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Short-Term Complications of Anterior Fixation of Odontoid Fractures

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Abstract

Study Design: Retrospective study.

Objective: Anterior fixation of odontoid fracture has been associated with high morbidity and mortality in small, single institution series. Identifying risk factors may improve risk stratification and highlight factors that could be optimized preoperatively. The objective of this study was to determine the 30-day complication rate following anterior fixation of odontoid fractures and to identify associated risk factors among patients in a large national database.

Methods: Patients who underwent anterior fixation were identified in the American College of Surgeons National Quality Improvement Program database (ACS NSQIP) from 2007 to 2012. Patient demographics, medical comorbidities, perioperative complications, and postoperative complications up to 30 days were analyzed by univariate and multivariate analysis.

Results: Overall, 103 patients met criteria for the study. The average age was 73.9 years and patients were predominantly white (85.4%). Cardiac comorbidity was common (66.0%), as were dependent functional status (14.6%) and bleeding disorders (13.6%). Complications occurred in 37.9% of patients, and mortality was high (6.8%). Age, white race, and history of bleeding disorders were independently predictive of complications in the multivariate analysis. The postoperative hospital stay was >5 days for 45.6% of patients.

Conclusion: In a large, multicenter database study, anterior fixation of odontoid fracture was associated with high morbidity and mortality. Although advanced age was associated with increased risk of complications, patients undergoing anterior fixation were older, on average, than in prior studies. Bleeding disorder was a potentially modifiable risk factor for complications that could be optimized prior to surgery.

Keywords

odontoid fracture, morbidity, mortality, National Surgical Quality Improvement Program, NSQIP, dens fracture, outcomes

Introduction

The odontoid process or dens of the C2 vertebrae restricts translational movements in the most mobile segment of the cervical spine, the C1-C2 complex.[1] Fractures of the odontoid process result from forceful flexion or extension of the cervical spine, which commonly occurs in motor vehicle accidents in younger patients or simple falls in the elderly.[2] The odontoid process is the most common site of fracture in the cervical spine, accounting for 9% to 15% of cervical spine fractures.[3-7] These injuries can cause neck pain and cervical instability that put patients at risk for catastrophic spinal cord compromise.[8-11]

The treatment of odontoid fractures depends primarily on fracture pattern, the degree of displacement, and patient age.[4,12] Treatments include cervical collar immobilization, rigid bracing with halo vest, posterior fusion of C1-C2, and anterior fixation with compression screws.[4,5,12]

Rigid bracing in the elderly has been associated with unacceptably high morbidity and mortality[13] and lower rates of fusion, prompting some surgeons to advocate for early surgical intervention.[4,14] Surgical intervention provides earlier patient mobilization and higher likelihood of successful fusion.

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Anderson and D'Alonzo classified odontoid fractures into Type I through the tip of the dens, Type II through the base of the dens, and Type III extending into the body of the axis. Grauer later subclassified Type II fractures based on the direction of the fracture line, with Type IIb or posterior oblique fractures being most amenable to anterior screw fixation. Studies of anterior fixation of Type II and III fractures have consistently shown high fusion rates of 83% to 100%.[1,2,4,5,9,11,12,15-23] An alternative approach to surgical correction, posterior arthrodesis of C1-C2, can be achieved by either Gallie and Brooks wire fixation, transarticular screw placement, or screws placed into the vertebra and connected by rods. In contrast to posterior arthrodesis, anterior screw fixation has the benefit of preserving rotation at C1-C2 and potentially providing a more reliable fusion in Type IIb injuries. Although anterior fixation is believed to preserve rotation at C1-C2, this was true for only a minority of patients in the study by Jeanneret et al.[24] Anterior fixation remains controversial due to high rates of morbidity and mortality reported in the literature.[15,16,25,26] Complications from surgical procedures lead to worse outcomes for patients, lower patient satisfaction, and increased hospital and patient expenditure. Although previous studies have reported surgical complications with anterior fixation, risk factors other than patient age have not been studied.

The purpose of this study is to describe the 30-day complications associated with anterior fixation of odontoid fractures in a large multicenter cohort and to identify patient characteristics and preoperative comorbidities that are risk factors for these complications.

