Published in final edited form as:

Spine J. 2012 March ; 12(3): 197–206. doi:10.1016/j.spinee.2011.11.008.

Risk Factors for Medical Complication after Spine Surgery: a multivariate analysis of 1591 patients

Michael J. Lee, M.D.^{*}, Mark A. Konodi, M.S., Amy M. Cizik, M.P.H.^{*}, Richard J. Bransford, M.D.^{**}, Carlo Bellabarba, M.D.^{**}, and Jens Chapman, M.D.^{**}

^{*}University of Washington, Department of Orthopedics and Sports Medicine, Seattle, WA

^{**}Harborview Medical Center, Department of Orthopedics and Sports Medicine, Seattle, WA

INTRODUCTION

There have been numerous study models utilized to describe peri-operative complications after spine surgery. Medicare⁵, Workmen's Compensation, and National Inpatient Sample (NIS)^{6,8} administrative data have all been examined to identify risk factors for complication after spine surgery.^{1,2,7,12,13} In addition, peri-operative complications have also been analyzed using retrospective chart review data.

The value in utilizing national databases is that one can simultaneously analyze thousands of patients. The disadvantage in using these databases is that conclusions lack specificity. These databases by their very nature, lack detailed information and are limited by reported codes. Medical co-morbidity, surgical invasiveness and instrumentation are likely to affect the occurrence of complication after spine surgery, yet these important factors may not be accounted for in these large national databases. In addition, not all peri-operative complications may be detected using these models. For example, the NIS only identifies inpatient complications and re-admission for complication may not be linkable to the original procedure. So while general conclusions can be made utilizing these data, specific commentary on individual risk factors may be limited.

Conversely, retrospective chart review analysis of complications in case-series allows for consideration of details that may not be captured in national databases. The obvious limitation in these studies is that smaller numbers preclude meaningful multivariate analysis. Furthermore the retrospective nature of data gathering is not ideal and important information may not be as accurately recorded as would be in a prospective study.

The Spine End Results Registry 2003-2004 is a registry of prospectively collected data of all patients undergoing spinal surgery at the University of Washington Medical Center and Harborview Medical Center. Detailed information regarding patient demographics, medical co-morbidity, surgical invasiveness, and adverse occurrences were obtained prospectively using previous published methods.^{9,10}

© 2011 Elsevier Inc. All rights reserved.

Corresponding Author –Michael J. Lee MD, 1959 Pacific Ave NE, Box 356500, University of Washington Medical Center, Department of Sports Medicine and Orthopaedic Surgery, Seattle WA 98195, mjl3000@uw.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

The purpose of the present study is to assess the relative risk of numerous co-variables for an array of peri-operative medical complications (cardiac, pulmonary, gastro-intestinal, hematological, renal, neurological, death) using univariate and multivariate log binomial analysis. We hypothesized that age, diabetes, revision surgery, medical co-morbidity, surgical invasiveness were significant risk factors for peri-operative morbidity after spine surgery.

MATERIALS and METHODS

Data Source

We examined data from a prospective cohort study of patients undergoing spinal surgery between January 1st 2003 and December 31st 2004 at two academic hospitals: a university based medical center, and a county hospital serving as the only Level I trauma center in a large multi-state area. All patients were prospectively followed for at least 2 years after their surgery using surveillance methods as previously described by Mirza et al.⁹ All patients were followed with institutional review board approval from the University of Washington Medical Center. Detailed information regarding patient demographics, medical co-morbidity, surgical invasiveness, and adverse occurrences were obtained prospectively using previous published methods.^{9,10}

Exclusion Criteria

We excluded patients younger than 18 years of age and those with missing surgical invasiveness data. We also excluded patients whose surgical invasiveness index was either missing or equal to zero as these included patients who did not actually have surgery (closed casting, placement of halo) (Figure).

Medical Complication and Risk Factor Definitions

Medical complications examined fell in to six different categories based on organ system (cardiac, pulmonary, gastrointestinal (GI), renal, neuro, hematological and renal). For each category, detailed definitions of complications are listed in Tables 1A-1F.

We assessed the relative risk of several risk factors using univariate and multivariate analysis. Risk factors assessed include age, gender, smoking status, alcohol abuse, drug use, diabetes, body mass index (BMI), medical co-morbidity (myocardial infarction, history of non MI cardiac disease (valve disease, prolapse, abnormal EKG), congestive heart failure, cerebrovascular disease, chronic obstructive pulmonary disease (COPD), asthma, hypertension, rheumatoid arthritis, renal conditions, pre-existing neoplasm, history of syncope or seizure, anemia, bleeding disorder), previous spinal surgery, primary diagnosis (degenerative, trauma, neoplasm, other), level of surgery (cervical, thoracic, lumbosacral), surgical approach (anterior, posterior, combined). In addition, we assessed the relative risk of death (within 2 years after the surgery) after the occurrence of medical complication based on organ system.

