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Hospital and Surgeon Variation in Complications and Repeat Surgery Following Incident Lumbar Fusion for Common Degenerative diagnoses

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Abstract

Objective—To identify factors that account for variation in complication rates across hospitals and surgeons performing lumbar spinal fusion surgery.

Data sources—Discharge registry including all non-federal hospitals in Washington State from 2004–2007.

Study Design—We identified adults (n = 6,091) undergoing an initial inpatient lumbar fusion for degenerative conditions. We identified whether or not each patient had a subsequent complication within 90 days. Logistic regression models with hospital and surgeon random-effects were used to examine complications, controlling for patient characteristics and comorbidity.

Principal findings—Complications within 90 days of a fusion occurred in 4.8% of patients, and 2.2% had a reoperation. Hospital effects accounted for 8.8% of the total variability, and surgeon effects account for 14.4%. Surgeon-factors account for 54.5% of the variation in hospital reoperation rates, and 47.2% of the variation in hospital complication rates. The discretionary use of operative features, such as the inclusion of Bone Morphogenetic Proteins, accounted for 30% and 50% of the variation in surgeons' reoperation and complication rates, respectively.

Conclusions—To improve the safety of lumbar spinal fusion surgery, quality improvement efforts that focus on surgeons' discretionary use of operative techniques, may be more effective than those that target hospitals.

Keywords

Lumbar; spine surgery; fusion; repeat surgery; safety; complications

Low back pain is a condition for which expanding treatments and surgical innovation have outpaced supporting scientific evidence of their effectiveness. {Deyo, et al. 2009} Policy makers are questioning the value of lumbar fusion surgery for certain indications, and insurance companies have recently tightened coverage for this common procedure. {BlueCross & BlueShield of North Carolina, 2010} Recent reviews of surgical efficacy suggest that fusion surgery is no better than multidisciplinary, intensive non-surgical treatment for discogenic back pain (pain due to degenerative discs, without sciatica), but with a worse safety profile and greater cost. {Mirza, Deyo 2007; Washington State Health Care Authority, 2007} Poor outcomes of lumbar fusion may be particularly pronounced in workers' compensation populations. {Maghout Juratli, et al. 2006} Lumbar fusion may have a clearer role for treating deformities such as degenerative spondylolisthesis and scoliosis. {Fischgrund, et al. 1997; Herkowitz, Kurz 1991} However, even when there is an indication for less invasive surgery, such as decompressive laminectomy for spinal stenosis, complex fusion procedures that increase the risk of a complication may be performed. {Deyo et al. 2010} Multilevel fusions and circumferential approaches are often performed without strong evidence of corresponding improvements in pain or physical functioning. A greater understanding of factors associated with lumbar fusion would help inform current debates.

Post-operative complications may be influenced by the choice of surgical technique, {Fritzell et al. 2002; Deyo et al. 2010; Cizik et al. 2012} underscoring the imperative to rigorously evaluate the safety of surgical treatments. However, population-based measures of safety have been only sparsely reported, and little is currently known about hospital and surgeon variation in rates of postoperative complications following spinal fusion.

Using a statewide inpatient discharge registry that allowed us to link successive episodes of care for the same patient across multiple years and institutions, we sought to determine the rates of postoperative complications following fusion for degenerative disease, assess the

variation in these rates across individual hospitals and surgeons, and identify how much of the variation is accounted for by operative features.

Methods

Data source

The Comprehensive Hospital Abstract Reporting System (CHARS) is an inpatient discharge database of all non-federal hospitals in Washington State. {Washington State Department of Health, 2011} Hospitals submitting data to CHARS receive quality reports that they then certify as being at least 95% accurate for reporting discharges. We examined CHARS data from 2004 through 2007 for all hospitals and attending surgeons who performed at least one inpatient lumbar fusion for a degenerative spinal diagnosis. A small number of cases were dropped because they appeared to be a duplicate record.

Study population

We identified adults (age 20 or older) who underwent an initial inpatient thoracolumbar, lumbar, or lumbosacral fusion operation for degenerative spinal conditions from 2004 through 2007. This starting year (2004) was selected because it corresponds to the first calendar year that codes for three or more disc levels fused (4 or more vertebrae) became available. Patients were identified using relevant diagnosis and procedure codes from the October, 2010 update of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). {Centers for Disease Control & Prevention, 2010} Details of our algorithm for classifying spine-related medical encounters, surgical characteristics, and safety can be obtained from the corresponding author.

CHARS allows up to nine diagnosis codes and up to six procedure codes for each admission. We searched all codes to identify patients undergoing fusion surgery for common degenerative spinal conditions, including disc degeneration (e.g. spondylosis), herniated discs, stenosis, spondylolisthesis, and scoliosis. We did not include patients who had non-degenerative spinal admissions in the previous year, such as spinal fracture, vertebral dislocation, spinal cord injury, or inflammatory spondylopathy. We also excluded patients who, in the previous year, had inpatient admission codes for accidents, neoplasm, HIV or immune deficiency, intraspinal abscess, osteomyelitis, infection, pregnancy, and cervical or thoracic spinal diagnoses and/or procedures.

All lumbar fusions were included, whether or not they were combined with a discectomy or laminectomy. Patients who had other types of spine-related procedures, including artificial disc replacement, corpectomy, osteotomy, kyphectomy, insertion of spacers, and insertion of dynamic stabilizing devices were excluded even if these were performed in conjunction with a fusion operation. We also excluded patients who, in the preceding 10 years, had any type of prior lumbar spine surgery, or had diagnosis or procedure codes that implied a previous lumbar operation (such as “reopening of laminectomy site”, “refusion”, or “removal of an internal fixation device”). Previous surgery has been shown to be an important predictor of higher complication and repeat surgery rates {Deyo 2011}.

