

Complications Associated with Mortality after Head and Neck Surgery: An Analysis of the NSQIP Database

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Abstract

Objective. To determine which complications, as defined by the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database, correlate with 30-day mortality in surgery for malignancies of the head and neck.

Study Design. Retrospective review of prospectively collected national database.

Setting. NSQIP.

Subjects and Methods. NSQIP data from 2005 to 2014 were queried for ICD-9 codes head and neck malignancies. Multivariate logistic regression was used to examine the correlation of individual complications with 30-day mortality.

Results. In total, 15,410 cases met criteria with 3499 complications in 2235 cases. After controlling for patient and surgical variables, postoperative pneumonia ($P = .02$; odds ratio [OR], 2.39; 95% confidence interval [CI], 1.15–4.72), progressive renal insufficiency ($P < .001$; OR, 21.28; 95% CI, 4.22–87.94), bleeding requiring transfusion ($P = .02$; OR, 2.10; 95% CI, 1.12–3.84), sepsis ($P = .02$; OR, 2.86; 95% CI, 1.15–6.46), septic shock ($P = .045$; OR, 2.87; 95% CI, 0.98–7.81), stroke ($P < .001$; OR, 19.81; 95% CI, 6.23–56.03), and cardiac arrest ($P < .001$; OR, 135.59; 95% CI, 65.00–286.48) were independently associated with increased odds of 30-day mortality.

Conclusion. The NSQIP database has been extensively validated and used to examine surgical complications, yet there is little analysis on which complications are associated with death. This study identified complications associated with increased risk of 30-day mortality following head and neck cancer surgery. These associations may be used as a measure of complication severity and should be considered when using the NSQIP database to evaluate outcomes in head and neck surgery.

Keywords

complications, head and neck, mortality, National Surgical Quality Improvement Program

Rates of postoperative complications and mortality are important benchmarks for evaluating the quality and safety of surgical procedures. Complications occur frequently after head and neck cancer surgery, with reported rates ranging from 17% to 29%.^{1–3} Postoperative death, although rare, is the ultimate complication and, undoubtedly, the most devastating outcome after any surgery. These outcomes are routinely analyzed in parallel; however, there is a paucity of analysis on which postoperative complications result in death following head and neck surgery.

The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) is a prospectively collected database that includes data from surgical procedures from over 500 participating hospitals across the country and was designed to evaluate surgical quality of care using 30-day morbidity and mortality as its primary outcomes. The database has been extensively used and validated since its establishment.^{4–6} Despite the widespread use of NSQIP to examine surgical outcomes, studies often

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report complications without differentiation based on severity, as analysis of complication severity is lacking.

Despite the complexity of many head and neck cancer procedures and the high burden of comorbidities among many head and neck surgery patients, rates of postoperative mortality are low.^{3,7-9} Even so, it is important to understand the patient-related, surgical, and postoperative factors that are associated with short-term mortality to identify potentially reversible risk factors for this devastating outcome. Furthermore, identification of associations between individual complications and 30-day mortality may provide a framework for evaluating the severity of individual complications, as such associations would provide compelling evidence of the increased severity of certain complications. The aim of this study was to determine which complications, as defined by NSQIP, correlate with 30-day mortality in procedures for head and neck malignancy.

Methods

NSQIP data from 2005 to 2014 were queried for ICD-9 codes for malignancies of the head and neck as previously described (see appendix at www.otojournal.org/supplemental).¹ Cases with a primary diagnosis of thyroid malignancy were excluded. This study was determined to be exempt by the Institutional Review Board of the Hospital of the University of Pennsylvania.

Patient encounters were identified within the participant use data files of the NSQIP database, which in 2014 included 517 community and academic hospitals throughout the United States with 323 variables for each case. Data are collected by trained nurses at participating institutions through systematic sampling of major operations performed. Each variable in the database is specifically defined, and data collectors are periodically audited to ensure standardization and accuracy of the content. To ensure a 30-day follow-up period, patients are contacted by letter or telephone survey following discharge. The list and definitions of variables collected in the database can be found at the American College of Surgeons National Surgical Quality Improvement Program website (<https://www.facs.org/quality-programs/NSQIP>). In addition to the predefined NSQIP variables, we calculated body mass index (BMI in kg/m²) for each encounter. Race designations besides white and black/African American were grouped as “Other.” Cases with free flaps were determined by inclusion of any of the following *Current Procedural Terminology (CPT)* codes in any procedure variable: 15757, 15756, 15758, 20969, 43496, 20955, 20962, 15842, 49006, 20956, 20957, and 20970.¹⁰

