Spine

SPINE Volume 38, Number 22, pp 1970-1976

Perioperative Complications and Mortality After Spinal Fusions

Analysis of Trends and Risk Factors

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Study Design. Retrospective review.

Objective. To analyze the trends in complications and mortality after spinal fusions.

Summary of Background Data. Utilization of spinal fusions has been increasing during the past decade. It is essential to evaluate surgical outcomes to better identify patients who benefit most from surgical intervention. Integration of empiric evidence from large administrative databases into clinical decision making is instrumental in providing higher-quality, evidence-based, patient-centered care.

Methods. This study used Nationwide Inpatient Sample data from 2001 through 2010. Patients who underwent spinal fusions were identified using the CCS (Clinical Classifications Software) and *ICD-9* (*International Classification of Diseases, 9th Revision*) codes. Data on patient comorbidities, primary diagnosis, and postoperative complications were obtained *via ICD-9* diagnosis codes and *via* CCS categories. National estimates were calculated using weights provided as part of the database. Time trend analysis for average length of stay, total charges, mortality, and comorbidity burden was performed. Univariate and multivariate models were constructed to identify predictors of mortality and postoperative complications.

Results. An estimated 3,552,873 spinal fusions were performed in the United States between 2001 and 2010. The national bill for spinal fusions increased from $10 billion to $46.8 billion. Today, patients are older and have a greater comorbidity burden than 10 years ago. Mortality remained relatively constant at 0.46%, 1.2%, and 0.14% for cervical, thoracic, and lumbar fusions, respectively. Morbidity rates showed an increasing trend at all levels. Multivariate analysis of 19 procedures and patient-related risk factors and 9 perioperative complications identified 85 statistically significant ($P < 0.01$) interactions.

Conclusion. The data on perioperative risks and risk factors for postoperative complications of spinal fusions presented in this study is pivotal to appropriate surgical patient selection and well-informed risk-benefit evaluation of surgical intervention.

Key words: spinal fusion, perioperative complications, costs, health care utilization, national trends, perioperative outcomes, comorbidities, risk factors, epidemiology.

Level of Evidence: N/A

Spine 2013;38:1970–1976

Spine-related conditions are one of the most common presenting complaints at health care visits, affecting more than 11% of the US population.[1] Spinal fusions, first described by Hibbs and Albee in 1911, have been used to treat a variety of spinal pathologies including deformity, trauma, degenerative disc disease (DDD), and spondylolisthesis.[2] These procedures have experienced a remarkable increase in utilization during the past decade.[3,4] A recent estimate suggests that more than 413,000 fusions were performed in the United States in 2008, accounting for $33.9 billion in total hospital costs.[3]

The integration of administrative health care databases into clinical research has recently seen increased adoption.[5–9] As these databases become more robust and offer finer granularity of clinical detail, this approach will allow integration of significant volumes of empiric evidence into clinical decision making and may lead to a higher quality of care.

This study aims to use the Nationwide Inpatient Sample (NIS) database to analyze the trends in patient demographics, comorbidities, perioperative complications, and mortality for spinal fusion surgery during a 10-year period. This study will also identify risk factors for specific perioperative complications. The empirical evidence provided in this study is crucial in defining surgical risks, and is integral in helping clinicians make well-informed decisions regarding patient selection for surgical intervention.

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Acknowledgment date: April 24, 2013. First revision date: June 21, 2013. Second revision date: July 13, 2013. Acceptance date: July 16, 2013.

The manuscript submitted does not contain information about medical device(s)/drug(s).

No funds were received in support of this work.

Relevant financial activities outside the submitted work: board membership, consultancy, grants/grants pending, payment for lectures, patents, royalties and stock/stock options.

