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Risk Factors for Failing to Reach a Minimal Clinically Important Difference Following Minimally Invasive Lumbar Decompression

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ABSTRACT

Background: Clinically important postoperative changes can be best evaluated through the minimal clinically important difference (MCID). Our study aims to evaluate risk factors associated with failure to achieve MCID following lumbar decompression (LD).

Methods: Demographics, perioperative characteristics, and patient-reported outcome measures (PROM) for pain, disability, and physical function were retrospectively reviewed and collected for patients undergoing LD. MCID achievement was calculated using established values. Relative risk of demographic and perioperative characteristics with failure to meet MCID for all PROMs was calculated. Least absolute shrinkage and selection operator (LASSO) was used to estimate individual risk factors, and postestimation logistic regression was performed.

Results: The study cohort included 811 patients. Comorbidity burden was associated with failed MCID for visual analog scale (VAS) back and leg pain and Oswestry Disability Index (ODI). Operative levels or duration was associated with failed MCID for VAS leg pain, 12-item short form physical component summary (SF-12 PCS), and the patient-reported outcomes measurement information system physical function (PROMIS PF). Preoperative spinal pathology was associated with failed MCID for VAS leg pain, ODI, SF-12 PCS, and PROMIS PF. Additional risk factors included the type of operation, insurance, age, and body mass index. LASSO selected insurance, age, comorbidity burden, blood loss, operative duration, and type of spinal pathology as significant risk factors for failure to reach MCID.

Conclusion: Failure to reach MCID was greatest for VAS back. Age, comorbidity burden, and prolonged procedures were significantly associated with risk for failure to reach MCID for a majority of PROMs. Comorbidity burden combined with operative outcomes may place patients at increased risk for failure to reach MCID for pain, disability, and physical function following LD.

Level of Evidence: 4.

Clinical Relevance: Establishes risk factors for failing to reach the threshold of meaningful difference in symptoms after LD surgery.

Lumbar Spine

Keywords: lumbar decompression, minimal clinically important difference, outcomes

INTRODUCTION

Globally, low back and neck pain were the leading causes of disability in 2015,[1] with reports estimating the cost of low back pain as more than $100 billion per year.[2] The significant disease burden that low back and neck pain place on the general population promotes the investigation into potential risk factors for poorer outcomes following surgical intervention. While traditional assessment of postoperative outcomes has heavily relied on physician-based or radiographic measures, patient-reported outcome measures (PROMs) provide a patient-centered evaluation of quality of life, pain, and disease-specific outcomes following surgery.[3] However, it has become difficult to determine clinically relevant improvements using PROMs because statistically significant differences in scores do not always correlate with a patient's postoperative satisfaction.[4]

To account for this shortcoming, investigators have begun using the minimal clinically important difference (MCID) to measure postoperative improvement. MCID is a calculated value that represents the smallest magnitude of change that a patient perceives as beneficial.[4] The clinical relevance of this metric has prompted others to investigate contributing factors for failure to achieve an MCID. Narain et al investigated these risk factors in patients undergoing anterior cervical discectomy and fusion, reporting a Charlson Comorbidity Index (CCI) ≥2 to be associated with a significantly lower rate of achieving MCID for visual analog

scale (VAS) arm pain.[5] Additionally, Hijji et al reported worker's compensation status to be negatively associated with MCID achievement for VAS back pain in those undergoing minimally invasive transforaminal lumbar interbody fusion (TLIF).[6] While both of these studies make important contributions to understanding MCID achievement in the spine population, their focus on anterior cervical discectomy and fusion and TLIF limits their applicability to risk factors associated with fusion procedures only.

Alternatively, lumbar decompression (LD) is another common surgical intervention used to treat low back pain. While there are similarities between LD and fusions, the two often have different indications and recovery times. Minimally invasive surgery (MIS) LD is used to to treat lumbar stenosis and neurogenic claudication, and it has demonstrated prolonged durability and lower reoperation rates than fusions and other spinal procedures.[7] In contrast to fusions, LD is indicated when a patient does not demonstrate instability or deformity prior to surgery.[8] Additionally, time until return to work for decompression patients has been reported to be as soon as 10 days postoperatively,[9] while MIS-TLIF patients may take as long as 3 months to return to work.[10] Given these substantial differences, it is necessary to assess MCID risk factors within the LD population specifically.

Risk factors for unfavorable outcomes following LD have been reported in past studies. Potential predictors include radiographic characteristics,[11–13] preoperative spinal pathologies such as double disc herniations,[14] and increased preoperative back pain.[15,16] However, these studies focused on the absolute values of PROM scores and were unable to account for the patient's perception of outcomes by utilizing MCID. More recent studies have attempted to address this problem, reporting that worse preoperative disability scores were associated with more favorable outcomes and achievements of MCID.[17] However, investigators limit their risk factor analysis to pain and disability. Therefore, the aim of the current study is to address this shortcoming through a more comprehensive risk factor analysis of pain, disability, and physical function PROMs. Through this analysis, we will elucidate potential risk factors associated with failure to achieve MCID following MIS LD.

