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The association between gastrostomy tube placement, poor post-operative outcomes, and hospital re-admissions in head and neck cancer patients☆

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ABSTRACT

Objectives: Investigate the relationship of G-tube placement timing on post-operative outcomes.
Participants: 908 patients underwent resection of head and neck upper aerodigestive tract tumors between 2007 and 2013. Patient charts were retrospectively screened for patient demographics, pre-operative nutrition variables, co-morbid conditions, Tumor-Node-Metastasis staging, surgical treatment type, and timing of G-tube placement. Exclusionary criteria included death within the first three months of the resection and resections performed solely for nodal disease.
Main Outcomes: Post-surgical outcomes, including wound and medical complications, hospital re-admissions, length of inpatient hospital stay (LOS), intensive care unit (ICU) time.
Results: 793 surgeries were included: 8% of patients had G-tubes pre-operatively and 25% had G-tubes placed post-operatively. Patients with G-tubes (pre-operative or post-operative) were more likely to have complications and prolonged hospital care as compared to those without G-tubes ($p < 0.001$). Patients with pre-operative G-tubes had shortened length of stay ($p = 0.007$), less weight loss ($p = 0.03$), and fewer wound care needs ($p < 0.0001$), when compared to those that received G-tubes post-operatively. Those with G-tubes placed post-operatively had worse outcomes in all categories, except pre-operative BMI.
Conclusions: Though having enteral access in the form of a G-tube at any point suggests a more high risk patient, having a G-tube placed in the pre-operative period may protect against poor post-operative outcomes. Post-operative outcomes can be predicted based on patient characteristics available to the physician in the pre-operative period.

1. Introduction

Nutritional status in the head and neck cancer population is of particular interest given the marked changes in swallowing that often occur due to tumor invasion, and after resection of upper aerodigestive tract cancers. Further, adjuvant therapies like chemoradiotherapy can further limit oral intake due to side effects such as trismus, mucositis, xerostomia, and fibrosis. Recent data also suggests that on initial presentation 40% of patients with head and neck cancer are already malnourished, thus the potential for suboptimal outcomes is high [1]. Proper planning in the pre-operative period to optimize the nutritional status is could prove to be essential for the best outcomes.

Comprehensive national guidelines currently do not exist on either the timing or the necessity of gastrostomy tube (G-tube) placement for head and neck cancer patients treated primarily with surgery as there is controversy regarding the utility and safety of

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gastrostomy tubes in the surgical population [2]. In order to better identify those with the greatest need for gastrostomy tube placement, a recent predictive model based on variables available to the surgeon in the pre-operative period was developed to identify patients at high risk of G-tube placement in the post-operative period. The goal of this model was to identify high risk patients early, prior to resection, in order to avoid poor outcomes potentially related to poor nutritional status [3]. The model gives each patient a predictive probability score for placement of a G-tube in the post-operative period by entering the presence or absence of several pre-operative variables into the predictive equation. With this model as a tool, we sought to determine any relationship between G-tube placement timing and post-operative outcomes in order to determine any benefit to placement of a G-tube in the pre-operative period. Also we set out to determine the reliability of the predictive model mentioned above to predict G-tube placement.

2. Methods

A retrospective review of patient charts from the Wake Forest Baptist Health Otolaryngology - Head and Neck Oncology clinic was performed. Patients were identified based on a comprehensive database of all surgical procedures performed by the three Head and Neck Oncology faculty between the dates January 1, 2007 to December 31, 2013 with the ICD-9 codes 140.0–149.9 and 160.0–162.0. This database was compiled and released by the WFBH Medical Records department after Institutional Review Board approval was obtained. Each patient chart from this database was screened for participation in this study.

The eligibility criteria included: all patients, aged 18 or over, who underwent surgical resection for head and neck upper aerodigestive tract cancer or benign lesions. In order to eliminate confounding factors as to why a G-tube may be placed other than the current disease and current surgical procedure, we used several exclusionary criteria. Patients who recovered swallowing function post-operatively, but had G-tubes placed more than 3 months after the resection or placed prophylactically due to anticipated effects of adjuvant therapy were excluded; these G-tubes were considered to have been placed due to factors other than the disease or effects of surgery. We also excluded patients that solely underwent resection of neck nodal disease without primary site resection or those patients whose primary tumor site was not in the upper aerodigestive tract (e.g., skin, parotid, thyroid). Patients with insufficient pre-operative clinical data were excluded. Finally, because their need for G-tube was unable to be assessed during our defined post-operative time period, we excluded patients that died within three months of the resection.

