

An analysis from the Quality Outcomes Database, Part 1. Disability, quality of life, and pain outcomes following lumbar spine surgery: predicting likely individual patient outcomes for shared decision-making

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OBJECTIVE Quality and outcomes registry platforms lie at the center of many emerging evidence-driven reform models. Specifically, clinical registry data are progressively informing health care decision-making. In this analysis, the authors used data from a national prospective outcomes registry (the Quality Outcomes Database) to develop a predictive model for 12-month postoperative pain, disability, and quality of life (QOL) in patients undergoing elective lumbar spine surgery.

METHODS Included in this analysis were 7618 patients who had completed 12 months of follow-up. The authors prospectively assessed baseline and 12-month patient-reported outcomes (PROs) via telephone interviews. The PROs assessed were those ascertained using the Oswestry Disability Index (ODI), EQ-5D, and numeric rating scale (NRS) for back pain (BP) and leg pain (LP). Variables analyzed for the predictive model included age, gender, body mass index, race, education level, history of prior surgery, smoking status, comorbid conditions, American Society of Anesthesiologists (ASA) score, symptom duration, indication for surgery, number of levels surgically treated, history of fusion surgery, surgical approach, receipt of workers' compensation, liability insurance, insurance status, and ambulatory ability. To create a predictive model, each 12-month PRO was treated as an ordinal dependent variable and a separate proportional-odds ordinal logistic regression model was fitted for each PRO.

RESULTS There was a significant improvement in all PROs ($p < 0.0001$) at 12 months following lumbar spine surgery. The most important predictors of overall disability, QOL, and pain outcomes following lumbar spine surgery were employment status, baseline NRS-BP scores, psychological distress, baseline ODI scores, level of education, workers'

ABBREVIATIONS ASA = American Society of Anesthesiologists; BMI = body mass index; BP = back pain; CAD = coronary artery disease; CI = confidence interval; IQR = interquartile range; LP = leg pain; MCID = minimal clinically important difference; NRS = numeric rating scale; ODI = Oswestry Disability Index; OR = odds ratio; PRO = patient-reported outcome; QOD = Quality Outcomes Database; QOL = quality of life.

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compensation status, symptom duration, race, baseline NRS-LP scores, ASA score, age, predominant symptom, smoking status, and insurance status. The prediction discrimination of the 4 separate novel predictive models was good, with a c-index of 0.69 for ODI, 0.69 for EQ-5D, 0.67 for NRS-BP, and 0.64 for NRS-LP (i.e., good concordance between predicted outcomes and observed outcomes).

CONCLUSIONS This study found that preoperative patient-specific factors derived from a prospective national outcomes registry significantly influence PRO measures of treatment effectiveness at 12 months after lumbar surgery. Novel predictive models constructed with these data hold the potential to improve surgical effectiveness and the overall value of spine surgery by optimizing patient selection and identifying important modifiable factors before a surgery even takes place. Furthermore, these models can advance patient-focused care when used as shared decision-making tools during preoperative patient counseling.

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KEY WORDS QOD; Quality Outcomes Database; patient-reported outcomes; predictive model; disability; pain; quality of life; lumbar

DEGENERATIVE lumbar spine pathology is a common indication for spine surgery, particularly with the aging US population. Over the past 2 decades, there has been a 300% increase in the number of low-back surgeries and a corresponding increase in the incidence and prevalence of lumbar fusion operations.^{24,54,59,64} A recent analysis from the Agency for Healthcare Research and Quality found that the greatest proportion of overall health care expenditure in US hospitals is spent on spinal fusion, costing \$12.8 billion in 2011.⁶⁶ The safety and effectiveness of spine surgery vary significantly at the individual patient level. Recent evidence suggests that as many as 25% of diagnostic and therapeutic spine interventions are unnecessary or ineffective.^{25,62} For this reason, providers, payers, and hospital systems all aim to identify which patient-specific or surgery-specific factors play significant roles in postoperative outcomes.

In the current era of patient-centered care, engaging patients in shared decision-making in their treatment planning is imperative. Shared decision-making is defined as a process “involving the patient and provider, both parties participating in the treatment decision-making process, requiring information sharing, and both parties agreeing to the treatment decision made.”^{17,23} True informed decision-making can be achieved if patients are provided with the factual probability of outcomes based on their individual risk factors. When applied in the preoperative setting, predictive models developed using patient-specific and surgery-specific factors have the potential to help patients achieve realistic expectations regarding postsurgical goals, identify modifiable patient- and system-related characteristics that can influence outcomes, and allow for the most efficient and efficacious application of health care resources.

Predictive models have been used as a decision-making tool across various disease processes in medicine.^{9,10,21,50,51,67,68} For example, Lee et al. introduced predictive models for complications⁴² and surgical site infection⁴³ following spine surgery. These models were designed to estimate the likelihood of complications or surgical site infection occurring after spine surgery based on the patient’s comorbidity profile and the invasiveness of the given surgery.^{42,43} Although this effort represents an important ad-

vance in modeling spine outcomes and promoting shared decision-making, a validated prediction model capable of providing individualized predictions of patient-reported outcomes (PROs) following elective lumbar spine surgery has not been developed. The absence of predictive models focusing on PROs is of significant clinical and societal importance, precisely because PROs are rapidly becoming the key element in assessing the effectiveness of patient-centered care. This is largely due to documented discrepancies between patient and clinician assessments of symptoms and functional impairment.³⁰ PROs, therefore, may be more reflective of underlying health status than physician-reported outcomes. PROs take on even greater relative importance in conditions where treatments are associated with lower rates of “observed” adverse outcomes (e.g., major morbidity or mortality), as has been reported for elective spine surgery.⁸ In this regard, the most conspicuous and potentially impactful care improvement opportunities in spine surgery involve optimizing outcomes of greatest importance to patients, specifically relief of pain and improvement of quality of life (QOL) as well as decrease of disability.