MATERIALS AND METHODS

Patient Inclusion and Exclusion Criteria

Prior to starting this study, per institutional and ethical guidelines, both Institutional Review Board approval (ORA 1405301) and written patient-informed consent were obtained. An established surgical registry that is prospectively updated was used for a retrospective review of eligible lumbar spine procedures performed between May 2005 and May 2020. Patients who underwent primary, single, or multilevel MIS LD were included in the study. Patients who underwent surgical treatment indicated for malignancy, infection, or trauma were excluded. Additionally, individuals who were missing preoperative PROMs or failed to complete any postoperative PROMs by 1 year were excluded from analysis.

Surgical Procedure

All included procedures were stand alone LDs without fusion. Decompression procedures were separated into either a laminectomy, discectomy, or laminectomy and discectomy. All patients also underwent a foraminotomy and facetectomy in conjunction with both laminectomy and discectomy procedures. All procedures were performed at either a hospital-based outpatient center or ambulatory surgical center by a single attending physician.

Data Collection

Patient demographic and perioperative information were collected for all patients included in this study. Demographic information entailed age, body mass index (BMI), and smoker and diabetic status at the time of the preoperative examination, American Society of Anesthesiologists (ASA) physical classification score, comorbidity burden as scored by ageless CCI, and insurance collected. Perioperative information included total operative length (skin incision to skin closure), estimated intraoperative blood loss (EBL), length of postoperative hospital stay, total number of operative levels, and associated spinal pathology.

The primary outcome of interest for this study was achievement of MCID of select PROMs for pain, disability, and physical function. Pain was evaluated using the VAS for back and leg pain. Disability was evaluated using the Oswestry Disability Index (ODI). Physical function was assessed using both the 12-item short form physical component summary (SF-12 PCS) and the patient-reported outcomes measurement information system physical function (PROMIS PF) questionnaire. All outcome measures were collected at a preoperative timepoint as their baseline, as well as at 6 weeks, 12 weeks, 6 months, and 1 year postoperatively. All PROMs were assigned and completed at the appropriate timepoint either during follow-up appointments or through a private online portal using a personal device.

Using the collected values for PROMs, achievement of MCID was evaluated by first calculating the change in postoperative values from the respective baseline and comparing the difference to established MCID thresholds. The following values were used to determine achievement of MCID: VAS back = 1.2,[18] VAS leg = 1.6,[18] ODI = 12.8,[18] SF-12 PCS = 4.9,[18] and PROMIS PF = 8.0.[19]

Statistical Analysis

Descriptive statistics were performed for all demographic and perioperative variables. Improvement from baseline values was evaluated for all PROMs at each postoperative timepoint using a paired *t* test. To determine relative risk of demographic and perioperative characteristics for failure to reach an MCID by 1 year for each PROM, bivariate analysis was performed using a Poisson logistic regression for robust error variance. Following the bivariate analysis, a least absolute shrinkage and selection operator (LASSO) was used to estimate individual demographic or perioperative variables that are associated with failure to reach and MCID by 1 year. Postestimation logistic regression was performed to determine the effect of the covariates identified by LASSO on failure to reach an overall MCID. All statistical analyses were performed using StataMP 16.1 (StataCorp LLC, College Station, TX). A *P* value was set at 0.050 for significance.

RESULTS

Baseline Demographics and Perioperative Information

A total of 941 patients were identified as eligible for this study. Following inclusion and exclusion criteria, a total of 811 patients were included in our study. The patient cohort had a mean age of 44.6 years, 70.1% were men, and 60.4% were nonobese (BMI < 30 kg/m^2). The majority of patients underwent a single-level procedure (81.7%), and mean operative duration was 45.7 minutes with an mean EBL of 31.4 mL and mean length of stay of 5.7 hours. The major spinal pathology associated with most patients was herniated nucleus pulposus (77.1%) (Table 1).

Table 1. Patient baseline characteristics.

Characteristic	% Total (*n* = 811)
Age (mean ± SD)	44.6 ± 13.6
Gender % (*n*)	
Female	29.9% (243)
Male	70.1% (568)
BMI	
<30 kg/m^2	60.4% (483)
≥30 kg/m^2	39.6% (317)
Smoking Status	
Nonsmoker	83.2% (675)
Smoker	16.8% (136)
Diabetes	
Diabetic	5.8% (47)
Nondiabetic	94.2% (764)
ASA score	
<2	34.5% (232)
≥2	65.5% (440)
Ageless CCI	
<1	58.8% (440)
≥1	41.2% (308)
Insurance	
Non-WC	69.4% (563)
WC	30.6% (245)
Operative length (min)	45.7 ± 15.0
EBL (mean ± SD; mL)	31.4 ± 14.2
LOS (mean ± SD; h)	5.7 ± 6.6
Operative technique	
Laminectomy	17.9% (144)
Discectomy	11.5% (92)
Laminectomy + discectomy	70.6% (567)
Number of operative levels	
Single	81.7% (663)
Multilevel	18.3% (148)
Spinal pathology	
HNP	77.1% (625)
Central stenosis	61.2% (496)
Foraminal stenosis	33.9% (275)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CCI, Charlson Comorbidity Index; EBL, estimated blood loss; HNP, herniated nucleus pulposus; LOS, length of stay; WC, workers' compensation.

Back and Leg Pain

Prior to analysis, patients were excluded for missing health questionnaires for VAS back and VAS leg, resulting in the analysis of 712 patients for VAS back and 494 for VAS leg. Both VAS back and VAS leg demonstrated significant improvement from baseline values at all postoperative timepoints (all $P < 0.001$; Table 2).

