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Complications And Length Of Stay Following Spine Surgery: Analyzing Local And National Cohorts

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Complications and Length of Stay Following Spine Surgery: Analyzing Local and National Cohorts

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COMPLICATIONS AND LENGTH OF STAY FOLLOWING SPINE SURGERY: ANALYZING LOCAL AND NATIONAL COHORTS

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Complications following spine surgery are widely reported but poorly characterized. The effect of preoperative comorbidities and postoperative complications on length of stay (LOS) has not been evaluated. It would be ideal to have a clearer understanding of the variables affecting LOS to facilitate setting expectations and control costs. Using complications and LOS as outcomes, we can also characterize the risks inherent with surgical practices, such as the use of iliac crest bone graph (ICBG) in spinal fusion.

The study consisted of three aspects. First, the effect of pre and perioperative variables on LOS for 103 patients undergoing posterior lumbar fusion at Yale was examined. Next, the National Surgical Quality Improvement Program (NSQIP) database was used to determine the variables associated with extended LOS and complications following 2,164 anterior cervical discectomy and fusion (ACDF) procedures. Finally, 13,927 spinal fusion cases from the NSQIP database were analyzed to determine the effect of harvesting ICBG on operative time, complications, LOS, and readmission. Multivariate analysis was used throughout the study to control for confounding while evaluating statistical significance.

For lumbar fusion, average LOS was 3.6 ± 1.8 days. 79% had a stay of four days or less. Preoperative variables associated with increased LOS were age and ASA score. Heart disease was significantly associated with decreased LOS. Postoperative complications occurred in 32% of patients and led to a LOS of 5.1 ± 2.3 days vs. 2.9 ± 0.9 days for patients with no complication. For ACDF, average LOS was 2.0 ± 4.0. Age ≥ 65, functional status, transfer from facility, preoperative anemia, and diabetes were the preoperative factors predictive of extended LOS. Major complications, minor complications, and extended surgery time were the perioperative factors associated with increased LOS. 71 (3.3%) had a total of 92 major complications. ASA score ≥ 3, preoperative anemia, age ≥ 65, extended surgery time and male gender were predictive of major complications. Meanwhile, postoperative blood transfusion (OR 1.5), extended operative time (+ 22.0 min) and LOS (+0.2 days) were significantly associated with ICBG use.

After lumbar fusion, patients that are older and have widespread systemic disease tend have longer LOS, but no single comorbidity was predictive of LOS. After ACDF, 1 in 33 patients develops a major post-operative complication, which are associated with an increased LOS of 5 days. Current ICBG usage in spinal fusion is low, with rates between 3.4% and 12.4% depending on approach. Use of ICBG is associated with extended operative time, extended LOS, and postoperative blood transfusion.

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Introduction:

Complications following spine surgery are widely reported but often poorly characterized. The patient and procedure specific factors leading to these complications are rarely considered. Meanwhile, complications and postoperative length of stay (LOS) are closely related outcomes, with postoperative complications often requiring additional medical or surgical management leading to a longer LOS. In the spine literature, LOS is an outcome often used in the comparison of two cohorts. However, the effect of preoperative comorbidities and postoperative complications with LOS as the dependent variable has not been considered.

LOS is important from a patient perspective, and is an important factor in determining health care costs in patients undergoing surgery. Costs associated with each additional day in the hospital are near $1,000, [1] and inpatient hospital charges (excluding implant or surgical charges) have been linked with LOS. [2]

LOS is important to consider for reasons other than cost, such as optimizing patient experience. Preoperative counseling before orthopedic procedures has been shown to reduce patient stress and hospital stay. [3] Further, increased LOS has been associated with adverse outcomes such as hospital acquired infections [4,5] and deep vein thrombosis (DVT). [6-8] It consumes physician and housestaff time and decreases the potential for additional surgical volume. Knowledge of the factors determining increased LOS can help surgeons guide treatment and preoperative expectations, and help patients plan postoperative care.

Using complications and LOS as outcome measures, we can also characterize the risks inherent with certain surgical practices and procedures, such as the use of iliac crest

bone graph (ICBG) in spinal fusion. ICBG is still considered the "gold standard" in grafting for progression of spinal fusion due to its osteoconductive, osteoinductive, and osteogenic properties. [9-11] However, morbidity associated with the harvest of ICBG is of clinical concern and has lead to significantly decreased usage over the past decade with the invention of artificial bone graft substitutes.

Postoperative donor-site pain is a commonly reported issue, [12-14 15-18] although may be overstated. [13,19,20] Other issues include hematoma, infection, pelvic fracture, and nerve palsy. [14,17,21] Increased blood loss, operating time and anesthesia time associated with the harvest procedure add additional risk. [21-24] Due to the above issues, patients receiving ICBG are at a risk for prolonged LOS. Several studies have reported differing results on increased LOS following ICBG harvest in spine surgery, although multivariate analysis has not been performed. [19,21-26]

Analysis of many postoperative complications can be difficult due to their relative rarity. Additionally, characterization of ICBG is becoming more challenging in modern clinical practice due to the decreased utilization of this practice. The use of a national database can allow for adequate numbers to support the analysis of rare complications and practices. The National Surgical Quality Improvement Progam (NSQIP) is a national database that captures clinical information and 30-day postoperative outcomes. Despite its shortcomings, including the lack of some procedure specific variables, it allows for investigators to perform large-scale multivariate analyses of rare events with greater power than smaller cohort studies are able to generate.

Ultimately the goals of this study are threefold: use multivariate analysis to examine LOS and complications following spine surgery in a local cohort, to examine LOS and complications following spine surgery in a national database, and to examine

the risks of using ICBG in spinal fusion with LOS and postoperative complications as the primary outcome variables. We hope that the findings in this study provide spine surgeons with useful information for setting preoperative patient expectations and for decision making with regards to patient selection and bone grafting methods.

Part 1: Factors Affecting Length of Stay Following Elective Posterior Lumbar Spine Surgery: A Multivariate Analysis

Abstract:

Introduction:

Elective posterior lumbar fusion is a common surgical procedure, but reported length of hospital stay is variable (usually 3-7 days). The effect of individual or select few factors on LOS has previously been evaluated. However, multivariate analysis using LOS as a dependent variable in order to separate potentially confounding variables has not been performed.

Purpose:

To facilitate setting of realistic expectations and considering the significant costs of hospitalization, it would be ideal to have a clear understanding of the variables affecting length of stay (LOS) for this surgery.

Methods:

Records for 103 patients undergoing elective, open 1-3 level posterior lumbar instrumented fusion (with or without decompression) by the orthopedic spine service at our institution between January 2010 and June 2012 were queried. LOS was determined from the date of surgery to the date of discharge. Preoperative factors (patient demographics, previous surgery, levels instrumented, American Society of Anesthesiologists (ASA) score, and major medical comorbidities including diabetes, hypertension, malignancy, pulmonary disease or heart disease); intraoperative factors (complications, drain placement, estimated blood loss, blood transfusion, fluids administered, operating room time, and surgery time); and postoperative factors (drain removal, blood transfusion, complications, and discharge destination) were collected and

analyzed with multivariable stepwise regression to determine predictors of LOS. "Postoperative complications" was excluded as an independent variable from the regression analysis because of its close relationship with LOS.

Results:

Our sample included 70 one-level, 26 two-level, and 7 three-level operations. Average LOS was 3.6 ± 1.8 days (mean+SD) with the range 0-12 days. Of this cohort, 79% (81 of 103) had a stay of four days or less. The only preoperative variables associated with LOS in the multivariable model were age ($p = 0.038$) and ASA score ($p = 0.001$). History of heart disease ($p= 0.005$) was significantly associated with a decreased hospital stay.

Intraoperative complications included six dural tears and one pedicle fracture. No intraoperative factors were found to be associated with a longer LOS.

Postoperative complications occurred in 32% of patients (33 of 103). Common complications included: anemia requiring transfusion(11), altered mental status (8), pneumonia (4), hardware complications requiring re-operation(3). Only one serious complication, renal failure, occurred. Average LOS for patients with a post-op complication was 5.1 ± 2.3 days vs. 2.9 ± 0.9 days for patients with no complication ($p < 0.001$). Discharge to a sub-acute or nursing facility ($p < 0.001$) was significantly associated with increased length of stay.

Levels fused was not predictive of LOS, possibly due to the skew towards one-level cases in our sample.

Conclusion:

Patients that are older and have widespread systemic disease tend to stay in the hospital longer after surgery. Contrary to our expectations, no single comorbidity was

predictive of longer hospital stays. Heart disease was associated with a shorter length of stay, but this may have been due to a more extensive preoperative workup and closer medical management. Intraoperative events did not affect LOS, however postoperative events did. This data should prove useful for counseling patients and setting expectations of patients and the health care team.

Introduction:

Decompression and instrumented fusion of the lumbar spine may be an appropriate option for certain conditions of the lumbar spine and is one of the most common procedures performed by spine surgeons. Average hospital stays after this procedure range from 3 to 6.7 days in previous studies.[27-29] This length of stay (LOS) variable is important from a patient perspective, and is an important factor in determining health care costs in patients undergoing spine surgery. Baseline costs of each extra day in the hospital run close to $1,000 dollars,[1] and inpatient hospital charges (not including instrumentation or surgical charges) are closely linked with LOS.[2]

In aggregate, treatments of lumbar pathology are associated with yearly costs approaching $50 billion in the United States alone.[30] Lumbar fusion costs represented about half of all spine surgery spending in 2003,[31] and the cost of hospitalization for spine surgery has been rising, with medical costs for lumbar fusion rising nearly 5-fold between 1992 and 2003.[31,32] These costs are not to be taken lightly.

LOS is important to consider for reasons other than cost. The importance of optimizing patient experience has clearly been receiving greater attention. It has been shown that preoperative counseling before orthopedic procedures can reduce patient stress, leading to a faster recovery and shorter hospitalization.[3] Further, increased LOS has been associated with adverse outcomes such as hospital acquired infections[4,5] and increased risk of deep vein thrombosis (DVT).[6-8] These are intermediate variables on the pathway to potentially life-threatening outcomes. Moreover, longer LOS consumes physician time and decreases a department's potential surgical volume. Knowledge of the factors determining LOS can help surgeons guide treatment and preoperative

expectations, and help patients and their families plan postoperative care and return to function.

Many independent variables have been shown to influence LOS. Preoperative variables associated with increased LOS include: increased age [33], morbid obesity [34], diabetes [35], metabolic syndrome, [36] opioid use, [37] greater number of comorbid conditions, [37] and unemployment, [37] Perioperative variables associated with increased LOS include: use of fibrin sealant, [1] open as opposed to minimally invasive surgery, [38] adverse intraoperative events, [39] fluids administered, [40] and drain use. [1] Postoperative variables including blood transfusion and complications have also been associated with increased LOS. [29]

Multivariate analysis is a powerful tool used to separate confounding variables that are often incorrectly believed to individually be potential outcome predictors. In the spine literature, such multivariate analyses have been reported for LOS with minimally invasive lumbar spine surgery (MIS) and revision spine surgery. [29,40] For MIS patients, a number of perioperative factors including blood loss, longer surgical time, and crystalloid administration were associated with a stay greater than 24 hours, while age was found to be the only significant predictor of longer hospital stays following revision surgery. To our knowledge, LOS has yet to be considered as the dependent variable in a multivariable analysis for traditional, open lumbar fusion.

The purpose of the present study is to identify variables via multivariate analyses that predict a longer hospital stay after open elective posterior lumbar fusions. We hope this information will be useful for guiding patient selection, preoperative counseling, and postoperative decision-making.

Methods:

Patients who underwent posterior lumbar fusion surgery at a single institution between January of 2010 and June of 2012 were identified and their electronic medical records and charts were reviewed. All procedures were consecutively performed by one of three fellowship-trained orthopedic spine surgeons at our institution. This study received approval from our Human Investigation Committee.

Patients treated with a combined anterior/posterior approach, patients treated with minimally invasive techniques, or patients requiring more than 3 levels of instrumentation were excluded. Trauma cases were also excluded.

Demographic data collected included: gender, age, body mass index (BMI), presence or absence of smoking / alcohol / opiate / or illicit drug use, marital status, and employment status. Workers compensation information and patient race were not collected.

Other pre-operative variables recorded included previous lumbar surgery, levels instrumented, American Society of Anesthesiologists (ASA) score, and history of major medical comorbidities (diabetes, hypertension, malignancy, pulmonary disease, or heart disease). Diabetes and hypertension were determined by a history of medication treatment for these conditions or by findings during the primary care preoperative assessment. Malignancy was defined as either a current or previous history of treatment with radiation or chemotherapy for a malignant tumor. Pulmonary disease was defined as asthma requiring hospitalization, chronic obstructive pulmonary disease, chronic bronchitis, or a history of pulmonary embolism. Heart disease was defined as a history of atrial fibrillation, murmur, arrhythmia, myocardial infarction, coronary artery disease,

mitral valve prolapse, or congestive heart failure. In order to determine whether a confluence of comorbidities in a patient might affect LOS, patients with greater than 3 comorbidities (hypertension, diabetes, morbid obesity, heart disease and pulmonary disease) were labeled as patients with multiple comorbidities or "high risk" for our analyses.

Intraoperative variables recorded included operating room time (the number of minutes the patient spent in the operating room), and surgery time (the number of minutes from the first incision to placement of the postoperative dressing after closure), use of colloids, amount of crystalloids administered, estimated blood loss, use of a surgical drain, and any operative complications.

Post-operative variables recorded included days until drain was removed (if used), transfusion of any blood products, return to surgery, any other notable postoperative events, discharge destination (home without services, home with services, or sub-acute care/nursing facility), and LOS. Postoperative pain control such as patient-controlled analgesia, narcotic use, or spinal anesthetic was not considered. Return to surgery occurred due to instrumentation complications discovered postoperatively. A "notable postoperative event" was defined as any adverse event noted in the chart that required further evaluation and treatment by either the orthopedic service or another service. Examples of notable postoperative events include well established complications like pneumonia, urinary tract infection, and renal failure as well as other issues including anemia requiring transfusion, altered mental status, cardiac complications, severe ileus, and severe hypertension.