Using data from the Quality Outcomes Database (QOD), formerly known as the N²QOD, we set out with the primary goal of creating a clinically relevant predictive model for postoperative disability, QOL, and pain severity.

Methods

The QOD Registry

Data from patients undergoing elective spine surgery for degenerative lumbar disease were entered into the multicenter prospective QOD registry over a 2-year period. The QOD is designed to establish risk-adjusted expected morbidity rates for the most common lumbar surgical procedures performed by spine surgeons.^{7,8} The QOD registry enrolls spine surgery patients from 74 participating centers across 26 US states via representative sampling and collects measures of surgical safety and PROs.⁴⁹

Inclusion and Exclusion Criteria

Patients undergoing lumbar surgery performed for

primary stenosis, spondylolisthesis, disc herniation, and symptomatic mechanical disc collapse, as well as patients undergoing revision surgery for recurrent same-level disc herniation and adjacent-segment disease, were eligible for inclusion. Exclusion criteria included the following: spinal infection, tumor, fracture, traumatic dislocation, deformity, pseudarthrosis, recurrent multilevel stenosis, neurological paralysis due to preexisting spinal disease or injury, age less than 18 years, and incarceration.

Demographic Variables

We recorded the following patient demographic variables when reviewing electronic medical records: age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) grade, history of surgery, history of diabetes, coronary artery disease (CAD), osteoporosis, dominant presenting symptom, presence of motor deficit on examination, symptom duration, diagnosis, preoperative ambulatory status, and surgery-specific variables, including approach (anterior, posterior), number of levels involved, need for arthrodesis, and presence/absence of an interbody graft. The following variables were obtained from the patient interview and then confirmed by reviewing the electronic medical records: race, smoking status, education, employment status, preoperatively employed but not working at the time of surgery, type of occupation, workers' compensation, liability insurance, and type of health insurance (private, uninsured, Medicaid, Medicare).

Interviews and PRO Questionnaires

Baseline (preoperative), 3-month, and 12-month postoperative disability, QOL, and pain levels were assessed either through telephone interviews conducted by a data coordinator not involved with clinical care, or through self-administration either during a clinic visit or by mail. The outcome scores were then entered into a national aggregate database through a secure, password-protected web-based portal (Research Electronic Data Capture).³⁴ In these interviews, validated questionnaires were used to collect data on the following outcome measures: 1) disease-specific physical disability (established using the Oswestry Disability Index [ODI]);²⁷ 2) preference-based QOL status (established using the EQ-5D instrument);²⁶ and 3) pain (established using the numeric rating scale [NRS] for back pain [BP] and leg pain [LP]).⁴¹ The anxiety/depression domain of the EQ-5D was used to define psychological distress. As a part of the EQ-5D questionnaire, the patients are asked if they are anxious or depressed; the responses are captured as 1) not anxious or depressed, 2) moderately anxious or depressed, or 3) extremely anxious or depressed. Patients from sites for whom 12-month PROs were completed as of July 2015 were included in analyses.

Statistical Analysis

Medians and interquartile ranges (IQRs) for continuous variables and frequencies for categorical variables were calculated for demographic and clinical characteristics. Multivariable proportional-odds ordinal regression

models were developed for each PRO measure: disability (ODI), pain (NRS-BP and NRS-LP), and QOL (EQ-5D). Patient-specific variables were included in the models: age, gender, BMI, race, education level, history of surgery, smoking status, comorbid conditions, ASA grade, symptom duration, predominant presenting symptom, workers' compensation, liability insurance, insurance status, ambulatory ability, and baseline PROs, as well as surgery-specific variables such as number of levels, need for arthrodesis, and surgical approach.

We assumed a linear relationship for the number of surgical levels operated upon (range 1–4 levels), baseline ODI score, baseline EQ-5D score, and baseline NRS-BP, and a smooth relationship for age, BMI, and baseline NRS-LP score using restricted cubic regression splines with 4, 4, and 3 knots, respectively. The locations of knots were chosen based on marginal quantiles for that variable. All other predictors were included as binary or categorical variables. Wald testing measured the importance of individual predictors by using the following formula: Wald chi-square value minus degree of freedom (to level the playing field) for each predictor. The higher the difference, the higher is the importance of that predictor in the model.

The effect of predictors on the probability of patients having better 12-month PRO scores was reported as an odds ratio (OR); the corresponding 95% confidence interval (CI) was calculated using the Wald method. Calibration and discrimination of the model were internally validated using bootstrap resampling to estimate likely performance of the model on a new sample of patients. The model performance was measured by the c-index. A c-index value of 0.5 is considered a random prediction and a value of 1 suggests that a model is perfectly discriminating.^{32,33} The c-index is generally smaller for ordinal endpoints than for binary outcomes, due to the difficulty of modelling outcomes such as ODI, EQ-5D, NRS-BP, and NRS-LP.

Risk-adjusted outcomes and probability of improvement in PROs for 2 hypothetical patients were calculated to provide an example of the models. In addition, the probability of achieving clinically meaningful outcome (minimal clinically important difference [MCID]) for ODI was derived for the hypothetical patients. The previously published value of MCID for ODI (14.9 points) was used.⁵⁷ In an effort to evaluate whether the sites with low follow-up rates would affect the results of our model, we performed a sensitivity analysis by building supplemental predictive models for PROs only including patients from sites with 12-month follow-up rates greater than 80%. The analysis was performed using the R (version 3.1.2; <https://www.r-project.org>) and regression modeling (rms; <https://cran.r-project.org/package=rms>) statistical packages.

