


True Differences in Poor Outcome Risks Between Revision and Primary Lumbar Spine Surgeries

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Abstract

Background: Previous studies have shown that the rates of complications associated with revision spine surgery are higher than those of primary spine surgery. However, there is a lack of research exploring the difference in magnitude of risk of poor outcomes between primary and revision lumbar spine surgeries. **Purposes:** We sought to compare the risks of poor outcomes for primary and revision lumbar spine surgeries and to analyze different measures of risk to better understand the true differences between the 2 forms of surgery. **Methods:** This retrospective observational study used data from the Quality Outcomes Database Lumbar Spine Surgical Registry from 2012 to 2018. We included individuals who received primary or revision surgery due to degenerative lumbar disorders. Outcome variables collected were complications within 30 days of surgery and 3 destination variables, specifically, (1) 30-day hospital readmission, (2) 30-day return to operating room, and (3) revision surgery within 3 months. Measures of risk considered were odds ratio (OR), relative risk (RR), relative risk increase (RRI), and absolute risk increase (ARI). **Results:** There were 31,843 individuals who received primary surgery and 7889 who received revision surgery. After controlling for baseline descriptive variables and comorbidities, revision surgery increased the odds of 4 complications and all 3 destination variables. Risk ratios reflected smaller magnitudes but similar findings as the statistically significant ORs. **Conclusion:** Revision surgery is related to higher overall risks than primary surgery, but the true magnitudes of these risks are very small. RRI and ARI should be included when reporting ORs to better clarify the significance.

Keywords

lumbar surgery, registry, revision surgery, risk

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Introduction

Over the last 2 decades, outpatient spine surgery has become increasingly prevalent, especially in Western countries [13]. During this time, the rate of complex fusion procedures has increased 15-fold [6]; the rate of minimally invasive surgery has increased substantially as well [2]. Overall, a majority of patients who undergo spine surgery report favorable outcomes [30], but, as with all invasive interventions, there are risks of complications. Complications are any deviation from the normal postoperative course; they may be minor or severe. The incidence of complications in older adults is higher in the lumbar spine (17.8%) than in the cervical spine (8.9%) because the risk of complications increases with the complexity of the procedure [22].

Surgical revision may be required in cases of significant complications, poor outcomes, disease progression, radicular/myelopathic changes, or instrumental failure [20].

Compared with primary surgeries, revisions are more challenging because of altered anatomical landmarks, avascular scars from previous surgery, and epidural fibrosis [9,11]. Most studies involving adults that directly compare complications between primary and revision spine surgeries incorporate small sample sizes that are not transferable to a larger

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population [12,17–19]. Two large-scale studies that investigated risks of complications in patients with spinal deformity found that revision increased risks of infection rates [7,25], whereas 1 study found complications involving the nervous system, hematoma/seroma formation, accidental vessel or nerve puncture, wound dehiscence, and acute respiratory distress system complications [7]. Another study found increased risks of revision instrumented fusions in Medicare recipients that were related to comorbidities [16]. Perioperative findings of fusion recipients demonstrate similar short- to medium-term results as, when compared with patients undergoing a primary lumbar fusion procedure, revision surgery increased the odds of developing neurologic complications including dural tears, nerve root injuries, deep venous thrombosis (DVT), pulmonary embolism (PE), wound infections and complications, and gastrointestinal complications [15].

Although it is understood that revision surgery is associated with increased complications, the *scale* to which the complications are higher in revision versus primary surgery is not entirely clear. The purpose of our study was to incorporate several different forms of comparative risk measures. We hypothesize that there will be notable differences in measures for risk of complications (eg, DVT, PE) and destination measures (eg, 30-day readmission to hospital) in individuals who underwent various lumbar surgical procedures. An understanding of the differences in risk measures should improve surgeons' and patients' ability to understand the true differences in risks between revision and primary spine surgery.

Methods

We conducted a retrospective, observational cohort study that used data from the Quality Outcomes Database (QOD) Spine Registry from 2012 to 2018. We included patients who received surgery from 2012 to 2016 and had a reported 2-year follow-up. The QOD Spine Registry serves as a continuous national clinical registry for common neurosurgical and spine procedures. Data for the registry are pulled from 145 hospitals in 38 states in the United States and include comprehensive descriptive health and surgical data and outcome measures with baseline, 3-month, 1-year, and 2-year follow-up.