LOS was defined as days after surgery that patient was discharged and was recorded as an integer. As such, no distinction was made between a discharge in the

morning or afternoon and each additional day represents a new calendar day, and not necessarily an additional 24-hour period. Any patients discharged on the day of surgery were recorded as a "0" day length of stay.

As with most centers, day of discharge was determined based on patients medical and rehabilitation status. Although it is difficult to delineate specific numeric criteria for discharge, it is standard practice that the medical service and rehabilitation service both weigh in to determine appropriateness for discharge based on established practice patterns.

Statistical Analysis

The extended stay cohort was determined by taking all patients with a LOS at least one standard deviation more than the mean. Based on this, bivariate independent samples *t*-tests were performed for all variables comparing the normal stay cohort to the extended stay cohort.

For multivariable analysis, LOS was treated as a continuous variable, rather than the binary outcome used above. Multivariable linear stepwise regression was performed with LOS as a continuous dependent variable for two cohorts of independent variables: preoperative and perioperative (which encompassed both intra- and postoperative variables). "Notable postoperative events" were not included in the multivariate model as controls for associations between pre and perioperative variables and LOS because notable postoperative events were considered to be on the casual pathway between these variables and LOS. The purpose of this study was to identify pre and perioperative variables associated with LOS in general, not necessarily those independent of any adverse events. For example, if someone with COPD got postoperative pneumonia and

that caused an increased LOS, we wanted to count that as an association between COPD and LOS. If we had controlled for the development of pneumonia, then we would not be not be identifying this event as an association between COPD and LOS. Separately, "notable postoperative events" was analyzed as the dependent variable for the preoperative cohort variables. As a stepwise regression, a series of iterative analyses were performed, excluding predictors by declining *p*-value until only variables with $p < 0.2$ remained as the final model covariates. The final regression was performed with these variables, with $p < 0.05$ indicating statistical significance.

Pierson bivariate cross-correlation analysis was performed on all independent variables found to be significantly associated with LOS to determine whether any of these factors were related. Two-sided *p*-values < 0.05 were considered statistically significant in all analyses.

All statistical analyses were performed using SPSS software (SPSS Inc., Chicago, IL).

Results:

One hundred and three posterior lumbar fusions were identified for analysis and met inclusion / exclusion criteria. The average length of stay was 3.6 ± 1.8 days (mean ± standard deviation) and median length of stay was 3 days. Based on these results, an extended LOS was defined as five days or greater (patients who stayed ~ greater than 1 standard deviation longer than the mean). Based on this cutoff, 79% (81 of 103) of patients had a regular LOS (four days or less) and 21% (22 of 103) had an extended LOS (five days or more). This data is depicted in Figure 1.

The female/male ratio was 1.4 and average age was 60.9 ± 13.6 years. Number of levels fused were 70 one-level, 26 two-level, and 7 three-level. Of these, 58 cases were primary surgeries and 45 were revision surgeries. LOS did not differ significantly between primary and revision cases ($p = 0.996$), although revision cases were associated with significantly longer surgical times (208 ± 70 min vs. 177 ± 47 min, $p = 0.007$).

Comorbid conditions included diabetes (n = 24, 23%), hypertension (n = 64, 62%), morbid obesity (n= 17, 16.5%), pulmonary disease (n=21, 21%) and heart disease (n = 27, 26%). The "high risk" cohort was comprised of 24 patients (23.3%).

Intraoperative complications were encountered for seven patients (7%): six dural tears and one pedicle fracture, all of which were recognized and corrected during the procedure. These patients stayed in the hospital longer (4.4 ± 1.5 days) than patients without intraoperative complications (3.5 ± 1.8 days), though the difference was not statistically significant ($p = 0.125$).

Notable postoperative events were encountered for 33 patients (32%). Of these patients, 18 had a stay of 5 days or longer. Average LOS for these patients was significantly longer (5.1 ± 2.3 days vs. 2.9 ± 0.9 days) than for patients with no postoperative events ($p < 0.001$). Notable postoperative events included anemia requiring transfusion (11), altered mental status (8), pneumonia (4), return to OR due to construct complication (3), cardiac complications (3), urinary tract infection (2), severe ileus (2), and one each of severe asymptomatic hypertension, hypovolemia, renal failure, renal insufficiency, urinary retention, and respiratory complications requiring bilevel positive airway pressure. One patient was forced to wait in the hospital for 2 days while waiting for an open nursing care facility bed.

Each of the above variables was assessed as independent variables with bivariate *t*-tests, with >4 days considered as extended LOS (Table 1). Female gender ($p = .030$), ASA score ($p= 0.043$), discharge to a nursing home/subacute facility ($p = 0.046$), and identifiable postoperative events ($p < 0.001$) were significantly different between the normal and extended LOS cohorts.

Identifiable postoperative events were assessed individually to determine which of those factors was responsible for driving a longer LOS. Patients experiencing any postoperative event were associated with a significantly longer hospital stay than patients not experiencing any event. (Table 2)

Of course, independent analyses can over or under estimate the impact of individual variables based on patterns of covariance. Thus, multivariable linear stepdown regression with LOS as a continuous variable was performed for both preoperative and perioperative factors. Based on this, the preoperative variables found to be associated with LOS were age ($p= 0.038$, $\beta = .209$) and ASA score ($p= 0.001$, $\beta = .334$). Paradoxically, history of heart disease was associated with a shorter hospital stay ($p = 0.005$, $\beta = -.301$). The only perioperative variable found to be associated with increasing LOS was discharge destination ($p < 0.001$, $\beta = .376$) (Table 3). No significant cross-correlative relationships among these significant variables were found. Furthermore, discharge destination was also not associated with any of the preoperative variables examined.

Once again, it should be noted that notable postoperative events were not included in the multivariate analysis of the factors effecting LOS because of concern they would wash out other lesser, but significant variables. Separate regression analysis found no preoperative variables to be predictive of these notable postoperative events.

Figure 1:

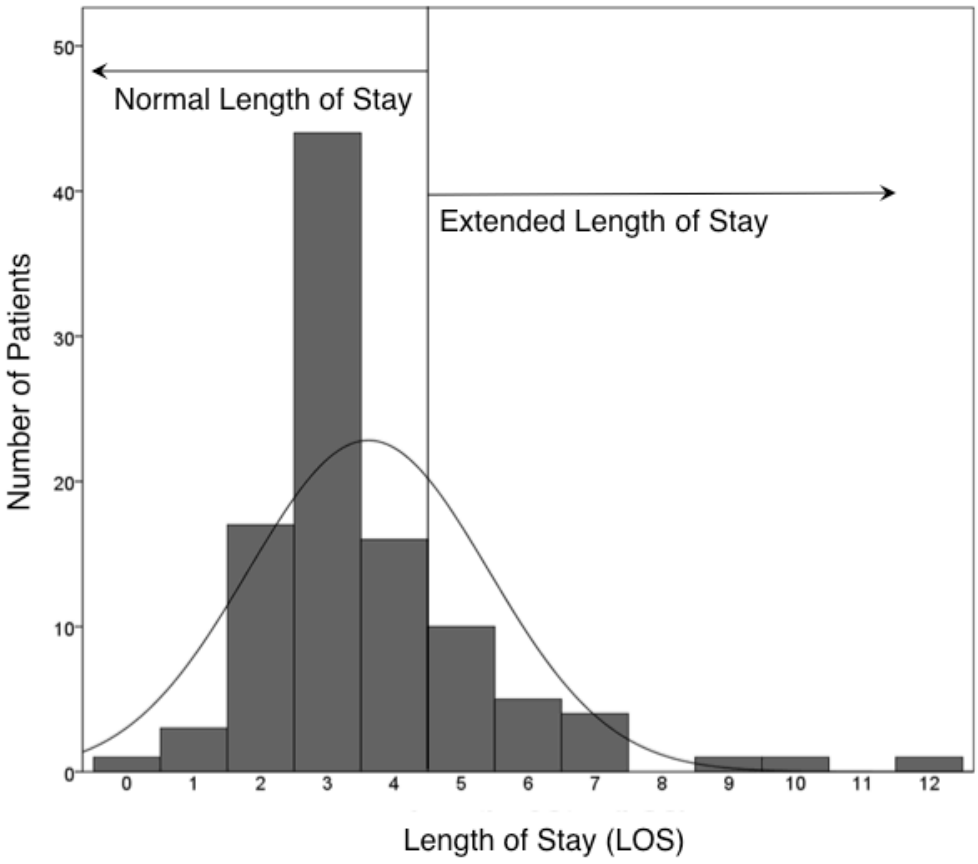
Normal Length of Stay
Extended Length of Stay
Number of Patients
Length of Stay (LOS)
0
10
20
30
40
50
0
1
2
3
4
5
6
7
8
9
10
11
12

Table 1:Demographic, Preoperative, and Perioperative Factors and Their Association With LOS

					95% Confidence Interval	
Variable	LOS	N	Mean	***P***	Lower	Upper
Sex (Male =1, Female =0)	Normal	81	.47			
	Extended	22	.23	***0.030***	0.025	0.459
Age	Normal	81	60.49			
	Extended	22	62.45	0.539	-8.382	4.461
Levels Fused	Normal	81	1.37			
	Extended	22	1.45	0.598	-0.406	0.238
Pre-op Narcotics[a]	Normal	81	.44			
	Extended	22	.41	0.772	-0.210	0.281
Revision Surgery[a]	Normal	81	.44			
	Extended	22	.41	0.772	-0.210	0.281
BMI	Normal	81	29.11			
	Extended	22	30.62	0.394	-5.105	2.072
Diabetes[a]	Normal	81	.23			
	Extended	22	.23	0.944	-0.202	0.217
Hypertension[a]	Normal	81	.60			
	Extended	22	.68	0.510	-0.311	0.158
Morbid Obesity[a]	Normal	81	.14			
	Extended	22	.27	0.201	-0.351	0.077
Pulmonary Disease[a]	Normal	81	.19			
	Extended	22	.27	0.417	-0.305	0.130
Heart Disease[a]	Normal	81	.30			
	Extended	22	.14	0.085	-0.023	0.343
High Risk[a]	Normal	81	.23			
	Extended	22	.23	0.944	-0.202	0.217
Malignancy[a]	Normal	81	.10			
	Extended	22	.05	0.349	-0.060	0.167
Smoking[a]	Normal	80	.41			
	Extended	22	.45	0.732	-0.290	0.206
Alcohol[a]	Normal	81	.63			
	Extended	22	.55	0.631	-0.270	0.439
ASA	Normal	81	2.38			
	Extended	22	2.64	***0.043***	-0.499	-0.009
Job[a]	Normal	76	.37			
	Extended	21	.33	0.826	-0.289	0.359
Married[a]	Normal	81	.69			
	Extended	21	.71	0.841	-0.254	0.208
EBL (mL)	Normal	75	330.73			
	Extended	22	403.41	0.320	-218.406	73.055

Perioperative Transfusion[a]	Normal	81	.19			
	Extended	22	.32	0.239	-0.359	0.093

Table 1. (Continued)

					95% Confidence Interval	
Variable	LOS Cohort	N	Mean	***P***	Lower	Upper
Crystalloid Administered (mL)	Normal	69	2306.52			
	Extended	19	2623.68	0.149	-754.841	120.516
Colloid Use[a]	Normal	81	.20			
	Extended	22	.23	0.772	-0.237	0.178
Drain Use[a]	Normal	81	.73			
	Extended	22	.68	0.683	-0.184	0.277
Drain Duration (days)	Normal	56	2.36			
	Extended	12	2.58	0.309	-0.682	0.229
Surgery Time (min)	Normal	80	185.30			
	Extended	22	210.50	0.088	-54.400	4.000
OR Time (min)	Normal	80	263.88			
	Extended	22	287.36	0.150	-55.896	8.919
Post-op complication[a]	Normal	81	.19			
	Extended	22	.82	***0.000***	-0.826	-0.440
Discharge Destination[b]	Normal	81	.72			
	Extended	22	.36	***0.046***	0.006	0.699

Significance is determined with equal variance not assumed.

[a] *Yes = 1, No = 0*

[b] *Home = 1, Subacute Care/Nursing Facility = 0*

Table 2: Identifiable Postoperative Events Associated With a Significantly Longer LOS

Variables	N	LOS	Stdev	***P***
Total patients[a]	33	5.09	2.25	<0.001
Anemia	11	3.82	0.87	.002
Delirium	8	7.71	2.69	<0.001
Pneumonia	4	7.00	2.16	<0.001
Return to OR	3	5.33	1.15	<0.001
Cardiac	3	6.00	3.46	<0.001
Other	11	4.45	1.92	<0.001

[a] *= All patients with an identifiable postoperative event. Note: Some patients had more than one event. P-values are in comparison to patients with no postoperative events.*

Table 3: Variables Significantly Associated With an Extended LOS by Multivariate Analysis

Variables	Standardized Coefficients (Beta)	*P*	95% CI Lower Bound	95% CI Upper Bound
Preoperative				
Age	.209	**.038**	.002	.055
ASA	.334	**.001**	.441	1.785
Heart	-.301	**.005**	-2.069	-.387
Perioperative				
Discharge to subacute/nursing	.376	**.000**	.664	2.150

CI indicates confidence interval; ASA, American Society of Anesthesiologists.

Discussion:

LOS after surgical intervention is clearly of significant importance from a patient and systems perspective. The purpose of this study was to determine pre- and perioperative variables that significantly affect LOS in patients undergoing elective, open lumbar posterior instrumented fusion.

Two studies in the spine literature have performed multi-variate analyses to determine pre- and perioperative variables associated with LOS. Zheng et al. retrospectively reviewed 112 patients undergoing revision surgery for posterior lumbar decompression and instrumented at a single institution between 1992 and 1999. [29] Average length of stay was 6.0 ± 2.4 days and increasing age was the only significant predictor of a longer hospital stay. Unemployment accompanying three or more comorbid conditions and complications were associated with longer LOS as well.

