Older Age and Leg Pain Are Good Predictors of Pain and Disability Outcomes in 2710 Patients Who Receive Lumbar Fusion

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Abstract *Background:* Identifying appropriate candidates for lumbar spine fusion is a challenging and controversial topic. The purpose of this study was to identify baseline characteristics related to poor/favorable outcomes at 1 year for a patient who received lumbar spine fusion. *Questions/Purposes:* The aims of this study were to describe baseline characteristics of those who received lumbar surgery and to identify baseline characteristics from a spine repository that were related to poor and favorable pain and disability outcomes for patient who received lumbar fusion (with or without decompression), who were followed up for 1 full

year and discriminate predictor variables that were either or in contrast to prognostic variables reported in the literature. *Methods:* This study analyzed data from 2710 patients who underwent lumbar spine fusion. All patient data was part of a multicenter, multi-national spine repository. Ten relatively commonly captured data variables were used as predictors for the study. Univariate/multivariate logistic regression analyses were run against outcome variables of pain/disability. *Results:* Multiple univariate findings were associated with pain/disability outcomes at 1 year including age, previous surgical history, baseline disability, baseline pain, baseline quality of life scores, and leg pain greater than back pain. Notably significant multivariate findings for both pain and disability include older age, previous surgical history, and baseline mental summary scores, disability, and pain. *Conclusion:* Leg pain greater than back pain and older age may yield promising value when predicting positive outcomes. Other significant findings may yield less value since these findings are similar to those that are considered to be prognostic regardless of intervention type.

Level of Evidence: Level II: Retrospective Prognostic Study.

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Introduction

Identifying appropriate candidates for lumbar spine fusion (LSF) is a challenging and controversial topic. Common indications for LSF include segmental instability, progressive deformity [12], spinal stenosis, or other progressive degenerative conditions [9, 23]. Despite the recommended indication, there are notable challenges with determining best candidates for success. First, the clinical tests and measures associated with fusion do not predict who is likely to benefit [38]. Second, it is well known that non-physical, non-pathoanatomical variables (e.g., depression) can independently influence outcomes after LSF [37]. Third, there is a notable lack of uniformity across clinical practice

guidelines with respect to suggesting appropriate candidates for LSF [6, 30].

Appropriate identification of predictive variables requires prognostic investigation. Carreon and colleagues [5] found that individuals with lower pre-operative SF-36 mental component summary scores and higher pre-operative Oswestry Disability Index scores had less improvement following LSF. However, it is well known that both of these variables are general prognostic factors for all forms of musculoskeletal disorders [25]. Variables such as these are not true effect modifiers; in other words, they do not directly specify which type of intervention is most appropriate for the patient, only that the patient is likely to improve regardless of the intervention provided (e.g., versus conservative, injection-based, supervised neglect, etc.). Findings such as these are less helpful when determining who are and are not candidates for surgery, although each does lend value in the grand scheme of clinical decision-making. This is a common problem that has been recognized previously and can lead to inappropriate decision modeling [21, 24].

Although most psychosocial characteristics negatively influence outcomes with surgery, it is well known that the majority of surgeons do not utilize standardized patient questionnaires assessing psychosocial risks secondary to respondent/administrative burden [18]. With the advent of data repositories, data that are normally collected at point of entry are being analyzed for their potential value in decision-making. For example, administrative data captured in electronic health records are being used to determine the potential for recovery or failure after a hospital stay or intervention [4, 15, 27, 34]. This form of analysis known as practice-based research allows the identification of processes based on real-world outcomes [23]. Spine data repositories collect administrative data and encompass multiple clinics and numerous surgeons. Data repositories reflect multiple geographic regions and can reduce the biases associated with randomized controlled trials demonstrating greater external validity [31].

The aims of this study were the following: (1) to describe characteristics of patients who received lumbar fusion surgery; (2) to identify baseline characteristics from a spine repository that were related to poor and favorable pain outcomes for patient who received lumbar fusion (with or without decompression), who were followed up for 1 full year; (3) to identify baseline characteristics from a spine repository that were related to poor and favorable disability outcomes for patient who received lumbar fusion (with or without decompression), who were followed up for 1 full year; and (4) discriminate predictor variables that were either unique (previously unreported) or in contrast to prognostic variables reported in the literature (provide findings that appear specific to the intervention applied).

