluating HTI from SF-36, we found that 73.3% of patients were much better or somewhat better than before surgery. When comparing patient satisfaction to SF-36 HTI we found that 86.2% in the satisfied group, 54.2% in the uncertain group, and 15.4% in the dissatisfied group reported that they were much better or somewhat better than the year before (Table 3).

In our study sample, 214 patients were employed or seeking employment before surgery. At 1-year follow-up 159 (74.3%) had returned to their preoperative working status. When comparing working status to postoperative satisfaction, we found that 83.3% of the satisfied group, 60.3% in the uncertain group and only 41.7% in the dissatisfied group were back to their preoperative working status after 1 year (Table 2).

When correlating satisfaction to NDI and VAS arm MCID, we found that of the patients who were satisfied after surgery, 70.8% achieved MCID for NDI, and 71.3% achieved MCID for VAS arm. In the uncertain group, 44.7% achieved MCID NDI, and 40.8% achieved MCID VAS arm. In the dissatisfied group, 25% achieved MCID for NDI and 12.5% achieved MCID for VAS arm (Table 4). When performing a logistic regression to predict satisfaction based on achieving MCID, we found an increased odds ratio of 3.42 for MCID VAS neck, and 2.33 for MCID SF36-PCS (Table 5).

Complications

The surgeon-reported complication rate was 4.1% (13/318). Complications reported included pulmonary embolus (1), deep vein thrombosis (1), postoperative surgical hematoma (2), Horner's syndrome (1), dural tear (7), and urinary tract infection (1). At 1 year, the patient-reported complications were 5.5% cases with self-reported postoperative paresis over the first 3 months, at the time of follow-up no cases had ongoing paresis. We found 67 (24.6%) cases with dysphonia lasting at least 1 month and 82 (30.1%) cases with dysphagia for at least 1 month.

Discussion

Anterior discectomy and fusion have shown clinical success with high patient satisfaction in earlier studies.[20,21] In our study, we demonstrate that ACDF surgery is capable of providing relief of symptoms and a positive outcome in most of our patients. Multiple randomized trials have compared ACDF with cervical disc replacement, and the short- and long-term results of these studies find that cervical disc replacement is a valid alternative to fusion surgery in terms of effectiveness and cost utility, in select patients with 1- to 2-level disease.[22-24] In

Table 2. Changes in 1-Year Outcome Scores From Baseline, and Return to Work Between Groups of Satisfaction.

Patient-Reported Outcomes	Satisfied (65.9%)	Uncertain (28.2%)	Dissatisfied (5.9%)	Overall	*P*
Neck Disability Index, mean (SD)	−22.7 (14.4)	−7.7 (16.1)	3.2 (14.3)	−17.3 (17.0)	<.001
EuroQOL-5D, mean (SD)	0.27 (0.32)	0.09 (0.35)	−0.22 (0.26)	0.20 (0.35)	<.001
Short Form 36 PCS, mean (SD)	9.8 (9.6)	2.0 (8.5)	−2.2 (8.2)	7.0 (10.0)	<.001
VAS neck pain, mean (SD)	−32.1 (30.6)	−6.3 (30.9)	0.2 (21.3)	−22.8 (32.7)	<.001
VAS arm pain, mean (SD)	−42.9 (31.5)	−19.3 (30.6)	−0.25 (18.0)	−34.0 (33.4)	<.001
Back to preoperative work status,[a] %	83.3	60.3	41.7	74.3	<.001

Abbreviations: PCS, Physical Component Summary; SD, standard deviation; VAS, visual analogue scale.
[a]Analysis of variance was used to compare outcome between groups of satisfaction.
[b]Chi-square-test was used to compare working status.

Table 3. Self-Reported Changes in Health Status, by Groups of Satisfaction.[a]

Health Transition Item	Satisfied (65.9%); n (%)	Uncertain (28.2%); n (%)	Dissatisfied (5.9%); n (%)
Much better now than 1 year ago	98 (59.1)	9 (12.5)	1 (7.7)
Somewhat better than 1 year ago	45 (27.1)	30 (41.7)	1 (7.7)
About the same	15 (9.0)	21 (29.2)	4 (30.8)
Somewhat worse than 1 year ago	8 (4.8)	6 (8.3)	5 (38.4)
Much worse than 1 year ago	0 (0.0)	6 (8.3)	2 (15.4)

[a]Chi-square test $P < .001$.

Table 4. Percentage of Patients Who Achieved MCID by Satisfaction Group.[a]

Variable	Satisfied, n (%)	Uncertain, n (%)	Dissatisfied, n (%)	*P*
NDI achieved MCID	126 (70.8)	34 (44.7)	4 (25.0)	
NDI did not achieve MCID	52 (29.2)	42 (55.3)	12 (75.0)	<.001
EQ-5D achieved MCID	73 (41.0)	27 (35.5)	3 (18.8)	
EQ-5D did not achieve MCID	105 (59.0)	49 (64.5)	13 (81.3)	.1836
VAS arm achieved MCID	127 (71.3)	31 (40.8)	2 (12.5)	
VAS arm did not achieve MCID	51 (28.7)	45 (59.2)	14 (87.5)	<.001
VAS neck achieved MCID	105 (59.0%)	18 (23.7)	3 (18.8)	
VAS neck did not achieve MCID	73 (41.0)	58 (76.3)	13 (81.2)	<.001
SF-36 PCS achieved MCID	134 (75.3)	38 (50.0)	7 (43.8)	
SF-36 PCS did not achieve MCID	44 (24.7)	38 (50.0)	9 (56.2)	<.001

Abbreviations: MCID, minimal clinical important difference; NDI, Neck Disability Index; SF-36 PCS, Short Form–36 Physical Component Summary; VAS, visual analogue scale.
[a]Chi-square test.

spite of this, cervical disc replacement is currently not an available treatment option in our institution.