The other study was a retrospective cohort study of 104 patients undergoing minimally invasive transforaminal lumbar interbody fusions (MIS TLIF). [40] In this study, Siemenow et al. reported an average length of stay of 2.3 ± 1.2 days. Patients in the extended stay cohort (>24 hours) had significantly higher estimated blood loss, longer surgical time, received more crystalloids, had higher total fluids, lower end of case temperature, lower hemoglobin during hospitalization, and lower pre-op narcotic use. Multiple regression demonstrated that post-operative creatinine, visual analogue scale (VAS) score, intra-operative colloids, fluids input at the end of the case, crystalloid to colloid ratio, fluid balance, post-op oxycontin use, mean percentage of FiO2, and pre-operative hemoglobin were all significant predictors of increased LOS. One of Siemenow's interesting findings was that higher pre-op narcotic use was associated with a shorter length of stay, in contrast to their original expectation that dependence on

painkillers preoperatively would make pain management postoperatively more difficult. In explaining their findings, they hypothesized that the use of pre-operative narcotics must provide a "protective" effect on pain pathways, reducing the normal pain responses provoked by the surgical procedure. This effect, however, was not seen in our study.

To our knowledge, we performed the first multivariate analyses evaluating preoperative and perioperative factors associated with hospital LOS after open lumbar decompression and instrumented fusion for all comers, which is one of the most common types of surgical intervention on the lumbar spine. We evaluated 103 patients who underwent surgery between January 2010 and June 2012 at a single academic institution by one of three fellowship trained orthopedic spine surgeons.

For posterior lumbar fusions, we typically tell our patients to plan for approximately a three-day stay. Our study does, in fact, support this-the average length of stay was 3.6 ± 1.8 days, with a median stay of 3 days. (Figure 1) Further, if we define extended LOS as greater than one standard deviation from the norm, an extended LOS is five days or more. Based on this, 21% of our patients had an extended LOS.

Multivariable regression determined that the preoperative variables associated with increasing hospital stay were age and ASA score. The only perioperative factor determined by regression analysis to be associated with increasing LOS was discharge destination, but cause and effect for this association can be questioned. Of course, identifiable postoperative events affect LOS, but were not included in the multivariate analysis because of its strong and potentially confounding association with LOS. Patients with an identifiable postoperative event stayed at the hospital a significantly longer period of time than those who did not experience any issue. Events such as delirium (7.7 ± 2.7 days), pneumonia (7.0 ± 2.2 days), return to OR (5.33 ± 1.15 days), and cardiac

complications (6.0 ± 3.5 days) were drivers behind this difference, while anemia requiring transfusion (3.82 ± 0.87) played a lesser but still significant role. (Table 2) On regression analysis, no preoperative variables were found to be significantly predictive of postoperative adverse events. This could suggest that factors leading to these complications are complex in nature and may largely take place during the perioperative period. Of course, some clinically important associations may also have been missed due to the small sample size of this study.

We found it interesting that no specific pre-operative comorbidity was found to be associated with an LOS in our multivariate analyses. It is likely that many of these factors did not have a large enough effect size to be found significant in this analysis. Higher numbers might have shown other factors to be significant, but the effect size would not be expected to be clinically significant if this was the case. Even when comorbidities were combined to identify "high risk" patients (three or more comorbidities), we could not find an association with LOS. Age and ASA score were the two preoperative factors that were found to be associated with increasing LOS. Possibly there are general health variables associated with both age and ASA score that were not well accounted for by the specific preoperative comorbidities captured in our analyses.

These results are consistent with previous findings for open revision spine surgery and for total knee and total hip arthroplasty patients. [29,41,42] Older and sicker patients are more likely to stay in the hospital longer, while surgeon- and hospital-related factors have little effect.

The result that a history of heart disease associated with a shorter LOS was an unexpected finding of this study. One potential explanation could be found in the use of diuretics in heart failure patients to lower volume load. Excess volume administration and

fluid balance after spine surgery has been shown to lead to more complications and a longer hospital stay [40,43,44]-it is possible that regular therapy given to heart disease patients lowers this fluid balance and allows them to leave the hospital sooner. More likely, however, is that the shorter LOS seen in these patients is due to a more extensive preoperative workup and closer medical management as a result of their pre-existing condition. These patients tend to be followed by two services postoperatively, allowing for greater fine-tuning of their hospital course and a faster discharge home.

Postoperatively, patients discharged to a nursing or subacute care facility were more likely to stay in the hospital longer than patients returning home, with or without services. However, it is difficult to determine the directionality of this relationship and whether it is causative or associative. Do factors leading to a longer LOS drive discharge to nursing facility? Or do patients being sent to a nursing facility have characteristics that make them stay in the hospital longer? It has been shown in total joint arthroplasty that patients that end up in rehabilitation facilities post-discharge are older, more likely to live alone, and have more co-morbid conditions. [45] However, we found no association between discharge to a subacute care facility and any preoperative factor. Additionally, it is not uncommon for patients to be kept in the hospital while waiting for a bed to open up at their discharge location. However, in this study, we could only identify this to have happened to one patient, who incurred a two-day wait once ready for discharge. It should also be noted that some insurance providers require a 2-3 day postoperative hospital stay before approving discharge to a subacute facility. This requirement has the potential to bias our results, although the "extended LOS" was considered >4 days for this study. Therefore, the "extended LOS" variable should be capturing patients that are remaining in the hospital for a reason other than needing to meet insurance requirements (just a 2-3

days stay) for postoperative care placement. Ultimately it is likely that patients with postoperative complications requiring longer LOS were preferentially discharged to a rehabilitation facility for further subacute follow-up.

Limitations of this study include its retrospective nature and sample size. Furthermore, cases were skewed towards one-level procedures. An ideal study would have matched numbers of one, two, and three level surgeries. Still, stratifying this variable in our regression analysis should have helped to minimize this potential source of bias. Additionally, variables such as race, workers compensation, and insurance provider were not controlled for in the analysis. Other potential limitations include that the study was performed at a single institution, although this could be considered a strength because surgeon and hospital related cofounders are controlled. This study also uses data representing surgeries performed by three different surgeons. Despite attempts to stratify other confounding factors, surgeon techniques and personal preferences could have played a role in determining LOS. Finally, even though LOS is a continuous variable and is treated as such in our analysis, it was recorded as an integer in our database. As a result, surgeries or discharges occurring on the same day were treated equally, whether occurring at 8AM or 8PM. However, differences in discharge time of day seem more often related to systems / rides issues than true medical considerations from our experience.

Understanding the risk factors that lead to increased hospital stay is crucial. Consideration of these factors could aid surgeons in patient selection, treatment choice, and preoperative counseling. Additionally, patients and their families can use this information to help schedule time off of work, arrange for transportation, and set-up post-discharge care. To our knowledge, this is the first study that has considered which factors

predict LOS following posterior lumbar spinal fusion. This study has identified several patient factors: age, ASA score, history of heart disease and discharge to a subacute/nursing facility, that are all associated significantly with hospital stay. Although it is questionable whether any of these factors are modifiable, their effect on LOS must be considered before every surgery. The finding that a history of heart disease is associated with a shorter LOS has important implications that warrant more in depth consideration in future studies as this may be related to more extensive preoperative workup and closer medical management that might benefit all patients.

Part 2: Factors Affecting Length of Stay and Complications Following Elective Anterior Cervical Discectomy and Fusion: A Study of 2,164 Patients from The ACS NSQIP Database

Abstract:

Introduction:

Elective anterior cervical discectomy and fusion (ACDF) is a commonly performed spinal surgery, renowned for its efficacy and safety. Many variables affect postoperative complications and hospital stay following this operation. The effect of individual preoperative factors on LOS and complications has been evaluated in small-scale studies. Large database analysis with multivariate analysis of these variables has not been reported.

Purpose:

To determine factors independently associated with increased length of stay (LOS) and complications following ACDF in order to facilitate preoperative planning and setting of realistic expectations for patients and providers.

Methods:

The American College of Surgeons-National Surgical Quality Improvement Program's participant-use file was queried between the years of 2007 and 2011 for patients undergoing ACDF procedures. Pre-, peri-, and postoperative variables associated with postoperative complications and LOS were collected for 2164 patients. Significant predictors of postoperative complications and LOS were determined by multivariate regression.

Results:

Average LOS was 2.0 ± 4.0 days (mean ± SD) with a range of 0 to 103 days. By multivariate analysis, age ≥ 65, functional status, transfer from facility, preoperative anemia, and diabetes were the preoperative factors predictive of extended LOS. Major complications, minor complications, and extended surgery time were the perioperative factors associated with increased LOS. The elongating effect of these variables was determined, and ranged from 0.5-5.0 days.

71 (3.3%) had a total of 92 major complications, including return to OR (40), venous thrombotic events (13), respiratory (21), cardiac (6), mortality (5), sepsis (4), and organ space infection (3). Multivariate analysis determined ASA score ≥ 3, preoperative anemia, age ≥ 65, extended surgery time and male gender to be predictive of major complications (odds ratios ranging between 1.756-2.609)

No association found between levels fused and LOS or complications.

Conclusion:

Extended LOS following ACDF is associated with factors including age, anemia, and diabetes, as well as the development of postoperative complications. One in 33 patients develops a major complication post-operatively, which are associated with an increased LOS of 5 days.

Introduction

Anterior cervical discectomy and fusion (ACDF) has become increasingly popular due to its excellent and reliable outcomes, fast recovery, and lack of morbidity relative to the posterior approach. [46,47] The number of ACDF procedures performed in the United States increased nearly 8-fold between 1990 and 2004, with over 700,000 of these procedures performed during this time period. [48,49]

As utilization has increased, length of stay (LOS) and postoperative complication rates have decreased and (LOS from 5.17 days to 2.38 days and complication rates from 4.36% to 3.03%), despite increases in medical comorbidities and age of patients. [48,50] These variable are certainly inter-related with post-operative complications associated with longer LOS, [49] and longer LOS predisposing to complications such as hospital-acquired infection and DVT. [4-8]

Many independent variables have individually been shown to influence LOS in all types of spine surgery patients. Preoperative variables associated with increased LOS include: age, [33] morbid obesity, [34] diabetes, [35] metabolic syndromes, [36] opioid use, increased number of comorbidities, and unemployment. [37] Operative variables associated with a longer hospital stay include: open surgery, [38] use of bone morphogenic protein, [51] intraoperative complications, [39] excess fluid administration, [40] and drain use. [1] Postoperative variables including blood transfusion and complications have also been associated with increased LOS. [29]

Multivariate analysis analyzing factors associated with prolonged LOS after ACDF is sparse. One study found preoperative variables such as older age and female gender, as well as postoperative complications such as cardiac, urinary and pulmonary issues to be associated with extended LOS. [52] Another study found preoperative coronary

artery bypass or stent, chronic renal disease, and preoperative opioid use correlated with the increased LOS typically seen in unemployed patients as compared to employed patients.[37] Post-operative complications were not considered. Finally, one large database study with a focus on hospital charges and demographics found male gender, black or Hispanic race, Medicare or Medicaid insurance, higher Charlson Comorbidity Index (CCI) score, and traumatic spine injury to be predictive of extended LOS.[53] Complications were not considered.

Many prior studies have looked at factors affecting long-term outcomes in patients who after ACDF.[47,54-60] Short-term complications after ACDF range from 1.6% to 31.0%, (partially affected by how "complications" are defined).[37,49,52,61-67] Short-term mortality has been reported between 0.1% and .3%.[49,54,62,66] Several studies have examined preoperative factors significantly associated with the occurrence of perioperative complications in all cervical spine surgeries, but did not attempt to differentiate between approaches and techniques in their analysis.[66,68-70] Others have examined preoperative factors responsible for postoperative outcomes like dysphagia, aspiration, and complications associated with BMP usage following ACDF.[51,71,72] However, multivariate analysis determining which preoperative factors are associated with serious postoperative complications has not been performed.

According to one study, inpatient hospital charges for this procedure can vary between $15,113 and $76,687, a variation that is largely attributed to variations in length of LOS (which is linked to complications).[2] Additionally, longer LOS increases physician time and resource utilization. Knowledge of the factors affecting complications and LOS may help surgeons guide treatment and preoperative expectations. Preoperative counseling before orthopedic procedures has been shown to reduce patient stress,

resulting in faster recovery, and facilitating discharge.[3]

As there are only a few small studies that address factors affecting LOS and risk of complications in ACDF patients, and these studies have differing results, it would be valuable to further characterize these factors on a larger, contemporary cohort. To our knowledge, no study has used these variables as dependent outcomes in a multivariate analysis model. This study's objective is to elucidate which factors significantly contribute to extended LOS and increased complications and after ACDF.

Methods:

Data Source

The National Surgical Quality Improvement Program (NSQIP) began in 1994 as a quality improvement initiative within the Veteran's Administration (VA) healthcare system. [73] The program was expanded to the private sector in 1999 after success within the VA. [74] The private sector NSQIP, referred to as ACS NSQIP, is a multi-center database that is available to participating hospitals in the United States.

In the ACS NSQIP, more than 135 preoperative, perioperative, and 30-day postoperative variables are prospectively sampled from patient medical records, operative reports, as well as patient interviews. The patients are identified prospectively and randomly sampled. Outcomes data are collected throughout the 30-day postoperative period, even after patient discharge from the hospital.

Data collection

The study population was drawn from the NSQIP participant-use data files for 2005 to 2010. Overall, this contains information on 1,334,886 patients from 258 hospitals. ACDF cases were identified based on Current Procedural Terminology codes (CPT 22551, 22554) for anterior cervical fusion in any of the 21 CPT input categories available in NSQIP. Due to the change in CPT coding for anterior cervical fusion and discectomy in 2011, [75] cases with CPT code 22551 were relatively rare in our dataset.