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DOI: 10.1097/BRS.0b013e3182a62527

MATERIALS AND METHODS

The study sample was obtained from the NIS database. NIS is part of the Healthcare Cost and Utilization Project sponsored by the Agency for Healthcare Research and Quality. This is the largest publicly available all-payer inpatient database in the United States comprised of an approximate 20% stratified sample of US hospital admissions, totaling between 7 and 8 million admissions per year.[10] The 46 states participating in the NIS account for more than 96% of the US population. The database contains information on patient demographics, hospital characteristics, length of stay (LOS), payment source, charges, and outcomes as well as procedure and diagnosis codes using the *International Classification of Diseases, 9th Revision* (*ICD-9*) system.

This study used NIS data spanning 10 years between 2001 and 2010. Patients who underwent spinal fusions were identified using the CCS (Clinical Classifications Software) procedure code 158 for spinal fusions.[11] Fusions were further subdivided by cervical, thoracic, or lumbar *via* corresponding *ICD-9* procedure codes. Data on patient comorbidities were obtained *via ICD-9* diagnosis codes and *via* the CCS categories provided by the Agency for Healthcare Research and Quality. Linear trends over time were analyzed for the following patient characteristics: age, sex, and comorbidity burden as estimated by the modified Charlson Comorbidity Index.[12,13] Trends in LOS, total charges and mortality were also investigated. National estimates were calculated using sample weights provided as part of the NIS database. All total charges were adjusted for inflation, and presented as US$ 2013.

Utilization rates for spinal fusions were adjusted using national census data to provide per capita estimates.[14] Preoperative spinal diagnoses were identified using corresponding *ICD-9* codes, and each diagnosis was trended over time (see Supplemental Digital Content Appendix A, available at http://links.lww.com/BRS/A806). Primary diagnoses investigated include DDD, spinal stenosis, spondylolisthesis, spinal deformity, trauma, and cancer. Postoperative complications were identified *via ICD-9* diagnosis codes (996.X–999.X) and trended over time (see Supplemental Digital Content Appendix B, available at http://links.lww.com/BRS/A807). Additional sensitivity analyses were performed for trends in utilization and total charges (see Supplemental Digital Content Appendix C, available at http://links.lww.com/BRS/A808).

Data in the NIS database is deidentified, and because this research does not include direct interaction with patients, it is exempt from review by the institutional review board.

Statistical Analysis

Time trend analysis for average LOS, total charges, mortality, and comorbidity burden was done *via* linear regression models. The same method was applied to analyze trends in perioperative complications, comorbidities, and primary diagnosis over time. R^2 correlation coefficients were calculated for each linear model. A *P* value less than 0.05 was considered significant.

Univariate analysis was used to identify patient and procedure-related factors that correlate with increased mortality. χ^2 tests and *t* tests were used for categorical and continuous variables, respectively. Variables that were statistically significant on univariate analysis were used as inputs for multivariate logistic regression models with mortality as outcome. Logistic regression models were created to identify independent risk factors for specific perioperative complications. Statistical analyses were performed using R statistical programming language.[15]

RESULTS

An estimated 3,552,873 spinal fusions were performed in the United States between 2001 and 2010. This accounted for more than $287 billion in total charges. The estimated aggregate national charges for spinal fusion-related admissions increased from $13.3 billion in 2001 to $49.9 billion in 2010. The number of fusions per 100,000 capita increased from 97 in 2001 to 151 in 2010, an increase of more than 55% (Figure 1). Lumbar fusions had the greatest increase (from 46 to 80 fusions per 100,000 capita), followed by cervical fusions (45 to 59), and thoracic fusions (from 6 to 12). The increase in utilization over time was statistically significant at all levels ($P < 0.01$ for all).

Mean age for cervical fusions increased from 49 years in 2001 to 54 years in 2010 ($P < 0.01$), 35 years to 45 years for thoracic fusion ($P < 0.01$), and 52 to 57 years for lumbar fusions ($P < 0.01$) (Figure 2). Patient sex did not significantly change for cervical and lumbar fusions, but thoracic fusions saw a decrease in female patients from 58% in 2001 to 55% in 2010 ($P = 0.029$) (Figure 3). The average modified Charlson Comorbidity Score increased from 0.08 to 0.16 for patients undergoing cervical fusions, from 0.16 to 0.27 for thoracic fusions, 0.10 to 0.17 for lumbar fusions (Figure 4).