To guide our reporting, we used REporting of studies Conducted using Observational Routinely-collected health Data (RECORD), which was developed to support studies based on routinely collected health data [3]. RECORD is an extension of the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guidelines, designed to improve transparency in presenting methods and results of data preparation and analysis [29].

The QOD Spine registry includes data on lumbar spine, cervical spine, and spinal deformity. In this study, we

included only those who underwent lumbar spine surgery from 2012 to 2018 due to degenerative lumbar disorders.

We grouped patients into 2 categories: (1) primary surgery or (2) revision surgery. Within the QOD, primary surgery is defined as the initial surgical attempt at a specific spinal problem. Revision surgery is defined as a procedure that takes place on a patient who had already undergone some form of spine surgery at any time point within the study period. The QOD does not include reasons for revision surgeries.

Outcome variables were divided into complications and destination variables; each of these is coded as either “present” or “absent” in the QOD. We included medically diagnosed complications that were present within 30 days of surgery, including DVT, PE, new neurogenic disorder, myocardial infarction, urinary tract infection, surgical site infection, hematoma, cerebrovascular accident, incidental durotomy, and pneumonia. Destination variables were associated with complications or other detrimental occurrences. Destination measures were (1) 30-day readmission to hospital, (2) 30-day return to the operating room, and (3) revision surgery within 3 months.

A variety of descriptive variables were captured to better reflect individual characteristics. We reported the preoperative descriptive variables of age, sex, race (white %), Hispanic ethnicity, body mass index (BMI), insurance type, admitting diagnosis, symptom duration (in months), American Society of Anesthesiologists (ASA) grade, patient educational status, dominant symptoms (pain, numbness, or weakness), use of pain medication, and employment status. The ASA Physical Status Classification System reflects the general health of an individual and is categorized into 6 categories. These are as follows: ASA 1—healthy individuals; ASA 2—mild systemic disease; ASA 3—severe systemic disease; ASA 4—patients with severe systemic disease that is a constant threat to life; ASA 5—moribund patients not expected to survive without the operation; and ASA 6—patients declared brain-dead whose organs are being removed for donor purposes [8].

Furthermore, we reported 3 preoperative patient-reported outcomes: the Oswestry Disability Index (ODI) [10], the Visual Analogue Scale (VAS) for leg pain and back pain [4], and the EuroQol 5 Dimension, 5-Level Visual Analogue Scale (EQ-5D-5L VAS) [21]. For the ODI, low scores indicate minimal disability, whereas high scores indicate severe disability (i.e., 0%–20% = minimal disability, 21%–40% = moderate disability, 41%–60% = severe disability, 61%–80% = crippled, and 80%–100% = bedbound or symptom exaggeration) [10]. Within the QOD, back pain and leg pain were each measured quantitatively using the 0 to 10 VAS, in which 0 represents “no pain” and 10 represents the “worst possible pain” [4]. Within the QOD, the EQ-5D-5L VAS is scored from 0 to 100 based on the following question: “I would now like you to tell me the point on this scale where

you would put your own health state today.” Lower values (closer to 0) indicate poorer health status, whereas higher values (closer to 100) indicate better health status [21].

To define the overall health variations between primary and revision recipients, we also captured preoperative (baseline) comorbidities. Within the QOD, comorbidities are coded as “present” or “absent.” We included symptoms of weakness and numbness, as well as medical diagnoses of diabetes, coronary artery disease, peripheral vascular disease, anxiety, depression, osteoarthritis, renal disease, chronic obstructive pulmonary disease, osteoporosis, Parkinson disease, and multiple sclerosis.

In addition to the aforementioned refinement of the database, we analyzed the effect of missing data within the sample. Missing values ranged from a low of 0.01% for nearly all the complications to up to 25% of comorbidity variables. Little’s test suggests that these variables were not missing at random and that imputation methods are inappropriate. Because the missing values associated with complications were very low, we elected to incorporate listwise deletion, a method for handling missing data, in which an entire record is excluded from analysis if any single value is missing [14].