To optimize capture of patients undergoing anterior fusion, CPT code 63075 (anterior discectomy) was included in our anterior cervical fusion cohort. Careful review of CPT codes in NSQIP showed that many cases with the anterior discectomy CPT code had additional codes indicating fusion (bone graft, instrumentation, etc.) indicating that

the discectomy occurred with fusion despite the absence of the specific anterior cervical fusion codes (22551, 22554). There were some cases in which only CPT 63075 was listed but because NSQIP requires only a singly primary code field per case, it is possible that associated codes were not always included. Given that cervical discectomy rarely occurs without fusion, we thought it justifiable to include those cases with primary CPT code of 63075 in our cohort.

Cases involving concomitant posterior cervical arthrodesis, thoracic or lumbar spine surgery, or any other unrelated procedures were excluded from analysis.

Independent Variables

Independent variables in this study included preoperative factors (patient demographics and medical comorbidities) and perioperative factors.

Patient demographics included gender, age, obesity (defined in this study as any patient with a body mass index (BMI) ≥ 30 (kg/m^2), smoking history within the past year, functional status (partially or totally dependent), and transfer status (home or care facility). Variables such as race, employment status, and workers compensation were considered in the analysis.

Functional status is determined by patients' abilities to perform activities of daily living (ADLs). Independent patients require no assistance in performing ADLs, while partially dependent patients and totally dependent patients require some level of assistance, and were grouped together for purposes of analysis. Transfer status is determined by whether the patient was admitted directly from home or from an outside facility such as a nursing home or subacute rehab.

Other preoperative variables collected include American Society of Anesthesiologists (ASA) score and a history of common medical comorbidities: diabetes, cardiovascular, pulmonary, hepatic, renal, neurological, preoperative anemia, and a history of bleeding disorder.

A cardiovascular comorbidity was defined as congestive heart failure (CHF) within 30 days before surgery, a myocardial infarction (MI) in the 6 months before surgery, history of previous percutaneous coronary intervention (PCI), previous cardiac surgery, angina within one month prior to surgery, history of revascularization or amputation due to peripheral vascular disease, and extremity rest pain or gangrene. Pulmonary comorbidity was defined as ventilator dependence, history of severe chronic obstructive pulmonary disease (COPD), or current pneumonia. Hepatic insufficiency was defined as the presence of ascites or esophageal varices. Renal insufficiency was defined as acute renal failure or current dialysis. Finally, a neurological comorbidity was defined as impaired sensorium, coma longer than 24 hours, hemiplegia, paraplegia, quadriplegia, tumor involving the central nervous system (CNS), and history of transient ischemic attack (TIA) or cerebrovascular accident (CVA). Preoperative anemia was defined as any patient entering surgery with a hematocrit <36. Of note, 200 patients did not have a hematocrit value on record in the database. A bleeding disorder was defined as any patient with a risk of excessive bleeding in the setting of an endogenous blood clotting element deficiency (hemophilia and thrombocytopenia), vitamin K deficiency, or on anticoagulants or antiplatelet agents. Chronic aspirin therapy is not included in this category. Chronic steroid use (regular use within 30 days before admission) was also assessed.

Operative time was the only intraoperative variable included in our analysis. The intraoperative "transfusion" variable was excluded from the analysis because over half of the values were unreported.

Outcome variables

The study endpoints were LOS, major complications, and infectious complications. LOS was defined as the number of days from the operation to discharge. For example, discharge the day after surgery was categorized as a LOS of 1 day.

Major complications were defined as any organ space infection, respiratory complication (pneumonia, unplanned intubation, ventilator dependence), cardiac complication (cardiac arrest, MI), sepsis or septic shock, pulmonary embolism (PE), deep vein thrombosis (DVT), acute renal failure, return to the operating room (OR), or death. Infectious postoperative complications included urinary tract infections (UTI) and superficial or deep incisional infections. Infections are defined in the NSQIP database using Center for Disease Control classifications. [76] In this study, patients with superficial or deep incisional infections were combined into a single group of wound infections.

Statistical analysis

SPSS v.19 (IBM, Chicago, IL) was used for all statistical analysis. Patient demographics, the prevalence of comorbidities, mean operative time, number of operated levels, and mean LOS were calculated. Extended operative time was defined as operations longer than the 75th percentile. Rates of major and infectious complications as well as LOS were determined for the study population overall, and stratified by age bracket, American Society of Anesthesiologist (ASA) class, and the various demographic and comorbidity variables. Student *t* test and Chi-square test were used for discrete and

categorical variables, respectively, and analysis of variance (ANOVA) for comparisons across three or more groups.

For major and infectious complications, bivariate regressions were performed with demographic, comorbidity, and intraoperative variables. Adjusted odds ratios and 95% confidence intervals (CI) were calculated for both outcome variables. Predictors significant to $p < .10$ were carried forward into a multivariate logistic regression model to determine independent associations to developing a major or infectious complication, with clinical covariates. A total of 14 variables were incorporated in the multivariate model for major complications. These were age, preoperative anemia, transfer status (from home vs. care facility), history of diabetes, preoperative functional health status, preoperative cardiac or pulmonary or neurological comorbidity, a history of bleeding disorder, ASA class, type of anesthesia (regional vs. general anesthesia), intraoperative blood transfusion, wound class, and operative time. Eight variables were incorporated in the multivariate model for incisional wound complications: patient sex, transfer status (home vs. care facility), a history of current smoking, preoperative pulmonary comorbidity, preoperative anemia, BMI more than 30 kg/m^2, intraoperative blood transfusion, and operative time.

For the LOS outcome variable, a similar process of bivariate egressions with demographic, comorbidity, and intraoperative variables was performed. Predictors significant to $p < .10$ were carried forward into a multivariate linear regression model to determine the adjusted change in LOS, in days, for each of the included predictors.

Throughout the study, two-tailed p values of $< .05$ were considered statistically significant.

Results:

This study identified 2,164 patients who underwent an ACDF between the years of 2005 and 2010. Single level fusions were performed for 1,839 (85%), and multi level fusions were performed for 325 (15%). Average LOS was 1.99 ± 3.914 (mean ± SD) with a range of 0 to 103 days. Figure 1 is a histogram showing the distribution of patients per length of stay.

Clinical characteristics of the patient population, including demographics and comorbidities are found in Table 4. Analysis of each of these factors' non-adjusted association with LOS, major complications, and infectious complications can be found in Table 5.

When evaluating LOS, multivariate analyses revealed the factors shown in Table 6 to be significant predictors of extended LOS when controlling for other variables. Preoperative variables associated with extended LOS included age ≥ 65, functional status, transfer from care facility, history of diabetes, and preoperative anemia. Perioperative factors associated with extended LOS include operative time > 171 min (>75th percentile), and both major and infectious complications. ASA score was not found to be a significant factor by multivariate analysis. The effect of each of the variable identified here had defined effects on extending the LOS that ranged from half a day to five days.

Table 7 details the incidence and type of major and infectious complications following ACDF. Overall, 71 (3.30%) patients experienced a total of 92 major complications, and 27 (1.25%) patients experienced 27 infectious complications.

Multivariate analyses revealed the variables shown in Table 8 to be significant predictor of complications when controlling for the other variables. Preoperative factors

associated with major complications included age ≥ 65, male gender, preoperative anemia, and ASA ≥ 3. Operative time >171 min (>75th percentile), was also predictive of a major complication. No variables were found to be significantly associated with infectious complications.

In order to better counsel our patients for two important preoperative variables, age and ASA scores, each factor was broken down into brackets and analyzed using ANOVA (Table 9). These findings show that patients in the older age brackets (65-74 years and ≥ 75 years) and with higher ASA scores can be expected to experience more major complications and a significantly longer LOS.

Table 4: Clinical characteristics of ACDF patient population

Variable	N	Percent
Total patients	2164	100%
Gender		
Male	1057	49.1%
Female	1107	50.9%
Age		
<65	1849	84.4%
≥65	315	15.6%
BMI		
<30	1232	57.3%
≥30	924	42.7%
Impaired Functional status		
No	2082	96.4%
Yes	80	3.7%
Transfer status		
No	2143	99.1%
Yes	21	0.9%
Smoking		
No	1414	65.3%
Yes	750	34.7%
Diabetes		
No	1890	87.3%
Yes	274	12.7%
Cardiovascular comorbidity		
No	2035	94.0%
Yes	129	6.0%
Pulmonary comorbidity		
No	2087	96.4%
Yes	77	3.6%
Hepatic insufficiency		
No	2163	100.0%
Yes	1	0.0%
Renal insufficiency		
No	2161	99.9%
Yes	3	0.1%
Neurological comorbidity		
No	1984	91.7%
Yes	180	8.3%
Chronic steroid use		
No	2107	97.4%
Yes	57	2.6%
Preoperative anemia		

No	1782	90.8%
Yes	181	9.2%
Bleeding disorder		
No	2134	98.6%
Yes	30	1.4%
ASA classification		
1	108	5.0%
2	1255	58.0%
3	750	34.7%
4	49	2.3%
ASA score 3/4		
No	1365	63.0%
Yes	799	37.0%
Operation time > 75th percentile (171 min)		
No	1627	75.2%
Yes	537	24.8%
Number of levels		
1	1839	85.0%
2	309	14.3%
3	16	0.7%
Multiple levels		
No	1839	85.0%
Yes	325	15.0%

BMI = Body Mass Index; ASA = American Society of Anesthesiologists

Table 5: Clinical characteristics of patient population and univariate association with LOS, major complications, and infectious complications

Variable		LOS (days)	Major complication	Infectious complication
Gender				
	Male	2.2 ± 5.1	4.35%	1.04%
	Female	1.8 ± 2.3	2.26%	1.45%
	p	0.061	0.006[a]	0.397
Age				
	<65	1.7 ± 2.1	2.43%	1.30%
	>65	3.6 ± 8.7	8.25%	0.95%
	p	<0.001[a]	<0.001[a]	0.610
BMI				
	<30	2.1 ± 4.9	3.49%	1.14%
	>30	1.8 ± 2.0	2.92%	1.41%
	p	0.095	0.462	0.576
Impaired Functional status				
	No	1.8 ± 3.5	2.88%	1.25%
	Yes	6.2 ± 8.8	12.50%	1.25%
	p	<0.001[a]	<0.001[a]	0.999
Transfer status				
	No	1.9 ± 3.8	3.13%	1.21%
	Yes	7.3 ± 10.9	19.05%	4.76%
	p	<0.001[a]	<0.001[a]	0.145
Smoking				
	No	2.0 ± 4.3	2.97%	1.20%
	Yes	2.0 ± 3.0	3.87%	1.33%
	p	0.741	0.266	0.794
Diabetes				
	No	1.9 ± 3.7	3.12%	1.11%
	Yes	2.7 ± 4.9	4.38%	2.19%
	p	0.001[a]	0.275	0.133
Cardiovascular comorbidity				
	No	1.9 ± 3.7	3.00%	1.23%
	Yes	3.2 ± 5.9	7.75%	1.55%
	p	<0.001[a]	0.003[a]	0.750
Pulmonary comorbidity				
	No	1.9 ± 3.8	2.92%	1.25%
	Yes	3.7 ± 5.3	12.99%	1.30%
	p	<0.001[a]	<0.001[a]	0.967
Hepatic insufficiency				
	No	2.0 ± 4.0	3.28%	1.25%
	Yes	3.0 ± 0.0	0.000%	0.000%
	p	0.796	0.854	0.911

Renal insufficiency				
	No	2.0 ± 3.9	3.29%	1.25%
	Yes	6.0 ± 5.0	0.00%	0.00%
	p	0.076	0.750	0.846
Neurological comorbidity				
	No	1.9 ± 3.7	2.87%	1.26%
	Yes	3.3 ± 5.5	7.78%	1.11%
	p	<0.001 [a]	<0.001 [a]	0.863
Chronic steroid use				
	No	2.0 ± 3.9	3.28%	1.23%
	Yes	2.5 ± 5.7	3.51%	1.75%
	p	0.342	0.922	0.727
Preoperative anemia				
	No	1.8 ± 2.2	2.92%	1.29%
	Yes	3.4 ± 5.6	8.84%	1.11%
	p	<0.001 [a]	<0.001 [a]	0.832
Bleeding disorder				
	No	2.0 ± 3.9	3.19%	1.22%
	Yes	3.4 ± 3.2	10.00%	3.33%
	p	0.047 [a]	0.038 [a]	0.300
ASA score ≥ 3				
	No	1.7 ± 3.8	1.54%	1.03%
	Yes	2.5 ± 4.0	6.26%	1.63%
	p	<0.001 [a]	<0.001 [a]	0.224
Operation time > 75th percentile (171 min)				
	No	1.8 ± 3.8	2.34%	1.17%
	Yes	2.7 ± 4.1	6.15%	1.49%
	p	<0.001 [a]	<0.001 [a]	0.560
Number of levels				
	1	2.0 ± 4.2	3.26%	1.25%
	2	2.0 ± 1.6	3.56%	1.29%
	3	1.6 ± 0.7	0.00%	0.00%
	p	0.896	0.734	0.901
Multiple levels				
	No	2.0 ± 4.2	3.26%	1.25%
	Yes	2.0 ± 1.6	3.38%	1.23%
	p	0.938	0.909	0.976

BMI = Body Mass Index; ASA = American Society of Anesthesiologists
[a] indicates statistical significance ($p < 0.05$)

Table 6: Significant Predictors of Extended LOS

Variables	Effect Change in LOS (± SE)	P value
Preoperative		
Functional status	3.3 ± 0.3	<.001
Transfer status	2.1 ± 0.6	<.001
Preoperative anemia	0.8 ± 0.2	<.001
Age ≥ 65	0.7 ± 0.2	<.001
Diabetes	0.5 ± 0.2	.008
Perioperative		
Major complication	5.0 ± 0.3	<.001
Infectious complication	1.2 ± 0.5	.016
Operative time > 171 min	0.7 ± 0.1	<.001

Table 7: Major and infectious complications following ACDF

	Total *n* = 2164
Number of patients with ≥ 1 major complications	71 (3.30%)
Total number of major complications	92
Acute renal failure	0 (0.00%)
Cardiac	6 (0.28%)
Death	5 (0.23%)
Organ space infection	3 (0.14%)
Respiratory	21 (0.97%)
Return to OR	40 (1.85%)
Sepsis/septic shock	4 (0.18%)
Venous thrombotic events	13 (0.60%)
Number of patients with ≥ 1 infectious complications	27 (1.25%)
Total number of infectious complications	27
Surgical site infection	14 (0.65%)
Urinary tract infection	13 (0.60%)

Table 8: Significant Predictors of Major Complications

	Odds Ratio	95% CI	P value
ASA ≥ 3	2.609	1.454-4.680	.001
Preoperative anemia	2.138	1.093-4.183	.026
Age ≥ 65	2.110	1.191-3.738	.010
Operative time > 171 min	2.095	1.237-3.548	.006
Male gender	1.756	1.027-3.003	.040

ASA = American Society of Anesthesiologists

Table 9: Complications and LOS by Age Bracket and ASA Score

Variable		N	LOS (days)	Major complication
Age Bracket				
	<35	103	1.6 ± 3.1	1.94%
	35-44	400	1.5 ± 1.6	2.25%
	45-54	789	1.7 ± 1.8	2.15%
	55-64	555	1.9 ± 2.6	3.06%
	65-74	248	2.9 ± 5.3	6.85%
	≥75	67	6.0 ± 15.7	13.43%
	p		<0.001*	<0.001*
ASA Score				
	1	108	1.3 ± 2.5	1.85%
	2	1255	1.7 ± 3.9	1.51%
	3	750	2.3 ± 3.4	5.47%
	4	49	5.7 ± 8.4	18.37%
	p		<0.001*	<0.001*

ASA = American Society of Anesthesiologists

Discussion

General

ACDF is one of the most commonly performed spinal surgeries due to its favorable outcomes and safety. Previous studies have reported on the relatively short LOS and low associated morbidity. [46,47] The purpose of this study was to determine the variables linked with longer hospital stays and higher incidence of complications following this operation and to quantify the effect of these variables. Both LOS and complications are closely related and of significant importance from both the patient and surgeon's perspective.