Results

A total of 10,705 patients undergoing elective spine surgery for degenerative lumbar disease were enrolled and eligible for 12-month follow-up at the time of analysis. Of those patients, 7618 (71.2%) from 39 sites completed a 12-month interview, and data on these patients form the basis of the present analyses.

TABLE 1. Patient demographic and clinical characteristics included in the model

Variable	No. of Patients
Age (Q1, Q2, Q3)	7603 (49, 60, 69)
Gender (%)	7615
Male	3941 (52)
Female	3674 (48)
BMI (Q1, Q2, Q3)	7599 (25.8, 29.3, 33.9)
Hispanic (%)	7598
Yes	169 (2)
No	7429 (98)
Race (%)	7618
Caucasian	6900 (90)
African American	504 (7)
Other	214 (3)
Education (%)	7561
Less than high school	423 (6)
High school diploma	3174 (42)
2-year college degree	1415 (19)
4-year college degree	1500 (20)
Post-college	1049 (14)
Smoker (%)	7547
No	6182 (82)
Yes	1365 (18)
Diabetes (%)	7617
Yes	1283 (17)
No	6334 (83)
CAD (%)	7604
Yes	872 (12)
No	6732 (88)
Osteoporosis (%)	7613
Yes	370 (5)
No	7243 (95)
Psychological distress (%)	7590
None	3775 (50)
Moderate	3255 (43)
Severe	560 (7)
Dominant symptom (%)	7618
Back dominant	1538 (20)
Leg dominant	2662 (35)
Back = leg*	3418 (45)
Motor deficit (%)	7607
Yes	2115 (28)
No	5492 (72)
Symptom duration (%)	7555
<3 mos	916 (12)
>3 mos	6639 (88)
Compensation (%)	7513
Yes	291 (4)
No	7222 (96)

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TABLE 1. Patient demographic and clinical characteristics included in the model

Variable	No. of Patients
Liability (%)	7461
Yes	349 (5)
No	7112 (95)
Insurance (%)	7601
Uninsured	84 (1)
Medicare	2777 (37)
Medicaid	316 (4)
Veterans Affairs/government	182 (2)
Private	4242 (55)
Ambulation (%)	6994
Independent	5990 (85)
With an assist device	960 (14)
Nonambulatory	44 (1)
Occupation (%)	7589
Sedentary	1213 (16)
Light	851 (11)
Medium	841 (11)
Heavy	659 (9)
Disability	679 (9)
Retired	2601 (34)
Others	745 (10)
Baseline PROs (Q1, Q2, Q3)	
ODI	38, 48, 60
EQ-5D	0.36, 0.60, 0.77
NRS-BP	5.0, 7.0, 8.0
NRS-LP	5.0, 8.0, 9.0

Q1 = lower quartile; Q2 = median; Q3 = upper quartile.

* Indicates pain is both leg and back dominant.

Patient Demographics and Surgical Characteristics

Patient and surgical variables included in the model are summarized in Tables 1 and 2. The median age of the 7618 patients was 60 years (IQR 49–69 years). In regards to diagnoses, 36% of patients (n = 2737) had disc herniation, 33% (n = 2493) stenosis, 20% (n = 1505) spondylolisthesis, 6% (n = 430) recurrent disc herniation, 5% (n = 378) adjacent-segment disease, and 1% (n = 72) symptomatic mechanical disc collapse. Decompression with fusion was performed in 36% (n = 2653) of patients, whereas decompression alone was performed in the remaining 64% (n = 4873).

Patient-Reported Outcomes

Because patients elect surgery when suffering from disability or pain, and due to the effect of surgery, significant improvement in all outcomes was documented between baseline (preoperative) and 12-month scores: median ODI (48 [IQR 38–60] vs 18 [IQR 6–38], p < 0.001), EQ-5D (0.60 [IQR 0.36–0.77] vs 0.82 [IQR 0.7–1.0], p < 0.001), NRS-BP (7.0 [IQR 5–8] vs 2 [IQR 0–5], p < 0.001), and NRS-LP (8 [IQR 5–9] vs 1 [IQR 0–5], p < 0.001).

TABLE 2. Surgery-related variables included in the models

Variable	No. of Patients (%)
ASA score	7543
1	503 (7)
2	4214 (56)
3	2826 (37)
No. of treated levels	7199
1	2818 (39)
2	3098 (43)
3	1011 (14)
4	272 (4)
Approach	7403
Posterior	7266 (98)
Anterior	137 (2)
Arthrodesis	7526
None	4873 (65)
Fusion w/ no interbody graft	412 (5)
Fusion w/ interbody graft	2241 (30)

Predictive Models

The importance of each predictor included in each model is depicted in Fig. 1. The “overall” importance is an average of the normalized percentage importance of each predictor for each of the 4 models. Figure 2 summarizes the adjusted effects of predictors for the ODI, EQ-5D, NRS-BP, and NRS-LP models.

Predictive Model for 12-Month Disability (ODI)

The performance measure (c-index) of the ODI predictive model was 0.69. Higher education ($p < 0.0001$), higher preoperative NRS-LP scores ($p < 0.0001$), and better baseline QOL ($p < 0.0001$) were associated with higher odds of having lower (better) disability outcomes. Regarding the type of surgery, compared with those undergoing fusion, the patients undergoing decompression only and those undergoing interbody fusion had higher odds of having better outcomes (lower ODI scores; $p = 0.0019$).