The primary outcome of interest was 30-day mortality. To identify patient and surgical factors potentially associated with mortality, univariate analysis was performed using Pearson χ^2 for categorical variables or Mann-Whitney tests for continuous variables. Those variables with $P < .2$ on univariate analysis and less than 10% missing data were included in the preliminary logistic model. Only cases with complete data for the variables of interest were included in the model. A forward and backward stepwise regression

algorithm was then used to select the best model by minimizing the Akaike information criterion (AIC) to determine the final model. Variables with $P < .05$ on the final multivariate logistic model were considered significant. All data processing and analysis was performed with Microsoft R Open v 3.2.3, via RStudio v. 0.99.467 (RStudio, Boston, Massachusetts).

Results

Overall, 15,410 cases met inclusion criteria and were used for analysis. Most patients included were white (81.9%) and male (65.7%). Mean age at surgery was 63 years (range, 16-90), and mean BMI was 27.6, with 28.3% of patients meeting criteria for obesity (BMI >30). Additional patient and surgical variables are detailed in **Table 1**.

A total of 3499 complications occurred in 2235 cases (14.5% of cases). Incidences of individual complications are listed in **Table 2**. Among patients who experienced complications, the majority (n = 1493) patients experienced one complication, 426 patients experienced 2, and 316 patients experienced 3 or more complications. Death within 30 days of the index surgical procedure occurred in 109 cases, yielding an overall 30-day mortality rate of 0.71%. Incidence and rates of mortality among patients who experienced individual complications are included in **Table 2**. The most common complications were bleeding requiring transfusion, superficial surgical site infection, and pneumonia.

The following preoperative and operative characteristics were included in the multivariate model based on the bidirectional stepwise regression algorithm: body mass index (BMI), age, dyspnea prior to surgery, disseminated cancer, bleeding disorder, ascites, renal failure, American Society of Anesthesiologists (ASA) class, inpatient status, emergency surgery, year of operation, and length of operation. Odds ratios (ORs) for preoperative and operative factors found to correlate with mortality are listed in **Table 3**. After controlling for all included variables, postoperative pneumonia ($P = .02$; OR, 2.39; 95% confidence interval [CI], 1.15-4.72), progressive renal insufficiency ($P < .001$; OR, 21.28; 95% CI, 4.22-87.94), bleeding requiring transfusion ($P = .02$; OR, 2.10; 95% CI, 1.12-3.84), sepsis ($P = .02$; OR, 2.86; 95% CI, 1.15-6.46), septic shock ($P = .045$; OR, 2.87; 95% CI, 0.98-7.81), stroke ($P < .001$; OR, 19.81; 95% CI, 6.23-56.03), and cardiac arrest requiring cardiopulmonary resuscitation (CPR) ($P < .001$; OR, 135.59; 95% CI, 65.00-286.48) were independently associated with 30-day postoperative mortality (**Table 4**). All other complications, including surgical wound infections, wound dehiscence, unplanned intubation, ventilator use greater than 48 hours postoperatively, urinary tract infection, myocardial infarction, deep vein thrombosis, pulmonary embolism (PE), and acute renal failure were not found to be significantly associated with 30-day mortality.

Due to the high occurrence of death following cardiac arrest requiring CPR, we analyzed patients who experienced both events to determine whether cardiac arrest could be a surrogate for inpatient death rather than a predictor of

Table 1. Patient and Surgical Characteristics of Patients in the National Surgical Quality Improvement Program Undergoing Head and Neck Surgery, 2005 to 2014.^a