All patients were prospectively followed for medical complication. However, some information about their risk factors, such as smoking status and alcohol use, were missing. We presumed that missing data on risk factors were not clinically significant and were therefore coded as “no” or “absent” or the risk. To test this assumption, we performed the analysis both with and without those who had missing data and it did not change the conclusions. Thus, we present our main findings including those who had missing risk factor data.

Surgical Invasiveness

The Surgical Invasiveness Index is a previously validated instrument that accounts for the number of levels decompressed, fused, or instrumented, posteriorly and anteriorly.¹⁰ It ranges from 0 to 48, with a higher score indicating greater invasiveness. The index is the sum of 6 weighted surgical components: anterior decompression (ad), anterior fusion (af), anterior instrumentation (ai), posterior decompression (pd), posterior fusion (pf), and posterior instrumentation (pi). The weights for each component represent the number of vertebral levels at which each it is performed.⁹ For example, in a C5 – C6 anterior discectomy, with fusion and plating, the score is 5 (ad=1 (one disc) + af = 2 (two vertebrae fused) + ai = 2 (plate at both levels)). For our purpose, we categorized the score into six groups: 1-5, 6-10, 11-15, 16-20, 21-25, greater than 25.

Analysis

Categorical data are presented as the number of cases and percentages. For categorical values, Pearson's Chi-square or Fisher's exact tests (where cell counts were low) were used to assess the effect of various risk factors. Relative risk (RR) and 95% confidence intervals (95% CI) were calculated for each of the categorical variables using univariate and multivariate log-binomial analysis. Multivariate log-binomial analysis was used to examine the association between risk factors and medical complication, adjusting for confounding risk factors. In the model we included risk factors that were deemed of clinical importance by the study investigators to contribute to SSI, were a known confounder, or had a univariate association of $p < 0.10$. Because surgical approach and the number of vertebral levels operated on are a component of the invasiveness index they were not included in the multivariate model.

Statistical analysis was performed using SAS 9.2 software (SAS Inc., Cary, NC) with hypothesis testing using a 2-tailed test of significance and an alpha level of $p < 0.05$.

RESULTS

The demographic distribution of the sample population is summarized in Table 2. The cumulative incidences of complication per organ system are as follows: cardiac - 8.4%, pulmonary – 13%, gastrointestinal – 3.9%, neurological – 7.35%, hematological – 10.75% and urologic complications – 9.18%. Details of these complications are listed in Tables 1A-1F. The figure lists the actual percentage of patients who experienced a medical complication, rather than the cumulative incidence, which is why these numbers differ. Demographic information is listed in Table 2.

The univariate analysis suggested several significant risk factors for medical complication after spine surgery (Table 3A-3B). Age greater than 65 and elevated surgical invasiveness were significant risk factors for complications in all six organ systems evaluated. Hypertension and anemia were significant risk factors for complication in five out of the six organs systems examined. Age 40-64, diabetes, history of congestive heart failure, COPD, or non MI cardiac event, and thoracic spine surgery were significant risk factors for four of the six organ systems evaluated.

The results of the multivariate analysis are summarized in Table 4. Elevated surgical invasiveness and age over 65 were significant risk factors for complication in five of the six organs systems reviewed. Relative risks for death after a complication are listed in Table 4. In both the univariate and multivariate analyses, the occurrence of cardiac and pulmonary complications significantly increased the risk for death. Patients who experienced a cardiac complication were 4.11 times as likely to expire within the study period, and those who

experienced a pulmonary complication were 10.76 times as likely to expire with the study period.

DISCUSSION

Peri-operative medical complications after spine surgery have been well described previously. Numerous risk factors have been suggested to be associated with medical complication throughout the literature; however, with marked inconsistency. For example, while it is intuitive that a larger surgical procedure with greater anesthetic time and blood loss would be associated with greater medical risk to the patient, this finding is inconsistently reported. Some studies have reported that arthrodesis increases medical complications^{1,5} as compared to non-fusion surgeries and other studies have suggested there is no correlation^{2,7,12}. Similarly, the associations of age and medical co-morbidity to post operative medical complication after spine surgery have been inconsistently reported.^{1,2,4,7,11,12}

There is variation in study model as well. Retrospective analyses are inherently limited in the method of data recording and the lower numbers. The observed lack of correlation of intuitive expected risk factors may be a result of insufficient power of these studies. Examination of larger databases such as NIS, Medicare or Workmen's compensation allow for analysis of very large numbers. However, these databases are reliant upon consistent coding among thousands of providers. Furthermore, important potential co-variables, such as surgical invasiveness, are often not accounted for in multivariate analysis.

Surgical invasiveness has been poorly evaluated in prior studies, largely due to the lack of standard metric. In 2006 Mirza et al proposed an index which quantifies the surgical invasiveness using a scoring system for each level decompressed, fused, instrumented, anterior and posteriorly¹⁰. This index has been validated and correlated with surgical blood loss⁹ and the rate of surgical site infection³ and is utilized in the present study.