Overall failure rate for MCID achievement was 28.2% for VAS back and 20.7% for VAS leg. The bivariate analysis identified ageless CCI (RR = 1.4; 95% CI [1.1–1.7], $P = 0.007$) and type of insurance (RR = 1.4; 95% CI [1.1–1.6]; $P = 0.001$) as risk factors for failure to reach an MCID by 1 year for VAS back (Table 3). Risk factors for failure to reach an MCID for VAS leg included age (RR = 1.4; 95% CI [1.1–1.8]; $P = 0.015$), ageless CCI (RR = 1.5; 95% CI [1.2–1.9]; $P = 0.005$), EBL (RR = 1.9; 95% CI [1.4–2.6]; $P = 0.001$), number of operative levels (RR = 1.7; 95% CI [1.3–2.3]; $P = 0.001$), performing a laminectomy without discectomy (RR = 1.6; 95% CI [1.2–2.0]; $P = 0.001$), performing a laminectomy with discectomy (RR = 0.6; 95% CI [0.5–0.8]; $P = 0.001$), diagnosis of herniated nucleus pulposus (RR = 0.6;

Table 2. Improvement of outcome measures.

Outcome measure	*n*	Mean ± SD	*P* value[a]
VAS back			
Preoperative	712	6.27 ± 2.45	**<0.001**
6 wk	594	2.78 ± 2.57	**<0.001**
12 wk	321	3.05 ± 2.83	**<0.001**
6 mo	221	3.20 ± 2.92	**<0.001**
1 y	121	3.27 ± 2.89	**<0.001**
VAS leg			
Preoperative	476	6.17 ± 2.57	**<0.001**
6 wk	377	2.87± 2.80	**<0.001**
12 wk	216	2.93 ± 2.87	**<0.001**
6 mo	164	3.12 ± 2.92	**<0.001**
1 y	120	2.77 ± 2.90	**<0.001**
ODI			
Preoperative	494	42.2 ± 17.6	**<0.001**
6 wk	391	25.0 ± 18.2	**<0.001**
12 wk	226	24.8 ± 20.8	**<0.001**
6 mo	170	31.9 ± 77.5	0.054
1 y	120	23.0 ± 20.8	**<0.001**
SF-12 PCS			
Preoperative	446	31.7 ± 7.91	**<0.001**
6 wk	288	38.2 ± 10.1	**<0.001**
12 wk	168	41.1 ± 10.9	**<0.001**
6 mo	146	40.7 ± 11.2	**<0.001**
1 y	141	42.3 ± 10.9	**<0.001**
PROMIS PF			
Preoperative	304	36.3 ± 6.8	**<0.001**
6 wk	212	42.7 ± 8.4	**<0.001**
12 wk	124	45.6 ± 10.1	**<0.001**
6 mo	111	43.4 ± 9.8	**<0.001**
1 y	101	45.5 ± 10.1	**<0.001**

Boldface indicates statistical significance.
[a]*P* values calculated difference from baseline values using paired *t* test.
Abbreviations: ODI, Oswestry Disability Index; PROMIS PF, patient-reported outcomes measures information system physical function; SF-12, 12-item short form; VAS, visual analog scale.

95% CI [0.5–0.9]; *P* = 0.003), central stenosis (RR = 1.5; 95% CI [1.1–2.0]; *P* = 0.008), and foraminal stenosis (RR = 1.3; 95% CI [1.1–1.7]; *P* = 0.042) (Table 4).

Disability

Prior to analysis, patients were excluded for missing health questionnaires for ODI resulting in the analysis of 494 patients. ODI demonstrated a significant improvement from baseline values at all postoperative timepoints (Table 2) and had an overall failure rate for MCID achievement of 26.8%. Risk factors for failure to reach an ODI MCID included age (RR = 1.6; 95% CI [1.3–2.0]; *P* = 0.001), ageless CCI (RR = 1.6; 95% CI [1.3–2.1]; *P* = 0.001), number of operative levels (RR = 1.7; 95% CI [1.3–2.1]; *P* = 0.001), performing a laminectomy without discectomy (RR = 1.5; 95% CI [1.1–1.9]; *P* = 0.001), and a spinal pathology of herniated nucleus pulposus (HNP) (RR = 0.6; 95% CI [0.5–0.9]; *P* = 0.003) or central stenosis (RR = 1.8; 95% CI [1.4–2.3]; *P* = 0.001) or foraminal stenosis (RR = 1.4; 95% CI [1.1–1.7]; *P* = 0.003) (Table 5).

Table 3. Bivariate analysis achievement for VAS back.

