The Spine Journal 19 (2019) 187–190

Clinical Study

Prognostic factors associated with best outcomes (minimal symptom state) following fusion for lumbar degenerative conditions

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Received 24 April 2018; revised 19 June 2018; accepted 19 June 2018

Abstract

BACKGROUND CONTEXT: Previous studies suggest that a postoperative symptom state with Oswestry Disability Index (ODI)≤20 and pain Numeric Rating Scales (NRS)≤2 following surgery for lumbar degenerative conditions are reasonable thresholds for best outcomes in which patients will be unlikely to seek additional medical care or require additional health-care resources.
PURPOSE: To identify prognostic factors that predict a "best outcome," defined as postoperative ODI≤20 and pain NRS≤2 following fusion for lumbar degenerative conditions.
STUDY DESIGN: Longitudinal observational cohort.
PATIENT SAMPLE: A total of 396 patients from a single site enrolled in the Quality Outcomes Database who underwent fusion for lumbar degenerative conditions.
OUTCOME MEASURES: Oswestry Disability Index, Back and Leg Pain NRS (0–10).
METHODS: Collected and analyzed variables included age, sex, body mass index, American Society of Anesthesia grade, number of surgical levels, surgical time, preoperative ODI, preoperative back pain, preoperative leg pain, workmen compensation status, surgical approach, smoking status, and principal diagnosis.
RESULTS: A total of 74 patients (19%) reported a minimal symptom state at 1-year postoperative (ODI≤20, back pain NRS≤2, and leg pain NRS≤2) and were included in the best outcomes group. Patients in the best outcomes group were older (62 vs. 57 years, p=.001), had lower preoperative ODI (43 vs. 56, p=.000), lower preoperative back pain (6.5 vs. 7.5, p=.000). They had fewer surgical levels (1.25 vs. 1.47, p=.005) and shorter operative times [OR] times (208 vs. 241 minutes, p=.002). They were more likely to have a preoperative diagnosis of spondylolisthesis or disc herniation and less likely to have a diagnosis of adjacent segment disease or mechanical disc collapse (p=.001). Stepwise forward regression analysis revealed diagnosis (p=.023, OR=0.75), age (p=.000, OR=1.04), baseline ODI (p=.000, OR=0.96), and number of levels (p=.019, OR=0.53) as predictive variables.
CONCLUSION: Achieving a minimal symptom state, defined here as a postoperative ODI≤20 and pain NRS≤2, following fusion for lumbar degenerative conditions is more likely in an older patient with a lower baseline ODI undergoing a single level lumbar fusion for spondylolisthesis.
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Keywords: Back pain; Best outcomes; Lumbar fusion; Lumbar degenerative disorders; Oswestry Disability Index; Patient reported outcomes

FDA device/drug status: Not applicable.

This study was reviewed and approved by the University of Louisville Institutional Review Board.

Author disclosure: ***CHC***: Nothing to disclose. ***SDG***: Nothing to disclose. ***MD***: Nothing to disclose. ***RKO***: Nothing to disclose. ***JLG***: Nothing to disclose. ***LYC***: Nothing to disclose.

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https://doi.org/10.1016/j.spinee.2018.06.348
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Introduction

The current state of the art for measuring treatment effectiveness following lumbar spine surgery includes the use of patient reported outcome (PRO) measures. Commonly used PROs for the lumbar spine include the Oswestry Disability Index (ODI, 0–100) [1,2], as well as numeric rating scores (NRS, 0–10) for back and leg pain [3,4]. Much work has been done to help clinicians, researchers, and policymakers understand and interpret the numeric scores associated with PROs [5–11]. Concepts such as substantial clinical benefit [9], minimum acceptable outcome [5], acceptable symptom state [8], and willingness to undergo same operation [12] suggest that obtaining a postoperative symptoms state with ODI≤20 and pain NRS≤2 are reasonable thresholds for best outcomes such that patients will be unlikely to seek additional medical care or require additional health-care resources.

The purpose of the current study is to identify factors associated with a best outcome following fusion for lumbar degenerative conditions. The knowledge gained from this study should help inform the preoperative decision making process for patients, clinicians, and policy makers alike.

Methods

Three hundred and ninety-six patients underwent fusion for lumbar degenerative conditions and were entered into a prospective quality improvement registry, the Quality Outcomes Database (QOD) [13–15]. These nearly 400 patients represent a series of patients with 1-year follow-up from a single center with eight board-certified orthopedic spine surgeons. The QOD lumbar module is a prospective observational registry that collects standard demographic and surgical data, as well as 30- and 90-day morbidity; and 3- and 12-month PROs. Six cases per site are enrolled per week on a rolling 6-day cycle. Hence, the first day of each 6-day week falls on each weekday with equal frequency. This creates a sampling method that prevents a disproportionate volume of enrollment on any one day of the week or from any one surgeon's schedule at any one site, thus limiting potential enrollment bias.