Patients and Methods

Study Design

This was a retrospective, prognostic study that used data obtained from a multi-institutional, prospective spine

outcomes registry. The spine outcomes registry involved data compiled from 14 spine surgical institutions in two countries (USA and Canada) and incorporated surgical results from 40 medical physicians who specialized in spine surgery. At the time of the data transfer, the prospective spine outcomes registry included surgeries such as discectomy, fusion, decompression, or decompression with fusion. This study explored a sample who received lumbar fusion surgery. Institutional review board approval was obtained by the local university health and ethics review board.

Participants

Participants for this study involved patients with lumbar disorders who received lumbar fusion surgery between the dates of 2002 to 2012. Only subjects with 1 year outcomes for Oswestry Disability Index (ODI) and a visual analog scale (VAS) for pain outcomes were included in the final tabulations ($N=2710$). There were no restrictions on type of diagnosis, type of surgical fusion approach, or age.

Procedures

A data transfer was initiated in December of 2014. Data were extracted from a Microsoft Excel file into a statistical management software system. Data include demographic variables, surgery type, surgery date, diagnoses, level (s) of surgery, outcomes, and complications at baseline and beyond.

Predictor Variables

Predictor variables included the following: (1) age, (2) body mass index (BMI), (3) gender, (4) previous back surgery history, (5) baseline ODI, unique baseline VAS for pain for both (6) low back and (7) leg pains, (8) baseline SF-12 Physical Component Summary (PCS) scores, (9) baseline SF-12 Mental Component Summary (MCS) scores, and (10) leg pain greater than back pain. ODI and VAS measures have been previously validated and are used widely in the spine surgery literature, with several studies showing their relevance to actual clinical practice [13, 14, 16, 20]. The SF-12 MCS scores and SF-12 PCS scores reflect the sub-scales for SF-12 Quality of Life questionnaire, which is routinely used in clinical practice for assessment of spine surgery [8]. Leg pain greater than back pain is a unique measure that was created by subtracting the total leg pain from the total back pain, during the baseline visit [17]. Values >0 were indicated as leg pain greater than back pain, whereas all other values (including equal findings) were considered otherwise.

Re-coding Predictor Variables

Because dichotomous variables are often easier to understand when using regression modeling (versus continuous variables), we explored clinically sensible and statistically significant cut points (thresholds) for each continuous variable [3]. Clinically sensible cut points are those that provide inherent value in clinical practice (e.g., heart rate of >100 when assessing potential for pulmonary emboli). When

evaluating for statistically appropriate cut points, we utilized a distribution-based method that identified a dichotomous threshold within the inner 80% of the distribution [1, 26]. Once identified using either mean or median values, we evaluating the two groups statistically with the outcome measure (ODI or VAS for pain) to determine if a statistical difference was present between the two newly created groups. Only then did we consider dichotomizing the continuous variables.

Using this strategy, statistically significant thresholds were found to dichotomize age (≥ 52 years), baseline ODI ($>52/100$), and VAS for back and leg pain ($>6/10$). The variables gender, previous surgical history, and leg pain greater than back pain were already dichotomous. Because we found no clinically sensible or statistically significant distribution trends, BMI, SF-12 MCS, and PCS were retained as continuous variables. Nonetheless, to further assess linearity and distribution normality of each variable, we ran a Kolmogorov-Smirnov (KS) test and plotted the variables to identify potential curvilinear relationships. Although all three of the variables were not normally distributed, there were no obvious trends with plotting to suggest a benefit of categorization.

Control Variables

Control variables used to statistically control interactions within the modeling included presence/absence of complications, levels of surgery, and diagnosis. Presence/absence of complications was calculated by identifying any form of complication during the surgical intervention (e.g., neural, bleeding, hardware, etc., serious or incidental) reported within the database. For each patient, level or levels of surgery were tabulated and the variable created was the sum of all levels surgically treated. Lastly, diagnoses included degenerative disc disease, spondylolisthesis, deformity, post-laminectomy syndrome, non-union, stenosis, instability, and other.