Methods

Data Acquisition and Patient Selection

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) collects more than 150 variables from surgical cases at participating hospitals in the United States. Certified reviewers collect hospital patient data as well as morbidity and mortality data in the 30-day postoperative period. The accuracy of this data is confirmed by routine audits, which have demonstrated interrater error rates of less than 2%.[27] The ACS NSQIP database is composed of HIPAA compliant, de-identified data that includes patient demographics, comorbidities, procedure codes, and 30-day perioperative outcomes. The ACS NSQIP database is validated for use in observational studies of short-term surgical outcomes,[28] and investigators have used it in many studies of spine surgery to date.[29-34] Since all ACS NSQIP records are de-identified, this study was exempt from review by the institutional review board.

Patients undergoing anterior fixation of odontoid fractures were identified from 2007 to 2012 ACS NSQIP participant use files by Current Procedural Terminology (CPT) codes 22318 and 22319. Both CPT codes are used for "open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation," with 22318 corresponding to procedures without grafting and 22319 to procedures with grafting.[35] We

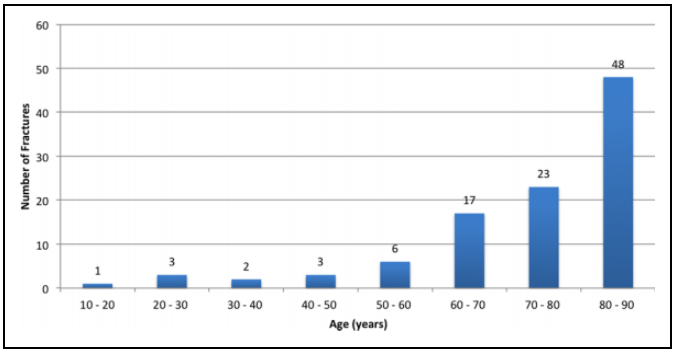

Figure 1. Age of patients undergoing anterior fixation of odontoid fractures.

assessed mortality and morbidity in these patients and divided them into 2 cohorts, one consisting of patients who experienced any complication and one with no complications. The following complications were included in the analysis: wound complications; sepsis; renal, central nervous system, cardiac, or pulmonary complications; venous thromboembolism; and unplanned reoperation. Detailed definitions of each of these complications can be found in the appendix.

Statistics

Demographics, comorbidities, and operative variables were compared in the complication and no complication groups using univariate analysis. Independent *t* tests were performed for continuous variables and χ^2 or Fisher's exact tests were performed for categorical variables. Median and interquartile ranges were reported for operative time and length of stay. Complications within 30 days of surgery were analyzed by univariate analysis. Complications that reached significance and preoperative variables that had *P* values <.1 in the univariate analysis were analyzed by multivariate logistic regression in order to determine which variables were independent predictors of morbidity. *P* values, odds ratios (ORs), and 95% confidence intervals (CIs) were reported for the analyses. All *P* values were 2-tailed with a cutoff value of $P < .05$. All statistical analyses were performed using SPSS v20 (Chicago, IL).

Results

The ACS NSQIP database returned 103 patients who underwent anterior fixation of odontoid fractures between 2007 and 2012. Grafting was used in only 4 of these cases (3.9%). The average age was 73.9 years, with a majority of patients above age 65 years (Figure 1). Gender was 61.2% female, race was 85.4% white, and the average body-mass index was 25.7. In terms of comorbidities, there was a high rate of cardiac comorbidity (66.0%), dependent functional status (14.6%), bleeding disorders (13.6%), smoking (12.6%), and diabetes (11.7%; Table 1). Cardiac comorbidity includes congestive heart failure, history of myocardial infarction, percutaneous cardiac intervention, cardiac surgery, angina, and medicated hypertension. Bleeding disorders are defined by ACS NSQIP as any

Table 1. Demographics and Preoperative Patient Characteristics.

Characteristic	Value
Age (range)	73.9 (19-90)
0-25, n (%)	4 (3.9)
25-50	5 (4.9)
50-75	34 (32.0)
75+	60 (58.3)
Gender, n (%)	
Female	63 (61.2)
Male	40 (38.8)
Race, n (%)	
White	88 (85.4)
Black	2 (1.9)
Unknown	13 (12.6%)
Body mass index (range)	25.7 (8.1-54.9)
0-20, n (%)	11 (10.7)
20-30	71 (68.9)
30-40	17 (16.5)
40+	4 (3.9)
ASA (range)	3.0 (1-4)
1, n (%)	2 (1.9)
2	20 (19.4)
3	60 (58.3)
4	21 (20.4)
5	0 (0.0)
Medical comorbidities, n (%)	
Cardiac comorbidity	68 (66.0)
Dependent functional status	15 (14.6)
Bleeding disorder	14 (13.6)
Smoker	13 (12.6)
Diabetic	12 (11.7)
Pulmonary comorbidity	10 (9.7)
Dyspnea	6 (5.8)
Chronic steroid use	4 (3.9)
Renal comorbidity	4 (3.9)
Recent weight loss	3 (2.9)
Outpatient	2 (1.9)

Abbreviation: ASA, American Society of Anesthesiologists.