Ascertaining adverse outcomes

We created a composite indicator of 90 day major surgical complications, defined as postoperative device complication, life-threatening complication, wound problem, or death occurring within 90 days. We separately examined the rates of repeat lumbar spine surgery. The presence of each complication (or repeat surgery) was coded as a dichotomous variable based on ICD-9-CM diagnosis and procedure codes. Each complication was attributed to the

hospital and attending surgeon performing the initial fusion, and was not counted as an index case or a complication for another hospital or surgeon.

Repeat surgery was identified as the first instance of any second lumbar spine operation (i.e. “reoperation”) and not necessarily a repeat of the same procedure or performed at the same vertebral level. Device complications were based ICD-9-CM diagnosis and procedure codes that indicate a problem with an internal orthopaedic device (e.g. “malfunction of orthopaedic device”). We did not count device complications or repeat spinal surgeries coded during the index admission, and also required that they be co-coded with a lumbar spine-specific diagnosis and/or procedure code.

We counted wound problems, life-threatening complications, and death if they occurred during the 90-day postoperative surveillance or during the index admission. We followed Deyo’s (2010) approach for identifying life-threatening and wound complications in spine surgery. {Deyo et al. 2010} Life-threatening complications included major medical events such as acute respiratory failure, cardiopulmonary resuscitation, endotracheal intubation, pneumonia, stroke, and mechanical ventilation. Life-threatening events have major consequences on health, and their ICD-9-CM coding is more reliable than those of minor complications. {Lawthers et al. 2000} Post-operative wound problems were identified using codes for hemorrhages, excisional debridement of infection, postoperative wound disruption, seroma, and hematoma complicating a procedure. Mortality was identified by linking each index case to the Washington State vital records.

Potentially confounding factors

Patient characteristics and operative features may explain variation in rates of complications and repeat surgery across hospitals and surgeons. We adjusted the rates of complications for differences due to patient age, sex, comorbidity, diagnosis, and primary insurance. We used Quan’s “enhanced” version of the Charlson index (categorized “none”, “one”, and “two or more”) to adjust for comorbidity, applying it to admissions occurring at or during the year preceding each index visit. {Quan et al. 2005} However, since the comorbidity index includes myocardial infarctions and strokes, and these are among the life-threatening surgical complications that we sought to identify, we only included these items in the comorbidity score if they occurred during the previous year and did not count them if they occurred during the index admission.

The primary source of payment was coded into the following groups: “Medicare”, “Medicaid”, “Health maintenance organization” (e.g. Kaiser, Group Health Cooperative), “Commercial insurance” (e.g. Mutual of Omaha, United Health Plan, Safeco), “Workers’ compensation”, “Health service contractor” (e.g. Premera, Premera/Blue Cross), and “Other”. The latter category included charity cases, self-pay, and “other government sponsored patients” (e.g. Tri-care, CHAMPUS, Indian Health, Corrections) that combine to account for 2.5% of the total cases. Variables for race or ethnicity were not provided in CHARS during the study years.

Some operative features that may be associated with outcomes are identifiable from ICD-9 codes, including use of bone morphogenetic protein (BMP), surgical approach (anterior, posterior, or combined/circumferential), an indicator of whether fusion was combined with a decompression, and an indicator of whether 3+ disc levels were fused. {Fritzell et al. 2002, Cizik et al. 2012, Deyo et al. 2010, Deyo et al. 2012, Mirza 2011}. We also included the attending surgeon’s fusion volume in the preceding 365 days to account for any potential association between surgeon experience and outcomes. {Silber et al. 2010}. This measure of recent volume may be a better indicator of surgeon experience than the annual or the

cumulative volume, both of which may be prone to misclassification. {French et al. 2011} We grouped the index cases into quartiles based on the ranking of the surgeon's volume.

Analysis

Bivariate associations between patient characteristics and complications were assessed using chi-square or t-test comparisons. We examined the risk for complications using logistic regression analysis, including only patients who had a minimum of 90 days of surveillance available in order to assess each outcome. For example, patients who had an initial operation in December of 2007 were not eligible to be assessed for the 90 day outcomes because the data only extend through 2007.

We used a logistic regression model that allowed a random-intercept for each hospital. {Rabe-Hesketh, 2008} These models prevent hospitals with a relatively small volume of cases from being misclassified when high sampling variability may account for apparently poor (or excellent) performance (i.e. through the use of "shrinkage factors"). The models also adjust the standard errors to account for similarities occurring among patients "clustered" within hospitals.

To compare risk-adjusted outcomes across hospitals, we used the results from the logistic regression models to estimate the risk of complication for an "average" patient. This was accomplished by setting the covariates for age, sex, comorbidity, insurance, and diagnosis to the mean statewide distributions and then reporting the mean rate of complications within each hospital, along with a 95% Empirical Bayes confidence interval.

To examine the influence of surgeon factors on the rates of complications, we then added an additional random-effect parameter to the previous ("hospital only") model. This parameter represents the variability attributed to surgeons' "nested" within each of the hospitals he/she operated in.