Upon review of the above criteria, 793 patients were identified for inclusion in our study. Using the electronic medical record, patient charts were screened for demographic characteristics including age, gender, and body mass index (BMI). Clinical history factors included history of weight loss, tobacco (oral or inhaled) use, heavy alcohol use (more than 2 drinks per day), medical comorbidities, and ASA class (American Society of Anesthesiology physical status). History of pre-operative radiation to the tumor site and history of dysphagia were also included. A patient's history of dysphagia was deemed “positive” if there was any subjective complaint of difficulty swallowing by the patient. Quantification of the severity of the dysphagia in the clinic notes was rare, therefore it was coded as a binary variable. Tumor characteristics such as Tumor – Nodal – Metastasis (TNM) staging were also recorded. Surgery information such as surgical type, type of reconstruction, placement of tracheotomy, and timing of G-tube placement (or lack thereof). The indications for placement of a G-tube in the post-operative period were based off the combined assessments of the surgeon and speech/language pathologist as to whether they predicted a prolonged recovery of swallowing. Though not all patients had post-operative swallowing evaluations, i.e. modified barium swallow or functional endoscopic evaluation of swallowing, evidence of aspiration on these studies certainly assisted the team in determining whether a G-tube was necessary. In general, the surgeons and speech pathologists recommend G-tubes in the setting of gross aspiration with poor adaptation and management of secretions.

During the primary hospitalization for resection, the LOS, time in ICU, and total complications were recorded. Complications were defined as either wound or non-wound related. Wound-related complications were defined as those that directly involved the surgical site, including flap failure, fistula, donor site breakdown, hemorrhage/hematoma, wound site infection, primary site breakdown, chyle leak, and cerebrospinal fluid leak. Non-wound related complications were defined as those that did not directly involve the surgical site, including pneumonia, cardiac, electrolyte, myocardial infarction, anemia, altered mental status, pulmonary, code event, clostridium difficile colitis, gastrointestinal, stroke, neurologic, urinary traction infection, sepsis, pulmonary embolism, renal failure, and death. Hospital discharge location, i.e. home, skilled nursing facility, rehabilitation facility was recorded. Wound care needs were also included however this only included wound care directly related to wound complications, such as packing of wounds. Hospital re-admissions within the first three months after discharge were recorded and categorized as either wound or non-wound related. Weights were recorded at the first post-operative visit for comparison to pre-operative weights.

In order to calculate a predictive score for the probability of G-tube placement in the post-operative period, the following variables were also collected for each patient: pre-operative radiation, surgery type, tracheostomy placement, clinical node stage, pre-operative weight loss, history of dysphagia, reconstruction type, and tumor stage. Each variable was then entered into the predictive equation to calculate a predictive score see Table 1 for lists of all variables assessed.

2.1. Statistical methods

Descriptive statistics for all patients were generated for all measures, including means and standard deviations for continuous measures and frequencies and proportions for categorical measures. Next, bivariate analyses were performed to examine the relationship between each of the individual patient measures and the three-level variable for G-tube use (No G-tube, Pre-operative G-tube and Post-operative G-tube). Logistic regression models were used to compare the odds ratios for G-tube use for dichotomous outcomes (hospital readmission, wound complications, non-wound complications, and total complications). For continuous variables (length of stay, ICU time, BMI, G-tube predictive score, weight change, and age) mean values were compared across the three-level G-tube use variable using one-way analysis of variance (ANOVA) models with pair-wise comparisons between groups. Next, two stepwise logistic regression models were fit to determine the best set of risk factors to predict total complications (dichotomous) and hospital readmissions (dichotomous). Finally, two stepwise linear regression models were fit to determine the best set of risk factors to predict length of stay and ICU time.

All analyses were performed using SAS 9.3 (Cary, NC).

2.2. Sample size and power

The primary comparisons in these analyses focus on comparing the 793 participants across three G-tube groups (pre-operative,

Table 1
Pre- and post-operative variables assessed.