Table 2. Thirty-Day Complications and Other Adverse Outcomes.

Complication	Patients (%)
Any complication	39 (37.9)
Major complications	18 (17.5)
Death	7 (6.8)
Unplanned reoperation	6 (5.8)
Failure to wean/re-intubation	5 (4.9)
Myocardial infarction	2 (1.9)
Sepsis	2 (1.9)
Stroke	2 (1.9)
Cardiac arrest	1 (1.0)
Septic shock	1 (1.0)
Coma	0 (0.0)
Deep vein thrombosis	0 (0.0)
Deep wound infection	0 (0.0)
Organ/space infection	0 (0.0)
Peripheral nerve injury	0 (0.0)
Pulmonary embolism	0 (0.0)
Minor complications	29 (28.2)
Blood transfusion	23 (22.3)
Pneumonia	4 (3.9)
UTI	3 (2.9)
Superficial surgical site infection	0 (0.0)
Wound dehiscence	0 (0.0)

Abbreviation: UTI, urinary tract infection.

condition that places the patient at risk for excessive bleeding requiring hospitalization due to a deficiency of blood clotting elements. Median operative time was 80 minutes (interquartile range = 48 to 124.5). Median length of stay was 5 days (interquartile range = 3 to 8.5).

Of the 103 patients, 64 experienced no complications while 39 experienced perioperative or postoperative complications within 30 days of the procedure (Table 2). The overall rate of major complications was 17.5%, which included death (6.8%), unplanned reoperation (5.8%), failure to wean from ventilator or re-intubation (4.9%), myocardial infarction (1.9%), stroke (1.9%), sepsis (1.9%), cardiac arrest (1.0%), and septic shock (1.0%). Minor complications occurred in 28.2% of patients, which included blood transfusion (22.3%), pneumonia (3.9%), and urinary tract infection (2.9%).

Univariate Analysis

Elderly patients (age ≥65 years) were significantly more likely to experience complications ($P = .003$), as were white patients ($P = .007$) and patients with bleeding disorders ($P = .028$). Use of graft was not associated with increased risk of complications ($P = .625$), although the sample size of only 4 grafted patients limits the utility of comparisons between grafted and non-grafted groups.

Multivariate Analysis

Age, white race, American Society of Anesthesiologists score ≥3, and bleeding disorder were all found to have P value <.1 in the univariate analysis and were therefore carried into the multivariate logistic regression (Table 3). Advanced age was found to be an independent risk factor for complications within 30 days (OR = 7.8; 95% CI = 1.5-39.4) as were white race (OR = 11.2; 95% CI = 1.3-96.2) and bleeding disorders (OR = 4.4; 95% CI = 1.0-18.2; Table 4).

Discussion

In this study, we tested the hypothesis that anterior fixation of odontoid fractures is associated with high morbidity and mortality in a large cohort using the ACS NSQIP database. Due to the rarity of anterior fixation of odontoid fractures, our 103-patient sample is one of the largest studies of this procedure to date. We showed that patients tended to be older (79.6% ≥65 years), predominantly white (85.4%), and had significant burden of cardiac disease (66.0%). Anterior fixation of odontoid fracture was associated with high 30-day mortality (6.8%), and patients suffered complications at a rate of 37.9%. Unplanned reoperations occurred in 5.8% of patients. Age, white race, and

Table 3. Univariate Analysis of Risk Factors for Any Complication Following Anterior Fixation of Odontoid Fracture.