Model construction was based on the principles by Hosmer & Lemeshow (2000), including checking for interactions. We used likelihood ratio and Aikake's Information Criteria (AIC) to identify the models with the best fit. An advantage of AIC is that it allows comparisons of models with the same number of parameters; a useful consideration when comparing random-effects models. The best-fitted model, with the lowest AIC, included patient and operative features along with surgeon random-effect. The specification for this final model, along with 95% Bayesian coverage intervals is:

$$\log\left(\frac{\mu_{ik}^{K_k}}{1-\mu_{ik}^{K_k}}\right) = \alpha + K_k + \beta X_{ik} \quad K_k \sim \text{Norm}(0, \sigma^2) \quad \text{Equation 1}$$

$$95\% \text{ CI}_k = \left(\widehat{K}_k - 1.96 \sqrt{\widehat{\sigma}_k^2}, \widehat{K}_k + 1.96 \sqrt{\widehat{\sigma}_k^2}\right) \quad \text{Equation 2}$$

In this specification, μ represents the probability of a complication for patient i , whose initial operation was performed by surgeon k . The terms α combined with represents a surgeon-specific intercept. X represents a vector of covariates with corresponding beta-coefficients for patient characteristics (age, sex, comorbidity, primary diagnosis and insurance) and operative features (surgical approach, multilevel fusion, BMP, surgeon volume, instrumentation).

We found no evidence of a poorly fitted model for complication ($p = 0.5615$) using Hosmer-Lemeshow goodness-of-fit statistic. We confirmed linearity between the logarithmic odds for reoperations with each of the variables in the model; and no issues were identified that forced us to transform any variables. No changes in parameter coefficients as variables were added to the model suggested evidence of multicollinearity; this was confirmed by examining variance inflation factors and tolerance statistics in the final model.

In all models we assumed that the random effects were additive and normally distributed. Empirical Bayes predictions of the random-effects were assessed for normality using a Q-Q plot. There were no serious violations in the random-effect distribution through the bulk of the data. However, at the high-end of the random-effect spectrum, several surgeons' complication rates deviated higher than predicted; indicating that they had unusually high complication rates. This finding translates into a conservative estimation (underestimate of their actual rates) of the complication rates for these particular surgeons, because they are "over-fitted" toward the overall state mean. Our final model had a C-statistic of 0.662 for the complication model and 0.660 for reoperation model.

We then estimated the proportion of total variation that was explained by the inclusion of hospital (or surgeon) effects. The total variability for a random-effect model of a dichotomous outcome is calculated as the sum of hospital (surgeon) -specific variance(s) (ψ) plus the mathematical constant $\pi^2/3$ {Rabe-Hesketh, 2008}. The proportion of total variation explained by covariates that are added to the previously null model (a model with random-effects parameter but no explanatory variables) is calculated using:

$$\frac{1 - \text{var}(\text{Full Model})}{\text{var}(\text{Null Model})} \quad \text{Equation 3}$$

An Intraclass Correlation Coefficient (ICC) was calculated for hospital (surgeon) effects to estimate the proportion of variation explained *within* the hospitals (surgeons) by patient characteristics and operative features. The ICC represents the percentage of total variability due to between- hospital (surgeon) differences not accounted for by covariates in the model. For a dichotomous outcome the ICC is calculated using the following equation:

$$\frac{\psi}{\psi + \pi^2/3} \quad \text{Equation 4}$$

To measure the proportion of hospital (surgeon) variation that was explained by the addition of covariates, a model with only random-effects (null) was compared to subsequent models with covariates. A reduction in the ICC as covariates are added to the model represents the proportion of hospital (surgeon) variation that is explained at that level by the added covariates.

We also examined our findings after excluding 6 (24%) hospitals that included only one surgeon who performed fusions because, in these instances, the random-effect models cannot differentiate the variation in complications at the hospital level from that of the surgeon level. All analyses were performed using Stata-MP, version 11 (College Station, TX), with hypothesis testing performed using a two-sided alpha level set at 0.05.

Results

Study population

A total of 7,680 patients were identified as having an initial inpatient fusion for lumbar degenerative conditions between 2004 and 2007. A total of 1,589 (20.7%) were excluded for reasons shown in table 1. The predominant reason for exclusion was lumbar surgery in the previous 10 years. Excluded patients were statistically older (57.7 years versus 56.4 years, $p=0.001$), but this was not clinically different. They were also less likely to be female (55.1% versus 60.7%, $p<0.001$), more likely to be insured by workers' compensation (16.6% versus 11.3%, $p<0.001$), to have a comorbidity score greater than one (41.8% versus 27.2%, $p<0.001$), less likely to have spondylolisthesis (33.1% versus 54.1%) and were more likely to have degenerative disc disease (24.9% versus 18.0%) and herniated disc (16.2% versus 9.4%).

The study population consisted of 6,091 patients who had an initial inpatient spinal fusion during the study period (table 2). The mean age of the cohort was 56.4 years (sd 13.9); 31.3% were insured by Medicare, 6.1% by Medicaid, 11.3% by workers' compensation; and 27.2% had a comorbidity index greater than zero. A diagnosis of spondylolisthesis accounted for the largest fraction of the fusion operations (54.1%), followed by degenerative disc disease (18.0%), herniated disc without myelopathy (9.4%), spinal stenosis (9.0%), scoliosis (7.1%), and herniated disc with myelopathy (2.3%). The index operations were performed by 298 surgeons, who on average performed 20 fusions each (range 1 – 333) during the study period. These were performed within 43 hospitals that performed an average of 142 (range 3 – 533) fusions during the study period.

Complication Rates

Age between 61 and 80, greater comorbidity, and Medicare and Medicaid insurance were associated with higher risk of having a complication within 90 days (table 2). Workers' compensation (a public payer in Washington State) and Health Maintenance Organizations had the lowest 90 day rates of complications among all types of insurance. Having 3+ disc levels fused, use of bone morphogenetic proteins, and anterior surgical approaches were associated with higher complication rates.

Unadjusted complication rates for herniated disc without myelopathy (2.6%) were lower than for disc degeneration (4.2%), spondylolisthesis (4.5%), spinal stenosis (6.4%), herniated disc with myelopathy (8.6%), or scoliosis (9.7%). Complications were not mutually exclusive. For example, the same patient may have had a device complication and a reoperation. Wound problems were the most common type of complications (3.1%), followed by repeat surgery (2.2%), life-threatening complications (2.0%), device problems (0.8%), and death (0.2%). Those with a diagnosis of scoliosis had a higher rate of complications than all other diagnoses, including a mortality rate of 1.2%.