The average total charges increased from $32,446 to $76,935, $95,558 to $205,078, and from $54,701 to $111,479 for cervical, thoracic, and lumbar fusions, respectively (Figure 5). The mean LOS decreased from 4.87 days in 2001 to 3.99 days in 2010 for lumbar fusions ($P < 0.01$), and did not show significant change over time for cervical fusions (between 2.9 and 3.5 d) or for thoracic fusions (between 9 and 10.5 d). Mortality rates did not show a significant change over time and remained at approximately 0.46%, 1.2%, and 0.14% for cervical, thoracic, and lumbar fusions, respectively.

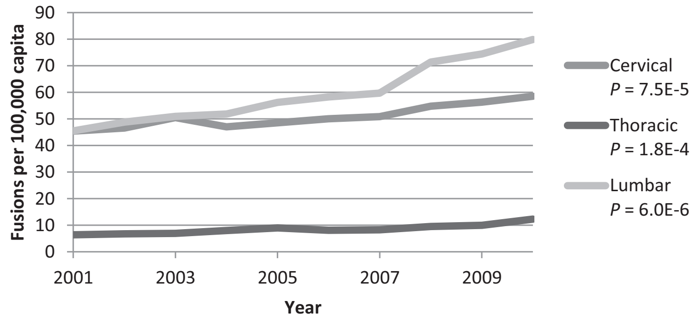

Figure 1. Trends in fusion rates per 100,000 capita between 2001 and 2010. *P* values correspond to statistical significance for change over time.

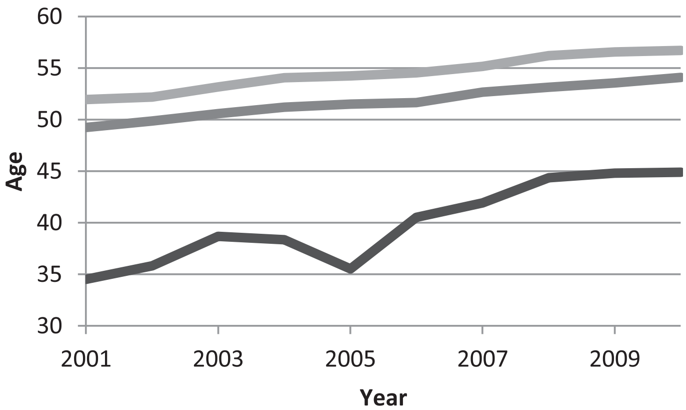

Figure 2. Average age of patients undergoing spinal fusions between 2001 and 2010.

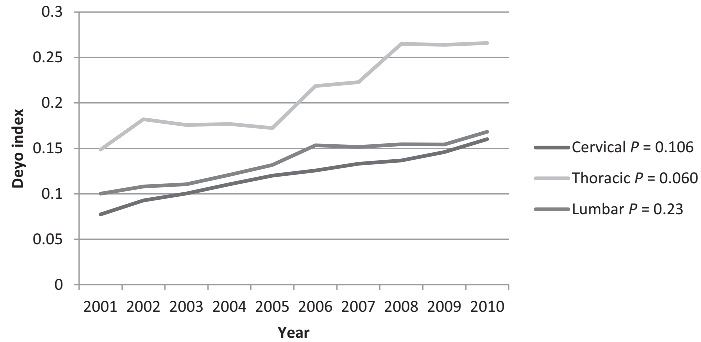

Figure 4. Trend in Deyo Comorbidity Index between 2001 and 2010.