The University of Washington Medical Center Spine End Results Registry 2003-2004 is a prospective observational cohort of all patients undergoing spine surgery from Jan 1, 2003 to Dec 31, 2004. Detailed information regarding patient demographics, medical co-morbidity, disease severity, surgical invasiveness, and adverse occurrences were prospectively recorded. All patients were followed prospectively for at least two years for the occurrence of medical complication.

The current study evaluates an exhaustive array of risk factors for medical complication after spine surgery utilizing univariate and multivariate analysis of prospectively collected data set of 1591 patients (Tables 3 and 4). Relative risks with 95% confidence intervals and p values are presented. In our multivariate analysis, surgical invasiveness, age older than 65 and previous cardiac event appear to be significantly associated with risk of medical complication in five of the six organ systems evaluated. Furthermore, this study has significantly associated cardiac and pulmonary complication to a 4 to 10 fold increased risk of death. While these findings are fairly intuitive, the present study quantifies these risks with relative risks and 95% confidence intervals. These data and statistical values can greatly equip providers and patients on decision-making when considering surgical and non-surgical treatment options.

Although the multivariate analysis accounts for confounders in its analysis and is technically more accurate than the univariate analysis, we chose to present both analyses in this manuscript. The significance of a risk factor in the univariate analysis, but not the multivariate analysis is likely due to confounding of other co-variables, but may also be due to insufficient sample size to demonstrate such an effect. For example, diabetes was a

significant risk factor for four of the six organ systems in the univariate analysis, but was not significant for any of the organs systems in the multivariate analysis.

To our knowledge, this is the largest study using prospectively collected data examining complications after spine surgery. While there have been larger studies performed, they have been limited by the retrospective nature of data collection and inadequate analysis of all possible confounding co-variables. A prior prospective analysis of complication after surgery was limited to the peri-operative period and its analysis also lacked inclusion of numerous risk factors, which may potentially confound their results. Though no single study is likely to account for all possible risk factors, which may influence the occurrence of a complication after spine surgery, this study represents the most exhaustive effort utilizing prospective data to date, in our opinion.

This study is an exhaustive multivariate analysis of prospectively recorded data; however, there are weaknesses. First, this was an observational cohort without randomization. Surgical decision-making was at the discretion of the surgeons and as such, patients with severe medical co-morbidity were likely advised to avoid surgeries. Although, a large number of patients were trauma patients, the majority of surgeries were elective for non-trauma diagnoses. This selection against patients with a perceived higher risk may have blunted the relative risk of medical complication. Secondly, the recording of data was largely categorical and not continuous. Although smoking and diabetes were recorded as a “yes” or “no”, severity of the condition was not assessed. Neither hemoglobin A1c values nor smoking duration were assessed in the current study.

Despite these weaknesses, the current study provides an exhaustive multivariate analysis of numerous risk factors for medical complication after spinal surgery in 1591 patients. The quantification of the relative risks with confidence intervals, of these co-variables can be beneficial in assisting the clinician and patient with risk stratification and decision-making regarding surgery on the spine. However, a substantial amount of data is presented in this manuscript and while scientifically sound, the presentation of relative risk values and confidence intervals may be difficult to communicate to the patient. The results of this study can serve as a foundation for creating a model to predict the likelihood (probability rather than relative risk) of complication after spine surgery, which may be more easily utilized in clinical settings.

Acknowledgments

UWMC IRB-approved

Supported by grants from the NIH/NIAMS 5K23AR48979 and 5P60-AR48093 and supported in part by the Spine End-Results Research Fund at the University of Washington Medical Center through a gift from Synthes Spine (Paoli, PA)

We would like to acknowledge Dr. Sohail Mirza (Dartmouth Medical Center) for his tremendous contribution to this manuscript.

References

1. Carreon LY, Puno RM, Dimar JR 2nd, et al. Perioperative complications of posterior lumbar decompression and arthrodesis in older adults. *J Bone Joint Surg Am.* 2003; 85-A:2089–92. [PubMed: 14630835]
2. Cassinelli EH, Eubanks J, Vogt M, et al. Risk factors for the development of perioperative complications in elderly patients undergoing lumbar decompression and arthrodesis for spinal stenosis: an analysis of 166 patients. *Spine (Phila Pa 1976).* 2007; 32:230–5. [PubMed: 17224819]