Table 3 presents the multivariate logistic regression models with surgeon random-effects used to estimate the risk-adjusted rates for complications within 90 days. The overall 90 day complication rates for surgeons, adjusted for patient age, sex, insurance type, comorbidity and diagnosis was 4.1% (95% CI 2.7 – 6.4), and the adjusted mean 90 day reoperation rate was 1.7% (95% CI 0.9, 3.7).

Anterior operative approaches were associated with a significantly higher risk for 90 day repeat surgery (OR 3.33; 95% CI 2.03 – 5.44), even after adjusting for patient characteristics, comorbidity, diagnosis, insurance status, and other operative features. Circumferential fusions were associated with a higher 90 day risk for complications (OR 1.24; 95% CI 0.82–1.89) and reoperations (OR 1.13; 95% CI 0.59–2.17); but did not reach

statistical significance in this small subset of patients. Patients who had 3+ disc levels fused had a higher risk for complications (OR 1.64 95% CI 1.12 – 2.40).

Higher surgeon case volume was not associated with a significantly lower 90 day repeat surgery or complication rate. The use of bone morphogenetic proteins (BMP) was associated with a non-significantly higher risk for complication (OR 1.20; 95% CI 0.88 – 1.63) and repeat surgery (OR 1.78; 95% CI 1.17 – 2.69). Having 3+ disc levels fused was also associated with an increased risk for complication (OR 1.64 95% CI 1.12 – 2.40) and repeat surgery (OR 1.78 95% CI 1.17 – 2.69).

Scoliosis was associated with a higher risk for complications within a given surgeon, while the risk for stenosis, spondylolisthesis, and herniated disk did not significantly differ from that of disc degeneration. Stenosis was associated with higher reoperation rates within a given surgeon, compared to degenerative disc disease. Adjusting for operative features lowered the odds ratio for complications among those with scoliosis from 1.94 (95% CI 1.23 – 3.09, not shown) to 1.58 (1.25 – 3.87, final model.)

The rates for complications are shown in figure 1, with each spike representing a single hospital or surgeon. We found that the nearly eightfold variation in risk-adjusted repeat surgery across surgeons was substantially attributed to a few surgeons (11/298, 3.7%) with rates significantly above the state mean (represented by a solid horizontal line). Limiting our analysis to the hospitals where more than one surgeon performed a fusion did not substantially change the variance estimates or lead us to alter our conclusions.

Total variation

Table 4 provides the random-effect variance and fit parameters for a model without any covariates (null model, containing only random effects), as well as for models adding patient characteristics and operative features. In the null model for reoperations, the proportion of total variation due to hospital effects decreased from 8.8% to 4.0% with the addition of a parameter for the surgeon effects (a reduction of 54.5%). Similar reductions in hospital-level variation were observed in the models containing patient characteristics and operative features. Hospital effects accounted for a smaller proportion of the total variation in complication rates (3.6%), but were substantially reduced by the inclusion of a surgeon-parameter.

Surgeon effects accounted for 14.4% of the total variation in reoperations and 5.0% of the total variation for complications. Surgeon-level variation for both repeat surgery and complications was greater than the variation observed among hospitals. For example, the variance for the surgeon effects for repeat surgery was 0.341 (9.0% of total), compared to 0.153 (4.0%) for hospitals.

Explaining hospital (surgeon) variation

The addition of patient characteristics did not reduce the variability in reoperation rates, but accounted for 32.6% of the between-surgeon variation in complication rates. The addition of operative features accounted for 4.4% of the total variation in reoperations (30% of the variability between surgeons), and 2.5% of the total variation in complications (50% of the between-surgeon variation).

Description of reoperations

The unadjusted rate of repeat lumbar spine surgery in our cohort was 2.2% at 90 days and 5.0% at 1 year. We found that 115/137 (84%) of the reoperations were performed by the same surgeon who performed the initial surgery. The most common diagnoses at the time of

these reoperations was spinal stenosis (21.2%), followed by disc degeneration (18.3%), spondylolisthesis (17.5%), disc herniation with myelopathy (13.1%), disc herniation (6.6) and scoliosis (5.8%). The remaining 16.1% were for non-degenerative diagnoses such as removal of internal orthopaedic device or surgical aftercare. Device complication codes were included in 36/137 (26%) of the all repeat surgeries within 90 days, and the code for “arthrodesis status” (implying a problem at the same vertebral level as the index surgery) in 53/137 (38.7%). The most common procedures coded at the time of reoperation were fusion or re-fusion (51.8%), decompression only (22.6%), and other spinal procedures such as removal of orthopaedic devices (25.5%).

Discussion

Complications within 90 days of an initial lumbar fusion operation for a degenerative diagnosis occurred in 4.9% of patients, and 2.2% of patients had a second operation within 90 days. After adjusting for patient characteristics and diagnosis we found that the mean 90-day complication rate for individual surgeons varied from 2.5% to 11.7%. The range for reoperations varied from 0.6% to 9.3%.

Estimating complications is notoriously difficult in studies involving surgical treatments; a fact that is reflective of the large unexplained variation in our models. Our findings that the majority of the total variability (~85%) occurred within (rather than between) surgeons or hospitals, suggests that complications and reoperations may be more encounter-specific than they are due to systematic difference in quality across surgeons or hospitals.

