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Int J Spine Surg published online 8 July 2019
https://www.ijssurgery.com/content/early/2019/07/08/6035

The International Journal of Spine Surgery
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International Journal of Spine Surgery, Vol. 00, No. 00, 0000, pp. 000–000
https://doi.org/10.14444/6035

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ABSTRACT

Background: The minimum clinically importance difference (MCID) represents a threshold for improvements in patient-reported outcomes (PROs) that patients deem important. No previous study has comprehensively examined risk factors for failure to achieve MCID after anterior cervical discectomy and fusion (ACDF) procedures for radiculopathic symptomatology. The purpose of this study is to determine risk factors for failure to reach MCID for Neck Disability Index (NDI), Visual Analog Scale (VAS) neck pain, and VAS arm pain in patients undergoing 1- or 2-level ACDF procedures.

Methods: A surgical registry of patients who underwent primary, 1- or 2-level ACDF from 2014 to 2016 was reviewed. Rates of MCID achievement for NDI, VAS neck pain, and VAS arm pain at final follow-up were calculated based on published MCID values. Patients were then categorized into demographic and procedural categories. Bivariate regression was used to test for association of demographic and procedural characteristics with failure to reach MCID for each PRO. The final multivariate model including all demographic and procedural categories as controls was created using backward stepwise regression.

Results: Eighty-three, 84, and 77 patients were included in the analysis for VAS neck, VAS arm, and NDI, respectively. Rates of MCID achievement for VAS neck, VAS arm, and NDI were 55.4%, 36.9%, and 76.6%, respectively. On bivariate analysis, patients with Charlson Comorbidity Index (CCI) ≥ 2 were less likely to achieve MCID for NDI than patients with CCI < 2 ($P = .025$). On multivariate analysis, CCI ≥ 2 ($P = .025$) was further associated with failure to reach MCID for NDI.

Conclusions: The results of this study suggest that the majority of patients do not reach MCID for arm pain. Additionally, higher comorbidity burden as evidenced by higher CCI scores is a negative predictive factor for the achievement of MCID in neck disability following ACDF.

Level of Evidence: 3

Cervical Spine

Keywords: anterior cervical discectomy and fusion, minimal clinically important difference, Visual Analog Scale, neck pain, arm pain, Neck Disability Index, Charlson Comorbidity Index

INTRODUCTION

Cervical radiculopathy is a common symptom of cervical disc degeneration. For patients experiencing symptoms that are unresponsive to conservative therapy, anterior cervical discectomy and fusion (ACDF) is a reliable surgical management option.[1–3]

ACDF has demonstrated a high success rate in relieving neck and arm pain, with patient-reported satisfaction rates approaching 96%.[4–6] Postoperative changes in disability and pain after spinal surgery are measured using patient reported outcomes (PROs). Neck disability index (NDI), visual analog scale (VAS) neck pain, and VAS arm pain are common PROs used in determining the effectiveness of cervical spine surgery.[7] The minimum clinically important difference (MCID) is a commonly used threshold value for PRO changes that represents changes that patients and clinicians are likely to consider clinically meaningful.[8] The most widely accepted method of calculating MCID is the

anchor-based approach, in which patient-perceived improvements are compared to PROs following surgery, allowing for the establishment of clinically important scoring benchmarks.[9]

Previous studies have identified risk factors for decreased PRO improvement after ACDF based on absolute PRO score differences.[10–13] However, few studies have assessed risk factors associated with failure to reach MCID for PROs after ACDF. The purpose of this study is to evaluate risk factors for failure to reach MCID for NDI, VAS neck pain, and VAS arm pain in patients undergoing 1- or 2-level ACDF procedures for radiculopathic pathology.

MATERIALS AND METHODS

Patient Population

A prospectively maintained surgical database of patients who underwent primary, 1- or 2-level ACDF for degenerative pathology between 2014 and 2016 was reviewed following institutional review board approval (ORA#14051301). All patients presented with radiculopathy including motor weakness or sensory loss. A single surgeon performed all procedures at an academic institution. Patients were excluded from the analysis if preoperative PRO survey data were incomplete or if they did not have minimum 6-month clinical follow-up.

Surgical Technique

Patients underwent routine ACDF utilizing the Smith-Robinson approach.[14] An interbody cage was prepared with local autograft and bone graft substitute for insertion into the intervertebral space.