3. Cizik AM, L M, Martin BI, Bransford RJ, Bellabarba C, Chapman JR, Mirza SK. Using the Spine Surgical Invasiveness Index to Identify Risk of Surgical Site Infection: A Multivariate Analysis. 2010 unpublished.
4. Cotton BA, Pryor JP, Chinwalla I, et al. Respiratory complications and mortality risk associated with thoracic spine injury. *J Trauma*. 2005; 59:1400–7. discussion 7-9. [PubMed: 16394913]
5. Deyo RA, Cherkin DC, Loeser JD, et al. Morbidity and mortality in association with operations on the lumbar spine. The influence of age, diagnosis, and procedure. *J Bone Joint Surg Am*. 1992; 74:536–43. [PubMed: 1583048]
6. Kalanithi PS, Patil CG, Boakye M. National complication rates and disposition after posterior lumbar fusion for acquired spondylolisthesis. *Spine (Phila Pa 1976)*. 2009; 34:1963–9. [PubMed: 19652635]
7. Lee DY, Lee SH, Jang JS. Risk factors for perioperative cardiac complications after lumbar fusion surgery. *Neurol Med Chir (Tokyo)*. 2007; 47:495–500. [PubMed: 18037802]
8. Li G, Patil CG, Lad SP, et al. Effects of age and comorbidities on complication rates and adverse outcomes after lumbar laminectomy in elderly patients. *Spine (Phila Pa 1976)*. 2008; 33:1250–5. [PubMed: 18469700]
9. Mirza SK, Deyo RA, Heagerty PJ, et al. Development of an index to characterize the “invasiveness” of spine surgery: validation by comparison to blood loss and operative time. *Spine (Phila Pa 1976)*. 2008; 33:2651–61. discussion 62. [PubMed: 18981957]
10. Mirza SK, Deyo RA, Heagerty PJ, et al. Towards standardized measurement of adverse events in spine surgery: conceptual model and pilot evaluation. *BMC Musculoskelet Disord*. 2006; 7:53. [PubMed: 16787537]
11. Patel N, Bagan B, Vadera S, et al. Obesity and spine surgery: relation to perioperative complications. *J Neurosurg Spine*. 2007; 6:291–7. [PubMed: 17436915]
12. Raffo CS, Laueran WC. Predicting morbidity and mortality of lumbar spine arthrodesis in patients in their ninth decade. *Spine (Phila Pa 1976)*. 2006; 31:99–103. [PubMed: 16395185]
13. Vaidya R, Carp J, Bartol S, et al. Lumbar spine fusion in obese and morbidly obese patients. *Spine (Phila Pa 1976)*. 2009; 34:495–500. [PubMed: 19212274]

Figure.

Flow chart of patients of the sample population including exclusion criteria.

Table 1

A Cardiac Complications	n (incidence)
air embolism Entrapment of air into the venous circulation and heart detected by any monitoring device including Doppler, TEE, or sudden decrease in end tidal CO ₂ , SpO ₂ , or blood pressure or air in coronary vessels on post-mortem exam	3 (0.19%)
arrest Cardiac output insufficient to maintain a palpable central pulse, and requiring CPR, electroshock therapy and/or vasoactive drugs to maintain an adequate perfusion pressure.	7 (0.44%)
arrhythmia(telemetry+Tx or mc06/death) Any cardiac rhythm which varies from baseline and requires either extra monitoring, drugs, consultations, or electroshock therapy, or results in hypotension or death.	47 (3%)
CHF(new S3/JVD+rales/CXR+Tx) An abnormality of cardiac function is responsible for the failure of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues, manifested by pulmonary edema, a new S3 gallop, jugular venous distension, rales, pleural edema or effusion, and requiring treatment.	2 (0.13%)
hypertension Sbp > 180 or Dbp > 100 for > 5minutes	4 (0.25%)
hypotension(sBP/MAP<50%base, >5min) Mean arterial pressure < 50% of baseline for > 5 minutes.	31 (2.0%)
infarction(mc09+enzymes/new Qs) Necrosis of heart tissue as evidenced by elevated ST segments or new Q waves or new wall motion abnormality associated with elevated cardiac enzymes (troponin, CK-MB)	19 (1.2%)
inappropriate or inadequate fluid therapy Insufficient replacement of volume with blood products, crystalloid or other colloid to maintain adequate perfusion and oxygenation of all tissues, as evidenced by inadequate urine output, low central filling pressures, elevated lactate, metabolic acidosis with pH < 7.35, and/or hypotension responsive to fluids. Criteria: (1) inadequate urine output (< 0.5 ml/kg/hr); (2) hypotension responsive to fluid challenge; (3) elevated lactate level; (4) metabolic acidosis (pH < 7.35); and/or (5) low central filling pressures.	7 (0.44%)
ischemia(sx/1mmST 2 leads, ROMI/Tx) Myocardial ischemia is a deficiency of the blood supply to the heart muscle, leading to symptoms, flat depression of the ST segment of more than 0.1 mV below the baseline (i.e., the PR segment) and lasting longer than 0.08 s, treatment, or rule-out MI monitoring.	4 (0.25%)
thermoregulation Temperature < 35°C for > 30min.	0
other cardiac occurrence Other circulation or cardiac-related occurrence.	10 (0.63%)
Total Cardiac Adverse Occurrences	134 (8.4%)
B Pulmonary Complications	n (incidence)
ARDS(FiO₂>50/vent>48h + mc04/mr05/BxAu)	21 (1.3%)