Nevertheless, the “explainable” variation among hospitals in the rate of complications was substantially reduced after including surgeon effects in our models. Furthermore, the discretionary use of BMP, 3+ disc levels fused, and surgical approach, accounts for 50% and 30% of the variation among surgeons’ complication and repeat surgery rates, respectively. This suggests that for improving safety, the addition of surgeon quality improvement efforts may be more effective than those solely targeting the hospital. However, surgeon quality improvement programs should not necessarily replace current hospital-level quality efforts.

Among 6,091 initial fusions, 366 patients had either a complication or a repeat surgery within 90 days (6.1%). When these were further examined within each type of adverse event, or attributed to individual providers, the uncertainty surrounding individual estimates became larger, potentially rendering individual surgeon estimates less informative. Taken in combination, these results highlight a conundrum facing policymakers: though discretionary physician decision-making may be a key to improving surgical safety, the low precision of surgeon-level empirical performance of complications in these data identified only a small number (3.7%) of surgeons with complication rates statistically above the statewide mean. Future efforts should examine provider-level empirical performance data in other populations and in relationship to external benchmarks that are not derived from the data. {Jones et al. 2010} At a policy level, the question is whether acting on surgeon-level adverse event data, with this known imprecision, will lead to better delivery of health care to a population. While the most serious or frequent harms that may arise from fusion operations may lead to more detailed review of a small number of specific surgeons, surgeon focused quality improvement efforts alone may be useful to address preventable harms.

The finding of a lower adverse event rate in the workers’ compensation population may seem surprising. Patient-reported outcomes of surgical procedures, including lumbar fusion, are consistently worse for workers’ compensation compared to non-workers’ compensation populations. {Harris et al. 2005} However, most of these studies did not specifically examine surgical complications or adjust for fusion indications or comorbidities. Because of poor

outcomes reported for fusion in Washington State, including high rates of reoperation, {Franklin et al. 1994; Martin et al. 2007} the Washington's workers' compensation program had a restrictive fusion coverage policy implemented through prospective utilization review during the years under study. These policies included limiting initial fusions to a single level, and requiring measureable instability for approval. {Wickizer et al. 2004} The proportion of workers' compensation patients who had 3+ disc levels fused in our study was 3.1%, compared to 8.5% for all other payers. Our finding of lower complication rates in these patients may suggest that the more parsimonious use of fusion in this population may have reduced complications.

In our data, we could not corroborate Bederman's (2009) {Bederman et al. 2009} finding in a Canadian population or Farjoodi's (2012) {Farjoodi et al. 2012} study of the Nationwide Inpatient Sample that patients operated on by high-volume surgeons had a significantly lower risk for reoperation. Differences in the study populations, type of procedure, and measurement of volume may explain the differences between these studies.

Administrative data generally allow for a longer duration of follow-up than clinical studies, and can often identify subsequent care even when it occurs at a different institution. Despite these strengths, our study has a number of limitations that arise from the analysis of observational data. Such data are susceptible to confounding factors that limit causal inference. The presence of such an unmeasured factor would have to have a large effect and be systematically disproportionate across providers in order to alter individual estimates. By excluding significant comorbidity, non-degenerative spinal pathology and previous surgery, as well as adjusting our model for comorbidity and diagnoses, we have accounted for some of this potential confounding.

The complication rates that we report may be an underestimate of the actual rates because we only counted those that were associated with a readmission. Some postoperative events, such as pneumonia, might have been treated in an outpatient setting and not counted as an adverse event in our analysis. In addition, the use of normally distributed random-effects results in a conservative estimation for a few providers with higher than expected rates. Future efforts should use sampling techniques to fit non-normally distributed random effects.

Although ICD-9-CM codes are commonly used in spinal research, they lack specific clinical detail, such as disease severity or pain intensity, specification of exact vertebral levels, and functioning. While this may lead to some imprecision, administrative data are reliable for ascertaining major complications. {Campbell et al. 2011, Lawthers et al. 2000}

We could not account for patient migration into or out of Washington State, which may influence the rates of complications that we observed. In addition, we were unable to identify lumbar operations occurring in our cohort prior to 1987, or those that occurred outside of Washington State. As a result, some patients in our analysis may have had a previous lumbar operation that was unknown to us.

The use of administratively derived patient safety indicators following fusion surgery has not been rigorously validated through a comparison of chart reviews. However, readmission, infections, mortality, and life-threatening complications are part of the National Surgical Quality Improvement Program (NSQIP) which has been used as the gold standard to improve the validity of patient safety indicators {Romano, 2009}. Furthermore, our estimates for repeat surgery and mortality following fusion surgery are similar to those reported in both administrative and clinical studies. {Juratli et al. 2009; Martin et al. 2007; Malter et al. 1998; Martin et al. 2011} Future research efforts should focus on the validation and improvement of claims-based methods, and seek to understand how physicians'

judgments, technical influences, or other factors may account for the variation in rates that we observed.

Safety data regarding spine surgery are available from only a few randomized trials. The Sport Patient Outcomes Research Trial (SPORT) did not focus on differences in outcomes based on the type of operative feature, was not limited to fusion procedures, and did not primarily focus on safety. {Weinstein et al. 2006; Weinstein et al 2008} Fritzell (2002) found that circumferential fusions had a higher rate of complications compared to posterolateral fusions. These findings have not been confirmed in a large population. Population-based studies allow us to provide empirical performance data for postoperative complications among surgeons performing lumbar fusion. Data on complications may be useful to inform policies that aim at making spinal fusion surgery safer. By helping patients to weigh the potential harms and potential benefits, such data may be useful for soliciting informed consent and for engaging them in “shared decision-making”. Future efforts should strive to clarify indications for complex fusion operations, where the risk for complications may be substantial.

