



Predicting critical care unit-level complications after long-segment fusion procedures for adult spinal deformity

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Background: To identify predictive factors for critical care unit-level complications (CCU complication) after long-segment fusion procedures for adult spinal deformity (ASD).

Methods: The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database [2010–2014] was reviewed. Only adult patients who underwent fusion of 7 or more spinal levels for ASD were included. CCU complications included intraoperative arrest/infarction, ventilation >48 hours, pulmonary embolism, renal failure requiring dialysis, cardiac arrest, myocardial infarction, unplanned intubation, septic shock, stroke, coma, or new neurological deficit. A stepwise multivariate regression was used to identify independent predictors of CCU complications.

Results: Among 826 patients, the rate of CCU complications was 6.4%. On multivariate regression analysis, dependent functional status (P=0.004), combined approach (P=0.023), age (P=0.044), diabetes (P=0.048), and surgery for over 8 hours (P=0.080) were significantly associated with complication development. A simple scoring system was developed to predict complications with 0 points for patients aged <50, 1 point for patients between 50–70, 2 points for patients 70 or over, 1 point for diabetes, 2 points dependent functional status, 1 point for combined approach, and 1 point for surgery over 8 hours. The rate of CCU complications was 0.7%, 3.2%, 9.0%, and 12.6% for patients with 0, 1, 2, and 3+ points, respectively (P<0.001).

Conclusions: The findings in this study suggest that older patients, patients with diabetes, patients who depend on others for activities of daily living, and patients who undergo combined approaches or surgery for over 8 hours may be at a significantly increased risk of developing a CCU-level complication after ASD surgery.

Keywords: Adult spinal deformity (ASD); Clavien-Dindo complications; major complications; critical care; National Surgical Quality Improvement Program (NSQIP)

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Introduction

Adult spinal deformity (ASD) has been increasingly recognized as an important cause of pain and disability, particularly in the elderly population (1). The etiology of ASD can be variable and include degenerative, idiopathic,

and iatrogenic causes but also can present as a progression of adolescent scoliosis. Surgery, although not without major risks, has been shown to provide excellent outcomes in most patients (2-5). While corrective surgeries are considered relatively safe procedures, major complications such as reintubation, myocardial infarction, cardiac arrest, among

others, may still occur.

The modified Clavien-Dindo classification system was developed in 2004 as a tool to help clinicians identify and describe surgical complications (6). This system categorizes postoperative complications into five grades, depending on the severity and, more importantly, on the therapy required to treat such complications (6). For example, Grade II complications include pneumonia or arrhythmia, both of which can be treated with medications. On the other hand, Grade 4 complications, including respiratory failure requiring intubation, or new stroke, require critical/intensive care and are usually defined as life-threatening.

The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) is a prospective surgical database developed as a tool to help identify patients at highest risk of postoperative complications, in an effort to reduce healthcare costs and improve treatment quality. Multiple studies have used it to identify patients at higher risk for complications after spine surgery (7-11), but there is limited data on complications requiring critical care. Thus, the purpose of the present study was to develop a predictive model to identify patients at risk for Clavien-Dindo Grade 4 complications, specifically after long-segment fusion procedures for ASD.

Methods

Study design and data source

This is a case-control retrospective study utilizing the ACS-NSQIP databases from 2010 to 2014 (<https://www.facs.org/quality-programs/acs-nsqip>). This study was deemed exempt from review by the local institutional review board [2016-6862]. NSQIP is a surgical database from over 500 hospitals in the United States that collects perioperative and 30-day follow-up data on randomly assigned cases. A trained surgical reviewer at each participating hospital collects data via chart reviews, letters, and/or phone calls. The current success rate in data capture and inter-rater reliability for all variables is approximately 95% (12).

Collected data

Adult patients over 18 years of age with a principal diagnosis of spinal deformity were first identified via use of ICD-9 codes for kyphosis (737.10), acquired postural kyphosis (737.10), postlaminectomy kyphosis (737.12), other acquired kyphosis (737.19), kyphoscoliosis (737.3),

idiopathic kyphoscoliosis (737.30), thoracogenic scoliosis (737.34), and other kyphoscoliosis (737.39). Only patients who underwent fusion of 7 or more spinal segments were identified via the CPT codes 22802, 22743, 22804, and/or 22844. Patients with ventilator dependency (n=5), cancer (n=3), quadraparesis (n=3), and history of previous stroke with neurological deficit (n=3) were excluded from this study.

Collected patient data included age, sex, body mass index (BMI), smoking status, history of chronic obstructive pulmonary disease, hypertension, diabetes, congestive heart failure, chronic steroid use, bleeding disorder, dependent functional status (requiring assistance from others for activities such as bathing, dressing, mobility, feeding, and toileting), preoperative albumin, and preoperative hematocrit.