Characteristic	N (%)	Complication		P
		No	Yes	
Total	103 (100.0)			
Age ≥65	82 (79.6)	70.3%	94.9%	**.003***
Female	63 (61.2)	56.3%	69.2%	.190
Race[a]				
White	88 (85.4)	78.1%	97.4%	**.007***
Black	2 (1.9)	3.1%	0.0%	.525
BMI >30	21 (20.4)	21.9%	17.9%	.631
ASA ≥3	81 (78.6)	73.4%	87.2%	**.099***
Dependent functional status	15 (14.6)	12.5%	17.9%	.447
Outpatient	2 (1.9)	3.1%	0.0%	.525
Smoker	13 (12.6)	17.2%	5.1%	.124
Chronic steroid use	4 (3.9)	4.7%	2.6%	1.000
Recent weight loss	3 (2.9)	1.6%	5.1%	.555
Diabetic	12 (11.7)	10.9%	12.8%	.762
Dyspnea	6 (5.8)	4.7%	7.7%	.671
Pulmonary comorbidity[b]	10 (9.7)	6.3%	15.4%	.173
Cardiac comorbidity[c]	68 (66.0)	62.5%	71.8%	.334
Renal comorbidity[d]	4 (3.9)	4.7%	2.6%	1.000
Bleeding disorder[e]	14 (13.6)	7.8%	23.1%	**.028***

Abbreviations: BMI, body mass index; ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; MI, myocardial infarction; HTN, hypertension.
[a]Race was reported as "Unknown" for 13 patients.
[b]Ventilator anytime during 48 hours before surgery, COPD, or pneumonia.
[c]CHF, history of MI, percutaneous cardiac intervention, cardiac surgery, angina, medicated HTN.
[d]Renal failure or dialysis.
[e]Any condition that places patient at risk for excessive bleeding requiring hospitalization due to a deficiency of blood clotting elements.
*Variables with $P < 0.1$ are included in the multivariate analysis.

Table 4. Multivariate Analysis of Risk Factors for Any Complication.[a]

Characteristic	P	OR (95% CI)
Age ≥65	**.01**	**7.8 (1.5-39.4)**
Race, White	**.03**	**11.2 (1.3-96.2)**
ASA ≥3	.38	1.7 (0.5-5.7)
Bleeding disorder	**.04**	**4.4 (1.0-18.2)**

Abbreviations: OR, odds ratio; CI, confidence interval; ASA, American Society of Anesthesiologists.
[a]Bold indicates values that reached statistical significance ($P < .05$).

bleeding disorders were independent predictors of complications following anterior fixation of odontoid fractures. Confidence intervals were wide for each of these risk factors; therefore, a larger study of odontoid fracture repair is needed to confirm these findings. Unsurprisingly, grafting was seen in a small minority of cases (4 of 103). The specifics of this rare technique are not available from the ACS NSQIP database; therefore, it would be helpful if authors using grafting with anterior fixation described their indications and technique in the literature.

Anterior fixation of odontoid fracture is a relatively uncommon procedure. A survey by Clark and White of 26 providers reported a total of only 11 cases of anterior fixation.[25] The highest frequency of anterior fixation in the literature was reported by Apfelbaum et al in their study of 147 cases at 2 hospitals over a 13-year period.[11] Our series of 103 cases reported by hospitals participating in NSQIP over a 6-year period suggests an even lower frequency of anterior fixation cases than previous studies. However, given the technical complexity of anterior fixation of odontoid fracture, it is likely that only a handful of hospitals participating in NSQIP actually perform this procedure.

The risks of anterior fixation were considered low in Bohler's seminal paper describing the technique,[2] although several studies after Bohler have shown high rates of morbidity and mortality, particularly among elderly patients. Muller et al showed a mortality of 40% among elderly patients with this approach, although the sample size was just 5 patients.[36] Our study captures one of the largest and most diverse samples to date, which, in contrast to the single institution studies that dominate the current literature, may provide a truer representation of preoperative comorbidities and the postoperative complications of anterior fixation.

The findings of our large multicenter study reinforce the assertion that the elderly are at increased risk for perioperative complications. Furthermore, we show that the elderly comprise a majority of patients undergoing anterior fixation of odontoid fractures at hospitals participating in ACS NSQIP. This is a surprising finding given that expert opinions by Hsu and Anderson[4] and Konieczny et al[37] favor posterior fusion or cervical immobilization in this demographic. The increased morbidity and mortality in the elderly has been shown previously in single-center studies. A recent study by Platzer et al[26] comparing outcomes in 69 young patients and 41 elderly patients undergoing anterior fixation showed significantly higher rates of complications (8% vs 22%) and perioperative mortality (1% vs 9%) in the elderly group, which is consistent with our results. Given that only 20.4% of patients in our study were <65 years of age, further study is needed to clarify the increased risk of complications with age.