Several previous studies have performed multi-variate analyses to determine pre- and perioperative variables associated with longer LOS following ACDF. Arnold et al. retrospectively reviewed 108 elective ACDF patients with an average LOS of 1.98 ± 1.6 days. Significant predictors included age > 50 and female gender, as well as postoperative cardiac, urinary, and pulmonary complications. [52] Meanwhile, Walid et al. in a study of 283 ACDF patients found that a history of previous coronary artery bypass or stent, chronic renal disease, and preoperative opioid use correlated with increased LOS seen in unemployed patients as compared to employed patients. [37] This study did not discuss post-operative complications. Limitations of both these analyses include small sample size from a single institution and retrospective data collection. Another recent analysis with similar demographics identified male gender, black or Hispanic race, Medicare or Medicaid insurance, higher Charlson Comorbidity Index (CCI) score, and traumatic spine injury as predictive of extended LOS. [53] This study, which used a different national database, the Nationwide Inpatient Sample, focused primarily on

demographics and finances, with no tracking or discussion of post-operative complications.

Several studies have been performed characterizing complications following all types of cervical spine surgery. [66,68,70] In a 2013 study utilizing ACS NSQIP, Schoenfeld et al. analyzed factors leading to increased complications for 5,887 patients following all types of spine surgery cases. [69] Age, pulmonary comorbidities, BMI, history of infection, ASA ≥ 3, neurologic conditions, resident (i.e., trainee) involvement, and procedural times >75th percentile increased the risk of complications. No attempt was made to stratify by type of spine surgery with that study. The ACS NSQIP database has also been used to study outcomes like LOS and risk of complications in other orthopedic operations, such as hip and knee arthroplasty. [77-79]

To our knowledge, there are have not been other studies with multivariate analysis of factors associated with LOS and postoperative complications following ACDF which are based on large multicenter database cohorts. We evaluated 2,164 patients who underwent ACDF at participating institutions between 2005 and 2010.

Length of stay (LOS)

For our elective ACDF procedures, patients are generally advised to expect a postoperative stay of one night in the hospital. This bore out to be true in this study, with the majority of the patients staying only one night in the hospital (LOS of one day), while the tail of the curve seen in Figure 1 lead to an average LOS of 1.99 ± 3.91 days, consistent with previously reported values. [50,52,53,66]

The important question addressed in this study is what variables were independently associated with longer hospital stay, and by how much. Multivariable

regression determined that the preoperative factors leading to an extended LOS were functional status (extended LOS by an average of 3.3 days), transfer status (extended LOS by an average of 2.1 days), preoperative anemia (extended LOS by an average of 0.8 days), age ≥ 65 (extended LOS by an average of 0.7 days), and diabetes (extended LOS by and average of 0.5 days). Perioperative factors leading to an extended LOS were major complications (extended LOD by an average of 5.0 days), infectious complications (extended LOS by and average of 1.2 days), operative time greater than 171 minutes or the 75th percentile time of surgery (extended LOS by and average of 0.7 days).

Increased age, functional status, and transfer status are descriptive variables that represent a baseline level of disability, and their association with extended LOS in this study confirms previous findings in the arthroplasty literature. [77-79] Meanwhile, diabetes is associated with poor wound healing, immune function, and complicates postoperative medical management, all issues that have previously been shown to put spine surgery patients at risk for a postoperative complication and extended LOS. [80]

Anemia is the one preoperative factor associated with extended LOS in this study that is potentially modifiable. Previously, anemia has been shown to be associated with increased risk of delirium, cardiac complications, mortality, infection, and major and infectious complications as well as extended LOS following spine surgery. [81-84] Further study is warranted regarding the merits and endpoints for treating anemia preoperatively.

The finding that complications lead to a longer hospital stay was expected, as it is these endpoints and their medical management that are the chief impetus keeping patients from being discharged. Major complications are especially important, as they increase LOS by nearly 5 days. Fortunately, they are infrequent in nature as just 3.3% of patients undergoing ACDF in this study experienced such events.

Complications

It is generally found that complication rates are low after ACDF. This study found 1 in 33 to experience a major complication based on the definition used for this study.

This finding is also in line with previously reported values in most studies. [48,49,66] However, there is a wide variation in the incidence of complications reported by different studies, a variation that can largely be attributed to varying definitions of "complication" between studies. For instance, in their small, single institution study, Arnold et al. reported a significantly higher perioperative complication rate of 31%. [52] This higher complication rate can be mostly be attributed to altering definitions of "cardiac" and "pulmonary" complications, as well as the inclusion of relatively infectious complications such as postoperative pain, anxiety, and dysphagia.

An important question addressed in this study is what variables were independently associated with increased risks of major complications by the 3.3% of the population that experienced them. Multivariable regression determined that the factors associated with major complications were ASA ≥ 3 (increased risk of a major complication by 2.6 times), preoperative anemia (increased risk of a major complication by 2.1 times), age ≥ 65 years old (increased risk of a major complication by 2.1 times), operative time greater than 171 minutes or 75^{th} percentile length of case (increased risk of a major complication by 2.1 times) and male gender (increased risk of a major complication by 1.8 times

An extended operative time has previously been correlated with increased risk of complications and postoperative infection spine patients in the NSQIP database. [69] It is

likely that extended operative time represents more complicated, extensive surgery on more difficult patients. Thus it is not necessarily an endpoint in itself but a representation of the patient and case. Surgeon technique, experience, and teaching responsibilities could also play a role.

Levels fused had no effect on length of stay or complication rates in this study. In previous literature, higher rates of complication have been seen in patients with multilevel fusion presumably as a result of increasingly complex operation marked by a more extensive dissection, extended operating time, and increased blood loss. [85] The findings of our study point to an improved management of the ACDF patient, both intraoperatively and postoperatively, regardless of the number of levels fused.

Study limitations, strengths and conclusions

There are several limitations to the study. The primary limitation with using a large database such as the NSQIP is that procedure specific variables are not collected. For example, dysphagia, with rates quoted up to 30% [64] and other neurologic complications specific to ACDF were not specifically captured in the dataset analyzed.

Further, certain variables such as preoperative anemia were missing for some of the patients enrolled in the dataset. It is presumed that such variables may be missing because the clinician was not specifically worried about obtaining this data prior to the surgery for patients for whom this would be expected to be normal, but this is not spelled out.

Despite its shortcomings, NSQIP is a large dataset that provides detailed clinical information on many patients from hospitals across the country, allowing for analysis of a broad cross-section of the population. The large number of patients in this dataset allows

for greater power and multivariate analyses that would not be possible from smaller cohort studies.

A final limitation of this study is the inability to determine the insurance status of each patient. Some insurers require a 2-3 day stay before discharge to a subacute or nursing facility. Although ACDF is typically a low morbidity surgery not requiring further intensive rehab, this requirement could introduce some potential bias into our study results by increasing LOS for this subset of patients.

Factors associated with increased LOS and complication risk following ACDF have been defined and quantified in this study. While it is questionable whether many of these factors are truly modifiable, each must be considering before surgery. Physicians and patients will hopefully be able to turn to the results of this analysis to set realistic expectations. Further investigation of the generalizability of large database studies such as this is encouraged. In addition, with preoperative anemia identified as a risk factor for extending LOS and major complications, potentially the ability to modify a factor such as this and the impact of potential improvement might be worthy of consideration and study.

Part 3: Iliac Crest Bone Graft Use in Spinal Fusion: Incidence and Short-term Postoperative Risk in a National Cohort

Abstract:

Introduction:

The use of iliac crest bone graft (ICBG) in spinal fusion has been associated with increased surgical time, increased hospital length of stay (LOS), and donor site morbidity associated with the harvest procedure. Development of expensive bone graft substitutes has been predicated on these issues and usage of ICBG in spinal fusion has certainly decreased. However, there are no recent studies that report the incidence of ICBG use. Additionally, data on the effect of bone graft harvest on LOS and readmission rate is sparse, and multivariate analysis has not been used to control for confounding factors.

Purpose:

The current study uses a large, national database to compare outcomes for those receiving ICBG to those who did not using multivariate analysis to control for confounding factors.

Methods:

A retrospective review of prospectively collected data from the American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP) 2010-2012 database was conducted.

The database was queried for patients undergoing spinal fusion with or without ICBG using CPT codes. Bivariate and multivariate analyses were performed to determine the effect of harvesting ICBG on operative time, postoperative adverse events, LOS, and readmission while controlling for comorbidities, demographics, and approach.

Results:

13, 927 patients undergoing spinal fusion were identified. Of these, only 820 (5.9%) utilized ICBG. Rates varied between 3.4% and 12.4% depending on approach.

Bivariate logistic regression (used for categorical variables) found the ICBG cohort was more likely to have a postoperative blood transfusion (11.6% vs. 5.5%, $p<0.001$). Bivariate linear regression (used for continuous variables) found the ICBG cohort to have an extended operative time (+36.0 min, $p<0.001$) and extended LOS (+0.6 days, $p<0.001$).

Multivariate analyses controlling for comorbidities, demographics, and approach determined postoperative blood transfusion (OR 1.5), extended operative time (+ 22.0 min, $p<0.001$) and LOS (+0.2 days, $p=0.037$) to be significantly associated with ICBG use.

No other adverse event was significantly associated with ICBG use. Readmission rates were not significantly different.

Discussion/conclusion:

Current ICBG usage in spinal fusion is low, with rates between 3.4% and 12.4% depending on approach.

The current study used a large national database cohort and confirmed ICBG use to be associated with extended operative time and postoperative blood transfusion on multivariate analysis. Extended LOS was seen in ICBG patients, but the effect size (+0.2 days) is not clinically relevant. Serious adverse events, infection, extended LOS, and increased readmission rates were not independently associated with ICBG use.

Despite a clear movement towards more expensive bone graft substitutes, ICBG remains a safe method for promotion of fusion in spine surgery.

Introduction:

Iliac crest bone graft (ICBG) is often considered to aid the progression of spinal fusion due to its osteoconductive, osteoinductive, and osteogenic properties. [9-11] However, morbidity associated with the harvest of ICBG is of clinical concern.

Postoperative donor-site pain is a commonly reported issue. However, reported numbers significantly vary. Acute pain has been reported in 2.8%-27.9% of patients [12-14] and chronic pain in 2.4-60% of patients. [15-18] Some suggest that donor site pain concerns are overstated, and persistent pain may be partially attributed to the primary spinal pathology. [13,19,20]

Other reported potential problems with ICBG use include hematoma, infection, pelvic fracture, and nerve palsy. [14,17,21] Additionally, the increased blood loss, operating time and anesthesia time associated with the harvest procedure add additional risk to the surgery. [21-24] The potential for donor site morbidity following ICBG harvest has been used to help justify the usage of more expensive artificial bone graft substitutes, such as bone morphogenic protein (BMP). [86]

Length of stay (LOS) is another important outcome to consider. Total hospital costs have been closely linked to LOS in spine surgery patients. [87,88] Additionally, longer LOS increases resource utilization and increases risk for life-threatening complications such as hospital acquired infection [4,5] and deep vein thrombosis (DVT). [6,8,89] Patients receiving ICBG are theoretically at a risk for prolonged LOS, due to increased donor site morbidity and pain leading to increased postoperative care needs. Various small studies have reported differing results on increased LOS following the use of ICBG, although multivariate analysis to control for potentially confounding factors has not performed. [19,21-26]

Readmission rate is an additional outcome increasingly used as an indicator of quality of care. This occurs as new health care guidelines mandate fines, a loss or decrease of reimbursement for surgical patients readmitted within 30 days of surgery, or reduced reimbursement to hospitals with high readmission rates. [90-93] However, data is sparse regarding this outcome in spine surgery patients.

This study seeks to characterize the short-term adverse events, LOS and readmission rates associated with ICBG use for spinal fusion. To our knowledge, no other study has performed multivariate analysis to control for confounding factors when reporting these results. In doing so we hope to gain further insight into the short-term morbidity caused by this technique while accounting for patient factors and operative approach.

Methods:

Data source

This study used the American College of Surgeons National Surgery Quality Improvement Program (ACS NSQIP) database to determine the effect of ICBG use on adverse events, LOS, and readmission rates following spinal surgery.

