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Iatrogenic Esophageal Perforation in Patients with Head & Neck Cancer: Evaluation of the SEER-Medicare Database

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Abstract

1. Determine rate of iatrogenic esophageal perforation in head and neck cancer patients
2. Identify risk factors for perforation
3. Determine effect of perforation on mortality

Study Design—Secondary data analysis

Setting—SEER-Medicare linked database

Subjects and Methods—Patients diagnosed with squamous cell carcinoma of the upper aerodigestive tract between January 1995 and December 2002 who underwent esophagoscopy were included. Primary outcome was rate of iatrogenic esophageal perforation. Secondary outcomes included identification of risk factors for perforation and effect of perforation on mortality. Logistic regression analysis and chi-square test were used to evaluate risk factors and 30-day mortality.

Results—There were 152 perforations in 126 patients, for a rate of 2.70% (95% C.I. 2.28 to 3.20) per patient (N=4,659) and 1.44% (1.21 to 1.67) per esophagoscopy (N=10,529). Odds of perforation were increased in patients with cancer of the pharynx (OR 4.49, 1.82 to 11.08), pyriform sinus (OR 5.00, 2.10 to 11.93), and larynx (OR 3.39, 1.57 to 7.34), and those who underwent both surgery and radiation (OR 1.75, 1.12 to 2.74). Each esophagoscopy increased odds of perforation by 22% (17 to 28). Compared to diagnostic esophagoscopy, perforation was 2.9 times (1.77 to 4.69) more likely when dilatation was performed. 30-day post-perforation mortality was 7.1%, a 3% absolute increase (−1.5 to 7.5) over the post-esophagoscopy rate in patients without perforation.

Conclusion—Head and neck squamous cell carcinoma patients are a high-risk population for iatrogenic pharyngoesophageal perforation. Perforation is related to esophagoscopy frequency and type, tumor location, and use of multi-modality therapy.

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INTRODUCTION

Esophageal perforation is a serious injury with an estimated mortality of 15–20%.¹ The majority of esophageal perforations are iatrogenic, with endoscopic procedures accounting for 59% of perforations in a recent series.² Iatrogenic perforations most often occur at normal anatomic narrowings, with the majority located in the hypopharynx secondary to exertion of force in passing the endoscope through the hypopharynx-cervical esophageal junction.³

Population-based data from the United States showed that up to 60% of patients with cancer of the head & neck undergo at least one esophagoscopy for detection of synchronous malignant lesions of the upper aerodigestive tract or management of treatment-related complications such as strictures.⁴ Given the frequency of procedures performed on head & neck cancer patients along with patient characteristics that increase susceptibility to injury, this population likely has a significantly higher rate of iatrogenic esophageal perforation compared to non-cancer patients.

In non-cancer patients, the rate of iatrogenic esophageal perforation varies with esophagoscopy type. Estimates of esophageal perforation rate from diagnostic esophagoscopy are 0.03% and 0.11% per procedure for flexible and rigid procedures respectively. Dilatation procedures are associated with a 10-fold higher rate than diagnostic esophagoscopy.⁵ The rate of perforations among head & neck cancer patients is currently unknown. It is also unclear whether certain sub-populations defined by demographic, clinical, tumor, or treatment characteristics are at higher risk of iatrogenic perforations.

The goal of this study is to determine the rate of iatrogenic esophageal perforation in patients with squamous cell carcinoma of the head & neck. In addition, we sought to identify predictors of increased risk of perforation and the effects of perforation on post-esophagoscopy mortality.

METHODS

DESIGN

Sources of Data—This is a secondary data analysis of the Surveillance, Epidemiology, and End Results (SEER)-Medicare linked database. This database links two population-based data sources: the SEER cancer registries data and the Medicare enrollment and claims files. The SEER-Medicare linked database reflects a collaborative effort between the National Cancer Institute (NCI), the SEER registries, and the Centers for Medicare and Medicaid Services (CMS).⁶

The SEER program data is contained in the Patient Entitlement and Diagnosis Summary File (PEDSF). This file includes patient demographics, age at cancer diagnosis, vital status and date of death, cancer site, tumor histology, tumor grade, morphologic stage, and therapy provided during the first four months following cancer diagnosis.

Persons in the SEER database who are also Medicare eligible are included in the SEER-Medicare dataset. The Medicare Claims data are included in several files:

1. The Medicare Provider Analysis and Review (MEDPAR) includes claims from Part A inpatient stays and includes ICD-9 codes for diagnoses and procedures provided during each hospitalization.