Older age ($p < 0.0001$), female sex ($p = 0.0001$), obesity ($p = 0.002$), African American race ($p < 0.0001$), smoking ($p < 0.0001$), preoperative psychological distress ($p < 0.0001$), dominant BP at presentation ($p < 0.0001$), baseline motor deficit ($p = 0.0089$), duration of symptoms greater than 3 months ($p < 0.0001$), assist device for ambulation ($p = 0.0002$), unemployment ($p < 0.0001$), workers' compensation ($p < 0.0001$), non-private health insurance ($p < 0.0001$), worse baseline disability scores ($p < 0.0001$), higher NRS-BP scores ($p < 0.0001$), and higher ASA scores ($p < 0.0001$) were associated with lower odds of having better disability outcomes (lower ODI scores). Regarding the surgical variables, patients undergoing an anterior approach had higher odds of having worse 12-month disability scores ($p = 0.0108$).

Predictive Model for 12-Month QOL (EQ-5D)

The performance measure (c-index) of the EQ-5D predictive model was 0.69. Older age ($p < 0.0001$), higher edu-

cation ($p < 0.0001$), better preoperative QOL ($p = 0.0001$), and higher preoperative LP scores ($p = 0.0012$) had greater odds of having higher (better) 12-month QOL outcomes.

Obesity ($p = 0.0023$), African American race ($p = 0.0001$), smoking ($p < 0.0001$), psychological distress ($p < 0.0001$), dominant BP at presentation ($p < 0.0001$), duration of symptoms greater than 3 months ($p < 0.0001$), assist device for ambulation ($p = 0.0218$), unemployment due to disability or employment with medium labor job ($p < 0.0001$), workers' compensation ($p < 0.0001$), Medicaid, uninsured, or Veterans Affairs/government payer status ($p = 0.0011$), worse baseline disability scores ($p < 0.0001$), higher baseline BP scores ($p < 0.0001$), and higher ASA grades ($p < 0.0001$) were associated with lower odds of having higher (better) QOL outcomes.

Predictive Model for 12-Month Back Pain (NRS-BP)

The performance measure (c-index) of the NRS-BP predictive model was 0.67. Older age ($p < 0.0001$), higher education level ($p < 0.0001$), and higher baseline QOL ($p = 0.0263$) had greater odds of resulting in lower (better) BP outcomes.

Worse baseline disability scores ($p = 0.0001$), higher baseline BP scores ($p < 0.0001$), obesity ($p = 0.0045$), African American race ($p < 0.0001$), being a smoker ($p = 0.0001$), psychological distress ($p < 0.0001$), dominant BP as presenting symptom ($p < 0.0001$), duration of symptom greater than 3 months ($p < 0.0001$), not employed due to disability or employed in heavy- or medium-labor job ($p < 0.0001$), workers' compensation ($p < 0.0001$), Medicaid payer status ($p = 0.0027$), and higher ASA score ($p = 0.0002$) were associated with lower odds of having lower (better) BP outcomes.

Predictive Model for 12-Month Leg Pain (NRS-LP)

The performance measure (c-index) of the NRS-LP predictive model was 0.64. Older age ($p = 0.0005$), higher education level ($p < 0.0001$), and arthrodesis ($p = 0.0014$), had higher odds of having lower (better) 12-month LP outcomes.

African American race ($p < 0.0001$), psychological distress ($p < 0.0001$), baseline motor deficit ($p = 0.0194$), duration of symptoms greater than 3 months ($p < 0.0001$), unemployment ($p < 0.0001$), workers' compensation ($p < 0.0001$), liability insurance ($p = 0.0010$), Medicaid payer status ($p = 0.0092$), higher baseline disability scores ($p < 0.0001$), higher baseline BP scores ($p < 0.0001$), and greater ASA scores ($p = 0.0049$) were associated with lower odds of having lower (better) LP outcomes.

Hypothetical Patients A and B

The predictive models can be used in the clinical setting to predict the PROs 12 months following spine surgery. Based on the model, we generated 2 hypothetical patients and predicted their 12-month PROs and probability of achieving MCID in PROs. Previously published MCID thresholds for ODI, EQ-5D, and NRS-LP and NRS-BP were used.⁵⁷ As detailed in Table 3, our hypothetical Patient A is a 35-year-old white woman with a post-college level of education who had a sedentary job and private