The ACS NSQIP is a prospective, risk-adjusted, multi-institutional outcomes program that began in 1994 in the Veteran's Administration (VA) healthcare system, and was expanded in 1999 to include other high volume hospitals in the United States. [73,94] The details of data collection, inclusion criteria, sampling procedures, and outcomes have been reported. [94,95] 135 preoperative, perioperative, and 30-day postoperative variables are prospectively sampled from patient medical records, operative reports, and patient

interviews to evaluate 30-day risk-adjusted surgical outcomes. Outcomes are collected throughout the 30-day postoperative period, even after discharge.

Data Collection

We conducted a retrospective study using the ACS NSQIP database. Patients who underwent spine procedures from 2010 to 2012 were selected using the following Current Procedural Terminology (CPT) codes: anterior cervical discectomy and fusion (22551, 22554, and 63075), anterior cervical corpectomy (63081), posterior cervical fusion (22600), posterior thoracic fusion (22610), anterior lumbar interbody fusion (22558), posterior lumbar interbody fusion (22612 and 22630). The number of levels was determined based on the presence of procedure-specific supplementary CPT codes for each additional level.

Patients were separated based on the use of iliac crest bone graft with CPT codes 20937 and 20938. Local autograft was not included in the ICBG cohort. Patients with multiple spinal procedures, spinal deformities, patients who underwent urgent or emergent surgery, and those with preexisting infection were excluded from analysis.

Among the variables available in the NSQIP are patient characteristics including sex, age, height, and weight. Body mass index (BMI) was calculated. The NSQIP also includes information on medical comorbidities and American Society of Anesthesiologists (ASA) class. A modified Charlson comorbidity index (CCI) [96] was calculated for each patient based on the available comorbidity data. Such modified CCIs have been shown to be similar in efficacy to the original CCI, [97,98] and the modified CCI employed in this study has been previously used with the ACS-NSQIP. [99] The

comorbidities used to determine the modified CCI included (followed by corresponding point values): myocardial infarction (1), congestive heart failure (1), peripheral vascular disease or rest pain (1), transient ischemic attack or cerebrovascular accident (1), chronic obstructive pulmonary disease (1), diabetes mellitus (1), hemiplegia (2), end stage renal disease (2), ascites or esophageal varices (3), and cancer (6). Finally, one point was added for each decade greater than 40 years of age.

Adverse Events

The NSQIP tracks patients for 23 individual adverse events in the first thirty postoperative days. A serious adverse event (SAE) was defined as the occurrence of any of the following: death, coma > 24 hours, on ventilator > 48 hours, unplanned intubation, stroke/cerebrovascular accident, pulmonary embolism, cardiac arrest, myocardial infarction, acute renal failure, sepsis, septic shock, wound disruption, deep surgical site infection, organ/space infection (other than surgical site), graft/prosthesis/flap failure, or return to the operating room. Minor adverse events (MAEs) included superficial surgical site infection, urinary tract infection, pneumonia, blood transfusion, progressive renal insufficiency, peripheral nerve injury, and DVT.

The categories SAE and MAE are reported per patient, not per event. Thus, a patient with two different MAEs would count as only one in the total MAE category.

Operative time and Length of Stay

Operative time was defined as the time from surgical incision to wound closure in minutes. LOS was defined as calendar days from operation to hospital discharge, and recorded as an integer. No distinction was made between morning or afternoon discharge

or surgery, and each additional day may not represent an additional 24-hour period. Operative time and LOS were treated as continuous variables for analysis.

Readmission

Thirty-day readmission data in the NSQIP was first collected in 2011. For this study, readmission was defined as positive when a patient had an unplanned readmission one or more times. Readmission data is collected for the 30-day period following the operation, not from discharge. As such, patients with LOS > 10 days were excluded from the readmission analysis to allow for a large enough window to capture readmissions that occurred between discharge and 30 postoperative days.

Analysis

Statistical analyses were conducted using STATA® version 11.2 (StataCorp, LP, College Station, Texas, USA). All tests were two-tailed and the statistical difference was established at a two-sided α level of 0.05 ($p < 0.05$). Patients treated with or without ICBG were first compared by demographic and comorbidity variables using Pearson's chi-squared test.

Percent of adverse events that occurred with or without ICBG were compared using bivariate and multivariate logistic regression, using non-ICBG cases as the reference. Multivariate logistic regression adjusted for demographic and comorbidity variables (age, sex, body mass index, ASA class, and modified CCI) and approach. Adverse events with at least one event in each cohort were compared. The continuous variables operative time and LOS were compared using bivariate and multivariate linear

regression. Readmission rates between the two groups were compared using bivariate and multivariate logistic regression.

Results:

This study identified 13,927 patients undergoing spinal fusion between the years of 2010 and 2012. Of these, 820 (5.9%) cases utilized ICBG. Clinical characteristics of the patient population, including demographics and comorbidities for the two cohorts can be found in Table 10. No significant baseline difference was seen for age, sex, BMI, ASA, or CCI. Only number of levels fused was found to be significantly different between the two cohorts, with ICBG cases more likely to be multi-level fusions (47.5% vs. 39.2%, $p<0.001$). However, overall, ICBG cases were still the minority in multilevel fusions (390 ICBG cases vs. 5,138 non-ICBG cases).

The use of ICBG for each type of procedure is detailed in Table 11. Depending on the procedure, this ranged from 3.4% to 12.4% of cases utilizing ICBG.

Bivariate logistic regression was used to test the association of ICBG with binary postoperative events (Table 12, bivariate columns). No SAEs were found to be associated with the ICBG group. There was an increase in aggregated minor adverse events for the ICBG group (OR=2.0, $p<0.001$) which seemed to be driven by only one significant minor adverse event which was blood transfusion (OR=2.3, $p<0.001$)

Multivariate logistic regression analyses was then used to control for comorbidities, demographics, and approach (Table 12, multivariate columns). Similar to the bivariate analyses, there were no differences in SAEs, but aggregated minor adverse

events (OR=1.4, p=0.008) and blood transfusions (OR=1.5, p=0.002) remained more common in the ICGB group.

Of the study population, 411 (3.6%) of 11,086 patients with LOS ≤ 10 days were readmitted. Of these patients, 681 (6.1%) had ICBG. Rates of readmission were not significantly different between the groups on bivariate or multivariate analysis.

It should be noted that the non-ICBG cohort was associated with 21 mortalities (0.2%) within 30 days of surgery, while the ICBG cohort was associated with 0 (0.0%). Because of the "0" value for the ICBG cohort, significance was unable to be determined.

Bivariate linear regression was used to test the association between ICBG use and the continuous variables LOS and operative time (Table 13). The ICBG cohort was found to have an extended operative time (+36.0 min, $p < 0.001$) and extended LOS (3.1 ± 2.9 days vs. 2.5 ± 3.5 days, $p < 0.001$) relative to those for whom ICBG was not utilized. Multivariate linear regression analysis controlling for comorbidities, demographics, and approach found extended operative time (+22 min, $p<0.001$) and LOS (+0.2 days, $p=0.037$) to be significantly associated with ICBG use.

Table 10: Patient demographics and comorbidities

	All Patients	No ICBG	ICBG	*p* [a]
Overall	13,927	13,107 (94.1%)	820 (5.9%)	
Age				0.686
18-39	11.5%	11.4%	12.2%	
40-49	24.5%	24.5%	23.2%	
50-59	30.3%	30.3%	29.0%	
60-69	20.8%	20.7%	22.1%	
≥70	13.0%	13.0%	13.5%	
Male sex	46.6%	46.5%	47.3%	0.650
Body mass index				0.155
18-25	21.6%	21.5%	23.0%	
25-30	34.2%	34.1%	36.6%	
30-35	24.9%	25.0%	22.9%	
≥35	19.3%	19.4%	17.5%	
ASA 3-4	39.6%	39.5%	40.9%	0.446
Modified CCI				0.809
0-1	33.3%	33.3%	32.8%	
2	26.8%	26.8%	26.2%	
≥3	39.9%	39.8%	41.0%	
Number of levels				**<0.001**
1	60.3%	60.8%	52.6%	
2	28.4%	28.0%	34.8%	
≥3	11.3%	11.2%	12.7%	

[a] Bolding indicates significance

ASA = American Society of Anesthesiologists Score, CCI = Charlson Comorbidity Index

Table 11: Operative characteristics

Procedure	Total	No ICBG	ICBG
Anterior cervical fusion	8,518	8,134 (95.5%)	384 (4.5%)
Anterior cervical corpectomy	99	93 (93.9%)	6 (6.1%)
Posterior cervical fusion	659	589 (89.4%)	70 (10.6%)
Posterior thoracic fusion	177	155 (87.6%)	22 (12.4%)
Anterior lumbar fusion	1,134	1,096 (96.7%)	38 (3.4%)
Posterior lumbar fusion	3,340	3,040 (91.0%)	300 (9.0%)

Table 12: Association of ICBG with adverse events and readmission in spine surgery patients

	Percent of non-ICBG cases with outcome	Percent of ICBG cases with outcome	Bivariate logistic regression		Multivariate logistic regression [a]	
			OR	*p*	OR	*p*
Serious adverse event	3.4%	4.2%	1.2	0.232	1.1	0.756
Death	0.2%	0.0%	-	-	-	-
Coma > 24 hours	0.1%	0.0%	-	-	-	-
Ventilator > 48 hours	0.4%	0.2%	0.6	0.466	0.6	0.451
Unplanned intubation	0.5%	0.6%	1.2	0.750	1.1	0.767
Stroke/cerebrovascular accident	0.1%	0.0%	-	-	-	-
Pulmonary embolism	0.3%	0.4%	1.3	0.698	1.0	0.938
Cardiac arrest requiring CPR	0.1%	0.4%	2.7	0.116	1.6	0.135
Myocardial Infarction	0.2%	0.2%	1.5	0.613	1.4	0.658
Acute renal failure	0.1%	0.0%	-	-	-	-
Sepsis	0.4%	0.5%	1.2	0.771	0.9	0.849
Septic shock	0.1%	0.1%	1.5	0.720	1.0	0.977
Return to the operating room	2.1%	2.7%	1.3	0.235	1.1	0.756
Wound dehiscence	0.2%	0.2%	1.5	0.570	1.0	0.972
Deep surgical site infection	0.4%	0.6%	1.7	0.240	1.3	0.580
Organ space infection	0.1%	0.0%	-	-	-	-
Graft/prosthesis/flap failure	0.1%	0.0%	-	-	-	-
Minor adverse event	7.6%	14.0%	**2.0**	**<0.001**	**1.4**	**0.008**
Superficial surgical site infection	0.7%	0.7%	1.1	0.838	0.8	0.639
Urinary tract infection	1.0%	1.0%	0.9	0.833	0.7	0.432
Pneumonia	0.7%	0.7%	1.1	0.859	1.0	0.932
Blood transfusion	5.5%	11.6%	**2.3**	**<0.001**	**1.5**	**0.002**
Progressive renal insufficiency	0.1%	0.1%	2.0	0.514	2.0	0.523
Peripheral nerve injury	0.1%	0.2%	2.5	0.236	1.9	0.401
DVT/thrombophlebitis	0.3%	0.6%	1.8	0.222	1.3	0.566
Readmission [b]	3.5%	4.1%	1.2	0.417	1.0	0.995

[a] Each line represents a separate multivariate analysis for each variable in order to give an adjusted OR and p-value by controlling for all demographics, comorbidities, and operative approaches found in Table 1 and Table 2.

[b] Readmission analysis used data from years 2011 and 2012 only and excluded patients with LOS >10 days, leaving 11,086 patients for analysis. 411 [3.6%] of 11,086 patients were readmitted, and 681 (6.1%) of 11,086 patients had ICBG.

Bolding indicates significance

Table 13: Association of ICBG with operative time and length of stay in spine surgery patients

	Non-ICBG Mean ± SD	ICBG Mean ± SD	Bivariate linear regression [a]		Multivariate linear regression [a]	
			Coef.	*p*	Coef.	*p*
Operative time	149.0 ± 90.0	187.0 ± 95.0	**+36.0**	**<0.001**	**+22**	**<0.001**
Length of stay (days)	2.5 ±3.5	3.1 ± 2.9	**+0.6**	**<0.001**	**+0.2**	**0.037**

[a] Unstandardized coefficient represents unit change in the outcome variable if the predictor variable is positive. For example, a statistically significant coefficient of 36.0 for operative time means that on average, ICBG is associated with an increase in operative time of 36.0 minutes.

Discussion:

Our study finds that ICBG is used in only 5.9% of fusions in current practice, with the value varying between 3-12% based on anatomic approach. Despite decreased utilization, ICBG continues to be considered the "gold standard" for achieving biologic union in spine fusion surgery. However, concerns for peri- and post-operative complications remain. The purpose of this study was to characterize the short-term adverse events, LOS, and readmission rates associated with ICBG use.

Analyses of the morbidity associated with ICBG are becoming more challenging in modern clinical practice due to the decreased utilization of ICBG. However, the use of a national database has allowed for adequate numbers to support the analyses performed in the current study.

Adverse Events:

Morbidity associated with the harvest procedure is often cited as a shortcoming of ICBG use. Economic analysis justifying use of expensive bone graft substitutes is predicated on this donor site morbidity. [86] Acute and chronic pain, increased blood loss, increased operating time, hematoma, infection, fracture and neurologic injury have been reported. [14,17,21-24] Meanwhile, other studies show no significant increase in postoperative morbidity. [13,19,21]

The rates for AEs in the current study do fall within the ranges reported in the literature, supporting their validity. [19] Multivariate regression found ICBG use to be significantly associated with aggregated minor adverse events (14.0% vs. 7.6%), postoperative blood transfusion (11.6% vs. 5.5%), and extended operating time (+22.0

min). The significant increase in minor adverse events is attributed mostly to the increase in blood transfusions.