Demographic	Clinical history	Tumor	Surgical	Post-operative
Age	Weight loss	Tumor stage	Surgery type	Wound complications
Gender	Tobacco	Nodal stage	Reconstruction type	Non-wound complications
Body Mass Index	Heavy Alcohol	Metastasis stage	Tracheotomy	Hospital re-admissions
	ASA class			ICU time
	Radiation			Length of hospital stay
	Dysphagia			Post-operative weight
				Discharge location
				Wound care needs
				Predictive score[a]

[a] Score as determined by using model from Mays AC, et al. [3].

post-operative, none), thus we estimate the power to detect differences between these pairs of groups for mean values (i.e. length of stay) or percents (i.e. proportion with wound complications). For continuous measures there was 80% power to detect a difference between groups equivalent to 0.401 standard deviations (i.e. an effect size of 40.1%) assuming a two-sided 2-sample t-test with alpha = 0.05. So for example, for a variable such as length of stay with a standard deviation of 9.1, this would be 80% power to detect a difference of approximately 3.65 days. For comparisons with the no G-tube group much smaller differences could be detected (since this group had the largest sample size). The detectable effect sizes were 0.37 and 0.232 for the pre-operative/no G-tube and post-operative/no G-tube comparisons, respectively. For dichotomous outcomes such as wound complications we can detect an odds ratio of 2.3 for comparing the pre-operative and post-operative G-tube groups (if the underlying rate of the outcome is 37% such as wound complications) using a 2-sided Z-test with alpha = 0.05. Likewise, for no G-tube versus post-operative we can detect an odds ratio of 1.6, and for no G-tube vs pre-operative we can detect an odds ratio of 2.1.

3. Results

908 head and neck resections were performed at our facility during the study time period. 14 died within the first three months after resection. One-hundred one patients did not have sufficient data for inclusion. Thus 793 resections were included for analysis in this study.

Of the 793 resections that were included, 8% of patients had G-tubes present pre-operatively and 25% subsequently required G-tube placement in the post-operative period.

See Table 2 for frequencies and means for the variables studied.

See Table 3, Figs. 1–2 for the differences in outcomes based on G-tube status.

3.1. Pre-operative body mass index

The average pre-operative BMI for all patients was 26. Those without G-tubes had an average BMI of 26.5 compared to 24.8 for those that required a G-tube at any time period (pre- or post-operative), $p < 0.001$. Patients with pre-operative G-tubes had an average pre-operative BMI of 23.5, compared to 25.2 for those with post-operative G-tubes, $p < 0.05$.

3.2. Total complications

Total complications was recorded as a binary variable, and inclusive of any wound or non-wound complication, or hospital re-admission. Fifty-six percent of patients had at least one complication or hospital re-admission. Of those patients that never received G-tubes, 46% had at least one total complication compared to 76% of those that received any G-tube ($p < 0.001$). 71% of patients with pre-operative G-tubes had at least one total complication versus 77% of those with post-operative G-tubes ($p = 0.29$).

The model for predicting total complications included tumor stage ($p < 0.0001$), tracheostomy placement ($p < 0.0001$), reconstruction type ($p < 0.0004$), ASA class ($p = 0.003$), dysphagia ($p = 0.016$), and gender ($p = 0.05$). In the reconstruction type category, primary closure and split thickness skin graft reconstructions were 53% less likely to have complications than free flap and pedicled rotation flap reconstructions. Females were 70% less likely than men to have complications.

See Table 4 for the complete predictive model for total complications.

3.3. Wound complications

Thirty-seven percent of patients developed at least one wound complication. Of those patients that never received a G-tube, 29% had a wound complication as opposed to 43% and 54% for those with pre-operative and post-operative G-tubes, respectively ($p < 0.001$). Patients with post-operative G-tubes had more wound complications than those with pre-operative G-tubes ($p = 0.11$).

3.4. Non-wound complications

Thirty-nine percent of patients developed at least one non-wound related complication. Of those patients that never received a G-tube, 31% had a non-wound related complication as opposed to 48% and 56% for those with pre-operative and post-operative G-tubes, respectively ($p < 0.001$). Patients with post-operative G-tubes had more non-wound complications than those with pre-operative G-tubes ($p = 0.24$).

3.5. Hospital re-admissions

Fifteen percent of patients were re-admitted during this time period. Of those patients that never received G-tubes, 10% were re-admitted compared to 24% of those that received any G-tube ($p < 0.001$). There was no significant difference between those with pre-operative G-tubes (22%) and those with post-operative G-tubes (25%), $p = 0.60$.