Examined operative parameters included revision status, laminectomy, interbody fusion, use of osteotomy, use of three-column osteotomy (3CO), pelvic fixation, combined anterior/posterior approaches, operative time, and use of blood transfusion.

Outcome measures

The primary outcome measure was development of at least one critical care unit (CCU)-level complication. Based on the Clavien-Dindo definition, these complications included intraoperative arrest/infarction, ventilation >48 hours, pulmonary embolism, renal failure requiring dialysis, cardiac arrest, myocardial infarction, unplanned intubation, septic shock, stroke, coma, or the occurrence of new neurological deficits (6,13,14).

Statistical analysis

All analyses were performed on Stata SE 12 (Stata Corp., College Station, Texas, USA). Descriptive statistics were used to describe the study population and comparison between groups (CCU *vs.* No-CCU) was done via *t*-tests or Pearson chi-squared tests. A stepwise multivariate logistic regression analysis with backward elimination was performed to identify significant predictors of CCU complications. Results are presented as odds ratios (OR) with 95% confidence intervals (CI). Significant predictors were used to construct the final predictive model and the area under the receiver operating characteristic curve (AUROC) was calculated. Statistical significance was set at $P < 0.05$.

Table 1 Critical care unit-level complications after long-segment fusion procedures for adult spinal deformity in 840 patients

| Complication | Frequency (%) |
|-------------------------------------|---------------|
| At least one complication | 53 (6.4) |
| Intraoperative arrest or infarction | 0 (0.0) |
| Prolonged ventilation | 20 (2.4) |
| Pulmonary embolism | 15 (1.8) |
| Renal failure requiring dialysis | 2 (0.2) |
| Cardiac arrest | 2 (0.2) |
| Myocardial infarction | 6 (0.7) |
| Unplanned intubation | 18 (2.1) |
| Septic shock | 4 (0.5) |
| Cerebrovascular accident | 2 (0.2) |
| Coma | 0 (0.0) |
| New neurological deficit | 1 (0.1) |

Results

A total of 826 patients who underwent more than 7-level fusion for ASD were included in this study, 53 of whom (6.4%) developed at least one CCU complication. The most common complication was prolonged ventilation (2.4%), followed by unplanned intubation (2.1%) and pulmonary embolism (1.8%) (Table 1). The average age of all patients was 56.0±18.1 years and 74.7% were female. Between the CCU and No-CCU groups, there were significant differences in age (61.3±13.1 vs. 55.6±18.3, $P=0.004$), prevalence of diabetes (17.0% vs. 8.3%, $P=0.031$), and prevalence of dependent functional status (17.0% vs. 6.3%, $P=0.003$) (Table 2).

Operative parameters were relatively similar between groups (Table 3). However, there were significant differences in the proportion of patients who underwent a combined approach (22.6% in the CCU group vs. 10.2% in the No-CCU group, $P=0.005$) and who underwent surgery for over 8 hours (39.6% vs. 25.5%, $P=0.024$).

Model construction

All factors with a P value less than 0.05 on univariate analysis were included in a stepwise multivariate logistic regression analysis with backward elimination to construct the predictive model (Table 4). Factors that were used to construct the model included dependent functional status

($P=0.004$), combined approach ($P=0.023$), age ($P=0.044$), diabetes ($P=0.048$), and surgery for over 8 hours ($P=0.080$). Although long operative time did not reach statistical significance, this parameter was included in the final model due to the growing body of evidence suggesting its association with worse short-term outcome after spine surgery (7,15,16).

The final model assigned 2 points for dependent functional status, 1 point for combined approach, 1 point for diabetes, and 1 point for surgery >8 hours. Furthermore, we subdivided age in subgroups assigning 0 points for patients aged <50, 1 point for patients between 50–70, 2 points for patients 70 or over (Table 5). The minimum score is 0 and the maximum is 7. The numeric point assignment was based on the relative P value on multivariate analysis.

Association of predictive model with outcome

There were 142 patients with 0 points (17.2%), 253 with 1 point (30.6%), 288 with 2 points (34.9%), and 143 patients with 3 or more points (17.3%); there was a significant increase in CCU complications with increasing points ($P<0.001$) (Figure 1): the rates of CCU complications was 0.7%, 3.2%, 9.0%, and 12.6% for patients with 0, 1, 2, and 3+ points, respectively ($P<0.001$). The AUROC was calculated at 0.721.

Discussion

Although surgical ASD correction has been shown to provide substantial benefits in terms of pain, self-image, quality of life, and function compared to non-operative treatment (17–19), surgery has been associated with significant morbidity and economic costs (2,20). As a consequence, efforts have been made to reduce postoperative complications, including identification of patient and/or operative risk factors to use in the surgical decision-making process (10,21,22). However, there is limited data about risk factors for CCU complications. The main objective of this investigation is to address this shortcoming.