Analysis of trends in perioperative complications showed that most increased over time (Figure 6). Perioperative complications of thoracic fusions were on average more frequent than at other levels. The most common primary diagnosis for cervical fusions was DDD, accounting for 84% of cervical fusions in 2001 and 77% in 2010. Thoracic fusions were mostly performed for spinal deformity (43% in 2001 and 32% in 2010) and trauma (19% in 2001 and 25% in 2010). DDD was the most common primary diagnosis for lumbar fusions (57% in 2001 and 54% in 2010).

A number of patient dependent factors were identified as independent predictors of mortality *via* logistic regression (Table 1). The following patient comorbidities were associated with an increased risk of mortality: metastatic cancer (odds ratio, 9.88), pathological weight loss (9.11), congestive heart failure (3.55), liver disease (3.07), renal failure (3.02), past myocardial infarction (2.14), dementia (2.12), neurological disorder (2.02), lymphoma (1.99), primary hypercoagulatable states such as protein C or S deficiency (1.50), peripheral vascular disease (1.31), chronic blood loss anemia (1.27), diabetes mellitus (1.14), chronic lung disease (1.13), valvular heart disease (1.10). Overall female sex was found to be protective with regards to mortality when adjusting for age and comorbidities (odds ratio, 0.48).

A series of logistic regression models identified a number of patient and procedure-related factors as independent risk factors for development of specific perioperative complications when adjusted for age and sex. A modified heat map was constructed using this data (Figure 7). Circle color represents the magnitude of the effect each risk factor had on a complication.

Primary hypercoagulatable state was a significant risk factor for the greatest number of complications including cardiac complications, venous thromboembolic events (VTE), development of hematomas, device-related complications, and postoperative shock. Other comorbidities associated with a number of complications were pathological weight loss and anemia secondary to chronic blood loss. Postoperative cardiac complications were associated with a history of MI or congestive heart failure. Thoracic fusions were associated with the most postoperative complications comparing with other surgical levels. Cervical fusion had a greater association with development of acute respiratory distress syndrome than any other level (odds ratio, 1.39).

DISCUSSION

This study analyzed national trends in outcomes and utilization of spinal fusions between 2001 and 2010. We identified risk factors for perioperative complications and provided a wealth of epidemiological data on outcomes. Utilization per capita for spinal fusions increased by 50%. Lumbar fusions saw the greatest increase from 46 to 80 fusions per 100,000 capita. The increase in utilization is consistent with previous literature.[6,16–18]

Spinal fusions were associated with a staggering $287 billion of total hospital charges. This includes all hospital charges

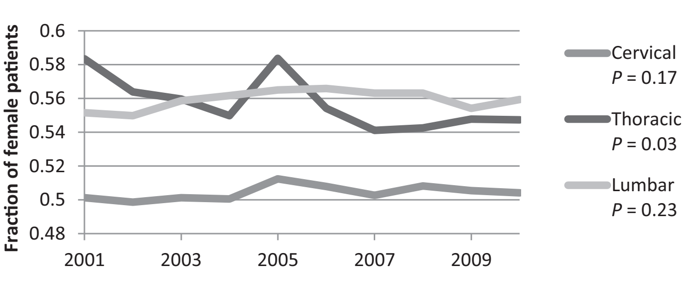

Figure 3. Trends in spinal fusion of female patients between 2001 and 2010.

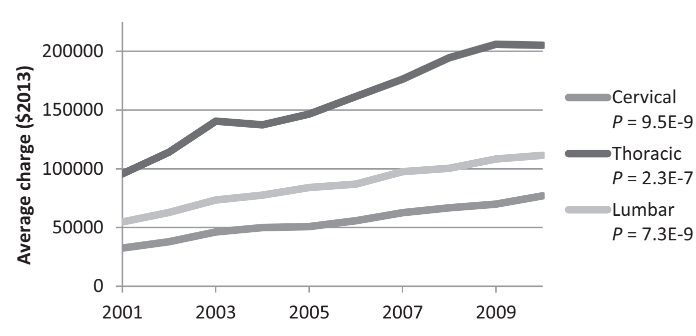

Figure 5. Average total charges of hospital admissions for spinal fusion. The total charges are adjusted for inflation, and presented as US$ 2013.