2. National Claims History (NCH) includes claims from Part B non-institutional physician services and includes ICD-9 codes diagnoses and CPT-4 codes for procedures performed during each visit.
3. The Outpatient Claims (OUTSAF) includes claims from Part B institutional outpatient services. It includes ICD-9 codes for diagnoses, and both ICD-9 and CPT-4 codes for procedures performed during each visit.

Study Population—Patients from the PEDSF file were included in the study if they were diagnosed with squamous cell carcinoma of the lip, tongue, gum, floor of mouth, tonsil, oropharynx, nasopharynx, pyriform sinus, hypopharynx, and larynx between January 1995 and December 2002. In order to ensure completeness of comorbidity information, patients were excluded if they were younger than 66 years of age at the date of cancer diagnosis. In addition, patients who did not have Medicare Part A and Part B coverage 12 months prior to the date of cancer diagnosis were excluded because their claims history were likely to be incomplete. There were 17,860 patients in the PEDSF file who met entry criteria for the study. This file was merged with the NCH, MEDPAR, and OUTSAF records of patients who had undergone at least one esophagoscopy from 90 days prior to date of cancer diagnosis until December 2005. A total of 4,659 patients met final criteria for entry into the study. The study was classified as IRB-exempt by the Washington University Human Research Protection Office.

VARIABLES

Iatrogenic esophageal perforation—Perforation was identified if the following ICD-9-CM diagnostic codes were present during a visit in which esophagoscopy occurred: esophageal perforation (530.4), accidental instrumental perforation (998.2), or pharyngeal perforation (478.29).

Esophagoscopy—Esophagoscopy was identified by ICD-9-CM and CPT-4 codes. ICD-9-CM codes identified patients who underwent esophagoscopy (42.23, 42.24), but did not specify the type of procedure. The following CPT-4 codes identified the type of esophagoscopy: diagnostic (43200, 43202), stenting (43219), or dilation (43220-43226). Total number of esophagoscopies were counted from 90 days prior to the date of cancer diagnosis. The indication for the esophagoscopy is not included in the dataset.

Comorbidity—The severity of comorbidity at the time of cancer diagnosis was calculated using the Charlson Comorbidity Index,⁷ which was adapted for use with ICD-9-CM administrative databases based on the algorithm by Deyo et al.⁸ The Deyo-modification of the Charlson index has been validated in head & neck cancer patients.^{9,10}

Tumor site—Tumor site was identified using the ICD-O-2 classification system. The following codes were used to identify sites of interest: lip (000-009), tongue (019-024, 028-029), gum (030-031, 039), floor of mouth (040-041, 048-049), palate (050-052, 058-059), other parts of mouth (060-062, 068-069), tonsil (090-091, 098-099), oropharynx (100-104, 108-109), nasopharynx (110-113, 118-119), pyriform sinus (129), hypopharynx (130-132, 138-139), and larynx (320-323, 328-329). In order to achieve adequate sample sizes during analysis, several sites were combined. The final categories were lip-mouth (lip, gum, mouth, palate), tongue, tonsil, pharynx (oro-, naso-, hypo-), pyriform, and larynx. The ICD-O-3 classification system was used to identify patients with squamous cell histology (8050-8052, 8070-8076, 8078, 8082-8084). In each patient, we focused exclusively on the first head and neck cancer that met entry criteria.

Tumor Stage—The morphologic extent of malignant disease was coded as local, regional, or distant as defined by SEER Historic Stage.

Treatment type—Cancer-directed treatment type within four months of the date of diagnosis was defined from PEDSF. Treatment type was classified as none, radiation only, surgery only, or both modalities. Due to absence of data on chemotherapy (Table 6), this modality was not analyzed in this study.

Mortality—In patients with perforation, 30-day mortality was calculated from the date of their first perforation. In patients without perforation, 30-day post-esophagoscopy mortality was calculated from the date of their final esophagoscopy.

Outcomes—The primary outcome measure was the rate of iatrogenic perforation after esophagoscopy. Secondary outcome measures included determination of risk factors associated with perforation and effect of perforation on post-esophagoscopy mortality.

STATISTICAL ANALYSIS

During the design phase of the study, we anticipated a fixed sample size of 7500 subjects and hypothesized a 1% perforation rate per patient. This sample size and perforation rate was expected to provide a width of the 95% confidence interval of approximately 0.5% around the observed iatrogenic perforation rate.

Univariate and bivariate analyses were performed for data exploration and to evaluate relationships between predictor variables. Standard descriptive statistics were used to describe the study population. Cases were defined as study subjects with at least one iatrogenic esophageal perforation. Controls were patients who underwent esophagoscopy but did not experience iatrogenic esophageal perforation. The esophageal perforation rate per patient was calculated by dividing the number of patients with at least one perforation by the total number of patients in the study. The esophageal perforation rate per procedure was calculated by dividing the number of perforations by the total number of procedures.