Statistical Analysis

Descriptive categorical and continuous variables were summarized using frequency counts (percentages) and means (SDs), respectively. For the descriptive analyses, linear mixed-effects modeling was performed for continuous variables. For the descriptive, comorbidity, and complication analyses, the Pearson χ^2 test was carried out for categorical variables. The Pearson χ^2 test was also used to calculate proportional differences in comorbidity and complication rates between revision and primary surgery recipients. Statistical significance was set at $P < .05$ for all tests.

Risk refers to the probability of occurrence of an event or outcome; there are several ways of reporting risk. Statistically, risk is defined as the chance of the outcome of interest out of all possible outcomes. Relative risk (RR) is the ratio of the risk of an event in one group (eg, revision surgery) versus the risk of an event in another group (eg, primary surgery) [26]. In contrast, odds ratio (OR) is a ratio of 2 odds, where odds refer to the probability of an event occurring/probability of an event not occurring. Although the 2 measures are related when there is a significant association between an exposure and an outcome, OR exaggerates the estimate of their relationship (is farther from 1.0 than RR). Thus, when RR is < 1.0 , the OR is notably lower than RR; by contrast, when RR is > 1.0 , the OR is notably higher than RR [26]. We ran ORs for each complication using baseline descriptive and comorbidity controls for variables that were significantly different in revision and primary surgeries. In each case, the “odds” of an event reflected a situation in which someone received revision

surgery versus primary surgery. Risk ratios were run independently but with the same premise.

Absolute risk increase (ARI) (also known as a risk difference) is the absolute difference in outcomes between one group (ie, revision surgery) in comparison with another group (ie, primary surgery). The value is always stated as a percentage, and it defines how much the risk of something happening decreases or increases if a certain intervention (or exposure) occurs. We also captured the relative risk increase (RRI) (or reduction) [23]. A value of RRI is an estimate of the percentage of baseline risk that is changed compared with another approach. It is calculated by dividing the ARI by risk in revision group (baseline risk) [27].

Results

In total, the data set represented 39,732 surgical recipients. Of these, 31,843 received primary lumbar surgery and 7889 received lumbar revision surgery. Significant differences were noted among characteristics of age ($P < .01$), sex (0.02), race ($P < .01$), ethnicity ($P < .01$), patient education ($P < .01$), ASA grade of 3 or higher ($P < .01$), dominant symptoms ($P < .01$), employment status ($P < .01$), ODI% ($P < .01$), EQ-5D VAS ($P < .01$), back pain VAS ($P < .01$), and leg pain VAS ($P < .01$). In summary, those who received revision surgery were younger, white, male, and non-Hispanic. Furthermore, revision surgery recipients had less education; were students or less frequently employed; had higher ASA scores; did not report pain as their dominant symptom; and reported poorer values for disability, back and leg pain, and quality of life (Table 1). Those who received revision surgery also had statistically higher proportions of comorbidities in nearly every category except multiple sclerosis (which was not significant), chronic renal disease, and osteoporosis; the latter 2 comorbidities were significantly higher in those receiving primary surgery (Table 2).

Revision surgery had higher percentages of complications within 30 days of surgery, including surgical site infection ($P = .01$), new neurological disorders ($P < .01$), myocardial infarction ($P < .01$), incidental durotomy ($P < .01$), and pneumonia ($P < .01$), and for the destination variables of 30-day readmission to hospital ($P < .01$), 30-day return to the operating room ($P < .01$), and revision surgery within 3 months ($P < .01$) (Table 3).

After controlling for baseline descriptive variables and comorbidities, revision surgery increased the odds of 30-day readmission to the hospital (OR = 1.16; $P < .01$), 30-day return to the operating room (OR = 1.34; $P < .01$), revision surgery within 3 months (OR=1.46; $P < .01$), as well as development of new neurological defect (OR = 1.59; $P < .01$), myocardial infarction (OR = 2.79; $P < .01$), incidental durotomy (OR = 2.02; $P < .01$), and pneumonia (OR = 2.14; $P < .01$) compared with the odds of primary surgery (Table 4). We also found that RRs reflected smaller

Table 1. Descriptive patient characteristics.