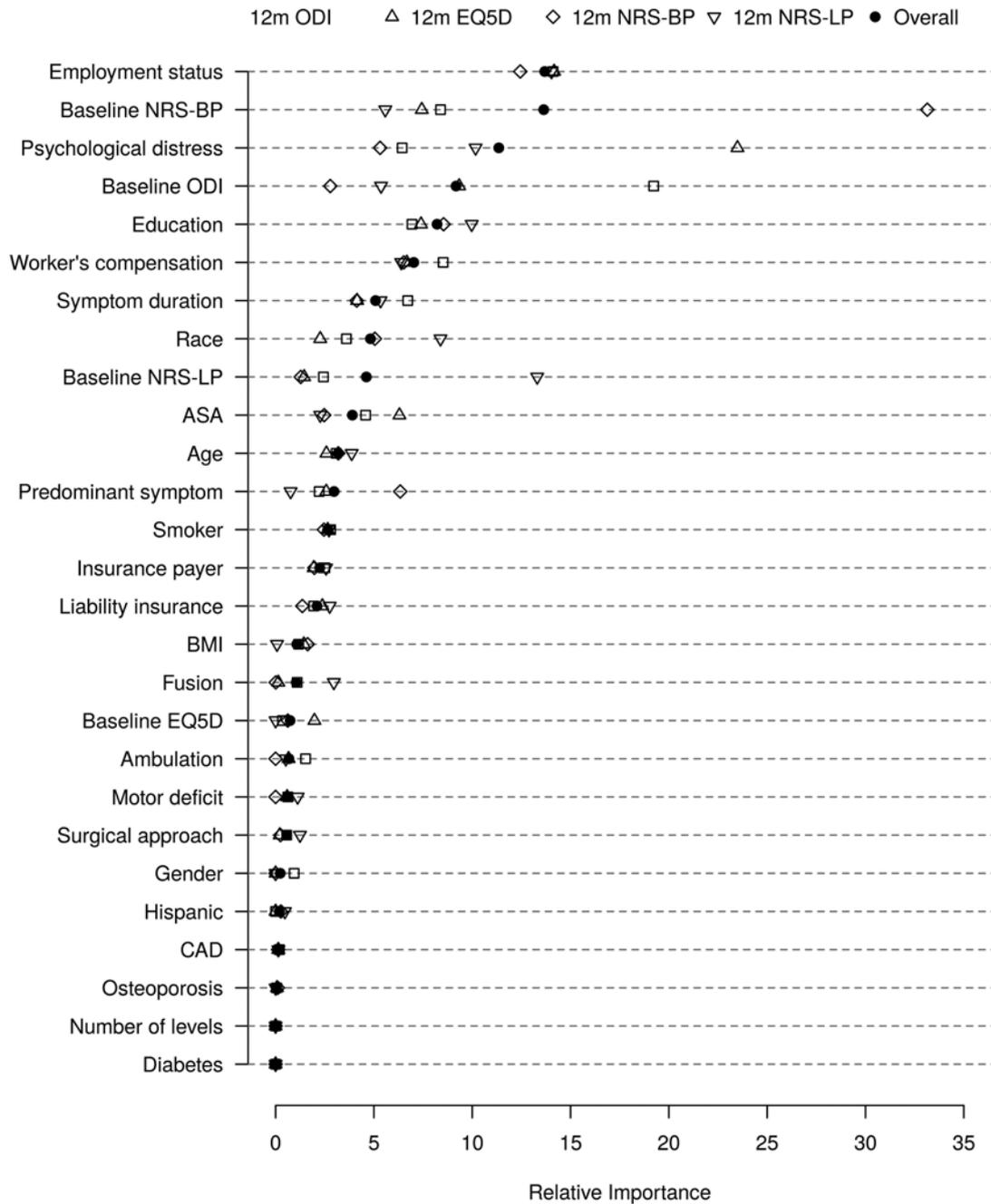


FIG. 1. Importance of predictors, measured by Wald chi-square value minus the degree of freedom of the predictor, based on multivariable models. The overall rank is based on the average of the normalized values of the 4 multivariable models.

health insurance. She had no other comorbidities, such as diabetes, anxiety, or depression, and presented with dominant LP that had been symptomatic for less than 3 months. Baseline PRO scores were as follows: ODI, 44; EQ-5D, 0.7; and NRS-BP and NRS-LP, 6 and 8, respectively. The patient underwent a 1-level laminectomy for disc herniation. The 12-month ODI score predicted by the model for this patient was 7.0 points (37-point improvement in ODI) and the probability of achieving a clinically meaningful improvement in ODI was 94.2%. These results stand in contrast to those in Patient B (Table 3), who had a lower probability of achieving MCIDs for ODI (25.8%) and the

model-predicted mean ODI score improvement of 8.3 points (59.7 absolute 12-month ODI score). This comparison offers a dramatic example of the utility of this model with respect to informed decision-making. Specifically, Patient A could be reassured that she has a high probability of achieving success (at least success as measured by PROs) with the proposed intervention. Patient B, however, would need to be counseled that his chance for success with the same operation is relatively low, and that he might want to defer the intervention until certain modifiable factors could be addressed (e.g., anxiety, obesity, smoking, proposed postsurgical work activities, etc.). Alternatively,