The need for perioperative transfusion in the ICBG cohort was the only specific postoperative adverse event found to be significantly different between groups in this study. The added soft tissue dissection, additional incisional site, and extended operative time associated with bone graft harvest may cause increased blood loss, leading to the need for transfusion. Additionally, in our study, the ICBG cohort had a higher percentage of multilevel fusion cases (47.5% vs. 39.2%), meaning larger incisions, longer surgeries and potentially more blood loss in that cohort. However, this effect size was small, and controlled for in multivariate analysis. Increased intraoperative blood loss for ICBG patients has previously been reported, [22,23,100,101] however few studies report on postoperative transfusion requirements. Of note, Radcliff et al. analyzed 354 patients from the spine patient outcomes research trial (SPORT) and found no increase in postoperative transfusions for ICBG use in lumbar spine fusion. [21]

Extended operative time was also associated with ICBG use. This is likely secondary to the additional incision site, although the use of ICBG in more complex, multilevel cases is also a potential factor. In this study operating time was extended even when controlling for number of levels fused. An increase in operating time is important, as it can represent more anesthesia time for the patient. Additionally, increased operating time has previously been associated with postoperative complications and infections. [69]

An important negative finding is that there was not an increase in infection rate in the ICBG group (at 30 day postoperative day follow up). There was also not an increase in return to the operating room.

Finally, a post-operative mortality rate of 0.2% (21 cases) was seen in the non-ICBG group, with 0% in the ICBG cohort. Despite this low rate, mortality in an elective procedure is serious enough to warrant further mention. Life threatening complications have been reported with the use of synthetic bone graft substitutes, like rh-BMP, especially with off-label use.[25] While we are unable to comment on the use of bone graft substitutes due to limitations in the NSQIP data reporting, ICBG use is not associated with additional risk of mortality in this cohort.

Length of Stay

Extended LOS following ICBG use has been reported in several studies, although confounding factors were not controlled for.[19,26,101] LOS is an important marker of short-term morbidity in these patients, as it is a reflection of the extra time needed to attend to immediate postoperative issues such as pain control, infection, and need for transfusion prior to discharge. As an endpoint, extended LOS also leads to increased costs and risk of serious complications.[4-6,8,89]

The current study found LOS to be significantly longer in ICBG patients (+0.2 days, $p = 0.008$) by multivariate analysis, although this statistical significance can largely be attributed to the high power of this study, rather than a large effect size. It is questionable whether an extended LOS of less than a quarter day is clinically significant. Still, as an overall average, it may be valuable as a marker representing increased requirements for postoperative care in the ICBG cohort.

Readmission Rate

Readmission rate has become an increasingly important outcome for surgeons and hospitals, as new health care laws begin to mandate decreased compensation and/or held reimbursements for patients readmitted with in 30 days of discharge. [90-93] Our study found no significant increase in readmission rates for ICBG patients within the 30 days post-surgery.

Previous literature on the subject of readmission rates is limited, although growing. Patients with a higher Charlson Comorbidity Index are more likely to be readmitted within 30 days for all orthopedic procedures. [102] In spine surgery, variables that were not linked to ICBG have been linked to readmission within 30 days (such as infection, medical management, and planned staged procedures). [103,104] As these variables were not associated with the use of ICBG in the current study, it seems reasonable that no increase in readmission was associated with the use of ICBG in the current study.

Study limitations, strengths and conclusions

Several limitations exist for this study. Primarily, procedure specific variables are not available in national databases such as the NSQIP database used here. This includes a lack of information about the ICBG harvest procedure and non-coded specifics about the primary surgical site, both of which could have a clear confounding effect on the results. Postoperative pain data, which is clearly of interest in the discussion of ICBG, was also not available. Additionally, readmissions are tracked until 30 days post-surgery, not 30 days post-discharge. Thus, the readmission rate values reported in this study do not fully reflect 30-day readmissions, an important marker for new health care laws.

Despite several shortcomings, NSQIP is valuable as a database that captures clinical information, including 30-day postoperative outcomes, from many hospitals across the country, allowing for large-scale multivariate analyses with greater power than smaller cohort studies are able to generate.

The effect of ICBG use on adverse events, LOS, and readmission rates in spine surgery was characterized and quantified in this study. It is of interest that only 5.9% of cases utilized ICBG in this national sample. Additionally, a greater percentage of ICBG cases are multilevel fusions (47.5% vs. 39.2%). Multivariate analyses controlling for comorbidities, demographics, approach and levels fused determined postoperative blood transfusion (OR 1.5), extended operative time (+ 22.0 min, $p<0.001$) and extended LOS (+0.2 days, $p=0.037$) to be significantly associated with ICBG use. No other adverse event was significantly associated with ICBG use. Readmission rates were not significantly different. This data should be helpful in that it characterized the morbidity associated with ICBG in current clinical practice.

Conclusions:

Understanding the risk factors that lead to postoperative complications and increased hospital stay is crucial. Knowledge of these factors could be useful for surgeons in patient selection, treatment choice, and preoperative counseling. Additionally, patients and their families can use this information to help schedule time off of work, arrange for transportation, and set-up post-discharge care. In this study, we set out to characterize LOS and complications for two different spinal fusion approaches and one grafting technique, using both a local cohort and a national database.

As study populations, both the local cohort and national database have varying strengths and weaknesses. Local cohorts are often small, making capturing and analyzing rare complications difficult. Single institution studies also have questionable external validity, although do allow for control of surgeon and hospital related cofounders and for detailed collection of patient factors, procedure details, and postoperative events. Meanwhile, the primary limitation with using a large database such as the NSQIP is that procedure specific variables are not collected. For example, dysphagia and other neurologic complications specific to ACDF were not captured in the dataset analyzed. Harvest site location and pain after ICBG usage was also not reported. Despite its shortcomings, NSQIP is a large dataset that provides detailed clinical information on many patients from hospitals across the country, allowing for analysis of a broad cross-section of the population. The large number of patients in this dataset allows for greater power and multivariate analyses that would not be possible from smaller, local cohort studies.

This is the first study to characterize factors predictive of extended LOS following posterior lumbar and anterior cervical fusion. Lumbar fusion patients that are older and

have widespread systemic disease tend have longer LOS, but no single comorbidity was predictive of LOS. After ACDF, 1 in 33 patients develops a major post-operative complication, which are associated with an increased LOS of 5 days. For each approach, it is questionable whether many of the predicting factors are truly modifiable, although each must be considered before surgery. Preoperative anemia was identified as a risk factor for extending LOS and major complications following ACDF, a potentially treatable, modifiable condition that may be worthy of future consideration and study. This is also the first study to characterize current ICBG usage rates and postoperative LOS and complications using a large, national database. Current ICBG usage in spinal fusion was demonstrated to be surprisingly low, with rates between 3.4% and 12.4% depending on approach. Use of ICBG is associated with extended operative time, extended LOS, and postoperative blood transfusion, confirming prior studies. No significant postoperative complications were associated with graft harvest.

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Figure Legend:

Figure 1**:** Length of stay following lumbar spinal fusion.

Histogram showing the distribution of patients per length of stay following lumbar fusion. An extended length of stay included all patients discharged after 5 or more days.

Figure 1:

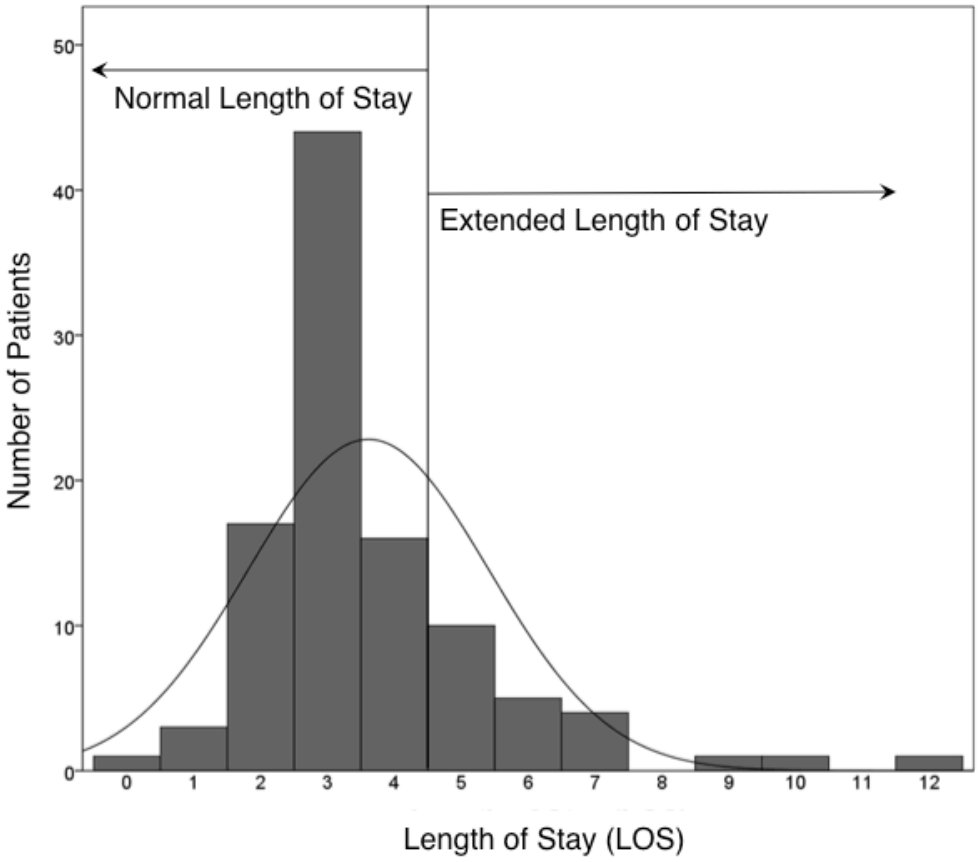
Normal Length of Stay
Extended Length of Stay
Number of Patients
Length of Stay (LOS)
0
10
20
30
40
50
0
1
2
3
4
5
6
7
8
9
10
11
12

Table 1:Demographic, Preoperative, and Perioperative Factors and Their Association With LOS

					95% Confidence Interval	
Variable	LOS	N	Mean	***P***	Lower	Upper
Sex (Male =1, Female =0)	Normal	81	.47			
	Extended	22	.23	***0.030***	0.025	0.459
Age	Normal	81	60.49			
	Extended	22	62.45	0.539	-8.382	4.461
Levels Fused	Normal	81	1.37			
	Extended	22	1.45	0.598	-0.406	0.238
Pre-op Narcoticsa	Normal	81	.44			
	Extended	22	.41	0.772	-0.210	0.281
Revision Surgery[a]	Normal	81	.44			
	Extended	22	.41	0.772	-0.210	0.281
BMI	Normal	81	29.11			
	Extended	22	30.62	0.394	-5.105	2.072
Diabetes[a]	Normal	81	.23			
	Extended	22	.23	0.944	-0.202	0.217
Hypertension[a]	Normal	81	.60			
	Extended	22	.68	0.510	-0.311	0.158
Morbid Obesity[a]	Normal	81	.14			
	Extended	22	.27	0.201	-0.351	0.077
Pulmonary Disease[a]	Normal	81	.19			
	Extended	22	.27	0.417	-0.305	0.130
Heart Disease[a]	Normal	81	.30			
	Extended	22	.14	0.085	-0.023	0.343
High Risk[a]	Normal	81	.23			
	Extended	22	.23	0.944	-0.202	0.217
Malignancy[a]	Normal	81	.10			
	Extended	22	.05	0.349	-0.060	0.167
Smoking[a]	Normal	80	.41			
	Extended	22	.45	0.732	-0.290	0.206
Alcohol[a]	Normal	81	.63			
	Extended	22	.55	0.631	-0.270	0.439
ASA	Normal	81	2.38			
	Extended	22	2.64	***0.043***	-0.499	-0.009
Job[a]	Normal	76	.37			
	Extended	21	.33	0.826	-0.289	0.359
Married[a]	Normal	81	.69			
	Extended	21	.71	0.841	-0.254	0.208
EBL (mL)	Normal	75	330.73			
	Extended	22	403.41	0.320	-218.406	73.055
Perioperative Transfusion[a]	Normal	81	.19			
	Extended	22	.32	0.239	-0.359	0.093

Table 1. (Continued)

Variable	LOS Cohort	N	Mean	***P***	95% Confidence Interval Lower	Upper
Crystalloid Administered (mL)	Normal	69	2306.52			
	Extended	19	2623.68	0.149	-754.841	120.516
Colloid Use[a]	Normal	81	.20			
	Extended	22	.23	0.772	-0.237	0.178
Drain Use[a]	Normal	81	.73			
	Extended	22	.68	0.683	-0.184	0.277
Drain Duration (days)	Normal	56	2.36			
	Extended	12	2.58	0.309	-0.682	0.229
Surgery Time (min)	Normal	80	185.30			
	Extended	22	210.50	0.088	-54.400	4.000
OR Time (min)	Normal	80	263.88			
	Extended	22	287.36	0.150	-55.896	8.919
Post-op complication[a]	Normal	81	.19			
	Extended	22	.82	***0.000***	-0.826	-0.440
Discharge Destination[b]	Normal	81	.72			
	Extended	22	.36	***0.046***	0.006	0.699

Significance is determined with equal variance not assumed.

[a] *Yes = 1, No = 0*

[b] *Home = 1, Subacute Care/Nursing Facility = 0*

Table 2: Identifiable Postoperative Events Associated With a Significantly Longer LOS

Variables	N	LOS	Stdev	***P***
Total patients[a]	33	5.09	2.25	<0.001
Anemia	11	3.82	0.87	.002
Delirium	8	7.71	2.69	<0.001
Pneumonia	4	7.00	2.16	<0.001
Return to OR	3	5.33	1.15	<0.001
Cardiac	3	6.00	3.46	<0.001
Other	11	4.45	1.92	<0.001

[a] *= All patients with an identifiable postoperative event. Note: Some patients had more than one event. P-values are in comparison to patients with no postoperative events.*

Table 3: Variables Significantly Associated With an Extended LOS by Multivariate Analysis

Variables	Standardized Coefficients (Beta)	*P*	95% CI Lower Bound	95% CI Upper Bound
Preoperative				
Age	.209	**.038**	.002	.055
ASA	.334	**.001**	.441	1.785
Heart	-.301	**.005**	-2.069	-.387
Perioperative				
Discharge to subacute/nursing	.376	**.000**	.664	2.150

CI indicates confidence interval; ASA, American Society of Anesthesiologists.