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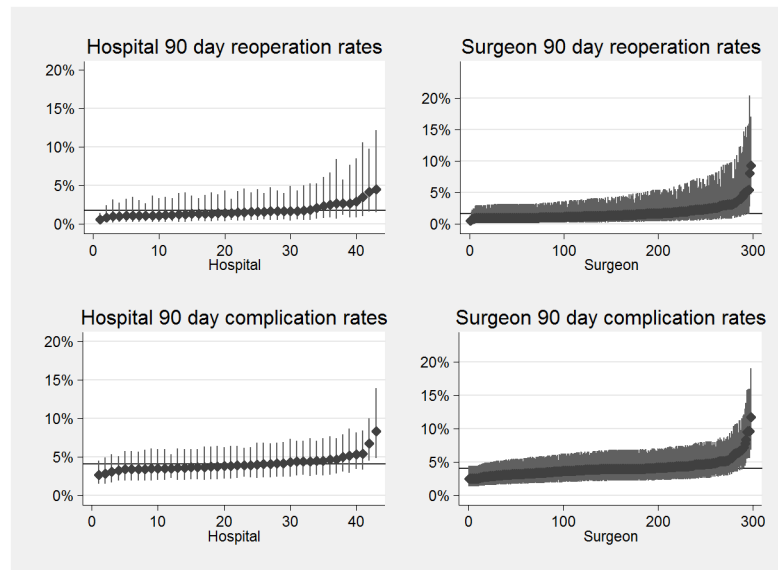


Figure 1. Risk-adjusted 90 day repeat surgery (top row) and complication (bottom row) rates following inpatient lumbar spinal fusion surgery for common degenerative diagnoses. Each spike represents 95% Bayesian confidence interval for the rates within a hospital (left) or surgeon nested within hospitals (right) in Washington State. The solid horizontal line represents the statewide mean.

Table 1

Reasons for exclusion from lumbar fusion safety study. Washington State Comprehensive abstract reporting system, 2004–2007.

Exclusion factors (not mutually exclusive)	Number excluded (n = 1589)
Cancer in previous year	114
Trauma in previous year	88
Drug abuse in previous year	30
Neurological impairment in previous year	20
HIV or immune deficiency in previous year	2
Intraspinal abscess in previous year	12
Osteomyelitis in previous year	41
Pregnancy in previous year	8
Non-degenerative spinal diagnosis in previous year (vertebral fracture, spinal cord injury, congenital anomaly, inflammatory spondylopathy, osteoporosis)	103
Lumbar spine surgery in previous 10 years	1,313
Any of the above	1,589

Table 2
Rates for any postoperative adverse events following lumbar spinal fusion surgery for common degenerative diagnoses (CHARS 2004–2007).

	Number eligible surveillance	Complications (or death) within 90 days, n(%)							Repeat lumbar surgery	
		Number (Column %)	Any	Device problem	Wound	Life threat	Death	90-days	1-year	
Number of complications or repeat surgery (%)		6091								
Age group	20–40	836 (13.7%)	298 (4.9)	49 (0.8)	191 (3.1)	124 (2.0)	14 (0.2)	137 (2.2)	238 (5.0)	
	41–60	2,781 (45.7%)	29 (3.5)*	7 (0.8)	17 (2.0)*	11 (1.3)*	0 (0)*	13 (1.6)	29 (4.2)	
	61–80	2,273 (37.3%)	120 (4.3)	24 (0.9)	78 (2.8)	42 (1.5)	4 (0.1)	65 (2.3)	103 (4.7)	
	81+	201 (3.3%)	138 (6.1)	18 (0.8)	90 (4.0)	64 (2.8)	9 (0.4)	56 (2.5)	100 (5.6)	
	Male	2,391 (39.8%)	11 (5.5)	0 (0)	6 (3.0)	7 (3.5)	1 (0.5)	3 (1.5)	6 (3.7)	
Sex, %	Female	3,700 (60.7%)	92 (3.8)*	8 (0.3)*	52 (2.2)*	44 (1.8)	8 (0.3)	39 (1.6)*	89 (4.7)	
	None	4,434 (72.8%)	206 (5.6)	41 (1.1)	139 (3.8)	80 (2.2)	6 (0.2)	98 (2.6)	149 (5.1)	
Charlson, %	1	1,268 (20.8%)	175 (3.9)*	36 (0.8)	100 (2.3)*	66 (1.5)*	7 (0.2)	94 (2.1)	173 (5.0)	
	2+	389 (6.4%)	86 (6.8)	11 (0.9)	63 (5.0)	34 (2.7)	5 (0.4)	33 (2.6)	46 (4.6)	
	Medicare	1,909 (31.3%)	127 (6.7)*	10 (0.5)	85 (4.5)*	68 (3.6)*	8 (0.4)	42 (2.2)	71 (4.8)	
Payer, %	Medicaid	374 (6.1%)	32 (8.6)	6 (1.6)	25 (6.7)	8 (2.1)	0 (0.0)	10 (2.7)	19 (6.4)	
	HMO	558 (9.2%)	18 (3.2)	7 (1.3)	6 (1.1)	4 (0.7)	3 (0.5)	10 (1.8)	15 (3.2)	
	Commercial	1,154 (18.9%)	45 (3.9)	13 (1.1)	21 (1.8)	16 (1.4)	2 (0.2)	36 (3.1)	55 (5.9)	
	WC	686 (11.3%)	19 (2.8)	7 (1.0)	12 (1.7)	4 (0.6)	0 (0.0)	11 (1.6)	29 (5.3)	
	Contract	1,271 (20.9%)	51 (4.0)	6 (0.5)	38 (3.0)	21 (1.7)	1 (0.1)	25 (2.0)	46 (4.7)	
	Other	139 (2.3%)	6 (4.3)	0 (0.0)	4 (2.9)	3 (2.2)	0 (0.0)	3 (2.2)	3 (2.8)	
	With AE	298 (4.9%)	5.0 (sd 3.6)*	4.7 (3.0)	4.8 (3.5)*	5.1 (3.4)*	7.3 (6.6)*	4.3 (2.8)	4.2 (2.6)*	
Length of stay, mean days (SD)	Without AE	5,793 (95.1%)	3.8 (sd 2.4)	3.8 (2.4)	3.8 (2.4)	3.8 (2.4)	3.8 (2.4)	3.8 (2.4)	3.9 (2.5)	
	Overall	6,091 (100%)	3.9 (sd 2.5)	3.9 (2.5)	3.9 (2.5)	3.9 (2.5)	3.9 (2.5)	3.9 (2.5)	3.9 (2.5)	
	Disc Deg.	1,097 (18.0%)	46 (4.2%)*	9 (0.8)	26 (2.4)*	21 (1.9)*	0 (0)*	23 (2.1)*	46 (5.3)*	
Diagnosis	Herniated	575 (9.4%)	15 (2.6%)	4 (0.7)	10 (1.7)	4 (0.7)	0 (0)	8 (1.4)	17 (3.7)	
	Herniated disc with myelopathy	140 (2.3%)	12 (8.6%)	1 (0.7)	8 (5.7)	5 (3.6)	0 (0)	3 (2.1)	11 (10.2)	