Outcomes Measures

For this study, two different outcome measures were used: (a) percent change in pain (VAS) [16, 20] and (b) percent change in disability (ODI) [13, 14]. Percentage change for pain and disability was calculated by taking the difference of the VAS for pain and the ODI score (from baseline to the 1 year follow-up), and then dividing the difference by the baseline score, followed by multiplying by 100. The end product was a positive or negative percentage change expressed as a whole number. Use of percent change and the inclusion of a minimum of two different outcome constructs have been recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group [11]. The IMMPACT work group recognized a 30% reduction in pain and disability from baseline as a lower threshold of success, whereas a 50% reduction from baseline is a substantially clinically important change [11].

Determining Appropriate Number of Observations per Variable

For simple univariate multinomial or logistic regression, Homer and Lemeshow [22] have recommended a minimum observation-to-variable ratio of 10 but cautioned that a number this low will likely overfit a model. That said, upon removal of variables that demonstrated multicollinearity, we adopted their preferred observation-to-variable ratio of 20 to 1 for the multivariate modeling. With 2710 participants with full 1 year outcomes, we were in no danger of overfitting the models.

Data Analysis

All analyses were performed using Statistical Package for the Social Sciences, version 20.0 (SPSS Inc., Chicago, Illinois). Baseline predictor characteristics (including control variables) were plotted by means and standard deviations or by frequencies for the 50% outcomes thresholds (substantially clinically important change) for both VAS and ODI. Univariate logistic regression analyses were performed for each of the independent variables for four unique models (VAS 30 and 50%, ODI 30 and 50%) [11]. For each univariate model, number of surgical levels, presence/absence of complication, and diagnoses were used as control variables, by incorporating these variables within the modeling and exploring the interactions to the main effect. For each univariate analysis, individual *P* values, odds ratios, and 95% confidence intervals were reported.

Findings in the univariate analyses that yielded *P* values of 0.10 and under were considered in four distinct multivariate predictive models (VAS 30 and 50%, ODI 30 and 50%) [11]. For each multivariate model, number of surgical levels, presence/absence of complication, and diagnoses were used as control variables. For each multivariate analysis, individual *P* values, odds ratios, 95% confidence intervals, and Nagelkerke values were reported. A Nagelkerke is a pseudo *R* square measure that investigates the usefulness of the model [28]. For all models, a *P* value of <0.05 was considered significant.

Results

Baseline descriptions of those who did and did not meet a 50% improvement from baseline are largely similar with the exception of age, baseline pain and disability status, baseline SF-12 MCS and PCS scores, complications, leg pain greater than back pain, and diagnostic criteria (Table 1). For the VAS for pain outcome, 56.1% of individuals met the 30% improvement from baseline, whereas 43% met the 50% improvement from baseline. For the 30% change of ODI from baseline, 48.4% reported improvement, whereas 32.4% reported a 50% change of the ODI from baseline.

For the univariate regression-based outcomes associated with 30% pain improvement at 1 year, older age, baseline VAS of $>6/10$ for back pain, and higher baseline SF-12 MCS and SF-12 PCS scores were associated with favorable results, whereas baseline ODI of $>52/100$ and previous surgical history were associated with poorer results. For the outcome

Table 1 Descriptive analyses for lumbar fusion surgery (*N*=2710)