Patients in our study were older than patients in previous studies of anterior fixation (mean 73.9 years, 79.6% ≥65 years), with a majority being older than 75 years of age. Patients studied by Bohler were an average age of 44.8 years of age. The 2 largest studies of anterior fixation, authored by Apfelbaum et al[11] and Platzer et al,[26] report outcomes in cohorts whose average age is 50.1 and 54 years, respectively. The reason for this difference in average patient age is unclear. Perhaps it is related to a difference in patient populations (hospitals across the United States participating in ACS NSQIP versus Vienna, Austria; Salt Lake City, Utah; and Budapest, Hungary) or a trend toward broader patient selection criteria for anterior screw fixation. Unfortunately, none of the aforementioned studies describes its criteria for patient selection, so an explanation cannot be further elucidated.

In the literature, mortality with anterior fixation ranges from 0% to 14%.[11,15,16,23,26,36-38] Mortality of 6.8% in our study is

high but within the reported range. We capture all deaths within 30 days of the procedure, which encompasses most all surgery-related deaths. In long-term follow-up studies by Apfelbaum and Platzer, all surgery related deaths occurred within 32 days of the primary procedure. Several authors have raised concerns about high mortality among elderly patients, which ranges from 6% to 11%.[23,26,38] Muller's frequently cited mortality rate of 40% among 5 elderly patients treated with anterior fixation is an outlier in a small sample and may be less representative. Henry showed that 89% of deaths in their study occurred in patients ≥79 years of age. In our study, one death occurred in a 65-year-old patient, and 6 deaths (86%) occurred in patients ≥82 years of age.

Reintubation or failure to wean occurred in 4.9% of patients. Hematoma, severe pneumonia, and pharyngeal edema are in line with other literature that have examined complications of anterior fixation of odontoid fractures,[15,23,26,36] and these may have contributed to reintubations in our study. Patients and their families may benefit from counseling on the likelihood of this outcome prior to surgery.

Unplanned reoperations occurred in 5.8% of patients. Reoperations cause distress for families and are associated with morbidity, increased hospital costs, and worse patient outcomes. Earlier studies report reoperations for loose screws, nonunion causing severe pain, postoperative hematoma, and fracture redisplacement.[11,15,36] Platzer et al reported that all reoperations were consequences of procedure-specific complications (eg, instrumentation failures, nonunion) and none from general, systemic complications (eg, cardiac, respiratory). ACS NSQIP is limited to reporting general complications; however, it is reasonable to assume that the causes of unplanned reoperations in our study are similar to earlier studies and, therefore, unplanned reoperations represent major procedure-specific complications that arose in our 103 patient sample. Our reoperation rate was comparable to other reports, which range from 3.4% to 8.7%.[11,26,36] Since our follow-up focuses on 30-day outcomes, the true rate of reoperation in our patient sample is likely higher.

Blood transfusion was a frequent complication, occurring in 22.3% of patients treated with anterior fixation. Blood transfusion is not uncommon in spine surgery. Buerba et al reported transfusion as a complication in 0.4% to 11.1% of patients undergoing cervical spine fusion in a recent ACS NSQIP study.[30] Butler reported transfusions in 25.9% of spine surgery patients in an Irish cohort of younger patients with predominantly cervical spine trauma.[39] In our study, transfusions likely resulted from the combination of trauma in conjunction with anticoagulant and antiplatelet medication use. These medications are prescribed widely among elderly patients with cardiac disease, which was present in 66.0% of patients in this series. In the setting of trauma, surgery may or may not be delayed for these medications to be metabolized and normalization of coagulation labs, so greater blood loss can occur. Risks of allogenic blood transfusion include transfusion reactions, hemolytic reactions, increased infection rates, and disease transmission. This is the first study to report the rate of blood transfusions associated with anterior fixation of odontoid fractures. With this information, patients may be more accurately counseled on the risks of transfusion associated with anterior fixation of odontoid fracture.

Bleeding disorder was a significant risk factor for complications. ACS NSQIP defines bleeding disorders as any condition that places the patient at risk for excessive bleeding requiring hospitalization due to a deficiency of blood clotting elements. Included are patients with vitamin K deficiency, hemophilias, thrombocytopenia, and chronic anticoagulation, while patients on aspirin therapy are excluded.[27] Considering these findings, preoperative optimization of coagulopathies warrants further study as a potential means to reduce complications.

White race has not previously been reported as a risk factor for complications in anterior fixation. Gender is a frequently reported demographic variable, although the variable of race has not been reported in studies of anterior fixation of odontoid fractures to date. The underlying cause of why white race might be associated with increased complications remains unclear. Only 2 patients were identified as black in our cohort, and race was unknown in 13 cases, which raises the question of whether the finding could be spurious. Further research would be needed to establish whether white race is a true risk factor for increased complications in anterior fixation of odontoid fractures.