Patient Demographics

Patients were categorized based on demographic and procedural characteristics. Demographic categories included age (18–50, >50 years), sex (female or male), body mass index (BMI) (<30, ≥30 kg/m^2), insurance status (workers' compensation, other), smoking status (current smoker, nonsmoker), and Charlson comorbidity index (CCI) (<2, ≥2). Operative characteristics included operative duration (≤50, >50 minutes), number of operative levels (1 level, 2 levels), and the incidence of intraoperative or postoperative medical or surgical complications. Of note, a modified CCI was utilized with the age component excluded such that age and CCI could be tested as independent variables in subsequent analyses.

PRO Analysis

PRO questionnaires were completed preoperatively and at 6-week, 12-week, 6-month, and 1-year postoperative time points. PROs measured included NDI, VAS neck pain, and VAS arm pain scores. NDI is comprised of 10 questions, each scored from 0 to 5 points, and measures functional disability associated with neck pain and is reported as a percentage of the total possible score (50 points).[15] Higher NDI scores are associated with greater disability. VAS neck and VAS arm assess pain in their specific anatomic region on a scale of 0 (no pain) to 10 (maximum pain).[16]

Rates of MCID achievement for NDI, VAS neck, and VAS arm were calculated at 6-month or 1-year postoperative follow-up. MCID values were adapted from a study by Parker et al[9] in which anchor-based approaches were utilized. The authors used a North American Spine Society patient satisfaction questionnaire as the anchor. The choices provided were (1) "The treatment met my expectations," (2) "I did not improve as much as I had hoped, but I would undergo the same treatment for the same outcome," (3) "I did not improve as much as I had hoped, and I would not undergo the same treatment for the same outcome," and (4) "I am the same or worse than before treatment." Patients answering choice 1 were categorized as responders, while those answering the other choices were considered nonresponders. The authors used a minimum detectable change approach for calculating MCID, which defines MCID as the smallest change that is above the measurement error with a given confidence level. This method provided a threshold above the 95% confidence interval of the unimproved patients while also being closest to the mean change score reported by the improved patients. Thus, MCID values were established for NDI, VAS neck, and VAS arm at –17.3%, –2.6, and –4.1, respectively.[9]

Statistical Analysis and Determination of Risk Factors

Statistical analysis was performed using Stata/MP 13.1 for Mac (StataCorp LP, College Station, Texas). To determine if risk factors for failure to achieve MCID were present, bivariate and multivariate Poisson regression with robust error variance was used to test for an association between

Table 1. Patient-reported outcomes.

Parameter	Mean ± SD
VAS neck (N = 83)	
Preoperative	6.0 ± 2.4
Final follow-up	3.2 ± 2.6
Δ at final follow-up	−2.9 ± 3.0
VAS arm (N = 84)	
Preoperative	5.7 ± 2.6
Final follow-up	2.8 ± 2.7
Δ at final follow-up	−3.0 ± 3.3
NDI score (N = 77)	
Preoperative	40.3 ± 18.5
Final follow-up	22.9 ± 19.1
Δ at final follow-up	−17.4 ± 17.6

Abbreviations: SD, standard deviation; VAS, visual analog scale; NDI, neck disability index.

demographic and procedural characteristics and failure to reach MCID for each PRO measured. Independent demographic or procedural risk factors for each PRO were determined by using a backward stepwise regression process. The level of significance was set at $P < .05$.

RESULTS

A total of 83, 84, and 77 patients had complete preoperative and postoperative survey data for VAS neck, VAS arm, and NDI, respectively (Table 1). Of note, no intraoperative or postoperative complications occurred within the investigated patient cohort up to 6 months postoperatively. As such, the incidence of perioperative or postoperative complications was not included in any subsequent bivariate or multivariate analyses.

A total of 55.4% (46/83) of patients achieved MCID for neck pain VAS at final postoperative follow-up (Table 2). No demographic or procedural factors were associated with failure to reach MCID on bivariate analysis. For VAS arm pain, 36.9% (31/84) of patients achieved MCID at final postoperative follow-up (Table 3). No demographic or procedural factors were associated with failure to reach MCID on bivariate analysis. A total of 76.6% (59/77) of patients achieved MCID for NDI at final postoperative follow-up (Table 4). On bivariate analysis, a CCI score ≥ 2 was associated with a significantly reduced rate of MCID achievement compared to a CCI score < 2 (12.50% versus 81.54%, relative risk [RR] = 0.39, 95% confidence interval [CI] = 0.17 to 0.89, $P = .025$). No other demographic or procedural factors were associated with failure to reach MCID.