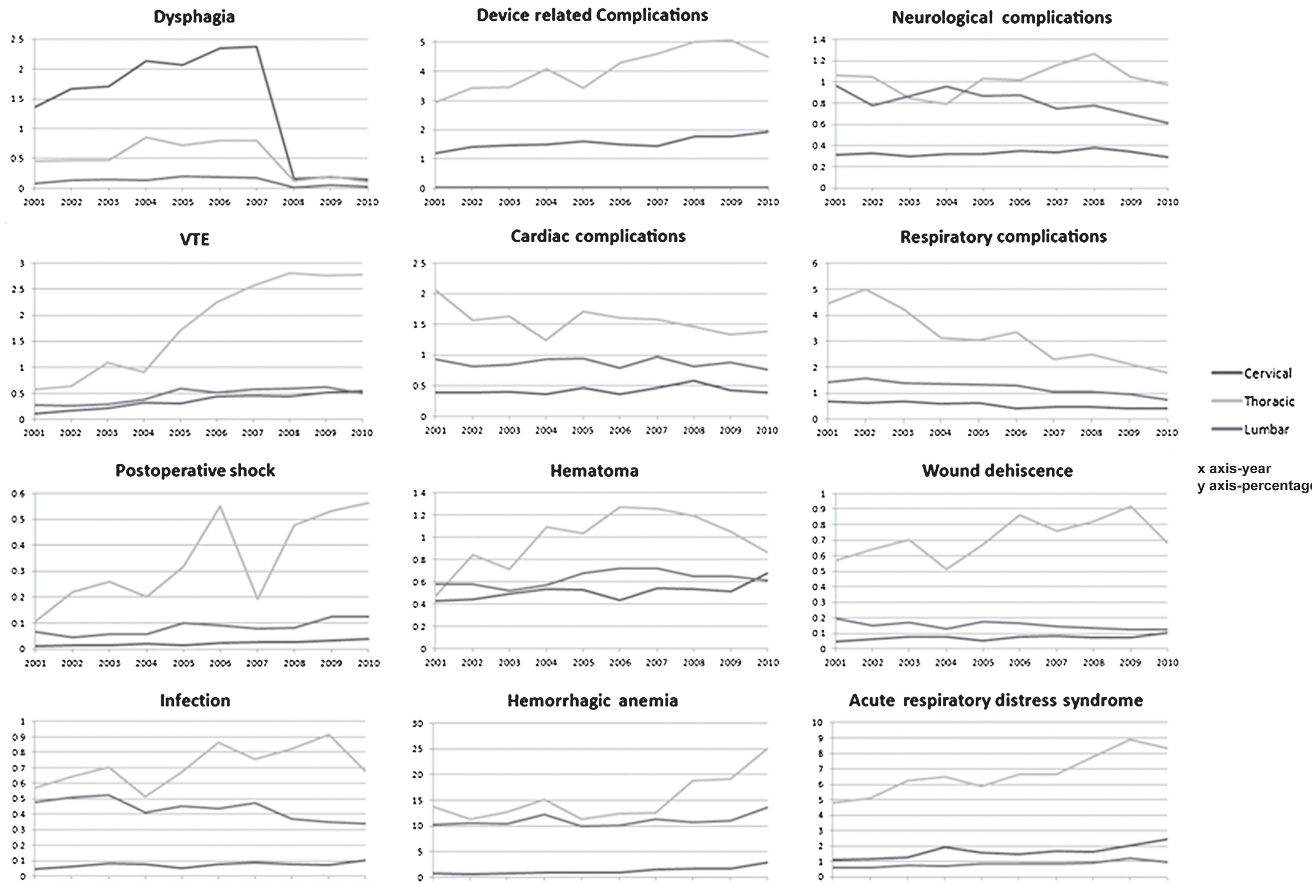

Figure 6. Trends in complications over time.