Bivariate analysis using Chi-squared test was used to compare demographic and clinical characteristics of the case and cohort populations. Categories that achieved a level of significance less than 0.2 in chi-squared analyses were included in a binary logistic regression model to determine the risk factors associated with perforation.

Bivariate analysis was done to check for predictor variable collinearity. Dummy variables were created for each categorical variable entered into the model (tumor site, treatment). The reference category for tumor site was 'lip-mouth,' the most proximal site evaluated in the dataset. 'Surgery only' rather than 'none' was chosen as the reference category for treatment due to the small number of subjects who did not undergo any treatment modality. Number of esophagoscopies was entered into the model as a continuous variable. The final model was created using the 'forced entry' method. Subsequent analysis using forward and backward stepwise regression analysis with inclusion and exclusion thresholds of 0.05 and 0.10, respectively, yielded similar results.

At the time of esophagoscopy, one or more types of esophagoscopies were occasionally performed, such as diagnostic and dilatation. In addition, the frequency of esophagoscopy types differs between initial and subsequent visits. For these and other reasons, we were unable to include esophagoscopy type in the logistic regression model. In order to evaluate whether certain esophagoscopy types (diagnostic, dilatation) were associated with a higher rate of perforation, we compared the odds of perforation during visits in which dilatation procedures occurred to odds of perforation during visits in which diagnostic

esophagoscopies were performed. Since stenting was rare in this cohort, it was excluded from analysis. The association between esophagoscopy type and risk of perforation was evaluated with the chi-squared test.

Since post-perforation mortality is likely to occur within 30 days, we compared 30-day mortality following the first iatrogenic perforation in patients with perforation to mortality associated with the last esophagoscopy performed in patients without perforation. 30-day mortality in the two groups was compared using the chi-squared test. All statistical analyses were done using SAS system version 9 and SPSS system version 15.0 for Windows.

RESULTS

A population of 4,659 patients with newly diagnosed squamous cell carcinoma of the lip, mouth, tongue, tonsil, pharynx, pyriform, and larynx who underwent at least one esophagoscopy after diagnosis was identified in the SEER-Medicare database. The cohort had a median age of 73 and was predominantly male and white. The majority of tumors were staged as regional at time of diagnosis and most patients received combined surgery and radiation (n=1476, 32%).

The rate of perforation per patient stratified by demographic, clinical, tumor, and treatment characteristics is described in Table 1 and Table 2. A total of 152 iatrogenic esophageal perforations were identified among 126 patients that had at least one perforation. The rate of iatrogenic esophageal perforation was 1.44% (95% C.I. 1.21 to 1.67) per esophagoscopy (N=10,529) and 2.70% (C.I. 2.28 to 3.20) per patient. Of the 152 iatrogenic perforations, 129 (84.9%) were located in the pharynx, 6 (3.9%) in the esophagus, and 17 (11.2%) had a site in the pharyngo-esophageal region that was not specified. The rate of perforation was unchanged when stratified by age, gender, race, severity of comorbidity, or cancer stage.

Of the 126 patients with at least one perforation, 18 (14.2%) had two perforations, two (1.6%) had three perforations, and one (0.8%) had four perforations. The 26 additional perforations resulted from 101 post-perforation esophagoscopies.

Tumor site, treatment modality, and number of esophagoscopies were entered into a multiple logistic regression model for prediction of perforation. In this model (Table 3), compared to cancer of the lip and mouth, the odds of perforation was significantly increased in patients with cancer of the pharynx (OR 4.49, C.I. 1.82 to 11.08), pyriform sinus (OR 5.00, C.I. 2.10 to 11.93), and larynx (OR 3.39, C.I. 1.57 to 7.34). The odds of perforation was also increased in patients who underwent both surgery and radiation treatment (OR 1.75, C.I. 1.12 to 2.74) compared to patients who underwent surgery alone. Finally, each additional esophagoscopy was associated with an increased odds of perforation (OR 1.22, C.I. 1.17 to 1.28).

The perforation rates per procedure type were 1.05% (C.I. 0.82 to 1.28) for diagnostic esophagoscopy and 2.97% (C.I. 1.72 to 4.22) for dilatation procedures (Table 4). Evaluation of the entire cohort revealed that patients were nearly three times (OR 2.88, C.I. 1.77 to 4.69) as likely to have a perforation during a visit in which dilatation occurred as compared to visits where diagnostic esophagoscopy was performed.