There are several limitations to this study, many of which are due to the generalized nature of the ACS NSQIP database. For instance, this study reports on the major causes of morbidity and mortality, but procedure-specific outcomes are not available. Dysphagia is a common complication of anterior fixation that would be useful to report; however, dysphagia is not specifically recorded in the ACS NSQIP database so we must look at its sequelae instead, such as pneumonia and other pulmonary complications. Our cohort is one of the largest to date on the subject of anterior fixation of odontoid fractures, yet with a sample of 103 patients, its power for detecting significance among risk factors for complications remains low. Additionally, there is no way of knowing the distribution of cases among the hospitals in the ACS NSQIP database as both patients and hospitals are de-identified. This potentially introduces sampling bias into our results. Last, with the ACS NSQIP data set we cannot appreciate the mechanism of injury, fracture pattern, acute neurologic status, or associated injuries of patients in the study.

Conclusion

Anterior fixation of odontoid fractures was associated with high morbidity and mortality in a large multicenter cohort. Advanced age, white race, and bleeding disorders were significant risk factors for complications within 30 days. Despite recent expert opinions recommending posterior fusion or cervical immobilization over anterior fixation for elderly patients with odontoid fractures, the majority of patients treated with this approach were older than 75 years. Specific complications and their frequencies reported here are valuable statistics for surgeons to use in management, preoperative patient counseling, and risk stratification.

Appendix

Complications Defined in Detail per ACS NSQIP User Guide

Complication	Definition[27]
Major Complications	
Death	Death within 30 days of the index procedure.
Unplanned reoperation	The patient had an unplanned return to the operating room for a surgical procedure related to either the index or concurrent procedure performed. This return must be within the 30-day postoperative period. The return to the OR may occur at any hospital or surgical facility (ie, your hospital or at an outside hospital).
Failure to wean/ re-intubation	Ventilator-assisted respiration lasting greater than 48 hours during postoperative hospitalization. This can occur at any time during the 30-day period postoperatively. This time assessment is cumulative, not necessarily consecutive. Ventilator-assisted respirations can be via endotracheal tube, nasotracheal tube, or tracheostomy tube. **OR** Patient required placement of an endotracheal tube or other similar breathing tube and ventilator support intraoperatively or within 30 days following surgery, which was not intended or planned. The variable intent is to capture all cause unplanned intubations, including but not limited to unplanned intubations for refractory hypotension, cardiac arrest, inability to protect airway. • Accidental self-extubations requiring reintubation would be assigned. • Emergency tracheostomy would be assigned. Patients with a chronic/long-term tracheostomy who are on and off the ventilator would not be assigned, unless the tracheostomy tube itself is removed and the patient requires reintubation (endotracheal or a new tracheostomy tube) or an emergency tracheostomy. • Patients undergoing time off the ventilator during weaning trials and who fail the trail and are placed back on the ventilator would not be assigned. • Intubations for an unplanned return to the OR would not be assigned, as the intubation is planned, it is the return to the OR which is unplanned. • In patients who were intubated for a return to the OR for a surgical procedure unplanned intubation occurs after they have been extubated after surgery. In patients who were not intubated for a return to the OR, intubation at any time after their surgery is complete is considered unplanned. • Intraoperative conversion from local or MAC anesthesia to general anesthesia, secondary to the patient not tolerating local or MAC anesthesia, would NOT be assigned.
Myocardial infarction	An acute myocardial infarction which occurred intraoperatively or within 30 days following surgery as manifested by one of the following: • Documentation of ECG changes indicative of acute MI (one or more of the following): – ST elevation >1 mm in 2 or more contiguous leads – New left bundle branch – New q-wave in 2 of more contiguous leads • New elevation in troponin greater than 3 times upper level of the reference range in the setting of suspected myocardial ischemia • Physician diagnosis of myocardial infarction
Sepsis	Sepsis is a vast clinical entity that takes a variety of forms. The spectrum of disorders spans from relatively mild physiologic abnormalities to septic shock. The intent is to capture the patient whose physiology is compromised by an ongoing infectious process after surgery. Patients are not counted if there is significant evidence that the sepsis or septic shock outcome was under way prior to the surgery performed. Sepsis is the systemic response to infection. Report this variable if the patient has 2 of the following clinical signs and symptoms of SIRS: • Temperature >38°C (100.4°F) or <36°C (96.8°F) • HR >90 bpm • RR >20 breaths/min or $PaCO_2$ <32 mm Hg (<4.3 kPa) • WBC >12 000 cell/mm3, <4000 cells/mm^3, or >10% immature (band) forms • Anion gap acidosis: this is defined by either: $[Na + K] - [Cl + HCO_3$ (or serum $CO_2)]$. If this number is greater than 16, then an anion gap acidosis is present. $Na - [Cl + HCO_3$ (or serum $CO_2)]$. If this number is greater than 12, then an anion gap acidosis is present. **AND** either A or B below: A. One of the following: • Positive blood culture • Clinical documentation of purulence or positive culture from any site for which there is documentation noting the site as the acute cause of sepsis