B Pulmonary Complications	n (incidence)
Acute hypoxemic respiratory failure due to pulmonary edema caused by increased permeability of the alveolar capillary barrier. Criteria: (1) FiO ₂ >50%; (2) Ventilator support for >48h; (3) PaO ₂ /FiO ₂ ≤ 300 mm Hg; and (4) bilateral lung infiltrates on CXR.	
empyema Purulent fluid collection in the pleural space confirmed by imaging studies and aspiration or by surgery.	1 (0.06%)
hemothorax Blood in the pleural space confirmed by imaging studies and aspiration or surgery.	2 (0.13%)
pleural effusion Pleural effusion is excess fluid in the pleural space.	20 (1.3%)
postop hypoxia(FiO₂>50×48h or suppl O₂×7d) Requirement for supplemental oxygen post-operatively, with FiO ₂ >50% for 48h or supplemental oxygen by nasal cannula for 7 days.	20 (1.5%)
pneumonia(>38.0+Cx/CXR and Tx) Infection of the lung parenchyma confirmed by fever, sputum or bronchial cultures, CXR, and requiring treatment.	77 (4.8%)
pneumothorax Accumulation of gas in the pleural space resulting in symptoms (tachycardia, hypotension), requiring extra surveillance (e.g. repeat CXRs or pulse oximetry) or treatment (chest tube placement).	9 (0.57%)
pulmonary embolus(CTA/VQ/Angio + Tx) Sudden onset of shortness of breath, tachypnea, cyanosis, tachycardia, hypotension, or chest pain confirmed to be a imaging studies to be a pulmonary thrombus, and requiring treatment; or diagnosis made at autopsy.	23 (1.4%)
respiratory arrest Sudden cessation of voluntary breathing, requiring CPR or mechanical ventilation.	10 (0.63%)
other respiratory Other respiratory problem.	18 (1.1%)
Total Respiratory Adverse Occurrence Events	201 (13%)

C Gastrointestinal Complications	n (incidence)
ascites Effusion and accumulation of serous fluid in the abdominal cavity leading discernable on physical examination or radiologic imaging (free peritoneal fluid >25 ml), leading to symptoms, unplanned evaluation, or requiring treatment.	2 (0.13%)
colitis Inflammation of the colon manifested as diarrhea or bloody diarrhea, sepsis, abdominal pain, or toxic megacolon. Criteria: 1. Rectal discharge; 2. Perineal ulceration; 3. Colonoscopic and biopsy evidence of inflammation.	2 (0.13%)
GI bleeding(heme pos + drop Hct 10% or Tx) Blood loss through the gastrointestinal tract, including hematemesis, melena, hematochezia, occult GI bleeding may be identified in the absence of overt bleeding by special examination of the stool (e.g., guaiac testing), or symptoms of blood loss or anemia such as lightheadedness, syncope, angina, or dyspnea. Criteria: 1. Bloody vomitus or stool; 2. Bleeding from the rectum; 3. Hct decrease > 10%; 4. Lightheadedness, syncope, angina, or dyspnea.	7 (0.44%)
ileus Abdominal distension and no passage of stool or flatus by postoperative day 3.	36 (2.26%)

C Gastrointestinal Complications	n (incidence)
obstruction Pseudo-obstruction is colonic distension in the absence of mechanical obstruction, with cecal diam > 9 cm and air in all colonic segments on plain radiographs.	1 (0.06%)
pancreatitis Acute inflammation of the pancreas with sudden onset of: (1) abdominal pain; (2) nausea; (3) vomiting; (4) high levels pancreas enzymes - serum amylase 3X normal.	1 (0.06%)
perforation Iatrogenic perforation of the stomach, small intestine, or large intestine during the procedure or perforation later caused by implants or instrumentation. Criteria: (1) nausea, vomiting, or ileus; (2) abdominal or groin pain and referred pain; (3) air in the abdomen on plain radiograph or CT or other imaging study; (4) abdominal distension and tenderness; OR surgical finding of perforation.	2 (0.13%)
peritonitis Inflammation or infection of the peritoneum with symptoms of: (1) abdominal pain and tenderness; (2) constipation; (3) vomiting; (4) moderate fever.	0
other GI occurrence Other GI-related occurrence.	11 (0.69%)
Total Gastrointestinal Adverse Occurrence Events	62 (3.90%)