Independent risk factors for failure to achieve MCID as identified through backward stepwise regression are presented in Table 5. CCI score ≥ 2

Table 2. Unadjusted rates of MCID for VAS neck pain (N = 83).[a]

	Number of Patients	Rate of MCID, % (n)	RR	95% CI	*P* Value[b]
Overall	83	55.4 (46)			
Age					.422
18–50 years	43	51.2 (21)	Ref.	—	
>50 years	40	60.0 (24)	1.17	0.80–1.73	
Sex					.472
Female	35	60.0 (21)	Ref.	—	
Male	48	52.1 (25)	0.87	0.59–1.28	
Obesity					.125
Nonobese (<30 kg/m^2)	53	62.3 (33)	Ref.	—	
Obese (≥30 kg/m^2)	30	43.3 (13)	0.70	0.44–1.11	
Insurance status					.228
Non-WC	62	59.7 (37)	Ref.	—	
WC	21	42.9 (9)	0.72	0.42–1.23	
Current smoker					.611
No	70	54.3 (38)	Ref.	—	
Yes	13	61.5 (8)	1.13	0.70–1.84	
Ageless CCI					.487
<2	68	57.4 (39)	Ref.	—	
≥2	15	46.7 (7)	0.81	0.45–1.46	
Operative duration					.860
≤50 minutes	48	56.3 (27)	Ref.	—	
>50 minutes	35	54.3 (19)	0.97	0.65–1.43	
Number of operative levels					.415
1	50	54.0 (27)	Ref.	—	
2	33	57.6 (19)	1.07	0.72–1.58	

Abbreviations: MCID, minimum clinically importance difference; VAS, visual analog scale; RR, relative risk; CI, confidence interval; WC, workers' compensation, CCI, Charlson comorbidity index; ACDF, anterior cervical discectomy and fusion.
[a]Patients undergoing ACDF reaching MCID for VAS neck pain with minimum 6-month follow-up.
[b]*P* value was calculated for each category using Poisson regression with robust error variance.

Table 3. Unadjusted rates of MCID for VAS arm pain (N = 84).[a]

	Number of Patients	Rate of MCID, % (n)	RR	95% CI	*P* Value[b]
Overall	84	36.9 (31)			
Age					.953
18–50 years	43	37.2 (16)	Ref.	—	
>50 years	41	36.6 (15)	0.98	0.56–1.73	
Sex					.620
Female	35	40.0 (14)	Ref.	—	
Male	49	34.7 (17)	0.87	0.49–1.52	
Obesity					.660
Nonobese (<30 kg/m^2)	54	35.2 (19)	Ref.	—	
Obese (≥30 kg/m^2)	30	40.0 (12)	1.14	0.64–2.01	
Insurance status					.191
Non-WC	63	41.3 (26)	Ref.	—	
WC	21	23.8 (5)	0.57	0.25–1.32	
Current smoker					.130
No	71	33.8 (24)	Ref.	—	
Yes	13	53.9 (7)	1.59	0.87–2.91	
Ageless CCI					.781
<2	69	36.2 (25)	Ref.	—	
≥2	15	40.0 (6)	1.10	0.55–2.22	
Operative duration					.392
≤50 minutes	49	40.8 (20)	Ref.	—	
>50 minutes	35	31.4 (11)	0.77	0.42–1.40	
Number of operative levels					.330
1	51	39.13 (21)	Ref		
2	33	31.25 (10)	0.74	0.40–1.36	

Abbreviations: MCID, minimum clinically importance difference; VAS, visual analog scale; RR, relative risk; CI, confidence interval; WC, workers' compensation; CCI, Charlson comorbidity index; ACDF, anterior cervical discectomy and fusion.
[a]Patients undergoing ACDF reaching MCID for VAS arm pain with minimum 6-month follow-up.
[b]*P* value was calculated for each category using Poisson regression with robust error variance.

Table 4. Unadjusted rates of MCID for NDI (N = 77).[a]

	Number of Patients	Rate of MCID, % (n)	RR	95% CI	*P* Value[b]
Overall	77	76.6 (59)			
Age					.084
18–50 years	40	85.0 (34)	Ref.	—	
>50 years	37	67.6 (25)	0.79	0.61–1.03	
Sex					.497
Female	33	72.7 (24)	Ref.	—	
Male	44	79.6 (35)	1.09	0.84–1.42	
Obesity					.073
Nonobese (<30 kg/m^2)	50	84.0 (42)	Ref.	—	
Obese (≥30 kg/m^2)	27	63.0 (17)	0.75	0.55–1.03	
Insurance status					.540
Non-WC	56	78.6 (44)	Ref.	—	
WC	21	71.4 (15)	0.91	0.67–1.23	
Current smoker					.450
No	65	78.5 (51)	Ref.	—	
Yes	12	66.7 (8)	0.85	0.56–1.30	
Ageless CCI					**.025**
<2	**65**	**81.54 (55)**	**Ref.**	—	
≥2	**12**	**12.50 (4)**	**0.39**	**0.17–0.89**	
Operative duration					.197
≤50 minutes	45	82.2 (37)	Ref.	—	
>50 minutes	32	68.8 (22)	0.84	0.64–1.10	
Number of operative levels					.134
1	47	81.40 (39)	Ref		
2	30	63.33 (20)	0.80	0.60–1.07	