Variable	VAS for pain 50% improvement from baseline		ODI 50% improvement from baseline	
	Met 50% improvement (<i>N</i> =1175)	Did not meet 50% improvement (<i>N</i> =1534)	Met 50% improvement (<i>N</i> =881)	Did not meet 50% improvement (<i>N</i> =1829)
Age	59.75 (12.65) 835≥52 301≤52	55.60 (13.18) 865≥52 629≤52	58.86 (13.33) 597≥52 245≤52	56.63 (12.99) 1099≥52 690≤52
BMI	29.31 (6.03)	29.69 (6.25)	29.04 (6.16)	29.76 (6.15)
Gender	458=Male 698=Female	607=Male 904=Female	335=Male 529=Female	1099=Male 690=Female
Previous surgical history	210=Yes 580=No	387=Yes 548=No	141=Yes 463=No	455=Yes 667=No
Baseline ODI	47.65 (14.40) 411≥52 764≤52	52.44 (16.13) 817≥52 717≤52	47.05 (14.45) 296≥52 585≤52	52.18 (15.63) 939≥52 890≤52
Baseline VAS (back)	7.44 (1.87) 890≥6 285≤6	7.08 (2.64) 1139≥6 395≤6	6.83 (2.44) 598≥6 283≤6	7.45 (2.27) 1436≥6 598≤6
Baseline VAS (leg)	6.66 (2.81) 743≥6 432≤6	6.59 (2.77) 946≥6 562≤6	6.56 (2.91) 551≥6 330≤6	6.67 (2.71) 1145≥6 658≤6
Baseline SF 12 PCS	28.26 (8.76)	26.43 (8.89)	28.97 (9.37)	26.31 (8.43)
Baseline SF 12 MCS	40.61 (15.00)	35.56 (15.27)	41.40 (15.20)	35.92 (15.13)
Leg pain greater than back pain	288=Yes 887=No	345=Yes 1189=No	282=Yes 599=No	352=Yes 1477=No
Levels	2.15 (1.19)	2.30 (1.19)	2.05 (1.14)	2.32 (1.20)
Complication	124=Yes 1051=No	345=Yes 1189=No	81=Yes 800=No	189=Yes 1640=No
Diagnoses	496=DDD 451=Spondy 102=Deformity 190=Post-Lam 116=Non-union 269=Stenosis 124=Adj Level Dx 51=Instability 13=Other	572=DDD 372=Spondy 147=Deformity 288=Post-Lam 246=Non-union 287=Stenosis 219=Adj Level Dx 87=Instability 31=Other	382=DDD 329=Spondy 67=Deformity 69=Post-Lam 125=Non-union 201=Stenosis 81=Adj Level Dx 37=Instability 8=Other	689=DDD 493=Spondy 66=Deformity 180=Post-Lam 350=Non-union 356=Stenosis 261=Adj Level Dx 100=Instability 35=Other

BMI body mass index, *ODI* Oswestry Disability Index, *VAS* visual analog scale for pain, *PCS* Physical Component Summary score, *MCS* Mental Component Summary score, *DDD* degenerative disc disease, *Spondy* spondylolisthesis, *Post-Lam* post-laminectomy syndrome, *Adj Level Dx* adjacent level disease

associated with 50% pain improvement at 1 year, older age, and baseline SF-12 MCS and PCS scores were associated with favorable outcomes, whereas baseline ODI of >52/100 and previous surgical history were associated with a poorer outcomes (Table 2). For the multivariate regression-based outcomes, all findings were similar to the univariate analyses with the exception of SF-12 PCS, which was not statistically significant in either 30 or 50% change (Table 3).

The same predictors were significant for a 30 and 50% change in disability at 1 year with the univariate analyses. Older age, leg pain greater than back pain, and higher baseline SF-12 MCS and SF-12 PCS scores were associated with favorable results, whereas higher baseline BMI, higher baseline report of disability, higher baseline report of back pain, and previous surgical history were associated with poorer results (Table 4). For the multivariate regression-based outcomes, all findings were similar to the univariate analyses with the exception of SF-12 PCS, which was not statistically significant in either 30 or 50% change and baseline pain which was not significantly associated with a 50% change (Table 5).

Discussion

The aims of this study were to describe characteristics of patients who received lumbar fusion surgery and identify predictive baseline characteristics from a spine repository that were related to poor and favorable pain and disability outcomes for patients who received lumbar fusion (with or without decompression), who were followed up for 1 full year. Further, we aimed to discriminate predictor variables that were either unique (previously unreported) or in contrast to prognostic variables reported in the literature. We did find a number of findings that were unique or conflicting versus those that are consistent prognostic variables for all musculoskeletal interventions. Because of their conflictive/unique nature, the values may suggest that these are indeed treatment effect modifiers and could guide decisions with respect to appropriate treatment choices (i.e., surgery versus another option) [21, 24]. In particular, we feel that the findings that older age is associated with a better outcome for both pain and disability, leg pain greater than was associated with improvement in disability, and higher BMIs associated with poorer outcomes is worth discussing

Table 2 Univariate logistic regression analyses for fusion with threshold of 30% improvement and 50% improvement in visual analog scale for pain modeling at 1 year. Analyses controlled for diagnosis, complication during surgery, and levels treated. *N*=2710