Characteristic	All Patients
Total number of patients	15,410
Mean age, y	63 ± 14
Male sex	10,120 (65.7)
Race	
White	12,623 (81.9)
Black/African American	751 (4.9)
Other/unknown	1,980 (12.8)
Mean BMI, kg/m ²	27.6 ± 6.6
Obese	4359 (28.3)
Overweight	5162 (33.5)
Underweight	602 (3.9)
Tobacco use	3429 (22.3)
Dyspnea on exertion or at rest	1289 (8.4)
Diabetes	2136 (13.9)
COPD	948 (6.2)
Hypertension requiring medication	7692 (49.9)
Disseminated cancer	982 (6.4)
Bleeding disorders	514 (3.3)
Renal failure	10 (0.1)
Functional status	
Independent	14,915 (96.8)
Partially dependent	366 (2.4)
Totally dependent	62 (0.4)
Unknown	67 (0.4)
ASA class	
1	475 (3.1)
2	5326 (34.6)
3	8457 (54.9)
4	810 (5.3)
5	4 (0.0)
Operative time, h	231 ± 201
Emergency surgery	124 (0.8)
Outpatient status	3654 (41.8)
Length of postoperative stay, d	4 ± 12
Wound class	
Clean	7154 (46.4)
Clean/contaminated	7746 (50.3)
Contaminated	397 (2.6)
Dirty/infected	113 (0.7)
Flap reconstruction	1668 (10.8)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease.

^aValues are presented as number (%) unless otherwise indicated.

mortality. A total of 28 patients died after experiencing cardiac arrest requiring CPR. Of these, only 5 patients remained inpatients at the time of death; all others had been discharged to home prior to time of death. For 12 patients whose surgeries occurred in 2012 or later for whom these data are available, we then examined whether patients had

been readmitted prior to death and found that zero of the 12 patients were readmitted.

Discussion

Over the past several decades, increasing scrutiny on the part of both patients and payers has driven efforts to evaluate the quality of health care delivery using defined metrics, in addition to efforts to improve quality of care.^{11,12} More recently, efforts have evolved in an attempt to use these metrics to predict individual patient outcomes after surgery.¹³⁻¹⁵ Two otolaryngology-specific individual risk calculators have been published by Awad et al¹⁴ and Santoro et al,¹⁵ which were designed to predict outcomes following oral cavity vs oropharyngeal and oral cavity cancer, respectively. These nomograms predict postoperative complications but do not address the increased risk of mortality associated with complications. In this era of increased scrutiny on postoperative outcomes, improved understanding of which factors increase the risk of postoperative mortality is imperative. In addition, there remains a need for improved understanding of complication severity so that complications may be more accurately used as measures of the safety and quality of surgical procedures. Association of individual complications with mortality provides compelling evidence for increased severity, and although complications and mortality are routinely reported and analyzed in parallel, the impact of individual complications on mortality rates in head and neck cancer surgery has not been extensively investigated. This study sought to identify correlations between complications in NSQIP and 30-day mortality following surgery for malignancy of the head and neck.

After adjusting for patient and surgical variables, we found that postoperative pneumonia, progressive renal insufficiency, bleeding requiring transfusion, sepsis, septic shock, stroke, and cardiac arrest were independently associated with increased odds of 30-day mortality. The American College of Surgeons online Risk Calculator, which is a tool that predicts individual patients' risk of mortality and complications, categorizes each of these complications excluding bleeding requiring transfusion as a serious complication (<http://riskcalculator.facs.org/>).¹³ In this study, the presence of any one of these complications more than doubled the risk of 30-day mortality among head and neck surgery patients. Not surprisingly, stroke and cardiac arrest most significantly increased risk of 30-day mortality, with odds ratios of nearly 20 and 140, respectively. Additional temporal analysis was performed to examine whether cardiac arrest could simply be a surrogate for inpatient death rather than a true predictor of mortality. That analysis showed that in most patients examined, patients had been discharged and were not readmitted prior to death, thus suggesting that cardiac arrest was not a surrogate for inpatient death and is instead an independent predictor of mortality.

Multiple infectious complications were associated with increased mortality. Sepsis and septic shock are well-known deadly complications. In this series, mortality rates of 5.9% and 19.1% were observed among patients with these

Table 2. Postoperative Complications after Head and Neck Surgery with Frequency in the National Surgical Quality Improvement Program Database, 2005 to 2014.