30-day post-esophagoscopy mortality was compared in patients with and without perforation (Table 5). A total of 9 out of 126 esophagoscopies in which first perforation occurred (7.1%, C.I. 2.6 to 11.6) were associated with death within 30 days of the event. In the 4533 patients without perforation, 30-day post esophagoscopy mortality was 4.1% (C.I. 3.5 to 4.7). The absolute increase in 30-day mortality associated with perforation was 3.0% (C.I. -1.5 to 7.5).

DISCUSSION

In this study, we found a baseline rate of iatrogenic esophageal perforation of 1.4% per procedure and 2.7% per patient with the majority of perforations occurring in the pharynx. The perforation rates per procedure were 1.05% for diagnostic esophagoscopy and 2.97% per dilatation procedure. Using multiple logistic regression analysis, higher rates of perforation were found in patients who underwent more esophagoscopies, had distal primary cancer sites (pharynx, pyriform sinus, larynx), or had received both surgery and radiation.

The rate of iatrogenic esophageal perforation in our head and neck cancer cohort was significantly greater than the rates described in prior publications in non-cancer patients.^{11,12} The fact that such a difference exists after controlling for number of esophagoscopies supports our hypothesis that characteristics unique to the head and neck cancer population likely predispose them to perforation. Since most perforations occur at or above the level of the cricopharyngeus, it is not surprising that our results showed that tumor sites closest to this area are associated with the highest perforation rates. This association is likely due in part to the local effects of the disease process, but is also due to the deleterious effects of cancer-directed therapy.

In addition to the differences in perforation rate described above, it is important to note that the rate of perforation per procedure after the initial perforation was 26%. This suggests that after initial perforation, patients are extremely vulnerable to subsequent iatrogenic esophageal perforations. While an increased rate is not surprising in this subset of patients, our point-estimate may overestimate the true value if patients with slow-healing perforations underwent esophagoscopy prior to complete healing or repair of the original perforation.

In this study, we examined the effect of perforation on mortality. The 30-day post-perforation mortality rate of 7.1% in this study is significantly lower than the rates of 15–20% often cited for iatrogenic esophageal perforation in non-cancer patients.¹ However, prior publications have shown that due to decreased risk of mediastinitis and sepsis, cervical esophageal perforation is associated with a significantly lower mortality rate than thoracic or abdominal esophageal perforation.¹³

There were several limitations to this study. First, while we know rigid esophagoscopy is the standard means of endoscopy in head and neck cancer patients, we were unable to differentiate rigid and flexible esophagoscopy in the study population. Since rates of perforation differ significantly between rigid and flexible esophagoscopy,¹¹ absence of this stratification limited our ability to directly compare rates observed in this study and those observed in other publications. Further, it prevented us from determining whether the higher perforation rate observed in this study is primarily due to the increased frequency of rigid esophagoscopy in our study population as compared to the non-cancer population.

The second limitation of this study was the absence of esophagoscopy type in 19% of visits. While the absence of this code decreased the strength of our conclusions about dilatation procedures, biological plausibility and the strength of the association suggest that our results cannot be fully explained by bias. In fact, if the missing CPT-4 codes were evenly split between dilatation and diagnostic non-perforation visits, this unlikely scenario would still yield a statistically significant association between dilatation and perforation.

The dataset provides limited information about the clinical context in which each esophagoscopy was performed. First, it does not include the indication for esophagoscopy. However, our clinical experience suggests that it is reasonable to assume that all esophagoscopies performed in this patient population within the time frame examined were performed to evaluate or manage symptoms and complications related to the primary head

and neck cancer. Second, the dataset includes the initial SEER stage, but does not provide information on tumor status at the time each esophagoscopy was performed. Given this limitation, predictors of perforation were calculated 'per patient' rather than 'per procedure,' justifying use of initial SEER stage as an independent predictor of perforation.

There were additional limitations associated with coding in the SEER dataset. The ICD-9 code used to detect pharyngeal perforation in this dataset is non-specific and is also used to code for 'other diseases of pharynx or nasopharynx.' In addition, perforations occasionally occurred during visits in which both diagnostic and therapeutic esophagoscopy were performed, making it impossible to determine which procedure caused the perforation. Finally, we defined iatrogenic esophageal perforation as an esophageal perforation that occurred during a visit in which esophagoscopy was performed, recognizing that other procedures such as intubation performed during the same visit may rarely cause perforation. These factors all suggest that in this study, the perforation rate, especially the rate associated with diagnostic esophagoscopy, is probably an overestimate, albeit small, of the actual rate.