Variables	Revision surgery N = 7889	Primary surgery N = 31,843	P value
Age, mean (SD)	58.94 (13.78)	59.78 (14.22)	<.01
Sex (male)	4300 (54.50%)	16,815 (52.81%)	.02
Race (white)	7138 (90.65%)	28,041 (88.20%)	<.01
Ethnicity (Hispanic or Latino)	185 (2.34%)	968 (3.04%)	<.01
Insurance status (VA, private, or Medicare)	7404 (94.05%)	29,930 (94.14%)	.76
Patient education (college or more)	3861 (50.67%)	16,328 (53.23%)	<.01
ASA grade (3 or higher)	3849 (49.82%)	13,443 (43.34%)	<.01
Dominant symptoms (pain)	7159 (92.45%)	29,984 (94.46%)	<.01
Symptom duration (>3 mo)	7024 (90.05%)	27,989 (89.59%)	.24
Employment status (employed or a student)	3304 (41.97%)	14,686 (46.21%)	<.01
ODI, % (SD)	49.67 (16.62)	46.01 (17.10)	<.01
EQ-5D VAS (SD)	57.44 (21.37)	60.16 (30.55)	<.01
Back pain VAS (SD)	6.98 (2.49)	6.65 (2.69)	<.01
Leg pain VAS (SD)	6.92 (2.63)	6.78 (2.73)	<.01

Values represent number (% of cohort) unless otherwise indicated.

ASA The American Society of Anesthesiologists (1 = a normal healthy patient, 2 = a patient with mild systemic disease, 3 = a patient with a severe systemic disease that is not life-threatening, and 4 = a patient with a severe systemic disease that is a constant threat to life), ODI Oswestry Disability Index, EQ-5D EuroQol 5 Dimension, VAS Visual Analogue Scale, VA Veterans Affairs.

Table 2. Preoperative (baseline) medical diagnoses comorbidities.

Variables	Revision surgery N = 7,889	Primary surgery N = 31,843	P value
Diabetes	1822 (23.11%)	6314 (19.84%)	<.01
Coronary artery disease	1015 (12.87%)	3542 (11.13%)	<.01
Peripheral vascular disease	237 (3.27%)	832 (2.62%)	.01
Anxiety	1763 (22.35%)	5985 (18.80%)	<.01
Depression	2063 (26.22%)	6802 (21.37%)	<.01
Osteoarthritis	1988 (27.53%)	7444 (23.48%)	<.01
Chronic renal disease	319 (4.40%)	1168 (6.03%)	.01
COPD	627 (8.64%)	1913 (6.03%)	<.01
Osteoporosis	367 (4.65%)	1490 (4.68%)	.02
Parkinson disease	68 (0.99%)	207 (0.66%)	.01
Multiple sclerosis	49 (0.71%)	201 (0.64%)	.43
Weakness	3,819 (48.63%)	14,439 (45.61%)	<.01
Numbness	4,237 (53.96%)	16,895 (53.41%)	<.01

COPD chronic obstructive pulmonary disease.

magnitudes but similar findings as the statistically significant ORs, with the addition of surgical site infection which was a statistically significant risk for revision surgery. The highest RRI was pneumonia at 61.2%, followed by myocardial infarction at 60.8% and incidental durotomy at 48.5%. The highest reported ARIs for revision surgery versus primary included incidental durotomy at 1.65% and 30-day hospital readmission at 1.22%.

Discussion

Our study aimed to compare different measures of risk to improve our understanding of the true differences in risks of complications between primary and revision lumbar spine

surgeries. The goal was to provide an understanding that can help inform surgeons and patients about the true risks associated with spine surgery (primary vs revision) [9]. Our findings are similar to past studies [7,15,16,25] that have shown that revision surgery is associated with higher odds of complications with values that have similar magnitudes [24]. However, previous studies did not report additional risk measures such as RR, ARI, and RRI, and we feel these deserve additional consideration. Past authors have advocated that to truly understand risks, it is inappropriate to report one value without reporting the others [23].

It is worth pointing out our study limitations. This study used a patient registry, and there are restrictions to the use of observational data in patient registries. Both primary

Table 3. Differences in complications and destination between revision and primary surgery.