Complication	Frequency	Percent	No. of Deaths	Mortality Rate, %
Bleeding requiring transfusion	1021	6.63	27	2.6
Superficial incisional SSI	390	2.53	5	1.3
Pneumonia	348	2.26	25	7.2
Ventilator >48 hours	283	1.84	24	8.5
Wound disruption	270	1.75	5	1.9
Sepsis	204	1.32	12	5.9
Deep incisional SSI	192	1.25	4	2.1
Unplanned intubation	181	1.17	21	11.6
Urinary tract infection	114	0.74	5	4.4
Organ/space SSI	105	0.68	3	2.9
DVT requiring therapy	77	0.50	4	5.2
Myocardial infarction	64	0.42	8	12.5
Septic shock	63	0.41	12	19.1
Pulmonary embolism	59	0.38	4	6.8
Cardiac arrest requiring CPR	55	0.36	28	50.9
Stroke	39	0.25	7	17.9
Progressive renal insufficiency	17	0.11	5	29.4
Acute renal failure	17	0.11	6	35.3
Total	3,499	22.7		

Abbreviations: CPR, cardiopulmonary resuscitation; DVT, deep vein thrombosis; SSI, surgical site infection.

Table 3. Patient and Surgical Risk Factors Associated with 30-Day Mortality on Multivariate Analysis following Head and Neck Surgery.

Risk Factor	P Value	OR	95% CI
Patient risk factors			
BMI	.03	0.96	0.92-0.94
Age (decade)	<.001	1.43	1.18-1.74
Dyspnea with exertion	.002	2.41	1.36-4.12
Disseminated cancer	<.001	2.67	1.14-2.2
Bleeding disorder	.004	2.81	1.34-5.44
Renal failure	.01	10.03	1.20-54.53
Surgical risk factors			
Outpatient surgery	.02	0.44	0.21-0.86
Emergency surgery	.007	4.00	1.32-10.17
Operative time (hour)	.03	0.92	0.85-0.99

Abbreviations: BMI, body mass index; CI, confidence interval; OR, odds ratio.

complications, respectively. These rates are consistent with prior literature.¹⁶ Pneumonia is a common postoperative complication among head and neck surgery patients, with a reported incidence of 3% to 9%.^{2,7,17,18} The risk of pneumonia is increased in patients with comorbid pulmonary disease, and risk of aspiration pneumonia is increased in patients with dysphagia; both of these conditions are particularly prevalent in head and neck cancer patients.¹⁷ The incidence of pneumonia in this study (2.26%) was lower

Table 4. Postoperative Complications Associated with 30-Day Mortality on Multivariate Analysis following Head and Neck Surgery.

Complication	P Value	OR	95% CI
Pneumonia	.02	2.39	1.15-4.72
Progressive renal insufficiency	<.001	21.28	4.22-87.94
Bleeding requiring transfusion	.02	2.10	1.12-3.84
Sepsis	.02	2.86	1.15-6.46
Septic shock	.045	2.87	0.98-7.81
Stroke	<.001	19.81	6.23-56.03
Cardiac arrest requiring CPR	<.001	135.59	65.00-286.48

Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; OR, odds ratio.

than in previous reports. However, the increased odds of mortality attributable to postoperative pneumonia ($P = .01$; OR, 2.42) is consistent with findings from 2 large population-based studies among head and neck surgery patients.^{8,17}

Progressive renal insufficiency (PRI) occurred in only 17 patients (0.1%) but strongly correlated with mortality (OR, 21.78; 95% CI, 4.30-89.83). The NSQIP defines PRI as decreased renal function as evidenced by a rise in serum creatinine of 2 mg/dL from its preoperative value but without the need for dialysis. Acute renal failure also occurred in a minority of patients (0.1%) and was not significantly associated with increased odds of mortality. Although the high odds ratio may be a reflection of the seriousness of

PRI, it should be considered in the context of the small number of patients affected and the resulting wide confidence interval. However, postoperative monitoring of renal function is common, and these findings suggest that measures should be employed to prevent and aggressively manage postoperative PRI.

Pulmonary embolism was not significantly associated with mortality in this study. Although PE is a potentially fatal postoperative complication, PE-related mortality has been reported as low as 1.8% to 2.5% with appropriate treatment.^{19,20} Pulmonary embolism was an infrequent event in this study, occurring in only 59 (0.38%) patients and was consistent with reported rates of venous thromboembolism among otolaryngology patients in the literature, which range from 0.05% to 6%.²¹⁻²⁵ Similarly, myocardial infarction (MI) was also an infrequent complication, occurring in 64 (0.42%) patients, and it was not found to be significantly correlated with increased odds of mortality. While it is possible that the low incidence rates of both PE and MI failed to unmask a correlation with mortality in this study, it should also be considered that these events may not significantly impact the risk of short-term mortality among patients with head and neck cancer.