Abbreviations: MCID, minimum clinically importance difference; NDI, neck disability index; RR, relative risk; CI, confidence interval; WC, workers' compensation; CCI, Charlson comorbidity index; ACDF, anterior cervical discectomy and fusion.
[a]Patients undergoing ACDF reaching MCID for NDI with minimum 6-month follow-up.
[b]*P* value was calculated for each category using Poisson regression with robust error variance.

Table 5. Independent risk factors for failure to reach MCID.[a]

	RR	95% CI	*P* Value[b]
NDI			
Ageless CCI			.025
<2	Ref.	—	—
≥2	0.39	0.17–0.89	
VAS neck			
No factors identified	—	—	—
VAS arm			
No factors identified	—	—	—

Abbreviations: MCID, minimum clinically importance difference; RR, relative risk; CI, confidence interval; NDI, neck disability index; CCI, Charlson comorbidity index; VAS, visual analog scale; BMI, body mass index.
[a]The final multivariate model was selected using a backward stepwise process initially including all variables and sequentially excluding variables with the highest *P* value until all remaining variables had $P < .05$. All models initially included age, sex, BMI, insurance status, smoking status, CCI, operative time, and number of operative levels. Only variables listed in this table remained following stepwise selection.
[b]*P* value was calculated for each category using a backward stepwise regression model.

(RR = 0.39, 95% CI = 0.17 to 0.89, $P = .025$) was identified as an independent risk factor for failure to achieve MCID for NDI. No independent risk factors for failure to achieve MCID were identified for VAS neck pain or VAS arm pain scores.

DISCUSSION

ACDF is a common procedure for the management of cervical degenerative disorders. Success of this procedure is often assessed via PROs such as NDI, VAS neck pain, and VAS arm pain scores.[7] However, the MCID is a frequently used threshold for changes in PROs that patients and clinicians deem important and can be of additional utility in the determination of surgical success.[8]

The results of this study suggest that the majority of patients undergoing primary 1- or 2-level ACDF for radiculopathy achieve MCID for both NDI (76.6%) and VAS neck pain (55.4%) scores. However, less than a majority of patients in this analysis achieved MCID for VAS arm pain scores (36.9%). No demographic or procedural factors were identified as negative predictors for MCID achievement for VAS neck pain and VAS arm pain scores. Comorbidity burden as evidenced by CCI score was identified through multivariate analysis as an independent predictor for failure to reach MCID for NDI score.

The results of the present study are similar to those of Sielatycki et al,[17] who examined 299 patients undergoing ACDF for degenerative pathology. In that study, a majority of patients achieved MCID for NDI (55.1%) and neck pain (53.5%), while a minority of patients achieved MCID for arm pain (41.4%). This finding may be best explained by the relatively low preoperative VAS arm pain scores (5.7 ± 2.6, mean ± SD) in the study population, thus limiting room for improvement in this measure and fewer patients achieving MCID. Other studies, however, have demonstrated marked variation in MCID achievement after ACDF with rates ranging from 20% to 85.9% and 47.5% to 87.8% for NDI and pain, respectively.[18,19] The variation in MCID achievement rates between studies may be due to differences in the threshold value for clinically significant changes in PROs.[9,17–19] Furthermore, this discrepancy in cutoff values suggests further investigation into a universal threshold for clinically relevant PRO change. This may be especially important, as PRO scores are increasingly utilized in the current health care environment as measures of surgeon outcomes and overall performance.[20]

The present study's results exhibit an association between greater comorbidity burden, as evidenced by increasing CCI scores, and failure to achieve MCID. This is consistent with other reports within the literature. Tetreault et al[23] evaluated cervical spine outcomes after decompression with or without fusion using the modified Japanese Orthopaedic Association (mJOA) score, a measure of motor and sensory dysfunction that has shown correlation to neck disability measures.[21,22] Patients with increased comorbidity burden were demonstrated to be at increased risk for failure to reach MCID for mJOA scores.[23] Similarly, an association between comorbidity burden and postoperative improvements in PROs has been demonstrated in degenerative lumbar populations.[24,25]