All PRO measures showed significant mean improvement after surgery. A majority of our patients (73.3%) reported improvement in general health at the 1-year follow-up; however, only 65.9% were satisfied with the surgical result, and 28.2% were undecided. This implies that satisfaction is multifactorial and not only associated with improvement in our measured outcome parameters. Patient expectations, preoperative health issues and psychological distress may affect satisfaction after surgery.[25]

There are only few available studies investigating the correlation between PROs and satisfaction in spine surgery.[26,27]

Table 5. Logistic Regression Model Predicting Patients Who Are Satisfied 12 Months After Surgery, Using MCID Obtained for the Included Variables.

Variable	OR	95% CI	*P*
NDI MCID	1.61	0.83-3.16	.158
EQ-5D MCID	0.83	0.44-1.6	.566
VAS arm MCID	2.01	1.07-3.78	.030
VAS neck MCID	3.42	1.79-6.56	<.001
SF-36 PCS MCID	2.33	1.23-4.41	.009

Abbreviations: CI, confidence interval; MCID, minimal clinical important difference; NDI, Neck disability index; OR, odds ratio; SF-36 PCS, Short Form–36 Physical Component Summary; VAS, visual analogue scale.

Our study finds correlation between obtaining MCID in VAS neck and MCID in PCS, and satisfaction. Our study supports the findings by Chotai et al[26] who found that the failure to obtain MCID on VAS neck/arm and NDI/ODI were predictors for dissatisfaction after spine surgery.

A recent study investigating predictors for anterior cervical spine surgery reported that VAS neck pain and NDI were significant predictors for satisfaction after 2 and 5 years.[28]

In a study by Godil et al,[27] investigators found NDI to be the most responsive measure for improvement after cervical surgery for neck and arm pain, followed by the VAS arm. For generic health-related questionnaires, the study found that EQ-5D was a poor discriminate for meaningful improvement, compared to SF12 PCS, after cervical surgery, which is similar to our findings.[29]

In our analysis, we found NDI and VAS neck to be correlated to each other, which may explain why NDI does not show statistical significance in the regression model. When NDI was analyzed without VAS neck in the model, it showed a strong correlation to patient satisfaction.

We found patient-reported neck pain to be statistically significantly improved, but only 59% of our cohort reached MCID. When correlating to satisfaction, we found only a minor improvement in neck pain in our undecided group. The minor improvement in VAS neck, in our cohort may be explained by the fact that neck pain may originate from multiple levels, and thus may not be relieved by decompression and fusion surgery on specific levels. As neck pain is not the primary indication for ACDF, it is important to make sure that patient and surgeon agree on the expected postoperative outcome on both arm and neck pain.

We found 24.6% smokers in our study population, this amount is comparable to the background population in Denmark, where it is estimated that around 22% are smokers.[30]

The perioperative complications were recorded when patients were discharged from hospital, thus probably underreporting surgical site infections and urinary infections, which may present itself after patients are discharged from hospital. The patient-reported complications may be overrepresented, and we did not have any data to evaluate duration of dysphonia and dysphagia after surgery, our patients reported the duration being above one month. Earlier studies have found the rate

perioperative complications in line with our relative low complication rates, the rate of transient dysphagia in around 60% and dysphonia in about 50% of patients found in previous studies, is also in line with our patient reported complication rates.[31,32]

An important limitation to this study is the fact that this was a register study, which has potential of informational bias. We had a follow-up rate of 85.5% in our cohort, which may account for some non-response bias, a dropout analysis was performed in 2016 on our database, and here Højmark et al[33] found that nonresponders often are younger, male patients, who report a better outcome than responders.

No control group is available for comparison; as such we cannot distinguish the natural course of neck and arm pain, and placebo effect of treatment, from the actual effect of surgery. Furthermore, we only have 1-year follow-up, and long-term results may improve or worsen on a longer term of follow-up.

Conclusion

The treatment of cervical radiculopathy with decompression and fusion is a relative safe procedure, with few lasting complications. Surgery is reserved for patients with lasting or progressive symptoms. 65.9% of our patients were satisfied 1 year postoperatively, and only 5.9% were dissatisfied. All PROs were improved significantly at 1-year follow-up, and 73.3% of our patients reported a positive change in postoperative health status. Most of our patients (74.3%) were returned to preoperative working status after 1 year. Achieving MCID in VAS neck and SF-36 PCS was strongly correlated to patient satisfaction.

Declaration of Conflicting Interests

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