Several patient characteristics, comorbidities, and operative variables were also found to be associated with mortality. Increased BMI, outpatient surgery, and increased length of operation were associated with a statistically significant decreased odds of mortality. The effect sizes for these variables were small, and this study was not designed to determine the underlying reasons for these seemingly paradoxical results. It is possible that patients might be underweight due to extent of disease or malnutrition, and patients with significant comorbidities may be less likely to have free flap reconstruction, which would have longer operative times. Further investigations will be required to determine the underlying causes for these correlations. More expectedly, increased age, emergency surgery, and multiple patient comorbidities were associated with a significant increase in mortality (**Table 3**). Of note, on univariate analysis, presence of free flap reconstruction was not a significant risk factor for mortality, and thus it was not included in the multivariate regression model.

As evidenced by the results from this large study population, the rate of 30-day mortality is low (0.7%) following head and neck cancer surgery. Published rates range from 0.4% to 3%.^{3,7-9} Although association of postoperative complications with mortality provides strong evidence for the severity of complications, the relatively low mortality rate in head and neck cancer surgery necessitates examination of additional outcomes to fully evaluate complication severity, as it may provide a limited picture of the burden of certain complications. Evaluation of additional outcomes such as reoperation, readmission, and increased cost or length of stay would provide additional information regarding the burden of individual complications.¹

The use of a large database such as NSQIP allows for meaningful evaluation of mortality, despite the low rate following head and neck cancer surgery. However, several

limitations exist in this analysis of risk factors for mortality after head and neck surgery using a large, risk-adjusted national database. First, NSQIP is designed to track a wide variety of operations and therefore includes numerous variables. Unfortunately, important variables associated with head and neck surgery are not currently included, including TNM classification and airway status. As with all large databases, missing and inaccurate data pose a significant challenge in NSQIP and are a limitation of this study. While numerous statistical approaches are employed to limit the effects of missing data in NSQIP, these methods are imperfect, and missing data remain a limitation of large database studies.^{26,27} Studies that have evaluated NSQIP's data abstraction process have shown that while it is generally accurate, there are limitations. Through direct comparison of patients' medical records and NSQIP data files, Awad and colleagues²⁸ demonstrated that while NSQIP accurately records major complications (defined by Clavien-Dindo grades II-V), minor complications (Clavien-Dindo grade I or II) were only recorded in 33% of cases.²⁹ Finally, this analysis does not definitively identify the individual complications as the immediate cause of death but instead provides evidence of the increased risk of all-cause mortality following postoperative complications and should be interpreted accordingly.

Conclusions

In this study, postoperative pneumonia, progressive renal insufficiency, bleeding requiring transfusion, sepsis, septic shock, stroke, and cardiac arrest were independently associated with increased odds of 30-day mortality. Efforts should be made to prevent and aggressively manage these complications to decrease the risk of postoperative mortality following head and neck cancer surgery. In addition, these findings provide context that may be useful when interpreting individual patients' risks of postoperative complications using predictive models. Finally, the increased risk of mortality seen following these individual complications also provides compelling evidence of their increased severity. These complications should be considered with increased weight when using the NSQIP database to evaluate outcomes in head and neck surgery. Additional measures such as cost, hospital readmission, and reoperation should be explored to fully evaluate the severity of individual complications following head and neck cancer surgery.

Ethical Approval

De-identified patient information is freely available to all institutional members who comply with the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) Data Use Agreement. The Data Use Agreement implements the protections afforded by the Health Insurance Portability and Accountability Act of 1996.

Author Contributions

Carolyn L. Mulvey, substantial contributions to the conception or design of the work and the acquisition, analysis, or interpretation

of data for the work and drafting the work or revising it critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Jason A. Brant**, substantial contributions to the conception or design of the work and the acquisition, analysis, or interpretation of data for the work; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Andrés M. Bur**, substantial contributions to the conception or design of the work, revising the work critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Jinbo Chen**, substantial contributions to the acquisition, analysis, or interpretation of data for the work; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **John P. Fischer**, substantial contributions to the conception or design of the work, revising the work critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Steven B. Cannady**, substantial contributions to the conception or design of the work, revising the work critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Jason G. Newman**, substantial contributions to the conception or design of the work, revising the work critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Disclosures

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Supplemental Material

Additional supporting information may be found at <http://oto.sagepub.com/content/by/supplemental-data>

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