Variable	Odds ratio (95% CI)	<i>P</i> value
Univariate modeling for 30% improvement in VAS at 1 year		
Age (≥52 years)	1.97 (1.65, 2.35)	<0.01
BMI	0.99 (0.98, 1.01)	0.32
Gender	0.86 (0.73, 1.01)	0.06
Previous surgical history	0.54 (0.42, 0.69)	<0.01
Baseline ODI (>52/100)	0.55 (0.47, 0.65)	<0.01
Baseline VAS (back) (>6/10)	1.41 (1.18, 1.69)	<0.01
Baseline VAS (leg) (>6/10)	1.01 (1.00, 1.21)	0.75
Baseline SF 12 PCS	1.01 (1.00, 1.02)	<0.01
Baseline SF 12 MCS	1.02 (1.01, 1.02)	<0.01
Leg pain greater than back pain	0.90 (0.75, 1.08)	0.28
Univariate modeling for 50% improvement in VAS at 1 year		
Age (≥52 years)	2.11 (1.76, 2.53)	<0.01
BMI	0.98 (0.97, 1.00)	0.16
Gender	0.95 (0.81, 1.11)	0.54
Previous surgical history	0.54 (0.42, 0.71)	<0.01
Baseline ODI (>52/100)	0.48 (0.42, 0.57)	<0.01
Baseline VAS (back) (>6/10)	1.14 (0.95, 1.37)	0.15
Baseline VAS (leg) (>6/10)	0.98 (0.84, 1.16)	0.89
Baseline SF 12 PCS	1.02 (1.01, 1.03)	<0.01
Baseline SF 12 MCS	1.02 (1.02, 1.03)	<0.01
Leg pain greater than back pain	1.01 (0.85, 1.22)	0.85

BMI body mass index, *ODI* Oswestry Disability Index, *VAS* visual analog scale for pain, *PCS* Physical Component Summary score, *MCS* Mental Component Summary score

Table 3 Univariate logistic regression analyses for fusion with threshold of 30% improvement and 50% improvement in Oswestry disability score modeling at 1 year. Analyses controlled for diagnosis, complication during surgery, and levels treated. *N*=2710

Variable	Odds ratio (95% CI)	<i>P</i> value
Univariate modeling for 30% improvement in ODI at 1 year		
Age (≥52 years)	1.80 (1.51, 2.15)	0.04
BMI	0.97 (0.96, 0.99)	0.01
Gender	0.91 (0.77, 1.06)	0.23
Previous surgical history	0.52 (0.40, 0.67)	<0.01
Baseline ODI (>52/100)	0.58 (0.49, 0.68)	<0.01
Baseline VAS (back) (>6/10)	0.77 (0.65, 0.93)	<0.01
Baseline VAS (leg) (>6/10)	1.01 (0.86, 1.19)	0.86
Baseline SF 12 PCS	1.02 (1.01, 1.03)	<0.01
Baseline SF 12 MCS	1.02 (1.01, 1.02)	<0.01
Leg pain greater than back pain	1.74 (1.45, 2.10)	<0.01
Univariate modeling for 50% improvement in ODI at 1 year		
Age (≥52 years)	1.67 (1.38, 2.02)	<0.01
BMI	0.98 (0.96, 0.99)	0.02
Gender	0.88 (0.74, 1.05)	0.17
Previous surgical history	0.51 (0.38, 0.67)	<0.01
Baseline ODI (>52/100)	0.49 (0.42, 0.59)	<0.01
Baseline VAS (back) (>6/10)	0.61 (0.51, 0.73)	<0.01
Baseline VAS (leg) (>6/10)	0.96 (0.81, 1.13)	0.63
Baseline SF 12 PCS	1.03 (1.02, 1.04)	<0.01
Baseline SF 12 MCS	1.02 (1.02, 1.03)	<0.01
Leg pain greater than back pain	1.88 (1.56, 2.27)	<0.01

BMI body mass index, *ODI* Oswestry Disability Index, *VAS* visual analog scale for pain, *PCS* Physical Component Summary score, *MCS* Mental Component Summary score

Table 4 Multivariate logistic regression analyses for fusion with threshold of 30% improvement and 50% improvement in VAS for pain modeling at 1 year. Analyses controlled for diagnosis, complication during surgery, and levels treated. Nagelkerke=0.13 and 0.14 for the models. *N*=2710