(continued)

Appendix (continued)

Complication	Definition[27]
	B. One of the following findings during the Principal Operative Procedure: • Confirmed infarcted bowel requiring resection • Purulence in the operative site • Enteric contents in the operative site, or • Positive intraoperative cultures
Stroke	Patient develops an embolic, thrombotic, or hemorrhagic vascular accident or stroke with motor, sensory, or cognitive dysfunction (eg, hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory) that persists for 24 or more hours. If a specific time frame for the dysfunction is not documented in the medical record, but there is a diagnosis of a stroke, assign the occurrence, unless documentation specifically states that the motor, sensory, or cognitive dysfunction resolved.
Cardiac arrest	The absence of cardiac rhythm or presence of chaotic cardiac rhythm, intraoperatively or within 30 days following surgery, which results in a cardiac arrest requiring the initiation of CPR, which includes chest compressions. Patients are included who are in a pulseless VT or Vfib in which defibrillation is performed and PEA arrests requiring chest compressions. Patients with automatic implantable cardioverter defibrillator (AICD) that fire but the patient has no loss of consciousness should be excluded.
Septic shock	For sepsis and septic shock within 30 days of the operation, please report the most significant level using the criteria that follow. *Severe sepsis/septic shock:* Sepsis is considered severe when it is associated with organ and/or circulatory dysfunction. Report this variable if the patient has the clinical signs and symptoms of SIRS or sepsis AND documented organ and/or circulatory dysfunction. Examples of organ dysfunction include oliguria, acute alteration in mental status, acute respiratory distress. Examples of circulatory dysfunction include hypotension, requirement of inotropic or vasopressor agents. For the patient that had sepsis preoperatively, worsening of any of the above signs postoperatively would be reported as a postoperative sepsis.
Coma	Patient is unconscious, or postures to painful stimuli, or is unresponsive to all stimuli (exclude transient disorientation or psychosis) for greater than 24 hours. Drug-induced coma (eg, Propofol drips) are excluded.
Deep vein thrombosis	The identification of a new blood clot or thrombus within the venous system which may be coupled with inflammation. The clot can be described in studies as present in the superficial or deep venous systems but requires therapy. This diagnosis is confirmed by a duplex, venogram or CT scan, AND the patient must be treated with anticoagulation therapy and/or placement of a vena cava filter or clipping of the vena cava. Example of clots that should be considered for this variable include internal jugular (IJ) line clots, PICC line clots and those found in the abdomen (portal vein).
Deep wound infection	Deep incision SSI is an infection that occurs within 30 days after the operation and the infection appears to be related to the operation and infection involved deep soft tissues (eg, fascial and muscle layers) of the incision and at least one of the following: • Purulent drainage from the deep incision but not from the organ/space component of the surgical site. • A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38°C), localized pain, or tenderness, unless site is culture-negative. • An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination. • Diagnosis of a deep incision SSI by a surgeon or attending physician. **Note:** • Infection that involves both superficial and deep incision sites is reported as deep incisional SSI. • An organ/space SSI that drains through the incision is reported as a deep incisional SSI.
Organ/space infection	Organ/space SSI is an infection that occurs within 30 days after the operation and the infection appears to be related to the operation and the infection involves any part of the anatomy (eg, organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following: • Purulent drainage from a drain that is placed through a stab wound into the organ/space. • Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space. • An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination. • Diagnosis of an organ/space SSI by a surgeon or attending physician.
Peripheral nerve injury	Peripheral nerve damage may result from damage to the nerve fibers, cell body, or myelin sheath during surgery. Peripheral nerve injuries that result in motor deficits to the cervical plexus, brachial plexus, ulnar plexus, lumbar-sacral plexus (sciatic nerve), peroneal nerve, and/or the femoral nerve should be included.
Pulmonary embolism	Lodging of a blood clot in a pulmonary artery with subsequent obstruction of blood supply to the lung parenchyma. A pulmonary embolism is diagnosed if the patient has a V-Q scan interpreted as high probability of pulmonary embolism or a positive CT exam, TEE, pulmonary arteriogram, CT angiogram, or any other definitive modality.