The model for predicting hospital re-admission included pre-operative radiation ($p = 0.039$), tumor stage ($p < 0.0001$) and ASA class ($p = 0.0005$).

See Table 5 for the complete predictive model for hospital re-admissions.

3.6. Length of hospital stay

The average LOS for all patients was 9.8. The average LOS was 7.2, 12, and 15 for the never, pre-operative and post-operative G-

Table 2
Frequencies and means for variables assessed.

Predictor	Frequency (percentage %)	Mean (standard deviation, SD)
Gender	Female: 212 (27%)	
	Male: 588 (73%)	
Tobacco Use	Y: 637 (80%)	
	N: 163 (20%)	
Heavy Alcohol Use	Y: 187 (23%)	
	N: 613 (77%)	
Pre-operative weight loss	Y: 281 (35%)	
	N: 519 (65%)	
ASA class	1: 0	
	2: 143 (18%)	
	3: 581 (73%)	
	4: 76 (9%)	
Pre-operative radiation	Y: 210 (26%)	
	N: 590 (74%)	
Dysphagia	Y: 310 (39%)	
	N: 490 (61%)	
Tumor Stage	1: 210 (26%)	
	2: 203 (25%)	
	3: 143 (18%)	
	4: 244 (31%)	
Nodal Stage	0: 511 (64%)	
	1: 105 (13%)	
	2: 184 (23%)	
	3: 0	
Tracheotomy placement	Y: 344 (43%)	
	N: 456 (57%)	
Reconstruction type	Primary closure/Split thickness skin graft: 407 (51%)	
	Pedicled flap/Free flap: 393 (49%)	
G tube status	Pre-op: 65 (8%)	
	Post-op: 202 (26%)	
	Never: 526 (66%)	
Hospital re-admission	Y: 118 (15%)	
	N: 682 (85%)	
Wound Complications	Y: 293 (37%)	
	N: 506 (63%)	
Non-wound Complications	Y: 312 (39%)	
	N: 488 (61%)	
Total Complications	Y: 450 (56%)	
	N: 350 (44%)	
Length of Stay		9.8 days (SD 9.1)
ICU Time		2.21 days (SD 3.4)
Pre-operative Body Mass Index		26 (SD 6.1)
Age		62 (SD 12.4)
G-tube predictive score [3]		0.25 (SD 0.23)
Weight Change between Pre- and Post-operative periods	Same weight: 38 (5%)	7.5 lbs or 3.9% (SD 13/6.8%)
	Weight increase: 132 (18%)	
	Weight Decrease: 577 (77%)	
Discharge Location	Home: 719 (91%)	
	SNF: 64 (8%)	
	Rehab: 4 (1%)	
Wound Care	Y: 248 (31%)	
	N: 543 (69%)	

tube patients, respectively ($p < 0.001$, adjusted R^2 27.7%). Those patients that required any G-tube had a LOS twice as long as those that never required a G-tube, $p < 0.001$. Patients with pre-operative G-tubes had significantly shorter LOS as compared to those with post-operative G-tubes ($p < 0.007$). LOS and ICU time were also highly correlated ($r = 0.68$, $p < 0.001$).

When a model was created to predict length of stay, the predictive score [3] was found to be the most predictive variable. However when other variables were entered into the model in a step-wise fashion, the predictive score fell out of the model given that many of the variables that compose the predictive score were the variables that entered the model. The predictive variables that entered the model were tumor stage ($p < 0.001$), tracheostomy placement ($p < 0.001$), pre-operative weight loss ($p < 0.001$), age ($p < 0.001$), reconstruction type ($p = 0.0002$), tobacco use ($p = 0.01$), and dysphagia ($p = 0.002$). For reconstruction type, primary closure and split thickness skin graft reconstruction had 2.5 days less LOS compared to free flap and pedicled rotation flap reconstruction. Patients without pre-operative weight loss had 3.3 days less LOS as compared to those with pre-operative weight loss.

See Table 6 for the complete LOS predictive model.