Characteristic	Failed MCID (%)	RR	95% CI	*P* value[a]
Overall	28.2%	–	–	–
Age				
18–50 y	61.8%	Reference		
<50 y	38.2%	1.1	(0.9–1.5)	0.176
Gender				
Male	68.6%	0.9	(0.7–1.2)	0.563
Female	31.4%	Reference		
BMI				
<30 kg/m^2	58.3%	Reference		
≥30 kg/m^2	41.7%	1.1	(0.9–1.3)	0.455
Smoking status				
Nonsmoker	79.9%	Reference		
Smoker	20.1%	1.2	(0.9–1.6)	0.103
Diabetes				
Nondiabetic	93.8%	Reference		
Diabetic	6.2%	1.1	(0.7–1.7)	0.806
Ageless CCI				
<1	**51.2%**	**Reference**		
≥1	**48.3%**	**1.4**	**(1.1–1.7)**	**0.007**
ASA score				
<2	32.6%	Reference		
≥2	67.4%	1.1	(0.8–1.4)	0.526
Insurance				
Non-WC	**61.1%**	**Reference**		
WC	**38.9%**	**1.4**	**(1.1–1.6)**	**0.001**
Operative length				
<50 min	69.0%	Reference		
≥50 min	31.0%	0.9	(0.8–1.0)	0.185
EBL				
<50 mL	50.0%	Reference		
≥50 mL	50.0%	1.1	(0.9–1.3)	0.411
Operative levels				
Single	71.7%	Reference		
Multilevel	28.3%	1.4	(1.2–1.7)	0.001
Operative technique				
Laminectomy	20.1%	0.9	(0.7–1.3)	0.945
Discectomy	-	-	-	-
Laminectomy + discectomy	74.3%	1.2	(0.9–1.5)	0.148
Spinal pathologies				
HNP	76.9%	0.9	(0.7–1.3)	0.858
Central stenosis	63.0%	1.1	(0.8–1.3)	0.508
Foraminal stenosis	31.7%	0.9	(0.7–1.1)	0.432

Boldface indicates statistical significance.
[a]*P* value calculated using Poisson regression.
Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CCI, Charlson Comorbidity Index; EBL, estimated blood loss; HNP, herniated nucleus pulposus; RR, relative risk; VAS, visual analog scale; WC, workers' compensation.

Physical Function

Prior to analysis, patients were excluded for missing health questionnaires for SF-12 PCS and PROMIS PF resulting in analysis of 446 and 306 patients, respectively. Physical function outcome measures both demonstrated significant improvements from preoperative values at majority of postoperative timepoints (all *P* < 0.001) (Table 2). SF-12 PCS had an overall failure rate for MCID achievement of 22.2%, and PROMIS PF had an overall failure rate of 17.0%. Risk factors for failure to reach an MCID for SF-12 PCS included

Table 4. Bivariate analysis achievement for VAS leg.

Characteristic	Failed MCID (%)	RR	95% CI	*P* value[a]
Overall	20.7%	–	–	–
Age				
18–50 y	**57.5%**	**Reference**		
<50 y	**42.5%**	**1.4**	**(1.1–1.8)**	**0.015**
Gender				
Male	72.0%	1.1	(0.8–1.5)	0.530
Female	28.0%	Reference		
BMI				
<30 kg/m^2	59.0%	Reference		
≥30 kg/m^2	41.0%	1.1	(0.8–1.4)	0.692
Smoking status				
Nonsmoker	81.0%	Reference		
Smoker	19.0%	1.2	(0.8–1.6)	0.369
Diabetes				
Nondiabetic	92.9%	Reference		
Diabetic	7.1%	1.3	(0.75–2.1)	0.389
Ageless CCI				
<1	**49.0%**	**Reference**		
≥1	**51.0%**	**1.5**	**(1.2–1.9)**	**0.005**
ASA score				
<2	36.3%	Reference		
≥2	63.7%	0.9	(0.7–1.3)	0.646
Insurance				
Non-WC	64.9%	Reference		
WC	35.1%	1.2	(0.9–1.5)	0.081
Operative length				
<50 min	66.7%	Reference		
≥50 min	33.3%	0.9	(0.9–1.0)	0.051
EBL				
<50 mL	**91.1%**	**Reference**		
≥50 mL	**8.9%**	**1.9**	**(1.4–2.6)**	**0.001**
Operative levels				
Single	**72.0%**	**Reference**		
Multilevel	**28.0%**	**1.7**	**(1.3–2.3)**	**0.001**
Operative technique				
Laminectomy only	28.1%	1.6	(1.2–2.0)	0.001
Discectomy only	-	-	-	-
Laminectomy + discectomy	71.0%	0.6	(0.5–0.8)	0.001
Spinal pathologies				
HNP	**69.1%**	**0.6**	**(0.5–0.9)**	**0.003**
Central stenosis	**70.2%**	**1.5**	**(1.1–2.0)**	**0.008**
Foraminal stenosis	**40.5%**	**1.3**	**(1.1–1.7)**	**0.042**

Boldface indicates statistical significance.

[a]*P* value calculated using Poisson regression.

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CCI, Charlson Comorbidity Index; EBL, estimated blood loss; HNP, herniated nucleus pulposus; RR, relative risk; VAS, visual analog scale; WC, workers' compensation.

Table 5. Bivariate analysis achievement for ODI.