(continued)

Appendix (continued)

Complication	Definition[27]
Minor Complications	
Blood transfusion	At least 1 unit of packed or whole red blood cells given from the surgical start time up to and including 72 hours postoperatively. If the patient receives shed blood, autologous blood, cell saver blood or pleurovac postoperatively, count this blood in terms of equivalent units. For a cell saver, every 500 mL of fluid will equal 1 unit of packed cells. If there are less than 250 mL of cell saver, round down and report as 0 units. If there are 250 cc, or more of cell saver, round up to 1 unit. The blood may be given for any reason. If greater than 200 units, enter 200 units. Record the number of units given. Record the date the blood was initially started (intra-operatively or postoperatively).
Pneumonia	Patients with pneumonia must meet criteria from both Radiology and Signs/Symptoms/Laboratory sections listed as follows: *Radiology:* One definitive chest radiological exam (X-ray or CT) with at least one of the following: • New or progressive and persistent infiltrate • Consolidation or opacity • Cavitation *Signs/Symptoms/Laboratory:* FOR ANY PATIENT, at least one of the following: • Fever (>38°C or >100.4°F) with no other recognized cause • Leukopenia (<4000 WBC/mm^3) or leukocytosis ($\geq$12 000 WBC/mm^3) • For adults $\geq$70 years old, altered mental status with no other recognized cause **And** At least one of the following: • 5% Bronchoalveolar lavage (BAL)—obtained cells contain intracellular bacteria on direct microscopic exam (eg, Gram stain) • Positive growth in blood culture not related to another source of infection • Positive growth in culture of pleural fluid • Positive quantitative culture from minimally contaminated lower respiratory tract (LRT) specimen (eg, BAL or protected specimen brushing) **Or** At least one of the following: • New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements • New onset or worsening cough, or dyspnea, or tachypnea • Rales or rhonchi • Worsening gas exchange (eg, O_2 desaturations [eg, $PaO_2/FiO_2 \leq 240$], increased oxygen requirements, or increased ventilator demand)
UTI	Postoperative symptomatic urinary tract infection must meet one of the following TWO criteria within 30 days of the operation: 1. One of the following: fever (>38°C), urgency, frequency, dysuria, suprapubic tenderness AND a urine culture of >105 colonies/mL urine with no more than 2 species of organisms **Or** 2. Two of the following: fever (>38°C), urgency, frequency, dysuria, suprapubic tenderness AND any of the following: dipstick test positive for leukocyte esterase and/or nitrate, pyuria (>10 WBCs/cc or >3 WBC/hpf of unspun urine), organisms seen on Gram stain of unspun urine, 2 urine cultures with repeated isolation of the same uropathogen with >102 colonies/mL urine in nonvoided specimen, urine culture with <105 colonies/mL urine of single uropathogen in patient being treated with appropriate antimicrobial therapy, physician's diagnosis, physician institutes appropriate antimicrobial therapy.
Superficial surgical site infection	Superficial incisional SSI is an infection that occurs within 30 days after the operation and the infection involves only skin or subcutaneous tissue of the incision and at least one of the following: • Purulent drainage, with or without laboratory confirmation, from the superficial incision. • Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision. • At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat AND superficial incision is deliberately opened by the surgeon, unless incision is culture-negative. • Diagnosis of superficial incisional SSI by the surgeon or attending physician. Do **not** report the following conditions as SSI: stitch abscess, infected burn wound, incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).
Wound dehiscence	A total breakdown of the surgical closure compromising the integrity of the procedure.

Abbreviations: OR, operating room; ECG, electrocardiogram; MI, myocardial infarction; SIRS, systemic inflammatory response syndrome; HR, heart rate; RR, respiratory rate; WBC, white blood cell; CPR, cardiopulmonary resuscitation; SSI, surgical site infection; PEA, pulseless electrical activity; CT, computed tomography; PICC, peripherally inserted central catheter; TEE, transesophageal echocardiography; UTI, urinary tract infection.

Declaration of Conflicting Interests

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