Variables	Revision surgery N = 7889	Primary surgery N = 31,843	P value
Complications within 30 days of surgery			
Deep vein thrombosis	37 (0.48%)	132 (0.42%)	.52
Pulmonary embolism	27 (0.35%)	77 (0.25%)	.12
Surgical site infection	87 (1.13%)	254 (0.82%)	.01
New neurological disorder	86 (1.20%)	222 (0.72%)	<.01
Urinary tract infection	70 (0.90%)	278 (0.89%)	.93
Cerebral vascular accident	11 (0.15%)	27 (0.08%)	.11
Myocardial infarction	18 (0.23%)	29 (0.09%)	<.01
Incidental durotomy	231 (3.40%)	535 (1.75%)	<.01
Hematoma	40 (0.51%)	151 (0.48%)	.73
Pneumonia	42 (0.62%)	76 (0.24%)	<.01
Destination			
30-day readmission to hospital	510 (6.64%)	1,672 (5.42%)	<.01
30-day return to OR	235 (3.05%)	704 (2.27%)	<.01
Revision surgery within 3 mo	168 (2.84%)	463 (1.91%)	<.01

OR operating room.

Table 4. Odds ratios, risk ratios, absolute risk increase, and relative risk increase for revision surgery for selected outcomes.

	Odds ratio (95% CI)	P value	Risk ratio (95% CI)	Absolute risk increase, %	Relative risk increase (%)
Complications within 30 days of surgery					
Deep vein thrombosis	1.17 (0.79-1.73)	.43	1.03 (0.95-1.11)	0.06	12.5
Pulmonary embolism	1.47 (0.93-2.34)	.10	1.08 (0.96-1.21)	0.11	31.4
Surgical site infection	1.27 (0.97-1.66)	.07	1.08 (1.01-1.14)	0.31	27.4
New neurological disorder	1.58 (1.21-2.08)	<.01	1.13 (1.05-1.21)	0.48	40
Urinary tract infection	1.07 (0.82-1.42)	.60	1.00 (0.95-1.06)	0.02	2.2
Cerebral vascular Accident	1.51 (0.60-3.46)	.33	1.14 (0.93-1.40)	0.07	46.6
Myocardial infarction	2.79 (1.52-5.10)	<.01	1.29 (1.04-1.63)	0.14	60.8
Incidental durotomy	2.02 (1.72-2.38)	<.01	1.17 (1.12-1.23)	1.65	48.5
Hematoma	1.04 (0.72-1.51)	.80	1.01 (0.94-1.09)	0.04	8
Pneumonia	2.14 (1.43-3.19)	<.01	1.27 (1.11-1.45)	0.38	61.2
Destination					
30-day readmission to hospital	1.16 (1.04-1.30)	<.01	1.05 (1.02-1.07)	1.22	18.3
30-day return to OR	1.34 (1.14-1.58)	<.01	1.07 (1.03-1.11)	0.78	25.5
Revision surgery within 3 mo	1.46 (1.20-1.78)	<.01	1.09 (1.05-1.15)	0.93	32.7

Control variables for odds ratio analyses include age, gender, race, ethnicity, educational status, employment status, ASA grade, dominant symptoms, baseline disability score, baseline pain intensity score for back and leg, baseline quality of life score, diabetes, coronary artery disease, peripheral vascular disease, anxiety, depression, osteoarthritis, chronic renal disorder, chronic obstructive pulmonary disease, osteoporosis, Parkinson disease, weakness, and numbness.

CI confidence interval, OR operating room, ASA American Society of Anesthesiologists.

and revision surgery descriptions are coded generically, so we are missing an understanding beyond procedural type and diagnosis. Within the registry, complications were only recorded if they required intervention from the recording surgeon; thus, values may be underreported; this could affect our statistics, specially the ARI. Complications are coded within a 30-day period only, so more complications could have been present but unrecorded within the 2-year follow-up. Some complications, such as adjacent-level surgery, were not included, and this should be recognized as a

limitation. Finally, there were very few missing values, and these were not missing at random. Our method of listwise deletion is appropriate for the analyses, but it also excludes information that may have influenced results.