of the surgical admission, but excludes any charges associated with readmissions, rehabilitation, prescription drugs, professional fees, or indirect costs associated with loss of productivity. The total annual charges for spinal fusion admissions increased by 375%. The estimated aggregate national charges for spinal fusions in 2010 were $49.9 billion, comprising 1.8% of total health care expenditures for that year.[19] The increase in total charges is not fully explained by increases in utilization. Average charges for cervical, thoracic, and lumbar fusions were 2.4, 2.1, and 2 times higher, respectively in 2010 than in 2001. Thoracic fusions are the most expensive with an average charge of $205,078, when compared with $111,479 for lumbar, and $76,935 for cervical fusions. These figures are consistent with previous literature.[3]

Although a number of factors are likely responsible for the substantial increase in cost and utilization of spinal fusions, the data used in this study does not allow for analysis of the financial impact of such factors. Increasing availability and variety of spinal fusion devices, novel alternatives in bone grafting materials including bone morphogenetic protein, development of novel surgical techniques and minimally invasive approaches, increasing evidence to the efficacy and cost effectiveness of spinal fusions, as well as an increase in surgeon comfort and competency with the procedures are just a few potential causes of the increasing use and cost of spinal fusions.[20–25] One thing is clear, spinal fusions are being performed with increasing frequency, and the cost of each surgery is rapidly rising. Careful patient selection is pivotal to controlling the skyrocketing costs and utilization of these procedures. Other cost lowering measures include lowering cost of implants, or use of generic implants to decrease the cost of instrumentation. Further studies using databases that can disaggregate total charges are necessary to identify key drivers of increasing health care costs.

On average, today, patients are older and have a greater comorbidity burden than 10 years ago. Patients with lumbar fusion tend to be older (57-year-old) than those undergoing thoracic (45-year-old) or cervical fusions (54-year-old). The estimated overall comorbidity burden has increased for all surgical levels. The highest comorbidity burden was observed in patients with thoracic fusion followed by patients with lumbar, and cervical fusions. The increasing patient age and comorbidity burden is consistent with previously reported literature.[4,6] Although surgeons have been operating on sicker and older patients, the mortality rates have remained relatively constant.

Thoracic fusions had the highest mortality rate of 1.2%. Cervical and lumbar fusions had mortality rates of 0.46% and 0.14%, respectively. These rates are consistent with previously reported literature.[16,26] Most perioperative complications have become more frequent. The increasing trends of pulmonary and cardiac complications have

TABLE 1. Multivariate Logistic Regression Model Identifying Risk Factors for Mortality

Risk Factor	Odds Ratio	*P*
Metastatic cancer	9.24	<0.001
Weight loss	7.44	<0.001
Pulmonary circulatory disease	4.43	<0.001
Renal failure	2.90	<0.001
Dementia	2.33	0.03
Past myocardial infraction	2.16	<0.001
Neurological disease	2.07	<0.001
Liver disease	1.88	<0.001
Peripheral vascular disease	1.28	0.02
Diabetes (with chronic complications)	1.11	0.40
Cardiac valvular disease	0.92	0.45

Odds ratio more than 1 represents an increase in risk.
This model takes into account patient age, sex, and comorbidity burden.

been previously reported in cervical and lumbar fusions.[8,26] Complications occur more frequently after thoracic fusions than at any other level. The reasons for the increasing rates of most complications in spinal fusions are difficult to elucidate. Age and presence of comorbidities have been linked with worse perioperative outcomes.[7,26,27] A plausible contributor to increasing complications is the changing methods of surgical patient selection. The increasing complication rates are likely reflective of the older, sicker patients undergoing spinal fusions.