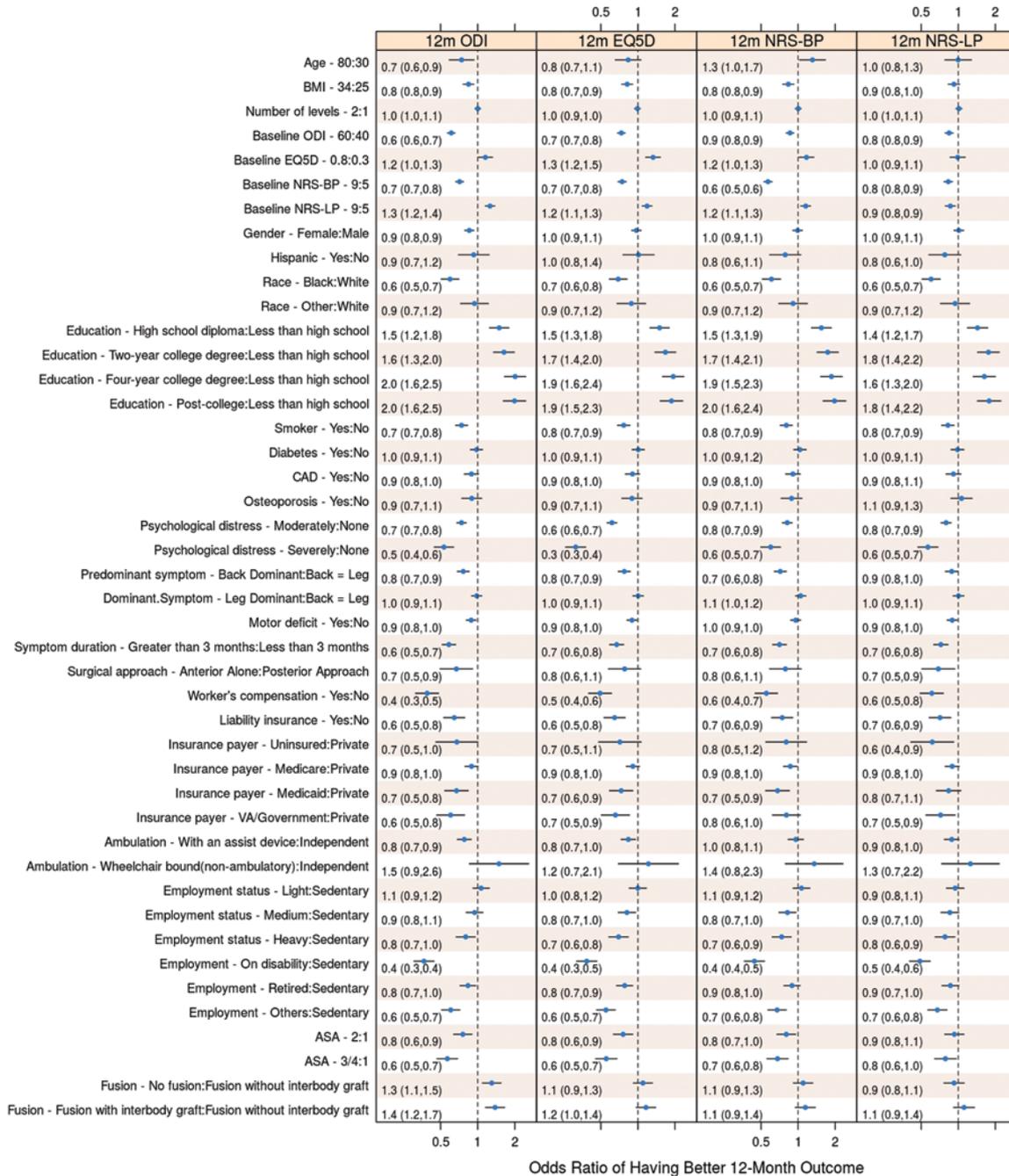


FIG. 2. Summary of ORs and 95% CIs for ODI, EQ-5D, NRS-BP, and NRS-LP models. The values to the immediate right of some variables are quartiles. Figure is available in color online only.

he could be advised that alternate therapies might offer a greater or equivalent benefit while posing less risk. At the very least, such decision tools would help establish appropriate expectations with respect to the outcomes of various interventions, thus increasing the likelihood that the patient will be satisfied with his or her care. Additionally, this tool could be used by a variety of health care stakeholders to identify and prevent ineffective care before it occurs, thus improving the overall value of medical services. Of course, from a registry such as this with no nonsurgical patient cohort, one cannot estimate the likelihood of im-

provement had surgery not been performed or estimate the effect of regression of the mean.

Sensitivity Analysis

Sensitivity analysis was performed for 2968 patients from 8 sites with 12-month follow-up rates greater than 80% (Supplemental Fig. 1). The model performance and the effect size of the predictors in the supplemental models were similar to the full model including all the patients with complete 12-month follow-up.

TABLE 3. Predicted probabilities of improvement 12 months after lumbar surgery derived from predictive model for 2 hypothetical patients (A and B)

Characteristic	Patient A	Patient B
Age	35	66
BMI	30	35
Gender	Female	Male
Race	White	White
Education	Post-college	Less than high school
Prior Surgery	No	Yes
Smoker	No	Yes
Insurance	Private	Medicare
Diabetes	No	Yes
CAD	No	Yes
Depression	No	Yes
Anxiety	No	Yes
Predominant symptom	LP	BP
Motor deficit	No	No
Duration of symptoms	<3 mos	>3 mos
ASA grade	1	2
Diagnosis	Disc herniation	Disc herniation
No. of levels	1	1
Surgical approach	Posterior	Posterior
Fusion	No	No
Occupation	Sedentary	Heavy manual labor
Workers' compensation	No	Yes
Liability insurance	No	Yes
Baseline ODI	44	68
Baseline EQ-5D	0.7	0.3
Baseline NRS-BP	6	9
Baseline NRS-LP	8	8
Predicted probabilities (95% CI)		
Mean ODI	7.0	60.6
Achieving MCID for ODI*	94.2% (92.6%–95.5%)	25.8% (18.0%–35.5%)
Improvement in ODI†	97.8% (97.2%–98.3%)	59.9% (48.4%–70.5%)
Mean EQ-5D	0.94	0.34
Improvement in EQ-5D†	97.6% (96.9%–98.2%)	53.0% (41.4%–64.4%)
Mean NRS-BP	1.3	7.8
Improvement in BP†	93.9% (92.2%–95.2%)	56.8% (45.1%–67.8%)
Mean NRS-LP	1.2	6.7
Improvement in LP†	96.7% (95.7%–97.5%)	48.1% (36.5%–60.0%)

* Probability of achieving MCID for ODI.

† Probability for improvement in ODI, EQ-5D, NRS-LP, and BP.