	Complications (or death) within 90 days, n(%)							Repeat lumbar surgery	
	Number (Column %)	Any	Device problem	Wound	Life threat	Death	90-days	1-year	
Procedure	Stenosis	549 (9.0%)	35 (6.4%)	3 (0.5)	25 (4.6)	14 (2.6)	2 (0.4)	20 (3.6)	28 (6.4)
	Spondylolisthesis	3,296 (54.1%)	148 (4.5%)	27 (0.8)	93 (2.8)	59 (1.8)	7 (0.2)	71 (2.2)	117 (4.5)
	Scoliosis	434 (7.1%)	42 (9.7%)	5 (1.2)	29 (6.7)	21 (4.8)	5 (1.2)	12 (2.8)	19 (5.6)
Instrumentation	Fusion only	2,179 (35.8%)	122 (5.6)	23 (1.1)	84 (3.9)*	56 (2.6)*	1 (0.0)*	49 (2.2)	82 (4.7)
	Fus + deco	3,912 (64.2%)	176 (4.5)	26 (0.7)	107 (2.7)	68 (1.7)	13 (0.3)	88 (2.2)	156 (5.1)
	No	2,203 (36.2%)	119 (5.4%)	18 (0.8%)	79 (3.6%)	51 (2.3)	9 (0.4)*	44 (2.0)	85 (4.7)
Multilevel	Yes	3,888 (63.8%)	179 (4.6%)	31 (0.8%)	112 (2.9%)	73 (1.9)	5 (0.1)	93 (2.4)	153 (5.1)
	No	5,612 (92.1%)	250 (4.5)*	43 (0.8)	159 (2.8)*	98 (1.7)*	11 (0.2)	123 (2.2)	212 (4.8)
	Yes	479 (7.9%)	48 (10.0)	6 (1.3)	32 (6.7)	26 (5.4)	3 (0.6)	14 (2.9)	26 (7.0)
BMP	No	4,924 (80.8%)	237 (4.8)	31 (0.6)*	164 (3.3)	99 (2.0)	11 (0.2)	89 (1.8)*	174 (4.4)*
	Yes	1,167 (19.2%)	61 (5.2)	18 (1.5)	27 (2.3)	25 (2.1)	3 (0.3)	48 (4.1)	64 (7.4)
	Posterior	4,926 (80.9%)	237 (4.8)	37 (0.8)	158 (3.2)	99 (2.0)	12 (0.2)	87 (1.8)*	157 (4.1)*
Approach	Anterior	690 (11.3%)	31 (4.5)	7 (1.0)	13 (1.9)	10 (1.4)	1 (0.1)	37 (5.4)	57 (10.6)
	Circum.	475 (7.8%)	30 (6.3)	5 (1.1)	20 (4.2)	15 (3.2)	1 (0.2)	13 (2.7)	24 (5.7)
	1 – 33	1,539 (25.3)	67 (4.4)	9 (0.6)	44 (2.9)	29 (1.9)	4 (0.3)	29 (1.9)	66 (5.3)*
Surgeon fusion volume quartile ^{1/1}	34 – 64	1,535 (25.2)	82 (5.3)	15 (1.0)	48 (3.1)	33 (2.1)	3 (0.2)	42 (2.7)	75 (6.2)
	65 – 96	1,512 (24.8)	85 (5.6)	12 (0.8)	58 (3.8)	36 (2.4)	4 (0.3)	41 (2.7)	53 (4.3)
	97 – 227	1,505 (24.7)	64 (4.3)	13 (0.9)	41 (2.7)	26 (1.7)	3 (0.2)	25 (1.7)	44 (4.0)

* significant difference within categories of variable (<0.05)

^{1/1} Surgeon 1-year fusion volume group is based on fusion volume for any type of fusion or re-fusion prior to applying exclusion criteria. Table 3. Multivariate models, with hospital and surgeon random effects, to estimate adverse events following lumbar fusion in Washington state between 1997 and 2007.