Dysphagia occurred more frequently after cervical surgery than after either lumbar or thoracic surgery. This trend is consistent with previous literature examining dysphagia after spinal surgery.[28–30] Cervical surgery requires extensive manipulation and retraction of the laryngeal anatomy. Local damage, hemorrhage, infection, or damage to the hypoglossal, superior laryngeal, or recurrent laryngeal nerves may contribute to dysphagia after cervical surgery.[31,32]

Using a series of multivariate regression models allowed us to identify patient risk factors that are independently associated with specific perioperative complications. Taking into account patient age, sex, and comorbidities, thoracic level fusion was an independent predictor of a number of complications (Figure 7). A number of confounding factors including length of surgery, estimated blood loss, and operative details such as number of levels fused potentially affect this analysis.

Another possible explanation for the worse outcomes seen after thoracic fusions is that spinal deformity is the most common primary surgical indication. This is in contrast to cervical and lumbar fusions that are primarily done for DDD. Fusions for spinal deformity are typically more extensive involving more levels than fusions for DDD. Cancer-related diagnoses are also significantly more common in thoracic fusions, being the primary diagnosis in about 4% to 5% of thoracic cases comparing with 0.2% to 0.4% of cervical and lumbar fusions.

Patients with primary hypercoagulatability disorders such as protein C or S deficiency or Factor V Leiden had an increased risk for 7 of the 9 postoperative complications investigated. The risk for postoperative VTE or cardiac complications was particularly increased. This association is consistent