Characteristic	Failed MCID (%)	RR	95% CI	*P* value[a]
Overall	26.8%	–	–	–
Age				
18–50 y	**53.7%**	**Reference**		
<50 y	**46.3%**	**1.6**	**(1.3–2.0)**	**0.001**
Gender				
Male	26.7%	1.2	(0.9–1.5)	0.231
Female	73.3%	Reference		
BMI, kg/m^2				
<30	60.3%	Reference		
≥30	39.7%	1.0	(0.7–1.3)	0.974
Smoking status				
Nonsmoker	82.5%	Reference		
Smoker	17.5%	1.1	(0.8–1.4)	0.731
Diabetes				
Nondiabetic	93.5%	Reference		
Diabetic	6.5	1.1	(0.7–1.8)	0.622
Ageless CCI				
<1	**46.9%**	**Reference**		
≥1	**53.1%**	**1.6**	**(1.3–2.1)**	**0.001**
ASA score				
<2	30.8%	Reference		
≥2	69.2%	1.2	(0.9–1.6)	0.241
Insurance				
Non-WC	69.1%	Reference		
WC	30.8%	1.0	(0.8–1.3)	0.725
Operative length				
<50 min	68.7%	Reference		
≥50 min	31.3%	0.9	(0.8–1.0)	0.158
EBL				
<50 mL	91.6%	Reference		
≥50 mL	8.4%	1.1	(0.7–1.6)	0.472
Operative levels				
Single	**72.8%**	**Reference**		
Multilevel	**27.2%**	**1.7**	**(1.3–2.1)**	**0.001**
Operative technique				
Laminectomy only	27.4%	1.5	(1.1–1.9)	0.001
Discectomy only	-	-	-	-
Laminectomy + discectomy	71.3%	1.0	(0.8–1.3)	0.796
Spinal pathologies				
HNP	**70.1%**	**0.6**	**(0.5–0.9)**	**0.003**
Central stenosis	**73.7%**	**1.8**	**(1.4–2.3)**	**0.001**
Foraminal stenosis	**41.9%**	**1.4**	**(1.1–1.7)**	**0.003**

Boldface indicates statistical significance.

[a]*P* value calculated using Poisson regression.

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CCI, Charlson Comorbidity Index; EBL, estimated blood loss; HNP, herniated nucleus pulposus; ODI, Oswestry Disability Index; RR, relative risk; WC, workers' compensation.

age (RR = 1.3; 95% CI [1.1–1.7]; $P = 0.035$), operative length (RR = 0.7; 95% CI [0.5–0.9]; $P = 0.025$), and a spinal pathology of HNP (RR = 0.7; 95% CI [0.6–1.01]; $P = 0.050$), central and foraminal stenosis (RR = 2.0; 95% CI [1.5–2.8]; $P = 0.001$) (Table 6). Risk factors for failure to reach an MCID for PROMIS PF included BMI (RR = 1.4; 95% CI [1.1–1.7]; $P = 0.002$), number of operative levels (RR = 1.4; 95% CI [1.2–1.7]; $P = 0.001$), and a spinal pathology of HNP (RR = 0.8; 95% CI [0.6–0.9]; $P = 0.015$) (Table 7).

Postestimation Regression Analysis

LASSO estimated a number of potential covariates for each PROM which are summarized in Table 8. Demographic and perioperative variables identified by LASSO were included in a postestimation logistic regression to determine their relative risk for failure

Table 6. Bivariate analysis achievement for SF-12 PCS.

Characteristic	Failed MCID (%)	RR	95% CI	*P* value[a]
Overall	22.2%	–	–	–
Age				
18–50 y	**58.9%**	**Reference**		
<50 y	**41.1%**	**1.3**	**(1.1–1.7)**	**0.035**
Gender				
Male	32.2%	0.9	(0.7–1.2)	0.451
Female	67.8%	Reference		
BMI				
<30 kg/m^2	57.1%	Reference		
≥30 kg/m^2	42.9%	1.1	(0.9–1.5)	0.306
Smoking status				
Nonsmoker	83.3%	Reference		
Smoker	16.7%	0.9	(0.7–1.4)	0.967
Diabetes				
Nondiabetic	94.4%	Reference		
Diabetic	5.6%	0.9	(0.5–1.7)	0.877
Ageless CCI				
<1	53.2%	Reference		
≥1	46.8%	1.3	(0.9–1.6)	0.085
ASA score				
<2	34.0%	Reference		
≥2	66.0%	1.0	(0.7–1.4)	0.888
Insurance				
Non-WC	70.6%	Reference		
WC	29.4%	1.1	(0.8–1.4)	0.663
Operative length				
<50 min	**74.4%**	**Reference**		
≥50 min	**25.6%**	**0.7**	**(0.5–0.9)**	**0.025**
EBL				
<50 mL	93.0%	Reference		
≥50 mL	7.0%	0.9	(0.6–1.3)	0.720
Operative levels				
Single	80.0%	Reference		
Multilevel	20.0%	1.1	(0.8–1.5)	0.486
Operative technique				
Laminectomy only	21.3%	1.2	(0.9–1.5)	0.076
Discectomy only	-	-	-	-
Laminectomy + discectomy	77.3%	0.8	(0.7–1.0)	0.096
Spinal pathologies				
HNP	**75.0%**	**0.7**	**(0.6–1.0)**	**0.050**
Central stenosis	**76.1%**	**2.0**	**(1.5–2.8)**	**0.001**
Foraminal stenosis	**50.0%**	**1.9**	**(1.5–2.5)**	**0.001**

Boldface indicates statistical significance.

[a]*P* value calculated using Poisson regression.
Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CCI, Charlson Comorbidity Index; EBL, estimated blood loss; HNP, herniated nucleus pulposus; RR, relative risk; SF-12, 12 item short form; WC, workers' compensation.

Table 7. Bivariate analysis achievement for PROMIS PF.