Past studies have reported differences in primary and revision surgery complications using measures of differences (eg, *t* test and χ^2) [7,25] and ORs [7,15,16,25]. Measures of differences will identify dissimilarities in proportions of complications between groups; however, unless an effect size is provided, the strength of that difference is

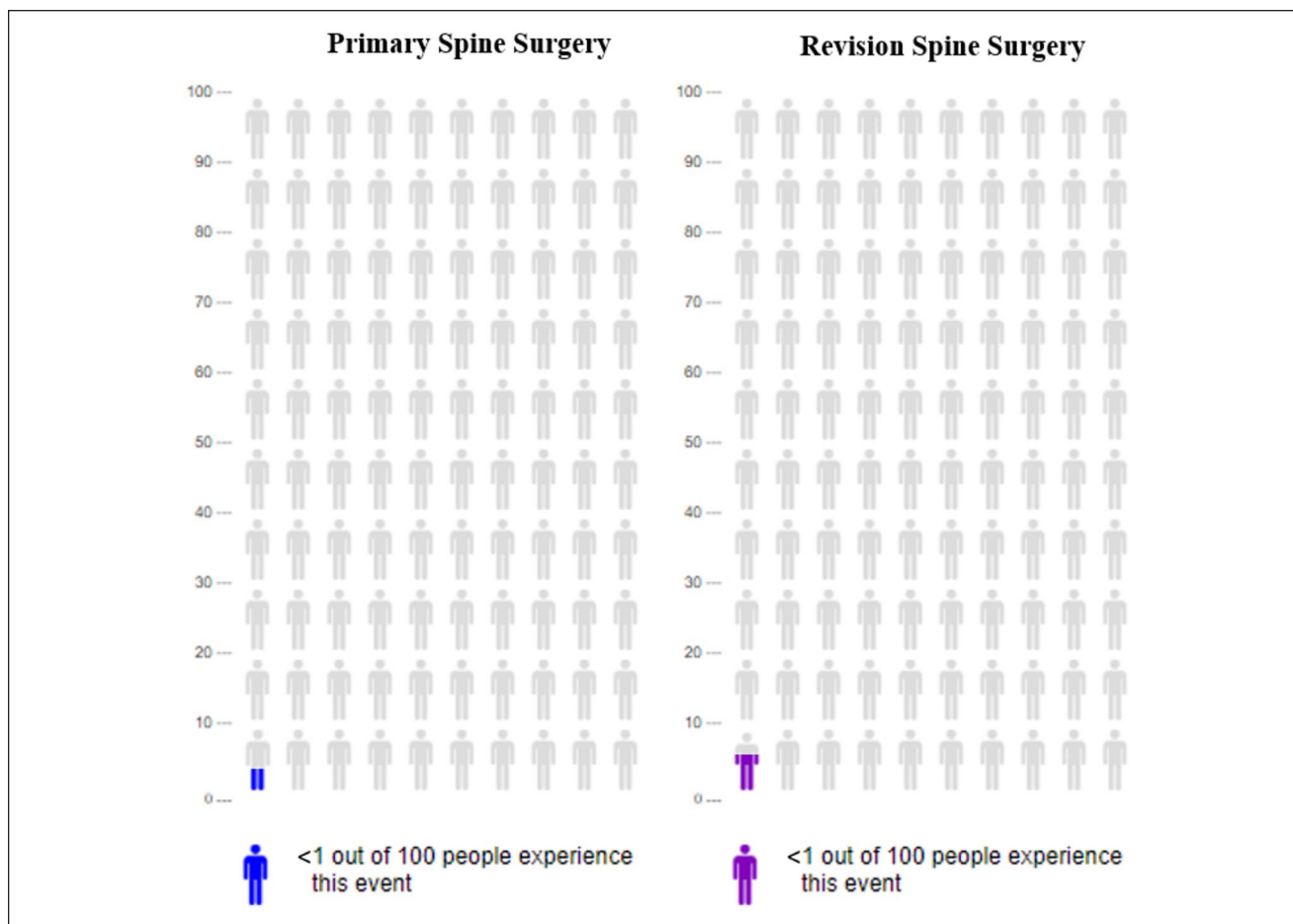


Fig. 1. Pneumonia complications associated with primary and revision spine surgeries.