D Neurological Complications	n (incidence)
CVA/TIA(new focal deficit orCT/MR orBxAu) The abrupt onset of a nonconvulsive and new focal neurologic deficit due to a reduction of blood flow to the brain, or abnormality on imaging studies suggestive of a CNS infarct, or CNS infarction confirmed by biopsy or autopsy.	8 (0.50%)
cerebral perfusion(ICP>20orCPP<30 for>5min) Reduction in the flow of blood to the brain during the procedure for > 5 minutes, with intracranial pressure >20 or cerebral perfusion pressure < 30 mmHg.	1 (0.063%)
delerium(confusion>24h +Tx/sitter/restraint) Acute change in level of consciousness characterized by reduced ability to maintain attention to external stimuli, lethargy, or agitation, and disorganized thinking as manifested by rambling, irrelevant, or incoherent speech. Criteria: (1) confusion > 24 hr; and (2) was not related to narcotics; and (3) patient required restraints or continuous supervision.	53 (3.33%)
diabetes insipidus Excessive urine production from reduced production or responsiveness to ADH. Diagnosis can be made by relating plasma to urine osmolality, particularly in postoperative neurosurgical patients or after head trauma, where its use can permit quick differentiation of diabetes insipidus from parenteral fluid excess.	0 (0%)
electrolyte change (Na<130/>150, K>5.5, other) The electrolyte balance of the extracellular fluid was sufficiently changed from normal to require extra monitoring, evaluation, or treatment beyond routine post-operative care. Specifically: Na < 130 or > 150 or K >5.5	20 (1.26%)
meningitis(pos Cx/Bx or CT/MR and Tx) Inflammation of the meninges (the pia-arachnoid) and the cerebrospinal fluid (CSF) of the subarachnoid space associated with symptoms of fever, headache, nausea/diarrhea/abdominal pain, and confirmed by CSF cultures or biopsy, imaging studies, and requiring treatment.	9 (0.57%)
SAH/intracerebral hemorrhage Hemorrhage in the space between the arachnoid membrane and pia matter (subarachnoid) causing compression of the brain associated with sudden headache, neurological deficit, and confirmed with imaging studies or blood in the CSF. May also occur in the spinal cord in association with sudden back pain.	1 (0.063%)

D Neurological Complications	n (incidence)
seizure A paroxysmal event due to abnormal, excessive, hypersynchronous discharges from an aggregate of central nervous system (CNS) neurons with manifestations ranging from convulsive activity to experiential phenomena not discernible by an observer, confirmed by EEG or neurology consultation.	1 (0.063%)
withdrawal, alcohol(history + mn03 + Tx) A patient with history of alcohol abuse exhibits anxiety, confusion and delirium after the cessation of alcohol intake, requiring treatment.	4 (0.25%)
withdrawal, narcotic The patient exhibits symptoms of nausea and diarrhea, coughing, lacrimation, mydriasis, rhinorrhea, profuse sweating, twitching muscles, and piloerection, or "goose bumps"; mild elevations in body temperature, respiratory rate, and blood pressure after reduction or cessation of narcotic intake, with improvement in symptoms after opioid administration.	1 (0.063%)
other neurologic occurrence Other neurologic occurrence.	19 (1.19%)
Total Neurologic Adverse Occurrence Events	117 (7.35%)

E Hematological Complications	n (incidence)
coagulopathy(INR>2 or Plts<50 or Fib<100) Any disorder reducing the ability of the blood to clot. Severity 1: INR>_1.5 and < 2.0, or platelets <_100k and >50k Severity 2: INR>_2.0 and < 3.0, or platelets <_50k and >20k Severity 3: INR>_3.0, or platelets <_20k	13 (0.82%)
DVT (confirmed by imaging) The presence of thrombosis of the iliac, femoral, or popliteal or other veins confirmed by imaging studies (duplex scan, CT, or MR) with or without swelling, warmth, erythema, or tenderness.	52 (3.27%)
OR hemorrhage >3000cc Blood loss of greater than 3 L during the procedure.	52 (3.27%)
transfusion occurrence The patient required an unplanned transfusion during or after the procedure, or adverse reaction to blood product transfusion.	48 (3.02%)
other hematologic occurrence Other hematologic adverse occurrence.	6 (0.38%)
Total Hematologic Adverse Occurrence Events	171 (10.75%)

F Urologic Complications	n (incidence)
Foley catheter trauma Injury to the urethra or bladder caused during normal insertion or removal of the Foley catheter, or during inadvertent removal of the catheter.	6 (0.38%)
renal insufficiency (Cr >2 over base) <i>Operational definition:</i> Failure of the kidneys characterized by rapid decline in glomerular filtration rate (hours to days), retention of nitrogenous waste products, and perturbation of extracellular fluid volume and electrolyte and acid-base homeostasis. Criteria: serum Cr >2 above baseline.	14 (0.88%)

F Urologic Complications	n (incidence)
urinary retention Inability to empty bladder under voluntary control.	34 (2.14%)
UTI The presence of large amounts of bacteria (>100,000 organisms/mL) in the upper or lower urinary tract associated with symptoms or requiring treatment.	89 (5.59%)
other urologic event Other urologic adverse occurrence.	3 (0.19%)
Total Urologic Adverse Occurrence Events	146 (9.18%)