Characteristic	Failed MCID (%)	RR	95% CI	*P* value[a]
Overall	17.0%	–	–	–
Age				
18–50 y	18.5%	Reference		
<50 y	81.5%	0.89	(0.7–1.1)	0.363
Gender				
Male	43.5%	1.1	(0.9–1.4)	0.309
Female	56.5%	Reference		
BMI				
<30 kg/m^2	**46.7%**	**Reference**		
≥30 kg/m^2	**53.3%**	**1.4**	**(1.1–1.7)**	**0.002**
Smoking status				
Nonsmoker	87.0%	Reference		
Smoker	13.0%	0.9	(0.6–1.3)	0.817
Diabetes				
Nondiabetic	79.3%	Reference		
Diabetic	20.7	1.2	(0.9–1.5)	0.099
Ageless CCI				
<1	3.3%	Reference		
≥1	96.7%	1.5	(0.7–3.5)	0.332
ASA score				
<2	63.0%	Reference		
≥2	37.0	1.1	(0.9–1.3)	0.487
Insurance				
WC	84.8%	Reference		
Non-WC	15.2%	1.1	(0.9–1.4)	0.508
Operative length				
<50 min	43.5%	Reference		
≥50 min	56.5%	1.1	(0.9–1.3)	0.508
EBL				
<50 mL	50.0%	Reference		
≥50 mL	50.0%	1.1	(0.9–1.3)	0.411
Operative levels				
Single	**71.7%**	**Reference**		
Multilevel	**28.3%**	**1.4**	**(1.2–1.7)**	**0.001**
Operative technique				
Laminectomy only	23.3%	1.3	(0.9–1.8)	0.077
Discectomy only	–	–	–	–
Laminectomy + discectomy	75.4%	0.8	(0.6–1.1)	0.147
Spinal pathologies				
HNP	**46.7%**	**0.8**	**(0.6–0.9)**	**0.015**
Central stenosis	10.9%	1.2	(1.0–1.5)	0.094
Foraminal stenosis	15.2%	1.3	(1.0–1.7)	0.088

Boldface indicates statistical significance.
[a]*P* value calculated using Poisson regression.
Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CCI, Charlson Comorbidity Index; EBL, estimated blood loss; HNP, herniated nucleus pulposus; PROMIS PF, patient-reported outcomes measures information system physical function; RR, relative risk; WC, workers' compensation.

to achieve an overall MCID for each PROM. For VAS back, insurance was identified as a significant risk factor (RR = 1.7; 95% CI [1.2–2.3]; $P = 0.001$). For VAS leg, ageless CCI (RR = 1.6; 95% CI [1.1–2.3]; $P = 0.024$), EBL (RR = 0.9; 95% CI [0.9–0.9]; $P = 0.001$), and a spinal pathology of HNP (RR = 0.6; 95% CI [0.4–0.9]; $P = 0.032$) were significant covariates for failure to achieve an MCID. For ODI, age (RR = 1.1; 95% CI [1.01–1.01]; $P = 0.032$), ageless CCI (RR = 2.2; 95% CI [1.4–3.5]; $P = 0.001$), and EBL (RR = 0.9; 95% CI [0.9–0.9]; $P = 0.001$) were significant risk factors for failure to achieve an MCID.

Postestimation regression analysis for physical function outcome measures identified spinal pathology of HNP (RR = 0.5; 95% CI [0.3–0.8]; $P = 0.016$) as a risk factor for failure to reach an MCID for SF-12

Table 8. Multiple regression analysis for MCID achievement.

Outcome Measure	RR	95% CI	*P* value[a]
VAS Back			
Insurance	**1.7**	**(1.2–2.3)**	**0.001**
VAS Leg			
Age	1.0	(0.9–1.0)	0.512
Ageless CCI	**1.6**	**(1.1–2.3)**	**0.024**
EBL	**3.3**	**(1.3–8.5)**	**0.010**
HNP	**0.5**	**(0.3–0.9)**	**0.032**
ODI			
Age	**1.1**	**(1.0–1.0)**	**0.032**
Ageless CCI	**2.2**	**(1.4–3.5)**	**0.001**
EBL	**1.0**	**(0.9–0.9)**	**0.001**
Smoking status	0.7	(0.4–1.3)	0.282
Operative length	0.9	(0.9–1.0)	0.772
Central stenosis	1.2	(0.7–1.9)	0.415
Foraminal stenosis	1.5	(0.9–2.3)	0.099
SF-12 PCS			
Age	1.0	(0.9–1.0)	0.103
Gender	0.9	(0.6–1.3)	0.522
BMI	1.2	(0.8–1.7)	0.451
Ageless CCI	1.6	(0.9–2.6)	0.056
EBL	1.2	(0.5–2.5)	0.627
Smoker status	0.7	(0.4–1.3)	0.318
Operative length	1.1	(0.7–1.8)	0.551
HNP	**0.5**	**(0.3–0.8)**	**0.016**
Foraminal stenosis	0.6	(0.4–1.0)	0.063
Laminectomy	2.5	(0.5–11.5)	0.252
PROMIS PF			
Gender	0.9	(0.6–1.5)	0.931
BMI	1.1	(0.8–1.7)	0.480
Diabetes	0.4	(0.1–1.3)	0.140
Insurance	**2.0**	**(1.1–3.8)**	**0.022**
EBL	**4.5**	**(1.1–17.6)**	**0.027**
No. of operative levels	1.3	(0.8–1.9)	0.287

Boldface indicates statistical significance.
[a]*P* value calculated using LASSO logistical regression model.
Abbreviations: BMI, body mass index; CCI, Charlson Comorbidity Index; EBL, estimated blood loss; HNP, herniated nucleus pulposus; RR, relative risk; VAS, visual analog scale.