Discussion

Model Performance

Predictive models provide individualized risk-adjusted postoperative outcome estimations, which in the absence of nonsurgical outcome data have tremendous potential to assist providers during the preoperative assessment of patients and to improve patient engagement in shared decision-making concerning treatment planning. Using a prospective, multicenter, longitudinal registry, we developed

4 predictive models for 12-month PROs after elective surgery for degenerative lumbar spine pathology. In descending order of importance, the most important predictors of overall disability, QOL, and pain outcomes following lumbar spine surgery were patient employment status, baseline NRS-BP scores, psychological distress, baseline ODI scores, level of education, workers' compensation status, symptom duration, race, baseline NRS-LP scores, ASA score, age, predominant symptom, smoking status, and insurance status.

Predictors of Outcome

Occupation-related factors, including employment status at the time of surgery and type of occupation, were the most important predictors of the overall outcomes. Patients not actively working (disability claim or retired) had significantly lower odds of having better outcomes at 12 months postoperatively than those who were actively employed. Furthermore, patients employed in medium- and heavy-labor jobs had lower odds of achieving better outcomes than those with a sedentary-type job. While these findings potentially can be explained in part by the presence of more severe back pathologies in patients with more laborious jobs and in those receiving disability funds, these factors cannot fully account for such findings. As such, the association between occupation and outcomes is likely multifactorial. Previous sociological models have revealed that patients' capacity for recovery and return to function also depends on psychological state, job satisfaction, physical demands at work, income, and social support.^{5,20,31,47,52}

A patient's baseline functional status was also found to be an important predictor of overall outcomes. The impact of baseline functional status on postoperative outcomes following lumbar spine surgery is a consistent finding in the literature.^{11,12,19,28,36–38,44,46,48,65} Analogous to our results, numerous previous studies have demonstrated that the patients whose baseline disability, pain, and QOL scores are, on average, worse than those of others are more likely to have poorer outcomes at 12 months.^{3,14,48} Conversely, we found that patients with higher baseline NRS-LP scores had greater odds of having better outcomes. Pearson et al. reported that surgery in patients with higher preoperative LP scores yielded significantly better pain relief than in those with higher preoperative BP scores.⁵⁸ This may be because the patients with higher LP scores often have associated radiculopathy or neurogenic claudication, which is typically more responsive to surgical decompression than BP. In a cross-sectional study assessing associations between patients' expectations for lumbar spine surgery and baseline characteristics, Mancuso and colleagues demonstrated that patients with greater preoperative disability—for whom the literature consistently demonstrates a lower odds of achieving better outcomes—have the greatest expectations for postoperative functional recovery.⁴⁵ This finding highlights the importance of adjusting for varying degrees of baseline disability, pain, and QOL status when assessing 12-month outcomes. This also underscores the importance of shared preoperative decision-making, facilitated with evidence-based decision support tools, such as the predictive models presented here.

Patients' preoperative psychological distress was an important predictor of overall outcomes and it was the one of the most important predictors of postoperative 12-month QOL (EQ-5D). A number of previous studies have reported that preoperative psychological distress is associated with worse outcomes following lumbar spine surgery.^{2,4,22,35,39,56,63} Sinikallio et al., in a prospective analysis of 96 patients, demonstrated that the patients with preoperative depression and those who had continuous depression postoperatively experienced poor outcomes. At the 2-year follow-up evaluation, the patients who recovered from de-

pression demonstrated postoperative improvement similar to the patients who had normal mood preoperatively and postoperatively.⁶⁰ In a recent randomized control trial, Archer et al. demonstrated that incorporating targeted cognitive behavioral therapy in postoperative care results in improved outcome 3 months after lumbar spine surgery.⁶ This suggests that medical and behavioral interventions for concomitant psychological disease during the preoperative and postoperative periods may help to improve outcomes in patients with psychological distress. We observed that a higher level of education was an important predictor for better overall PROs. Authors of previous studies have also indicated that higher education has a positive effect on patient outcomes.^{40,55,61} Further support of the importance of education on clinical outcomes is the observation of some authors that a correlation exists between lower levels of education and treatment noncompliance, and other health-compromising behaviors.⁵⁵

With respect to surgical procedures, the surgery-specific factors analyzed in the present study, including fusion, surgical approach, and number of vertebral levels involved, was observed to have a lower overall predictive importance compared with other variables (and, therefore, a lower impact on predicting PROs). These findings reinforce numerous and consistent previous observations that patient-specific factors are primary drivers of outcomes following spine surgery.^{1,16,19,38,48,52}

Based on our data, we found that other baseline patient-specific factors—workers' compensation, symptom duration, race, smoking status, preoperative comorbidities, and insurance status—also strongly influence outcomes following lumbar surgery, a finding consistent with those reported in a number of studies.^{3,11,13,15,18,19,48}

Application to Real-World Practice

The 4 predictive models described provide individualized risk-adjusted postoperative outcome projections. The cases presented represent hypothetical case scenarios comparing patient characteristics that predict better or worse outcomes after surgical therapy for lumbar degenerative diseases. Although this information may potentially be used to tailor the application of invasive therapies (particularly to help avoid care that is highly likely to be ineffective) the authors caution that restriction of surgical therapy based solely on patient characteristics such as race, socioeconomic status, and/or age is inappropriate, potentially discriminatory, and is not the intended use of these models. In that regard, we would like to emphasize that no single variable is likely to influence ultimate outcomes, that all variables have differential effects in individual patients, and that all of the predictors used in this model have an additive effect on predicting surgical outcomes. The predictive models presented here are primarily intended to engage patients in shared decision-making and facilitate true patient-centered care. Furthermore, the decision to offer surgery to any given patient requires consideration of numerous factors including, but certainly not restricted to, likely longer-term (e.g., 12-month) outcomes. As long-term expected clinical outcomes are only one element of the surgical decision process, results of this model would not necessarily deter clinicians from operating on

patients with negative predictors of outcome, such as low baseline function.