Collected and analyzed variables included: age, sex, body mass index, American Society of Anesthesia grade, smoking status, preoperative ODI, preoperative back pain, preoperative leg pain, workers compensation status, number of surgical levels, surgical time, surgical approach (posterior spinal fusion, transforaminal lumbar interbody fusion, anterior lumbar interbody fusion, combined anterior lumbar interbody fusion and/or posterior spinal fusion), and principal diagnosis (adjacent segment, spondylolisthesis, stenosis, mechanical disc collapse, and lumbar disc herniation).

All statistical analyses were performed using IBM SPSS Statistics for WindowsV25 (Armonk, NY). Differences between the two groups were analyzed using unpaired *t* tests for continuous variables, Fisher's exact test for categorical variables and Wilcoxon test for ordinal or non-normal variables. Stepwise forward binary logistic regression was performed to identify associations between the variables above and the odds of achieving best outcomes.

Results

Seventy-four patients (19%) reported a minimal symptom state at 1-year postoperative (ODI≤20, and back pain NRS≤2, and leg pain NRS≤2) and were included in the best outcomes group. Patients in the best outcomes group (Table 1) were older (62 vs. 57 years, p=.001), had fewer surgical levels (1.25 vs. 1.47, p=.005) and shorter OR times (208 vs. 241 minutes, p=.002). They were more likely to have a preoperative diagnosis of spondylolisthesis or disc herniation and less likely to have a diagnosis of adjacent segment disease or mechanical disc collapse (p=.001). They had lower preoperative ODI (43 vs. 56, p=.000) and lower preoperative back pain (6.5 vs. 7.5, p=.000) (Table 2). Stepwise forward regression analysis revealed diagnosis (p=.23, odds ratio [OR]=0.75), age (p=.000, OR=1.04), baseline ODI (p=.000, OR=0.96), and number of levels (p=.019, OR=0.53) as predictive variables (Table 3).

Table 1
Summary of demographic and surgical data

	Rest	Best outcomes	p
value			
N	322	74	
Age, years, mean (SD)	62.15 (10.80)	57.47 (12.48)	.001
BMI, kg/m^2, mean (SD)	30.88 (6.08)	31.47 (6.20)	.456
Males, N	118 (36.6)	32 (43.2)	.291
Workers compensation, N (%)	19 (5.9)	1 (1.4)	.351
ASA grade, mean (SD)	2.66 (0.50)	2.72 (0.56)	.385
Smoking status, N (%)			.038
Never smoker	140 (43.5)	40 (54.1)	
Former smoker	112 (34.8)	25 (33.8)	
Current smoker	59 (18.3)	5 (6.8)	
Principal spine diagnosis, N (%)			.001
Adjacent segment disease	62 (19.3)	6 (8.1)	
Spondylolisthesis	143 (44.4)	50 (67.6)	
Stenosis	58 (18.0)	8 (10.8)	
Mechanical disc collapse	36 (11.2)	3 (4.1)	
Lumbar disc herniation	22 (6.8)	5 (6.8)	
Number of levels, mean (SD)	1.25 (0.50)	1.47 (0.86)	.005
Surgical approach, N (%)			
PSF	135 (41.9)	32 (43.2)	.395
TLIF	130 (40.4)	34 (45.9)	
ALIF	12 (3.7)	3 (4.1)	
ALIF/PSF	45 (14.0)	5 (6.8)	
OR time	208.00 (78.71)	240.54 (88.43)	.002

PSF, posterior spinal fusion; TLIF, transforaminal lumbar interbody fusion; ALIF, anterior lumbar interbody fusion; OR, odds ratio; SD, standard deviation; BMI, body max index; ODI, Oswestry Disability Index.

Twelve month back pain ≤2 and leg pain ≤2 and ODI score ≤20.

Table 2
Summary of patient reported outcomes

Baseline	Best outcomes Mean (SD)	Rest Mean (SD)	p value
Back pain	6.50 (2.08)	7.53 (1.75)	.000
Leg pain	6.19 (2.66)	6.98 (2.24)	.020
ODI	42.78 (12.23)	55.52 (14.74)	.000
Twelve-month			
Back pain	0.70 (0.64)	5.56 (2.44)	.000
Leg pain	0.46 (0.73)	4.64 (3.00)	.000
ODI	8.25 (6.27)	45.08 (18.13)	.000
Twelve-month change			
Back pain	5.80 (2.18)	1.98 (2.49)	.000
Leg pain	5.73 (2.62)	2.34 (3.08)	.000
ODI	34.53 (14.36)	10.45 (14.81)	.000

SD, standard deviation; ODI, Oswestry Disability Index.