PCS; whereas, only insurance collected (RR = 0.3; 95% CI [0.2–0.5]; $P = 0.001$) and EBL (RR = 4.5; 95% CI [1.1–17.6]; $P = 0.027$) were significant risk factors for PROMIS PF. Among all postestimation regression analyses, EBL was a significant risk factor for failure to achieve an MCID among the majority of PROMs except VAS back and SF-12 PCS.

DISCUSSION

Traditionally, patient improvement has been gauged based on both radiographic measures and clinical evaluations. Over time, PROMs have become an additional asset to the evaluation of postoperative improvement. However, while PROMs may provide statistical insight into a significant change in symptoms, MCID may provide a more patient-centered assessment of a clinically important change. Understanding risk factors associated with failure to achieve an MCID may allow surgeons greater insight as to which individuals are most likely to experience meaningful benefits from surgery. While previous studies have established risk factor assessment following both cervical and transforaminal lumbar fusions,[5,6] LD constitutes both a different procedure as well as a different subset of indications. This study investigated the demographic and perioperative characteristics that may contribute to a higher risk for failure to achieve an MCID for five different commonly used PROMs. We present the most prevalent risk factors for failure to achieve an MCID as they relate to patient demographics, operative characteristics, and underlying spinal pathology.

Among the 5 PROMs assessed for failure to reach an MCID, all outcome measures demonstrated that a majority of patients (<80%) were able to achieve a clinically important difference. For those patients who were unable to achieve an MCID, the demographic variables which had the most significant impact were largely factors which contribute to comorbidity burden. More specifically, ageless CCI was the most common significant risk factor across all PROMs, except PROMIS PF, and age similarly increased the risk for failure to achieve an MCID for all outcome measures except VAS back. Although few, if any, previous studies have examined MCID risk factors for MIS LD, a number of investigators have suggested that comorbidity burden increases risk for unfavorable outcomes in a number of outcome measures. Paulsen et al[20] reported that poorer satisfaction following decompression surgery for spinal stenosis was associated with patient comorbidities, smoking, and duration of symptoms. A similar finding was demonstrated in a study of laminectomy patients where a lower CCI was also associated with an overall favorable functional outcome.[21] However, other studies have suggested that CCI does not predict worse outcomes for lower back pain and disability and instead suggest that BMI may be a stronger factor.[22] Even with contrasting results, our analysis demonstrated that the comorbidity burden placed patients at increased risk for failed achievement of an MCID for not just one but multiple PROMs. This may indicate that special considerations or patient counseling should be made for patients who carry a larger comorbidity burden.

Although age is a part of the CCI score, we opted to analyze the ageless CCI to determine the effect of advanced age on risk for MCID failure in isolation. Not surprisingly, age, as a risk factor for failure to achieve an MCID, coincided with PROMs that also identified ageless CCI as a risk factor. Although age is a well-known risk factor for poorer outcomes, only a select few studies have established this for LD outcomes. Krutko et al[23] reported that younger patients had a

"more successful" treatment for lumbar disc herniations and was substantiated by a study that reported that deterioration of outcomes, defined as an 8-point increase in ODI, was associated with age, smoking, ASA score, and previous operations at the same or other lumbar levels.[24] This result is of interest because of the age cutoff we set at 50 years. Trends in lumbar disc herniation indicate that the highest incidence of lumbar disc herniation occurs in the lower lumbar spine in patients aged 25–55 years, but other studies demonstrate that it has a smaller impact among elderly patients.[25,26] Regardless, it can be inferred that the elderly may need to curb expectations and clinicians may need to adjust their preclinical counseling for MIS LD patients.

Interestingly, although not specifically included in the CCI, BMI was also identified as a risk factor only for PROMIS PF. Previous studies among decompression patients were able to also identify BMI as a risk factor for poorer operative outcomes and failure to reach an MCID following MIS LD.[27]

One of the most interesting aspects of this study was identifying insurance status as a potential risk factor influencing MCID failure for VAS back. This relationship was also estimated by LASSO and confirmed by postestimation regression analysis. More specifically, being listed as having workers' compensation was associated with an increased risk for MCID failure, which may be attributed to more severe nonage-related spinal pathology of the intervertebral disc space in this population. Previous MCID studies reported that worker's compensation was a risk factor for outcomes in transforaminal lumbar fusion patients[6] and was similarly identified in a systematic review, which established the association between compensation status and poorer postoperative outcomes.[28,29] Other studies also implicate insurance collected as a prognostic factor, as achievement of MCID and sustained improvement of lower back pain following decompression surgery was reportedly associated with lack of compensation claims and absence of narcotic usage.[30] Furthermore, Koerner et al[31] also demonstrated that having no litigation pending and use of nonworkers' compensation payment sources were associated with better treatment effects at 2 years. With a depth of evidence, these results, in addition to our results, may indicate that workers' compensation patients endure a more severe spinal pathology and therefore a lower chance of achieving an MCID. Unfortunately, workers' compensation status is beyond the control of surgeons and may be relatively nonmodifiable, but our study demonstrated that a number of modifiable operative characteristics were associated with failure to achieve an MCID and may be of greater interest.