The data on chemotherapy was limited, thus preventing us from including this important treatment modality in our analysis. Finally, the generalizability of our results is limited by the fact that the dataset only includes patients greater than 65 years of age.

CONCLUSION

Head and neck squamous cell carcinoma patients are at higher risk than non-cancer patients for iatrogenic pharyngoesophageal perforation. Within this population, the subset of patients with primary cancers closest to the cricopharyngeus, those treated with surgery and radiation, and those with prior perforation are at higher risk, especially when concurrent dilatation procedures are performed. This study provides normative baseline data against which future studies can be compared.

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Table 1

Demographics and Clinical Characteristics

Variable	Patients (N)	Patients with perforation N (%)	Chi square (df)	p-value
Total	4659	126 (2.7)	---	---
Age at Diagnosis				
66–70	1526	41 (2.6)	1.64 (3)	0.65
71–75	1497	37 (2.5)		
76–80	981	32 (3.3)		
81	655	16 (2.6)		
Gender				
Male	3169	85 (2.7)	0.02 (1)	0.89
Female	1490	41 (2.8)		
Race				
White	3913	113 (2.9)	3.14 (2)	0.21
Black	474	8 (1.7)		
Other	272	5 (1.8)		
Comorbidity Index				
0	3699	100 (2.7)	0.04 (2)	0.98
1–2	915	25 (2.8)		
3	45	1 (2.2)		
# of esophagoscopies				
1	1533	16 (1.0)	179.10 (5)	< 0.001
2	2151	30 (1.4)		
3	365	23 (6.3)		
4–5	418	30 (7.2)		
6–8	124	15 (12.1)		
9	68	12 (17.6)		

Table 2

Tumor and Treatment Characteristics

Variable	Patients (N)	Patients with perforation N (%)	Chi square (df)	p-value
Tumor sites				
Lip-mouth	773	8 (1.0)	30.40 (5)	< 0.001
Tongue	839	13 (1.5)		
Tonsil	333	4 (1.2)		
Pharynx	381	15 (3.9)		
Pyriiform	379	20 (5.3)		
Larynx	1954	66 (3.4)		
Cancer stage				
Localized	1577	38 (2.4)	0.84 (2)	0.66
Regional	2482	71 (2.9)		
Distant	442	13 (2.9)		
Treatment modality				
None	224	5 (2.2)	12.68 (3)	0.005
Rads only	1251	30 (2.4)		
Surg only	1019	18 (1.8)		
Both	1476	59 (4.0)		

Table 3

Predictors of esophageal perforation (Logistic Regression Analysis)

Variable	Coefficient	S.E.	Wald's chi	p-value	OR	95% CI
Tumor sites	Reference	---	---	---	---	---
Lip-mouth						
Tongue	0.58	0.47	1.55	0.21	1.79	0.72 to 4.47
Tonsil	0.30	0.63	0.22	0.64	1.35	0.39 to 4.63
Pharynx *	1.50	0.46	10.6	0.001	4.49	1.82 to 11.1
Pyriiform *	1.61	0.44	13.2	0.000	5.00	2.10 to 11.9
Larynx *	1.22	0.39	9.60	0.002	3.39	1.57 to 7.34
Treatment						
None	0.11	0.49	0.05	0.83	1.11	0.42 to 2.92
XRT only	-0.04	0.27	0.03	0.87	0.96	0.57 to 1.61
Surgery only	Reference	---	---	---	---	---
Both *	0.56	0.23	5.92	0.02	1.75	1.12 to 2.74
Esophagoscopies *	0.20	0.02	73.0	0.00	1.22	1.17 to 1.28

* p < 0.05

Table 4

Effect of esophagoscopy type on perforation rate

Esophagoscopy type	Number of procedures		Chi-square	p-value
	Entire cohort	At perforation		
Overall	10529	152 (1.44 %)	---	---
Diagnostic	7725	81 (1.05 %)	55.09 (1)	< 0.001
Dilatation	708	21 (2.97 %)		

Table 5

30-day mortality following final esophagoscopy

	No perforation	Perforation	Chi-square	p-value
Total patients	4533	126	2.82 (1)	0.093
30-day post-esophagoscopy mortality	186 (4.1%)	9 (7.1%)		

Table 6

Other treatment options (in addition to surgery and/or radiation)

	Frequency	Percent
No other cancer-directed therapy	3773	81.0
Other cancer-directed therapy	3	0.1
Other experimental cancer-directed therapy	0	0
Double-blind study, code not yet broken	0	0
Unproven therapy	0	0
Refused therapy	1	0
Recommended, unknown if administered	1	0
Unknown	52	1.1
Missing data	829	17.8