Table 3

Multivariate analysis of repeat surgery and complications and within 90 days of an initial inpatient lumbar fusion in Washington State (CHARS 2004–2007)

Characteristics		Final models using surgeon-level random effects.	
		Reoperation within 90 days	Other major complication
Age group	20–40	1.00 (ref)	1.00 (ref)
	41–60	1.41 (0.76 – 1.78)	1.15 (0.85 – 2.06)
	61–80	1.73 (0.73 – 1.96)	1.17 (0.78 – 2.14)
	80+	1.04 (0.44 – 2.14)	0.90 (0.45 – 2.38)
Sex	Male	1.00 (ref)	1.00 (ref)
	Female	1.63 (1.01 – 1.71)	1.31 (0.97 – 1.66)
Any comorbidity	None	1.00 (ref)	1.00 (ref)
	One	1.16 (1.20 – 2.07)	1.57 (1.19 – 2.09)
	Two or more	1.24 (1.41 – 3.05)	2.05 (1.49 – 3.28)
Insurance	Medicare	1.00 (ref)	1.00 (ref)
	Medicaid	1.49 (0.66 – 3.39)	1.50 (0.89 – 2.40)
	HMO	1.11 (0.51 – 2.44)	0.63 (0.30 – 0.98)
	Commercial	1.31 (0.73 – 2.35)	0.69 (0.42 – 1.03)
	W/C	0.99 (0.45 – 2.22)	0.62 (0.33 – 1.05)
	Contract	0.95 (0.52 – 1.76)	0.71 (0.45 – 1.01)
	Other	1.14 (0.33 – 3.98)	0.77 (0.31 – 1.80)
Diagnosis	Disc Deg	1.00 (ref)	1.00 (ref)
	HNP	0.90 (0.39 – 1.32)	0.72 (0.69 – 1.60)
	HNP w/myelop	0.94 (0.27 – 3.31)	2.08 (1.05 – 4.12)
	Stenosis	2.44 (1.26 – 4.75)	1.37 (0.71 – 1.48)
	Listhesis	1.45 (0.85 – 2.49)	0.99 (0.70 – 1.33)
	Scoliosis	1.75 (0.77 – 3.95)	1.58 (1.24 – 3.87)
Surgeon previous year volume quartile	1 – 29	1.00 (ref)	1.00 (ref)
	30 – 60	1.41 (0.84 – 2.36)	1.21 (0.85 – 1.70)
	61 – 93	1.22 (0.70 – 2.11)	1.21 (0.84 – 1.73)
	94 – 242	0.94 (0.50 – 1.78)	1.03 (0.69 – 1.52)
Surgical Approach	Posterior	1.00 (ref)	1.00 (ref)
	Anterior	3.33 (2.03 – 5.44)	0.98 (0.64 – 1.50)
	Combined	1.13 (0.59 – 2.17)	1.24 (0.82 – 1.89)
BMP	No	1.00 (ref)	1.00 (ref)
	Yes	1.78 (1.17 – 2.69)	1.20 (0.88 – 1.63)
four or more vertebrae fused	No	1.00 (ref)	1.00 (ref)
	Yes	1.22 (0.64 – 2.32)	1.64 (1.12 – 2.40)
Variance estimate of surgeon random effects, v^2		0.383	0.086
Adjusted mean rate across all surgeons (95% CI)		1.7 (0.9 – 3.7)	4.1 (2.7 – 6.4)

[†]Odds ratio based on generalized linear & latent mixed models using Stata-MP command (GLLAMM)

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Table 4

Random-effects variance and model fit parameters of multivariate models for repeat surgery and complications within 90 days of an initial inpatient lumbar fusion in Washington State (CHARS 2004–2007)

Fixed effects	Random-effects	Hospital level variance (% of total variability)	Surgeon level variance (% of total variability)	Reduction in total variability compared to null model	Reduction in hospital and surgeon variability compared to null model	df	AIC	LL
		$\frac{\psi}{\psi + \pi^2 / 3}$	$\frac{\psi}{\psi + \pi^2 / 3}$					
Reoperation within 90 days								
Null model	Hospital	0.318 (8.8%)	--	$\frac{1 - \text{var}_{FULL}(\psi + \pi^2 / 3)}{\text{var}_{NULL}(\psi + \pi^2 / 3)}$ Equation 5	$\frac{1 - \text{var}_{FULL}(\psi)}{\text{var}_{NULL}(\psi)}$ Equation 6	2	1294.4	-644.91
	Surgeon	--	0.551 (14.4%)			2	1287.2	-641.61
	Both	0.153 (4.0%)	0.341 (9.0%)			3	1290.5	-642.26
Patient-factors	Hospital	0.331 (9.1%)	--	0%	0%	19	1306.5	-634.20
	Surgeon	--	0.567 (14.7%)	0%	0%	19	1298.8	-630.40
	Both	0.150 (3.9%)	0.361 (9.5%)	0%	0%	20	1302.8	-631.41
Operative features	Hospital	0.269 (7.6%)	--	1.3%	15.1%	26	1278.8	-613.40
	Surgeon	--	0.383 (10.4%)	4.4%	30.4%	26	1276.3	-612.41
	Both	0.133 (3.6%)	0.250 (6.8%)	3.0%	22.6%	27	1278.3	-612.16
Complications within 90 days								
Null	Hospital	0.124 (3.6%)	--	--	--	2	2376.2	-1186.11
	Surgeon	--	0.174 (5.0%)	--	--	2	2372.3	-1184.14
	Both	0.065 (1.9%)	0.112 (2.6%)	--	--	3	2375.8	-1184.89
Patient factors	Hospital	0.07 (2.1%)	--	1.7%	43.4%	19	2327.7	-1144.85
	Surgeon	--	0.118 (3.4%)	1.7%	32.6%	19	2326.2	-1144.10
	Both	0.050 (1.5%)	0.068 (2.0%)	1.7%	33.1%	20	2328.7	-1144.34
+ Operative features	Hospital	0.057 (1.7%)	--	2.0%	53.7%	26	2330.2	-1139.11
	Surgeon	--	0.087 (2.6%)	2.5%	50.0%	26	2329.6	-1138.82
	Both	0.043 (1.3%)	0.044 (1.3%)	2.6%	50.5%	27	2331.8	-1138.92