Discussion

Despite over a decade of work in which PROs have been used to evaluate the efficacy of lumbar fusion surgery, surgical indications remain inconsistent. This may result in part from the fact that standards of acceptable outcome are not rigorous. One of the most common thresholds of acceptable outcome is the minimal clinically important difference. Although this is often positioned as an appropriate surgical target, it is defined as the smallest change that a patient can reproducibly identify. It is therefore unsurprising that this threshold does not drive ideal patient selection. The purpose of this study is to focus on best outcomes in an effort to better hone surgical decision-making and informed consent.

Previous authors have used other study designs and methodologies to identify thresholds of improvement or acceptable final outcome scores. In 2008, Glassman et al. [9] published the concept of substantial clinical benefit following lumbar spine fusion surgery. Substantial clinical benefit calculations for back pain and leg pain numeric rating scales using the 1 to 10 scale were a 2.5 point net improvement or a final raw score of less than 3.5 points. In 2010, Carragee et al. [5] published the concept of minimum acceptable outcome following lumbar spine fusion surgery, reported as pain score equal to or below 3 on a 1 to 10 point scale. In 2016, Fekete et al. [8] reported that patients were happy to live with a pain score less than 3 on a 1 to 10 point scale following surgery, including nonfusion surgery, for lumbar degenerative conditions. In 2017, Crawford et al. [12] reported that patients in the N2QOD dataset who choose "surgery met my expectations" on the postoperative satisfaction question, had mean pain scores on a 1 to 10 point scale of 1.8 for back and 1.4 for leg. Based on the above studies and clinical experience, we chose to set the threshold for "best outcomes" as an ODI<20, back pain <2, and leg pain <2. The expectation is that patients who report these scores will be satisfied with treatment and will be unlikely to require additional diagnostic or treatment resources.

Table 3
Variables predictive of best outcomes

Variables	p value	OR	95% confidence interval
Diagnosis*	.023	0.75	0.59–0.96
Age	.000	1.04*	1.02–1.06
Baseline ODI	.000	0.96*	0.94–0.97
Number of levels	.019	0.53*	0.31–0.90

OR, odds ratio; ODI, Oswestry Disability Index.

* Diagnostic categories: 1=lumbar disc herniation (reference), 2=stenosis, 3=spondylolisthesis, 4=mechanical disc collapse, 5=adjacent segment degeneration. Lumbar disc herniation is the reference category. Comparing one diagnostic category to another (ie, mechanical disc collapse to spondylolisthesis, the likelihood of getting "Best outcomes" decreases by an odds of 0.75).

The results of this study show that achieving a "minimal symptom state" or "best outcome" following fusion for lumbar degenerative conditions is more likely in an older patient with a lower baseline ODI undergoing a single level lumbar fusion for spondylolisthesis. These data can help inform patients, clinicians, and policy makers who are involved in the preoperative decision-making process. Although this "minimal symptom state" may be the ideal outcome from the perspective of all those involved, it is unlikely to be a realistic expectation for the majority of patients with degenerative lumbar spine conditions. Only 19% of patients in the current study reached this goal in which their lumbar condition was essentially "cured." The majority of the patients who underwent a lumbar fusion in our series continued to have more than minimal symptoms at 1-year follow-up. Many of the patients who had residual symptoms may have obtained a clinically important improvement from their preoperative condition and should not necessarily be considered failures of treatment. This study cannot answer the question of whether individual patients would have improved more or less with a different treatment.

The limitations of this study include the single center design, which may not be generalizable to all patient populations. Although local cultural and institutional treatment biases likely exist, the large patient sample and multiple surgeon involvement should mitigate some of these biases. Additionally, the database design limits analysis of factors such as complications, reoperations, coexisting musculoskeletal disease, coexisting medical comorbidities, coexisting psychosocial issues, and other factors that undoubtedly can influence PROs. Another limitation would be the variability of diagnosis (ie, which category does a patient with a mild spondylolisthesis and foraminal disc protrusion fall?) as well as fusion technique (eg, was the patient treated with posterior only or interbody fusion?).

Future comparative treatment studies may be improved by focusing on specific patient populations with well-defined diagnostic categories including those who have been identified to have a significant chance of obtaining a minimal symptom state following treatment.

Acknowledgment

No external funding was received for this study.

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