Table 4: Clinical characteristics of ACDF patient population

Variable	N	Percent
Total patients	2164	100%
Gender		
Male	1057	49.1%
Female	1107	50.9%
Age		
<65	1849	84.4%
≥65	315	15.6%
BMI		
<30	1232	57.3%
≥30	924	42.7%
Impaired Functional status		
No	2082	96.4%
Yes	80	3.7%
Transfer status		
No	2143	99.1%
Yes	21	0.9%
Smoking		
No	1414	65.3%
Yes	750	34.7%
Diabetes		
No	1890	87.3%
Yes	274	12.7%
Cardiovascular comorbidity		
No	2035	94.0%
Yes	129	6.0%
Pulmonary comorbidity		
No	2087	96.4%
Yes	77	3.6%
Hepatic insufficiency		
No	2163	100.0%
Yes	1	0.0%
Renal insufficiency		
No	2161	99.9%
Yes	3	0.1%
Neurological comorbidity		
No	1984	91.7%
Yes	180	8.3%
Chronic steroid use		
No	2107	97.4%
Yes	57	2.6%

Preoperative anemia		
No	1782	90.8%
Yes	181	9.2%
Bleeding disorder		
No	2134	98.6%
Yes	30	1.4%
ASA classification		
1	108	5.0%
2	1255	58.0%
3	750	34.7%
4	49	2.3%
ASA score 3/4		
No	1365	63.0%
Yes	799	37.0%
Operation time > 75th percentile (171 min)		
No	1627	75.2%
Yes	537	24.8%
Number of levels		
1	1839	85.0%
2	309	14.3%
3	16	0.7%
Multiple levels		
No	1839	85.0%
Yes	325	15.0%

BMI = Body Mass Index; ASA = American Society of Anesthesiologists

Table 5: Clinical characteristics of patient population and univariate association with LOS, major complications, and infectious complications

Variable		LOS (days)	Major complication	Infectious complication
Gender				
	Male	2.2 ± 5.1	4.35%	1.04%
	Female	1.8 ± 2.3	2.26%	1.45%
	p	0.061	0.006[a]	0.397
Age				
	<65	1.7 ± 2.1	2.43%	1.30%
	>65	3.6 ± 8.7	8.25%	0.95%
	p	<0.001[a]	<0.001[a]	0.610
BMI				
	<30	2.1 ± 4.9	3.49%	1.14%
	>30	1.8 ± 2.0	2.92%	1.41%
	p	0.095	0.462	0.576
Impaired Functional status				
	No	1.8 ± 3.5	2.88%	1.25%
	Yes	6.2 ± 8.8	12.50%	1.25%
	p	<0.001[a]	<0.001[a]	0.999
Transfer status				
	No	1.9 ± 3.8	3.13%	1.21%
	Yes	7.3 ± 10.9	19.05%	4.76%
	p	<0.001[a]	<0.001[a]	0.145
Smoking				
	No	2.0 ± 4.3	2.97%	1.20%
	Yes	2.0 ± 3.0	3.87%	1.33%
	p	0.741	0.266	0.794
Diabetes				
	No	1.9 ± 3.7	3.12%	1.11%
	Yes	2.7 ± 4.9	4.38%	2.19%
	p	0.001[a]	0.275	0.133
Cardiovascular comorbidity				
	No	1.9 ± 3.7	3.00%	1.23%
	Yes	3.2 ± 5.9	7.75%	1.55%
	p	<0.001[a]	0.003[a]	0.750
Pulmonary comorbidity				
	No	1.9 ± 3.8	2.92%	1.25%
	Yes	3.7 ± 5.3	12.99%	1.30%
	p	<0.001[a]	<0.001[a]	0.967
Hepatic insufficiency				
	No	2.0 ± 4.0	3.28%	1.25%
	Yes	3.0 ± 0.0	0.000%	0.000%
	p	0.796	0.854	0.911

Renal insufficiency				
	No	2.0 ± 3.9	3.29%	1.25%
	Yes	6.0 ± 5.0	0.00%	0.00%
	p	0.076	0.750	0.846
Neurological comorbidity				
	No	1.9 ± 3.7	2.87%	1.26%
	Yes	3.3 ± 5.5	7.78%	1.11%
	p	<0.001 [a]	<0.001 [a]	0.863
Chronic steroid use				
	No	2.0 ± 3.9	3.28%	1.23%
	Yes	2.5 ± 5.7	3.51%	1.75%
	p	0.342	0.922	0.727
Preoperative anemia				
	No	1.8 ± 2.2	2.92%	1.29%
	Yes	3.4 ± 5.6	8.84%	1.11%
	p	<0.001 [a]	<0.001 [a]	0.832
Bleeding disorder				
	No	2.0 ± 3.9	3.19%	1.22%
	Yes	3.4 ± 3.2	10.00%	3.33%
	p	0.047 [a]	0.038 [a]	0.300
ASA score ≥ 3				
	No	1.7 ± 3.8	1.54%	1.03%
	Yes	2.5 ± 4.0	6.26%	1.63%
	p	<0.001 [a]	<0.001 [a]	0.224
Operation time > 75th percentile (171 min)				
	No	1.8 ± 3.8	2.34%	1.17%
	Yes	2.7 ± 4.1	6.15%	1.49%
	p	<0.001 [a]	<0.001 [a]	0.560
Number of levels				
	1	2.0 ± 4.2	3.26%	1.25%
	2	2.0 ± 1.6	3.56%	1.29%
	3	1.6 ± 0.7	0.00%	0.00%
	p	0.896	0.734	0.901
Multiple levels				
	No	2.0 ± 4.2	3.26%	1.25%
	Yes	2.0 ± 1.6	3.38%	1.23%
	p	0.938	0.909	0.976

BMI = Body Mass Index; ASA = American Society of Anesthesiologists
[a] indicates statistical significance ($p < 0.05$)

Table 6: Significant Predictors of Extended LOS

Variables	Effect Change in LOS (± SE)	P value
Preoperative		
Functional status	3.3 ± 0.3	<.001
Transfer status	2.1 ± 0.6	<.001
Preoperative anemia	0.8 ± 0.2	<.001
Age ≥ 65	0.7 ± 0.2	<.001
Diabetes	0.5 ± 0.2	.008
Perioperative		
Major complication	5.0 ± 0.3	<.001
Infectious complication	1.2 ± 0.5	.016
Operative time > 171 min	0.7 ± 0.1	<.001

Table 7: Major and infectious complications following ACDF

	Total *n* = 2164
Number of patients with ≥ 1 major complications	71 (3.30%)
Total number of major complications	92
Acute renal failure	0 (0.00%)
Cardiac	6 (0.28%)
Death	5 (0.23%)
Organ space infection	3 (0.14%)
Respiratory	21 (0.97%)
Return to OR	40 (1.85%)
Sepsis/septic shock	4 (0.18%)
Venous thrombotic events	13 (0.60%)
Number of patients with ≥ 1 infectious complications	27 (1.25%)
Total number of infectious complications	27
Surgical site infection	14 (0.65%)
Urinary tract infection	13 (0.60%)

Table 8: Significant Predictors of Major Complications

	Odds Ratio	95% CI	P value
ASA ≥ 3	2.609	1.454-4.680	.001
Preoperative anemia	2.138	1.093-4.183	.026
Age ≥ 65	2.110	1.191-3.738	.010
Operative time > 171 min	2.095	1.237-3.548	.006
Male gender	1.756	1.027-3.003	.040

ASA = American Society of Anesthesiologists

Table 9: Complications and LOS by Age Bracket and ASA Score

Variable		N	LOS (days)	Major complication
Age Bracket				
	<35	103	1.6 ± 3.1	1.94%
	35-44	400	1.5 ± 1.6	2.25%
	45-54	789	1.7 ± 1.8	2.15%
	55-64	555	1.9 ± 2.6	3.06%
	65-74	248	2.9 ± 5.3	6.85%
	≥75	67	6.0 ± 15.7	13.43%
	p		<0.001*	<0.001*
ASA Score				
	1	108	1.3 ± 2.5	1.85%
	2	1255	1.7 ± 3.9	1.51%
	3	750	2.3 ± 3.4	5.47%
	4	49	5.7 ± 8.4	18.37%
	p		<0.001*	<0.001*

ASA = American Society of Anesthesiologists

Table 10: Patient demographics and comorbidities

	All Patients	No ICBG	ICBG	*p* [a]
Overall	13,927	13,107 (94.1%)	820 (5.9%)	
Age				0.686
18-39	11.5%	11.4%	12.2%	
40-49	24.5%	24.5%	23.2%	
50-59	30.3%	30.3%	29.0%	
60-69	20.8%	20.7%	22.1%	
≥70	13.0%	13.0%	13.5%	
Male sex	46.6%	46.5%	47.3%	0.650
Body mass index				0.155
18-25	21.6%	21.5%	23.0%	
25-30	34.2%	34.1%	36.6%	
30-35	24.9%	25.0%	22.9%	
≥35	19.3%	19.4%	17.5%	
ASA 3-4	39.6%	39.5%	40.9%	0.446
Modified CCI				0.809
0-1	33.3%	33.3%	32.8%	
2	26.8%	26.8%	26.2%	
≥3	39.9%	39.8%	41.0%	
Number of levels				**<0.001**
1	60.3%	60.8%	52.6%	
2	28.4%	28.0%	34.8%	
≥3	11.3%	11.2%	12.7%	

[a] Bolding indicates significance

ASA = American Society of Anesthesiologists Score, CCI = Charlson Comorbidity Index

Table 11: Operative characteristics

Procedure	Total	No ICBG	ICBG
Anterior cervical fusion	8,518	8,134 (95.5%)	384 (4.5%)
Anterior cervical corpectomy	99	93 (93.9%)	6 (6.1%)
Posterior cervical fusion	659	589 (89.4%)	70 (10.6%)
Posterior thoracic fusion	177	155 (87.6%)	22 (12.4%)
Anterior lumbar fusion	1,134	1,096 (96.7%)	38 (3.4%)
Posterior lumbar fusion	3,340	3,040 (91.0%)	300 (9.0%)

Table 12: Association of ICBG with adverse events and readmission in spine surgery patients

	Percent of non-ICBG cases with outcome	Percent of ICBG cases with outcome	Bivariate logistic regression		Multivariate logistic regression [a]	
			OR	*p*	OR	*p*
Serious adverse event	3.4%	4.2%	1.2	0.232	1.1	0.756
Death	0.2%	0.0%	-	-	-	-
Coma > 24 hours	0.1%	0.0%	-	-	-	-
Ventilator > 48 hours	0.4%	0.2%	0.6	0.466	0.6	0.451
Unplanned intubation	0.5%	0.6%	1.2	0.750	1.1	0.767
Stroke/cerebrovascular accident	0.1%	0.0%	-	-	-	-
Pulmonary embolism	0.3%	0.4%	1.3	0.698	1.0	0.938
Cardiac arrest requiring CPR	0.1%	0.4%	2.7	0.116	1.6	0.135
Myocardial Infarction	0.2%	0.2%	1.5	0.613	1.4	0.658
Acute renal failure	0.1%	0.0%	-	-	-	-
Sepsis	0.4%	0.5%	1.2	0.771	0.9	0.849
Septic shock	0.1%	0.1%	1.5	0.720	1.0	0.977
Return to the operating room	2.1%	2.7%	1.3	0.235	1.1	0.756
Wound dehiscence	0.2%	0.2%	1.5	0.570	1.0	0.972
Deep surgical site infection	0.4%	0.6%	1.7	0.240	1.3	0.580
Organ space infection	0.1%	0.0%	-	-	-	-
Graft/prosthesis/flap failure	0.1%	0.0%	-	-	-	-
Minor adverse event	7.6%	14.0%	**2.0**	**<0.001**	**1.4**	**0.008**
Superficial surgical site infection	0.7%	0.7%	1.1	0.838	0.8	0.639
Urinary tract infection	1.0%	1.0%	0.9	0.833	0.7	0.432
Pneumonia	0.7%	0.7%	1.1	0.859	1.0	0.932
Blood transfusion	5.5%	11.6%	**2.3**	**<0.001**	**1.5**	**0.002**
Progressive renal insufficiency	0.1%	0.1%	2.0	0.514	2.0	0.523
Peripheral nerve injury	0.1%	0.2%	2.5	0.236	1.9	0.401
DVT/thrombophlebitis	0.3%	0.6%	1.8	0.222	1.3	0.566
Readmission [b]	3.5%	4.1%	1.2	0.417	1.0	0.995

[a] Each line represents a separate multivariate analysis for each variable in order to give an adjusted OR and p-value by controlling for all demographics, comorbidities, and operative approaches found in Table 1 and Table 2.

[b] Readmission analysis used data from years 2011 and 2012 only and excluded patients with LOS >10 days, leaving 11,086 patients for analysis. 411 [3.6%] of 11,086 patients were readmitted, and 681 (6.1%) of 11,086 patients had ICBG.

Bolding indicates significance

Table 13: Association of ICBG with operative time and length of stay in spine surgery patients

	Non-ICBG Mean ± SD	ICBG Mean ± SD	Bivariate linear regression [a]		Multivariate linear regression [a]	
			Coef.	*p*	Coef.	*p*
Operative time	149.0 ± 90.0	187.0 ± 95.0	**+36.0**	**<0.001**	**+22**	**<0.001**
Length of stay (days)	2.5 ±3.5	3.1 ± 2.9	**+0.6**	**<0.001**	**+0.2**	**0.037**

[a] Unstandardized coefficient represents unit change in the outcome variable if the predictor variable is positive. For example, a statistically significant coefficient of 36.0 for operative time means that on average, ICBG is associated with an increase in operative time of 36.0 minutes.