Categorization of an LD procedure may vary across different providers; however in the current study, procedures were limited to laminectomy, discectomy, or a combination of both performed in conjunction with foraminotomy and facetectomy. Patients who underwent a laminectomy procedure without discectomy were noted to have an increased risk for failing to achieve an MCID for VAS leg and ODI only. These results also coincide with both central and foraminal stenosis being significant risk factors for failed VAS leg MCID achievement. Previous studies comparing revision rates between decompression and fusion patients noted that at 1 year, rates were higher among patients who underwent an index-level decompression surgery, which included laminectomy alone, as compared to spinal fusion procedures.[32] However, authors of the same study noted that revision rates by the 4-year timepoint were identical. It may be inferred by these results that laminectomy with foraminotomy and facetectomy for the treatment of degenerative changes may require additional recovery time to resolve leg pain and associated disability. It is also interesting to note that performing a laminectomy and discectomy demonstrated a protective effect for failing to achieve an MCID for leg pain and physical function; however, only results for VAS leg reached significance. This coincides with the observation that a spinal pathology of HNP also was protective against failed MCID.

Operative characteristics such as blood loss, number of levels decompressed, and underlying spinal pathology are significant risk factors for failure to reach an MCID following MIS LD. Although operative time and blood loss are believed to be associated with one another, there was no direct correlation between operative variables. However, these operative risk factors have both demonstrated negative impacts on postoperative outcomes and been associated with increased incidence of complications. A large spine surgical registry study evaluated over 4000 patients who were treated for lumbar spinal stenosis and determined that in addition to increased VAS back pain at baseline, the vertebral levels involved were associated with negative outcomes.[16] Alternatively, there is evidence that the invasiveness of a surgical procedure, number of levels decompressed, fused, or instrumented and approach type may predict risk for poorer outcomes.[33] Interestingly, among our results, EBL and number of levels decompressed were suggested as risk factors for only VAS leg, ODI, and PROMIS PF, a finding supported by LASSO postestimations for VAS leg and PROMIS PF only. These results suggest that for a common procedure such as MIS LD, operative characteristics that may prolong the procedure and increase blood loss

can result in lower chance of reaching an overall MCID. This finding places further emphasis on the surgeon's ability to discern the necessity of an additional operative level and may aid in providing guidance for future multilevel MIS LD procedures.

MIS LD is believed to be an effective treatment for symptomatic lower back pain. However, the current study suggests that the spinal pathology clinical symptoms may predict risk of failure to achieve an MCID for a number of commonly used PROMs. Of particular interest is the reduced risk that was associated with having a spinal diagnosis of HNP for all PROMs except for VAS back. This was further supported by our results from LASSO, which suggested HNP was a protective factor for VAS leg and SF-12 PCS. Among the most common spinal diagnoses in our cohort, HNP is believed to be highly amenable to treatment, with numerous studies reporting favorable surgical outcomes. Although our study does support these findings, the severity of herniation must be addressed as a number of studies have suggested its influence on postoperative outcomes. Specifically, transligamentous, caudal migrations, or large annular defects can lead to increased recurrence of herniations and poorer outcomes.[34–37] Given that our cohort demonstrated a reduced relative risk associated with HNP, it may be presumed that these patients underwent treatment of relatively uncomplicated symptomatic disc herniations. Collectively, these results suggest that more complex spinal pathologies and procedures may increase the risk for a failed MCID.

Use of MCID to objectively assess postoperative outcomes may provide benefits to the clinician, but it also has its share of limitations. Achievement of MCID may provide context to the magnitude of improvement in terms of patient satisfaction, as prior studies have anchored their established thresholds on satisfaction questionnaires.[38–40] Although achievement and nonachievement may represent a "satisfied" and "not-satisfied" patient, there are inherent limitations to this type of analysis, and may not be a suitable replacement for other objective measures such as physical function tests (time to ambulation, dynamometer, range of motion, and gait assessment). Even though the current study provides potential baseline characteristics that are associated with a failure to achieve a meaningful difference, from the perspective of the patient, it may not be a suitable replacement of continuous measures that other clinicians may rely on to determine the acceptable level of postoperative improvement.

Limitations

There are a number of limitations that must be considered when interpreting our results. First, generalizability is restricted because all procedures were performed at a single institution by a single fellowship-trained spine surgeon. Additionally, as with any self-reported outcomes, our results may be at risk for bias, which could potentially skew our reported MCID achievement rates. Another limitation involves the use of MCID achievement, whereby the values were obtained from established studies. These values may vary based on the methodology used to calculate MCID values. Whether an anchor-based method or a distribution-based method was used can cause variation and may alter the proportion of patients who have or have not achieved an MCID for our study.

CONCLUSION

Patients undergoing MIS LD may have a number of different risk factors for failure to reach an MCID for commonly used PROMs. VAS back demonstrated the largest number of risk factors for failure to reach an MCID. Age, comorbidity burden, blood loss, and number of operative levels were among the most common risk factors for failure to reach an MCID across all PROMs. Additionally, use of LASSO substantiated the comorbidity burden, spinal diagnosis of HNP, and EBL as potential risk factors for failure to reach an MCID for the majority of PROMs. These results suggest that patients with a combination of greater comorbidity burden and higher risk operative characteristics may experience limited or prolonged postoperative recovery following MIS LD.

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