Variable	Odds ratio (95% CI)	<i>P</i> value
Multivariate modeling for 30% improvement in pain at 1 year		
Age (≥52 years)	1.67 (1.33, 2.12)	<0.01
Baseline ODI (>52/100)	0.51 (0.41, 0.74)	<0.01
Baseline VAS (back) (>6/10)	1.79 (1.39, 2.20)	<0.01
Previous surgical history	0.56 (0.43, 0.74)	<0.01
Baseline SF-12 MCS	1.01 (1.00, 1.02)	<0.01
Gender	0.89 (0.72, 1.11)	0.33
Baseline SF-12 PCS	1.00 (0.99, 1.02)	0.69
Multivariate modeling for 50% improvement in pain at 1 year		
Age (≥52 years)	1.69 (1.33, 2.13)	<0.01
Baseline ODI (>52/100)	0.54 (0.44, 0.68)	<0.01
Previous surgical history	0.57 (0.43, 0.75)	<0.01
Baseline SF 12 MCS	1.01 (1.00, 1.02)	0.03
Baseline SF 12 PCS	1.01 (0.99, 1.02)	0.54

BMI body mass index, *ODI* Oswestry Disability Index, *VAS* visual analog scale for pain, *PCS* Physical Component Summary score, *MCS* Mental Component Summary score

since these may serve as discriminant predictors, especially since each of these is contradictory to what is considered within the literature or as a general prognostic factor.

Before discussing the discriminant predictors, it is worth noting that there are a number of limitations in this study. This retrospective study looked at relationships at baseline to 1 year outcomes. A comparative arm would likely assist in identifying unique predictive characteristics that are unique to surgery and are not general predictive findings of outcome with any kind of intervention. Further, the study outcomes are only for 1 full year. Longer-term outcomes would

Table 5 Multivariate logistic regression analyses for fusion with threshold of 30% improvement and 50% improvement for Oswestry Disability Index modeling at 1 year. Analyses controlled for diagnosis, complication during surgery, and levels treated. Nagelkerke=0.13 and 0.15. *N*=2710

Variable	Odds ratio (95% CI)	<i>P</i> value
Multivariate modeling for 30% improvement in ODI at 1 year		
Leg pain greater than back pain	1.72 (1.31, 2.26)	<0.01
Previous surgical history	0.53 (0.39, 0.69)	<0.01
Baseline SF 12 MCS	1.01 (1.00, 1.02)	<0.01
Age (≥52 years)	1.53 (1.21, 1.95)	<0.01
Baseline VAS (back) (>6/10)	1.42 (1.08, 1.86)	0.01
Baseline ODI (>52/100)	0.73 (0.58, 0.93)	0.01
BMI	0.98 (0.96, 0.99)	0.01
Baseline SF 12 PCS	1.01 (0.99, 1.02)	0.25
Multivariate modeling for 50% improvement in ODI at 1 year		
Leg pain greater than back pain	1.82 (1.38, 2.40)	<0.01
Previous surgical history	0.49 (0.36, 0.67)	<0.01
Baseline ODI (>52/100)	0.66 (0.52, 0.86)	<0.01
Baseline SF 12 MCS	1.01 (1.00, 1.02)	<0.01
BMI	0.97 (0.96, 0.99)	0.02
Age (≥52 years)	1.30 (1.04, 1.68)	0.04
Baseline SF 12 PCS	1.01 (0.99, 1.02)	0.39
Baseline VAS (back) (>6/10)	1.01 (0.76, 1.34)	0.94

provide more valuable predictive ability and a notable estimate on the influence of surgery recipients.

Most prognostic studies suggest that younger individuals are more likely to demonstrate a better outcome, with any form of intervention [27]. A past case series demonstrated that poor satisfaction, implant loosening, and underlying osteoporosis were common in older individuals who received multilevel spinal fusions [32]. Older age has been identified as a predictor of greater frequency of surgical complications [2]. There are many possible reasons for our finding that older age is associated with improved outcomes with fusion, including the method in which we categorized age (i.e., ≥ 52 years and other). However, we noticed a continued trend toward improved outcomes, even when ages much older than 52 were analyzed. Additionally, one may argue that older individuals are better candidates physiologically for a decompression-based surgery since they are likely to encounter degenerative changes that lead to nerve root irritation [20]. Lastly, the elderly may be less sensitive to psychological and compensational influences (work-related issues), which have been shown to negatively influence the outcomes of spine fusion surgery [19]. We are unaware of any studies that have examined age as a predictor for outcomes for fusion while controlling for potential interactions. Certainly, more studies are needed to explore this finding.