not notably meaningful to the reader. ORs are a measure of association and represent the odds that an outcome will occur given a particular exposure (eg, revision surgery) compared with the odds of the outcome occurring in another exposure (eg, primary surgery) [28]. Values above 1.0 suggest greater odds than those of a particular outcome than that of the comparative group, but ORs are often difficult to interpret, especially when the outcome of interest occurs in greater than 10% of cases [5]. ORs have been converted to Cohen's d (a standardized mean difference between 2 groups) to better understand the magnitude. Cross tabulations show that a Cohen's d of <0.2 (small effect or weak association) occurs when OR is <1.5 , whereas a Cohen's d of >0.8 (large effect or strong association) is present when OR is >5.0 . Using this comparison, nearly all the statistically significant ORs in our study, indicating revision increases odds of complications, exhibit only weak associations. Nonetheless, during consultation of risks associated with revision surgery, an explanation of "weak associations" is not likely meaningful to the surgeon or the patient.

We found similar risk findings with our RR measures to those measured with OR. If the risk ratio is 1.0 (or close to 1.0), it suggests no difference or little difference in risk (incidence in each group is the same). The highest RRs were for myocardial infarction and pneumonia, at 1.29 (95% confidence interval [CI] = 1.04-1.63) and 1.27 (95% CI = 1.11-1.45), respectively. Thus, for interpretation, those receiving revision surgery are 1.29 times more likely to have a myocardial infarction and 1.27 times more likely to acquire pneumonia. These values are relatively low and may be meaningful to patients and surgeons.

To understand the differences in risks between complications of primary or revision surgery, we also measured ARI and RRI. The RRI is an estimate of the percentage of baseline risk that is changed by receiving one approach (ie, revision) versus another (ie, primary). Expressed as a percentage, the RRI is less likely to be influenced by low prevalence or low risks. In our study, revision surgery always had higher RRI than primary surgery, with complications ranging from a low of 2.2% for urinary tract infection to a high of 61.2%

for pneumonia. In fact, many of the complications exhibited high RRI, including myocardial infarction (60.8%), incidental durotomy (48.5%), revision surgery within 3 months (32.7%), and cerebral vascular accident (46.67%). Indicating RRI in the 40% to 60% range could potentially be very meaningful for the patient, but one must consider these values in context with the *rates of complications* that actually occurred. To do so, one needs to consider the ARI.

The ARI is the absolute difference between a control event rate (ie, primary surgery) and the event rate of interest (ie, revision surgery). The ARI implies that a risk increases with the event rate of interest; essentially, it suggests a negative effect of a treatment strategy in a given population. The ARIs in our study were very small. Of the 13 complications, 11 had ARIs that were less than 1% between primary and revision surgeries. Moreover, of the 2 complications that were above an ARI of 1% (incidental durotomy and 30-day hospital readmission), the values were still lower than 2%. When informing patients about the risks of complications, it is important to indicate that revision surgeries do have higher risks of complications. But because complication rates are relatively low, the ARI is actually minimal.

Surgeons and patients are influenced not only by the results of studies but also by how authors present the results [1]. Depending on the choice of the analyses (OR, RR, RRI, or ARI), the effect of an intervention may appear large and alarming or small and insignificant, even though the underlying data are the same. It has been recommended that all risk values should be reported to give better context to true risk [23]. Indeed, in our sample, we found minimal ARIs, which present a markedly different picture than the RRIs. Using pneumonia as an example, either one could indicate that the RRI of a complication of pneumonia for revision is 61% or one could say that the ARI is minuscule and is actually less than one half of 1% (Fig. 1).

Conclusion

In conclusion, past studies are consistent in recognizing an increase in risk of complications with revision surgery versus primary surgeries. But the scale of risk had not been reported in a way that is meaningful to surgeons and patients. Risk is complex, and all risk measures should be included during reporting of findings. We found that revision surgery is related to higher overall risks than primary surgery, but the true magnitude of these risks is very small. Hence, when reporting ORs, RRI and ARI should also be included to further clarify the risk of poor outcomes. This can help support more informed decisions by surgeons and patients who are considering spine surgery.

Declaration of Conflicting Interests

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Human/Animal Rights

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

Informed Consent

Informed consent was waived from all included patients due to the retrospective nature of this study.

Level of Evidence

Level III: Retrospective study

Required Author Forms

Disclosure forms provided by the authors are available with the online version of this article as supplemental material.

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