We examined 826 patients who underwent adult scoliosis and found a 6.4% CCU complication rate. Logistic regression analysis then revealed five factors to be the strongest predictors of CCU events, including patient age, diabetes, dependent functional status, combined approach and length of surgery. The final predictive model assigned various points for each parameter, ranging from 0 to a

Table 2 Demographics of 840 patients who underwent fusion of 7 or more spinal segments for adult spinal deformity (univariate analysis)

| Parameter | All patients | CCU | No-CCU | P value |
|-----------------------------|--------------|-----------|-----------|---------|
| Number of cases | 826 | 53 | 773 | – |
| Mean age | 56.0±18.1 | 61.3±13.1 | 55.6±18.3 | 0.004* |
| Male | 25.3 | 28.3 | 25.1 | 0.604 |
| Female | 74.7 | 71.7 | 74.9 | |
| Average BMI | 27.8±6.6 | 28.5±8.8 | 27.7±6.4 | 0.506 |
| Obesity | 33.1 | 37.7 | 32.7 | 0.454 |
| Smoker | 15.0 | 15.1 | 15.0 | 0.986 |
| COPD | 5.2 | 7.6 | 5.1 | 0.428 |
| Hypertension | 48.3 | 60.4 | 47.5 | 0.069 |
| Diabetes | 8.8 | 17.0 | 8.3 | 0.031* |
| Congestive heart failure | 0.2 | 0.0 | 0.2 | 0.711 |
| Chronic steroid use | 5.0 | 5.7 | 4.9 | 0.809 |
| Bleeding disorder | 1.8 | 3.8 | 1.7 | 0.270 |
| Dependent functional status | 7.0 | 17.0 | 6.3 | 0.003* |
| Preoperative albumin | 4.0±0.5 | 4.0±0.6 | 4.0±0.5 | 0.956 |
| Preoperative hematocrit | 38.4±5.0 | 38.1±6.4 | 38.5±4.9 | 0.733 |

*, statistically significant result. CCU, critical care unit; BMI, body mass index; COPD, chronic obstructive pulmonary disease.

Table 3 Operative parameters (univariate analysis)

| Parameter | All patients | CCU | No-CCU | P value |
|-----------------------------|--------------|---------|---------|---------|
| Number of cases | 826 | 53 | 773 | – |
| Revision (%) | 9.2 | 5.7 | 9.4 | 0.357 |
| Laminectomy (%) | 29.8 | 32.1 | 29.6 | 0.706 |
| Interbody fusion (%) | 27.5 | 28.3 | 27.4 | 0.890 |
| Osteotomy (%) | 44.3 | 45.3 | 44.2 | 0.883 |
| 3-column osteotomy (%) | 12.8 | 15.1 | 12.7 | 0.611 |
| Pelvic fixation (%) | 46.5 | 55.9 | 46.0 | 0.260 |
| Combined approach (%) | 11.0 | 22.6 | 10.2 | 0.005* |
| Operative time (mean hours) | 6.7±2.4 | 7.9±3.0 | 6.6±2.4 | 0.004* |
| Surgery >8 hours (%) | 26.4 | 39.6 | 25.5 | 0.024* |
| Blood transfusion (%) | 69.5 | 77.4 | 69.0 | 0.199 |

*, statistically significant result. CCU, critical care unit.

Table 4 Multivariate analysis

| Variable | OR | 95% CI | P value |
|-----------------------------|------|-----------|---------|
| Increasing age | 1.02 | 1.00–1.04 | 0.044* |
| Diabetes | 2.21 | 1.00–4.88 | 0.048* |
| Dependent functional status | 3.21 | 1.45–7.13 | 0.004* |
| Combined approach | 2.30 | 1.12–4.74 | 0.023* |
| Surgery >8 hours | 1.71 | 0.93–3.13 | 0.080** |

*, statistically significant result; **, included in the model. OR, odds ratio; CI, confidence interval.

Table 5 Scoring system for predicting CCU complications after long-segment fusion procedures for adult spinal deformity

| Component | Points |
|-----------------------------|--|
| Dependent functional status | 2 points if yes |
| Age | 0 points if age <50 1 point if age 50–70 2 points if age ≥70 |
| Diabetes | 1 point if yes |
| Combined approach | 1 point if yes |
| Surgery >8 hours | 1 point if yes |

Score ranges from 0 to 7. CCU, critical care unit.