Probabilistic discussions regarding postoperative outcomes during preoperative assessment can assist providers in setting realistic presurgical expectations for patients and families and help improve patient satisfaction with care. Clinicians can use these tools to adjust modifiable patient characteristics preoperatively to help modify postoperative outcomes. They can also use predictive models to help identify patient populations to recognize potentially ineffective care before it is given, thus facilitating greater surgical effectiveness and increasing the overall value (cost-benefit ratio) of spine surgery. The tools can also be used to provide meaningful comparisons of performance between service providers, by allowing for the generation of risk-stratified benchmarks for care. By comparing actual and expected (i.e., risk-adjusted) outcomes, providers who typically take care of the sickest and highest-risk patients (e.g., those in tertiary care centers) can do so with diminished concern of financial penalty in an increasingly value-based reimbursement environment.

As predictive models can be challenging to apply in “real-world” clinic settings, we have created a user-friendly, online application that can be more easily used in the spine clinic to predict PROs (http://statcomp2.vanderbilt.edu:37212/app_0/). By enabling patient-specific probabilistic counseling at the point of care, we seek to facilitate involvement of all stakeholders in true, shared decision-making. This activity holds promise with respect to improving patient outcomes and increasing health care savings.

Study Limitations and Strengths

The limitations and weaknesses inherent in the current study have implications for the interpretation of its findings. Without controls, outcomes of patients can be compared but not outcomes of competing therapies. An intrinsic limitation of predictive models is the discrete number of variables that are inputted into its creation. In the present analysis, we included 30 patient-specific and surgery-specific variables collected as a part of the multicenter QOD registry. It is possible that variables not collected and therefore not accounted for in this analysis will play a significant role in a patient’s disability, QOL, and pain status after surgery. Such missing data would affect the performance of the models in discriminating accurately between observed and predicted outcomes. With exponentially increasing numbers of patients enrolled in the QOD registry, and with further refinement of variables collected, we will be able to update the predictive model and thereby increase its performance and accuracy.

Nonetheless, our risk-adjusted predictive models provide value as a starting point for patient-level assessment to guide shared decision-making and optimize outcomes at the individual patient and population levels. The c-index for our models was in the range of 0.64–0.69, which reflects a “good” discrimination index.^{32,33} Finally, the patients included in the QOD registry are enrolled from 74 centers across the US representing all practice types, i.e., academic, community, small, large, rural, and urban.^{7,29,53} The diverse mix of practices included and patients en-

rolled generate a representative sample of patients undergoing elective lumbar spine surgery, allowing these results to be generalizable (i.e., applicable) to most spinal surgery practices.

Conclusions

In this study we introduce 4 novel predictive models for PROs utilizing patient-specific and surgery-specific variables. PRO measures of treatment effectiveness at 12 months are significantly impacted by several preoperative patient-specific factors. Using these tools to optimize patient selection and improve modifiable factors may facilitate greater surgical effectiveness and increase the overall value (cost-benefit ratio) of spine surgery. Furthermore, these robust predictive models can be used as a shared decision-making tool during preoperative patient counseling. While additional studies and controlled therapeutic comparisons focused on better understanding the associations described in this analysis are clearly warranted, the current study demonstrates that patient-specific factors beyond medical comorbidities, surgical indications, and surgical approaches can play a significant role in influencing overall patient outcomes.

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Appendix

Quality and Outcomes Database (QOD) Vanguard Sites

Anthony L. Asher, MD,¹ Matthew J. McGirt, MD,¹ Clinton J. Devin, MD,² Joseph S. Cheng, MD,² Kevin T. Foley, MD,³ Jeffrey M. Sorenson, MD,³ John J. Knightly, MD,⁴ Steven D. Glassman, MD,⁵ Thomas B. Briggs, MD,⁶ Adam Kremer, MD,⁷ Wesley E. Griffith, MD,⁸ Noam Y. Stadlan, MD,⁹ Thomas W. Grahm, MD,¹⁰ Meic H. Schmidt, MD,¹¹ Praveen Mummaneni, MD,¹² and Mark E. Shaffrey, MD.¹³

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Disclosures

Dr. McGirt has served as a consultant to Stryker. Dr. Devin has served as a consultant to PACIRA and as a defense expert witness for Medtronic. Dr. Shaffrey has served as a consultant to

Medtronic, NuVasive, K2M, and Zimmer-Biomet; has direct stock ownership in NuVasive; and is a patent holder for Medtronic, NuVasive, and Zimmer-Biomet. Dr. Foley has served as a consultant to Medtronic; has direct stock ownership in Medtronic, NuVasive, SpineWave, and Discgenics; is a patent holder for Medtronic and NuVasive; and has received royalties from Medtronic.

Author Contributions

Conception and design: Asher, McGirt. Acquisition of data: Chotai, Nian. Analysis and interpretation of data: Chotai, Nian, Harrell. Drafting the article: Asher, Chotai, Parker. Critically revising the article: Asher, McGirt, Archer, Chotai, Harrell, Speroff. Reviewed submitted version of manuscript: Asher, McGirt, Bydon, Archer, Chotai, Parker, Nian, Harrell, Speroff, Dittus, Shaffrey, Foley. Statistical analysis: McGirt, Nian, Harrell. Administrative/technical/material support: Chotai, Philips. Study supervision: Asher, McGirt, Bydon, Harrell.

Supplemental Information

Online-Only Content

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Companion Papers

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