Leg pain greater than back pain is a unique (or conflicting) finding that deserves further attention. A past systematic review [35] that focused on sciatica (which was defined as low back-related leg pain and related disabilities) found very few characteristics associated with a positive or negative recovery (with conservative care or surgery). In their study, they did not specify the intensity or ratio of leg pain versus back pain. Our definition required leg pain greater than back pain, a symptomatic distinction that greatly limited the numbers of those with sciatica/leg pain who qualified as a positive finding in our study. In our full sample, 93.5% of individuals reported some level of leg pain. Yet of these individuals, only 24.9% (634) identified leg pain greater than back pain. It is our perception that leg pain greater than back pain implies a nerve-related disorder; one that may be amenable to fusion/decompression methods. Further, it is known that those with leg pain and neurological signs have been shown to improve the greatest from baseline with surgery [29, 36].

We found higher BMI to be a predictor of poorer outcomes with surgery. This is in contrast to others that have explored the predictive capacity of BMI with fusion outcomes [10, 33]. Djurasovic and colleagues [36] investigated the influence of BMI after dichotomizing the variable to ≥ 30 , which was different than the method used for coding in our study (a continuous code). In contrast, Rosen et al. [33] did not find statistical significance when BMI was used as a continuous code but did when they categorized BMI. In both studies, the sample size of 270 was just a tenth of the total in this study, which could have influenced the capacity of the analyses to identify statistical significance, and although our finding was statistically significant, it is questionable whether it is of clinical significance.

A number of findings were prognostic, but are not true effect modifiers. For example, SF-12 (or SF-36) MCS scores and higher baseline disability have been recognized by other as general prognostic variables [5]. Previous surgical history [7] has been recognized as a “biological condition” since it can lead

to weakness, spinal limitations, and prolonged recovery, yet there are likely psychosocial characteristics affiliated with the condition as well. It is our perception that although this knowledge is useful when determining projected outcomes with fusion, these variables are not essential findings when predicting specific outcomes for surgical fusion versus another comparative treatment. Certainly, one should not withhold fusion as a surgical option based on the presence of these factors at baseline.

We used the IMMPACT criteria [11] to categorize those who met a lower level of success and who met a substantially clinically important change. Yet, it is also useful to look at improvement without the boundaries placed on our outcomes. In the repository sample, 66% of fusion recipients reported at least some improvement in pain at 1 year, whereas 79% of recipients reported an improvement in disability. No improvement was defined as reporting any values equal to or lower than the originally reported baseline variable ($\leq 0\%$ change). Because of differences in the way outcomes are reported across studies, it is difficult to compare our results to those in the literature. Nonetheless, we feel these values are promising and would likely continue to improve as further exploration on appropriate selection variables continues.

Prognostic variables suggesting a favorable outcome from this repository sample included age ≥ 52 years and leg pain greater than back pain. These findings are unique or novel when compared to previous literature and may be useful when determining spine fusion candidacy. Further, the variables used are commonly captured in conventional clinical practice.

Disclosures

Conflict of Interest: Anthony K. Frempong-Boadu, MD, and Isaac Karikari, MD, have declared that they have no conflict of interest. Robert Isaacs, MD, reports grants and personal fees from NuVasive, Inc. and personal fees from Association for Collaborative Spine Research, outside the work. Chad E. Cook, PhD, PT, is paid consultant for Hawkins Foundation of Carolinas, outside the work. Kristen Radcliff, MD, reports grants from Depuy, Medtronic, NuVasive, and Pacira; personal fees from Depuy, Medtronic, Orthofix, Orthopedic Sciences, Inc., 4 Web Medical, NEXXT Spine, Stryker, Altus Spine, and Globus; non-financial support from LDR; and other from Association for Collaborative Spine Research, outside the work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was obtained from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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