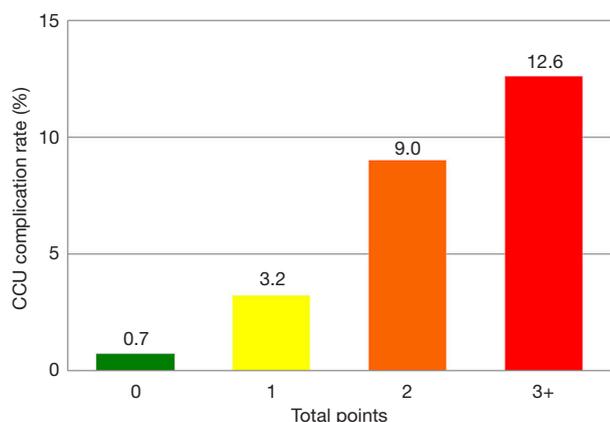


Figure 1 Complication rates based on total points in the predictive model (P<0.001). CCU, critical care unit.

maximum of 7 points. Complication rates significantly increased with increasing points. Although multiple studies have identified factors associated with complication occurrence after ASD surgery, our present study offers a relatively simple 5-element scoring system that could

potentially be the foundation for future predictive models, particularly for CCU complications.

Patient age has been shown in multiple studies to be associated with worse outcomes after spine surgery (8,9,23–25). Phan *et al.* examined 5,095 patients who underwent surgery for adult scoliosis, finding 30-day complication rates of 19.4%, 21.8%, 27.4%, and 31.4% for patients aged <52, 53–61, 62–69, and 70 or older, respectively (P<0.001) (9). In their study, they postulated that while chronological age and biological age are not directly correlated, the former may still be used as a valuable tool for preoperative risk stratification (9).

The second parameter that was included in our predictive model was diabetes. This comorbidity is currently one of the top 10 causes of mortality in the United States, with an estimated prevalence of approximately 9% of the population (26). Several studies have also suggested an increase in perioperative complications after spinal surgery (27–29). Klemencsics *et al.* examined 1,030 patients who underwent elective routine lumbar spine surgery, and found a surgical site infection rate of 3.5%. Multivariate analysis to build a predictive model identified diabetes as an independent predictor for infections (27). Similarly, Bohl *et al.* found both non-insulin and insulin-dependent diabetes to be significant risk factors for postoperative pneumonia after lumbar spine surgery, with relative risks of 2.4 and 2.9, respectively (29).

Preoperative functional status, as assessed in the NSQIP database, indicates whether a person requires assistance for activities of daily living. While it may be the result of a patient’s baseline comorbidities or severe spinal deformity leading to pain/disability, a recent study examining 1,247 patients who underwent deformity surgery found that being dependent on others increased the risk of major postoperative complications by a factor of 2.09 after multivariate adjustment (17.1% rate in dependent patients and 9.2% in independent patients, P=0.0200) (7).

Lastly, combined approaches and long operative time were also associated with CCU complications in our study. Pourfeizi *et al.* compared 25 patients treated via a posterior approach to 25 patients treated via a combined approach for the treatment of scoliotic curves of over 70 degrees (30). The authors found that patients treated via combined approaches had significantly longer total lengths of stay (26.5 vs. 11.8 days, P<0.001) and intensive care unit stay (4.7 vs. 1.5 days, P<0.001) (30). Prolonged operative time (defined as over 8 hours in our study) has also shown to be an important predictor of perioperative complications

(7,31,32); Puffer *et al.*, for example, showed that both total operative time and anesthetic time were associated with wound infection following spine surgery (31). Prolonged operative time leaves the wound exposed for longer periods of time, is associated with higher blood loss, prolonged anesthetic use, and others, all of which could contribute to the increased rate of complications after deformity surgery.

Overall, the findings of the present study may provide the foundation towards a clinical predictive model to assist patients and clinicians in preoperative risk stratification for deformity surgery, particularly for complications that may require critical care or are potentially life threatening. Although NSQIP has built a risk calculator for all surgical procedures (<http://riskcalculator.facs.org/RiskCalculator/>), our current model is tailored to long-segment fusion procedures for scoliosis, with an AUROC of 0.702 suggesting good model fit. Nonetheless, there are limitations to the use of this database for spine surgery patients, such as lack of radiographic parameters or more specific clinical findings. Although there was a significant stepwise association between increasing score and complications, other unmeasured variables may alter the results, and future validation is needed.

Conclusions

A scoring system for patients undergoing long-segment fusion procedures for ASD was built and shown to predict 30-day complications requiring critical care. Although future research is needed to corroborate our findings, this may provide a framework for identification of patients at highest risk for major complications following deformity surgery.

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None.

Footnote

Conflicts of Interest: The abstract of this manuscript was presented as an electronic poster in Congress of Neurological Surgeon's Annual Meeting 2017 in Boston Massachusetts, October 7–11, 2017.

Ethical Statement: This study was deemed exempt from review by the local institutional review board [2016-6862]. The ACS-NSQIP and the hospitals participating in the ACS-NSQIP are the source of the data used herein; they

have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

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