Table 2

Demographic Tables

Risk Factors	N = 1591	Risk Factors	N = 1591
Age (yr), mean (sd)	49.6 (16.0)	Gender	
18 - 39	431 (27%)	Male	914 (57%)
40 - 64	859 (54%)	Female	677 (43%)
≥65	301 (19%)		
Smoking		Surgical Approach	
No	1024 (68%)	Posterior	934 (59%)
Yes	488 (32%)	Anterior	292 (18%)
Alcohol		Combined	365 (23%)
No	923 (58%)		
Yes	668 (42%)	Revision	
Drug Use		No	1306 (82%)
No	1424 (90%)	Yes	285 (18%)
Yes	167 (10%)		
Diabetes		Diagnosis Level	
No	1412 (89%)	Cervical	582 (37%)
Yes	179 (11%)	Thoracic	242 (15%)
		Lumbar	754 (47%)
BMI	27.7 (6.5)	Sacral	13 (1%)
Underweight (< 18.5)	10 (7%)		
Normal (18.5 - < 25)	47 (9%)	Diagnosis Group	
Overweight (25 - < 30)	54 (11%)	Degenerative	991 (62%)
Obese (30 - < 35)	28 (10%)	Trauma	372 (23%)
≥ 35	22 (13%)	Neoplasm	117 (7%)
		Infection	59 (4%)
		Other	52 (3%)
Charlson Comorbidity, mean (sd)	1.2 (1.6)	Invasiveness Index, mean (sd)	8.5 (7.5)
0	723 (48%)	1 - 5	733 (46%)
1	319 (21%)	6 - 10	410 (26%)
2	187 (12%)	11 - 15	240 (15%)
3	135 (9%)	16 - 20	92 (6%)
4	77 (5%)	21 - 25	47 (3%)
≥ 5	80 (5%)	> 25	69 (4%)

Table 3**A: Significant Risk Factors for Medical Complication after univariate analysis**

Risk Factors for Cardiac Cx			
	RR	p	95% CI
Age 40-64 (ref 18-40)	2.87	0.006	1.30 - 6.35
Age >65 (ref 18-40)	12.1	<0.001	5.59 - 26.1
Diabetes	2.07	0.001	1.33 - 3.22
Previous cardiac incident	3.88	<0.001	2.62 - 5.76
Prior Myocardial Infarction	2.9	<0.001	1.77 - 4.76
Congestive Heart Failure	5.91	<0.001	3.88 - 9.00
Cerebrovascular Disease	3.08	<0.001	1.89 - 5.02
COPD	2.28	0.002	1.36 - 3.81
Hypertension	2.29	<0.001	1.59 - 3.31
History of Cancer	1.98	0.002	1.27 - 3.07
Revision Surgery	1.98	<0.001	1.34 - 2.94
Syncope or Seizure	1.87	0.05	1.01 - 3.45
Anemia	1.85	0.02	1.09 - 3.14
Surgical Invasiveness (ref score 1-5)	2.37	0.008	1.25 - 4.48
Risk Factors for Pulmonary Cx			
Age >65 (ref 18-40)	2.28	<0.001	1.50 - 3.46
Smoking	1.42	0.04	1.02 - 1.97
Diabetes	2.16	0.001	1.33 - 3.22
Previous cardiac incident	2.44	<0.001	1.67 - 3.58
COPD	2.5	<0.001	1.65 - 3.78
Hypertension	1.46	0.02	1.07 - 2.00
Cancer	1.93	<0.001	1.33 - 2.82
Anemia	1.88	0.005	1.22 - 2.90
Surgical Invasiveness	4.44	0.001	1.70 - 11.6
Trauma Dx (ref degenerative)	5.13	<0.001	3.59 - 7.34
Infection Dx (ref degenerative)	2.87	0.006	1.34 - 6.12
Neoplasm Dx (ref degenerative)	3.31	<0.001	1.92 - 5.70
Thoracic (ref cervical)	2.12	<0.001	1.51 - 2.98
Lumbar (ref cervical)	0.48	<0.001	0.33 - 0.72
Surgical Invasiveness (ref score 1-5)	2.42	0.002	1.39 - 4.23
Risk Factors for GI Cx			
Age 40-64 (ref 18-40)	3.11	0.01	1.22 - 7.94
Age >65 (ref 18-40)	5.73	<0.001	2.17 - 15.1
Previous cardiac incident	2.46	0.004	1.33 - 4.55
Hypertension	1.99	0.008	1.19 - 3.32
Bleeding Disorder	1.77	0.14	0.82 - 3.83
Anemia	2.97	<0.001	1.58 - 5.59
Revision surgery	1.83	0.03	1.04 - 3.23