The etiology of the association between comorbidity burden and failure to achieve MCID has been difficult to elucidate. The most prevalent theory attributes the inferior outcomes to increased postoperative complication rates in patients with higher comorbidity burden.[26] However, this is unlikely in our patient population, as no perioperative or postoperative complications occurred. Another possible explanation may be that patients with higher comorbidity burden have difficulty in meeting discharge and outpatient physical therapy requirements. As such, they may experience a prolonged recovery time and decline in physical function that manifests as reduced improvements in PROs. The implications of this association may drive further investigation, particularly regarding whether certain comorbidities can be modified preoperatively to

improve postoperative outcomes.[25] Furthermore, patients with higher comorbidity burden undergoing ACDF can be counseled regarding their increased risk for poor functional outcome postoperatively.

The present study demonstrates that workers' compensation status is not an independent predictor of MCID achievement. This result is supported by multiple studies in the literature regarding ACDF. In a study of 80 patients undergoing ACDF, Goldberg et al[27] noted that workers' compensation status did not affect postoperative functional outcome, VAS pain scores, or radiographic outcomes. Brodke and Zdelick[28] exhibited similar results in a study of 51 patients with cervical degenerative disease. Patients with workers' compensation had no evidence of lower fusion rates or worse outcomes following ACDF. Finally, in an analysis of 122 patients, Bohlman et al[29] demonstrated that workers' compensation status was not associated with postoperative pain following ACDF for the treatment of cervical radiculopathy. These results suggest that patients carrying workers' compensation should be counseled as to expect similar PRO improvements and rates of clinically important functional changes after ACDF compared to those without workers' compensation.

Patient age also did not exhibit an association with MCID achievement in the current study. This result is in contrast to previous literature on the subject. Omidi-Kashani et al,[30] in a study of 68 patients undergoing ACDF for cervical spondylotic radiculopathy, identified that patients younger than 45 years had less improvement in NDI scores postoperatively. The reported changes in NDI scores were –51.8% and –64.2% for cohorts younger and older than 45 years, respectively. While that study may indicate that the difference in NDI score varies based on age, the results may not reflect the clinical significance of those changes. While absolute score may differ by age, the rate of clinically relevant change may not. This further demonstrates a fallacy of outcomes reporting where conclusions based on absolute differences in outcomes scores are not validated against a measure of clinical relevance.

This study is not without limitations. First, this study was performed utilizing patients of a single surgeon at an academic center. As such, unique characteristics of this patient population, such as the high percentage of workers' compensation patients, may limit generalizability. Second, the retrospective nature of this study imparts inherent risks of both selection and reporting bias. Third, this analysis was limited to patients treated for radiculopathy in order to limit variations that can exist in PRO measures and postoperative improvements with differing diagnoses. However, the variability in ACDF clinical outcomes may have stemmed from other radiculopathic factors that were not investigated, such as differences in duration or severity of neural compression. Fourth, due to varying survey response rate from patients, each PRO had different sample sizes included in their analysis. As such, reductions in sample sizes may limit the statistical power of the resulting analyses. While this study is the first to assess risk factors for failure to reach MCID for PROs in radiculopathic ACDF patients, more work is needed to further characterize these predictors for poor outcomes. Fifth, administration of a depressive symptoms questionnaire was not part of the study design, thus preventing the analysis of depression as a risk factor for failure to achieve MCID following ACDF. Finally, the threshold values used for MCID were based on reported values in the literature. As multiple studies reporting MCID values are available, the results of this study may have been different if alternative values had been utilized. Furthermore, the chosen values were calculated using 3-month outcome data instead of longer-term postoperative time points. However, MCID values from a study by Parker et al[9] were utilized due to its similarities in patient population and surgical indications with those included in the present study.

CONCLUSIONS

The present study indicates that a majority of patients undergoing ACDF achieve MCID for NDI and neck pain, while a minority achieve MCID for arm pain. Of the demographic and procedural factors characterized, only a greater CCI score was found to be predictive of failure to achieve MCID in one of these PROs—specifically NDI. This relationship has implications regarding preoperative modification of comorbidities to improve patient outcomes. Additionally, patients with higher comorbidity indices may require further counseling regarding expected functional improvement after surgery. However, further investigation is required to delineate which specific comorbidities are most

strongly associated with poor outcomes after ACDF.

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Disclosures and COI: No funds were received in support of this work. No benefits in any form have been or will be received from any commercial party related directly or indirectly to the subject of this manuscript.

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Published 0 Month 2019