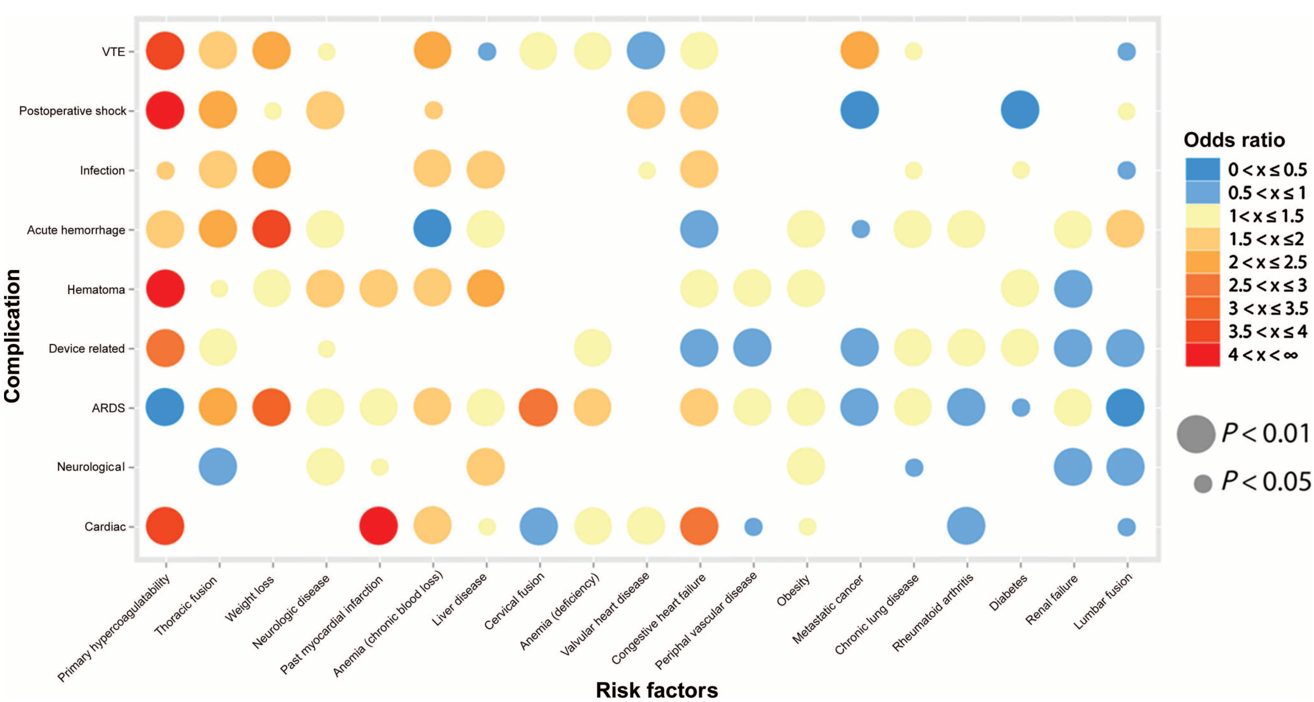

Figure 7. Modified heat map identifying independent predictors of specific postoperative complications. Circle color corresponds to the magnitude of the effect each risk factor had on a complication, circle size corresponds to the statistical significance of that interaction.

with previously published reports.[8,33] The association between thrombophilias and VTE has been observed in a number of patient populations.[34,35] Cardiac complications were more common in patients with past myocardial infractions and congestive heart failure. This is consistent with the Goldman Cardiac Risk Index, a commonly used tool for assessment of perioperative cardiac risk.[36]

Weight loss and chronic blood loss anemia were associated with a number of postoperative complications. Pathological weight loss can represent cachexia secondary to malignancy, malnutrition, or a number of systemic diseases. Chronic blood loss in the elderly is a common symptom of gastrointestinal malignancy. The inferior outcomes observed in patients with chronic blood loss anemia and weight loss are likely a reflection of overall health status and may not represent a direct relationship between the 2 comorbidities and observed complications.

A number of limitations affect this study. Administrative databases use coding systems that allow for organization of large volumes of data, but limit the granularity of data. The presence of specific comorbidities and postoperative complications was detected *via ICD-9* codes, thus the trends observed could be reflections of clinical events or changes in coding practices.

The NIS does not include patient reported outcomes necessary to assess the impact of spinal fusions on health related quality of life measures. The nature of the database allows for identification of events that happened during the index operative admission, but prevents the detection of events that occurred after the initial discharge. Further research is needed using databases that contain patient reported outcomes such as pain and function scores as well as allow for longitudinal tracking of patients to capture events that occur after the index operative admission. Data from such databases would capture more accurate mortality and complication rates.

The epidemiological data on perioperative risks of spinal fusions presented in this study is pivotal to appropriate surgical patient selection and well-informed risk-benefit evaluation of surgical intervention. Analysis of patient comorbidities that predispose to specific postoperative complications will allow for a patient-centered evidence-based approach to selection of surgical candidates. The wealth of empiric evidence available in large administrative databases has the potential to revolutionize our approach to patient care. As the available databases become more sophisticated, so will the surgeon's approach to patient selection. It is important to note that the risks and benefits of surgical intervention only make sense within the context of patient preference. This additional data will allow for a more-informed conversation between patient and physician regarding management options, and will encourage a shared decision-making approach.

CONCLUSION

This study confirms a nationwide increase in spinal fusions. These procedures are being performed on older patients with more comorbidities. Mortality rates have been relatively stable, whereas a number of perioperative complications have increased. The hospital charges for spinal fusions have seen a dramatic increase. This study also identifies patient-related risk factors for specific postoperative complications. Future studies using more sophisticated databases will be able to better define which patients stand to benefit most from surgery.

➢ Key Points

- ❑ The total annual number of spinal fusions and the average cost per fusion has been steadily increasing between 2001 and 2010.
- ❑ Patients undergoing spinal fusions are on average older, and have a greater comorbidity burden than 10 years ago.
- ❑ A number of independent risk factors have been identified for 9 perioperative complications.
- ❑ Patients with primary hypercoagulatability disorders and weight loss had the highest risk of a number of perioperative complications.

Acknowledgment

The authors thank Alexandra Lee for her help and contribution to this project.

Supplemental digital content is available for this article. Direct URL citations appearing in the printed text are provided in the HTML and PDF version of this article on the journal's web site (www.spinejournal.com).

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