Risk Factors for Cardiac Cx			
	RR	p	95% CI
Combined Approach (ref posterior)	2.77	<0.001	1.61 - 4.76
Surgical Invasiveness (ref score 1-5)	3.98	0.007	1.61 - 9.85
B: Significant Risk Factors for Medical Complication after univariate analysis			
Risk Factors for Neurological Cx			
Age 40-64 (ref 18-40)	2.79	0.003	1.38 - 5.61
Age >65 (ref 18-40)	6.05	<0.001	2.97 - 12.3
Diabetes	2.18	<0.001	1.38 - 3.44
Female	1.63	0.01	1.10 - 2.40
Previous cardiac incident	2.79	<0.001	1.74 - 4.84
Congestive Heart Failure	2.81	<0.001	1.54 - 5.15
Cerebrovascular Disease	2.39	0.003	1.36 - 4.22
COPD	3.19	0.003	1.36 - 4.22
Hypertension	2.16	<0.001	1.47 - 3.16
Cancer	2.08	0.002	1.32 - 3.27
Syncope/Seizure Hx	2.06	0.02	1.11 - 3.82
Anemia	2.05	0.009	1.20 - 3.50
Thoracic (ref cervical)	1.97	0.006	1.21 - 3.20
Bleeding Disorder	1.86	0.03	1.05 - 3.31
Combined Approach (ref posterior)	1.77	0.006	1.18 - 2.66
Surgical invasiveness	7.21	<0.001	4.03 - 12.9
Risk Factors for Hematological Cx			
Age 40-64 (ref 18-40)	2.33	<0.001	1.40 - 3.89
Age >65 (ref 18-40)	3.54	<0.001	2.05 - 6.09
Female	1.47	0.02	1.07 - 2.03
BMI>35 (ref 18.5 -25)	1.72	0.03	1.07 - 2.76
Congestive Heart Failure	1.91	0.04	1.05 - 3.45
Hypertension	1.43	0.03	1.03 - 1.98
Rheumatoid Arthritis	2.21	0.002	1.35 - 3.61
Renal Disease	1.89	0.008	1.19 - 2.99
Anemia	1.82	0.01	1.15 - 2.89
Bleeding Disorder	2.79	<0.001	1.87 - 4.15
Dx Infection (ref degenerative)	2.1	0.04	1.11 - 3.99
Dx Neoplasm (ref degenerative)	1.76	0.03	1.05 - 2.97
Thoracic (ref cervical)	2.09	0.003	1.28 - 3.43
Lumbar (ref cervical)	1.89	0.002	1.26 - 2.83
Revision surgery	1.94	<0.001	1.38 - 2.73
Combined Approach (ref posterior)	2.48	<0.001	1.79 - 3.44
Surgical Invasiveness	7.37	<0.001	4.27 - 12.7
Risk Factors for Urological Cx			
Age >65 (ref 18-40)	2.26	<0.001	1.41 - 3.61
COPD	1.83	0.02	1.13 - 2.98

Risk Factors for Cardiac Cx			
	RR	p	95% CI
Diabetes	1.88	0.003	1.25 - 2.82
Rheumatoid Arthritis	2.5	0.003	1.37 - 4.57
Renal disease	1.74	0.03	1.07 - 2.85
Thoracic (ref cervical)	1.75	0.01	1.14 - 2.69
Dx Trauma (ref degenerative)	2.57	<0.001	1.79 - 3.68
Surgical Invasiveness	2.81	0.002	1.47 - 5.35

TABLE 4

Significant Risk Factors for Medical Complication after multivariate log-binomial regression analysis

Risk Factors for Cardiac Cx			
	RR	p	95% CI
Age >65 (ref age 18-40)	3.15	<0.0001	2.11 - 4.75
Congestive Heart Failure	3.08	<0.0001	2.03 - 4.5
Prev Cardiac Hx	1.83	0.002	1.19 - 1.91
Syncope/Seizure Hx	1.83	0.002	2.03 - 4.50
Surgical Invasiveness (ref score 0-5)	1.87	<0.0001	1.35 - 3.97
Risk Factors for Pulmonary Cx			
Female	0.65	0.024	0.43 - 0.94
Age >65 (ref age 18-40)	1.61	0.008	1.12 - 2.34
Congestive Heart Failure	1.99	0.007	2.01 - 3.29
COPD	1.97	0.0009	1.34 - 2.98
Surgical Invasiveness (ref score 0-5)	3.23	<0.0001	1.40 - 4.76
Dx Trauma (ref Degenerative)	5.5	<0.0001	3.54 - 8.76
Dx Neoplasm (ref Degenerative)	2.68	0.003	1.51 - 5.51
Risk Factors for GI Cx			
Age 41-64 (ref age 18-40)	2.77	0.032	1.18 - 8.10
Age >65 (ref age 18-40)	4.05	0.005	1.61 - 12.28
Ant-Post Approach (ref posterior)	2.66	0.0003	1.56 - 4.52
Risk Factors for Neurological Cx			
Age 41-64 (ref age 18-40)	2.77	0.018	1.28 - 7.22
Age >65 (ref age 18-40)	4.26	0.001	1.89 - 11.38
COPD	2.08	0.002	1.25 - 3.31
Cerebrovascular Disease	4.77	<0.0001	2.85 - 7.80
Surgical Invasiveness (ref score 0-5)	3.81	<0.0001	2.03 - 5.76
Risk Factors for Hematological Cx			
Age 41-64 (ref age 18-40)	1.96	0.03	1.10 - 3.81
Age >65 (ref age 18-40)	2.32	0.015	1.21 - 4.75
Surgical Invasiveness (ref score 0-5)	2.57	0.002	1.41 - 4.81
Risk Factors for Urological Cx			
Dx Trauma (ref Degenerative)	2.28	0.006	1.23 - 4.11
Rheumatoid Arthritis	2.42	0.014	1.09 - 4.64
Surgical Invasiveness (ref score 0-5)	2.83	0.009	1.18 - 5.81
Death			
Cardiac Cx	4.11	<0.0001	2.09 - 8.23
Pulmonary Cx	10.76	<0.0001	5.16 - 22.72