3.7. Length of ICU time

The average ICU time for all patients was 2.2 days. For patients that never required a G-tube, the average ICU time was 1.4 days, compared to 3.2 days and 3.7 days for pre-operative and post-operative, respectively ($p < 0.001$, adjusted R^2 17.7%). There was no significant difference between ICU time in the pre- and post-operative G-tube groups ($p = 0.24$). Those patients that required any G-tube had average ICU time of over two times as long as those that never required a G-tube, $p < 0.001$.

Table 3
Differences in outcomes based on G-tube status.

Predictor	No G-Tube	Pre-operative G-Tube	Post-operative G-tube	Overall P value (adjusted R^2, where appropriate)	Any G tube (pre- or post-): n (%), P value, adjusted R^2, where appropriate	Odds ratio [95% Confidence interval], p value	T Test
Hospital re-admission	54 (10%)	14 (22%)	50 (25%)	p < 0.001	64 (24%), p < 0.001	None vs Pre: 2.4 [1.2 −4.6, p = 0.01 None vs Post: 2.9 [1.9 −4.4], p < 0.001 Pre vs Post: 1.2 [0.61 −2.3], p = 0.60 Never vs Any:2.8 [1.8 −4.1], p < 0.001	
Wound Complications	153 (29%)	28 (43%)	110 (54%)	<0.0001	138 (52%), p < 0.001	None vs Pre: 1.8 [1.1 −3.1], p = 0.02 None vs Post: 2.9 [2.1 −4.1], p < 0.0001 Pre vs Post: 1.6 [0.90 −2.8], p = 0.11 Never vs Any: 2.6 [1.9 −3.4], p < 0.0001	
Non-wound Complications	161 (31%)	31 (48%)	113 (56%)	<0.0001	144 (54%), p < 0.001	None vs Pre: 2.1 [1.2 −3.5], p = 0.006 None vs Post: 2.9 [2.1 −4.0], p < 0.0001 Pre vs Post: 1.4 [0.80 −2.4], p = 0.24 None vs Any: 2.5 [1.9 −3.5], p < 0.0001	
Total Complications	246 (46%)	46 (71%)	156 (77%)	<0.0001	202 (76%), p < 0.001	None vs Pre: 2.9 [1.6 −5.0], p = 0.0002 None vs Post: 4.0 [2.8 −5.8], p < 0.001 Pre vs Post: 1.4 [0.75 −2.6], p = 0.29 Never vs Any: 3.6 [2.6 −5.0], p < 0.001	
Length of Stay	7.2 days (SD 5.4)	12 (SD 14)	15 (SD 12)	<0.0001 (27.7%)	14.7 (SD 12.3), p < 0.001 15%		None vs Pre: 4.6, <0.0001 None vs Post: 12, <0.0001 Pre vs Post: 2.7, p = 0.007
ICU Time	1.4 days (SD 2.1)	3.2 (SD 4.1)	3.7 (SD 4.8)	<0.0001 (17.7%)	3.6 (SD 4.6), p < 0.001, 8%		None vs Pre: 4.1, <0.001 None vs Post: 8.5, <0.0001, Pre vs Post: 1.2, p = 0.24
Pre-operative Body Mass Index	26.5 (SD 6.3)	23.5 (SD 5.4)	25.2 (SD 5.6)	0.0002 (2.2%)	24.8 (SD 5.6), p = 0.0002, 1.7%		None vs Pre: −3.72, p = 0.0002 None vs Post: −2.58, p = 0.01 Pre vs Post: 1.9, p = 0.05
G-tube Predictive Score	0.17 (SD 0.16)	0.53 (SD 0.23)	0.38 (SD 0.24)	<0.0001 (29%)	0.41 (SD 0.25), p < 0.0001, 26%		None vs Pre: 14, p < 0.0001 None vs Post: 13, p < 0.0001 Pre vs Post: −5.6, p < 0.001
Weight Change between Pre- and Post-operative periods	7.2 lbs or 3.7% (SD 13/6.5%)	5 lbs or 2.2% (SD 16/7.3%)	9 lbs or 5% (SD 12/7.2%)	0.08 (68%)	8.1 lbs or 4.3% (SD 13/ 6.5%), p = 0.35, 0.11%		None vs Pre: −1.2, p = 0.23 None vs Post: 1.7, p = 0.08 Pre vs Post: 2.1, p = 0.03
Age	62 (SD 12.6)	61.3 (SD 11.7)	60.5 (SD 12)	p = 0.23 (0.37%)	61 (SD 12), p = 0.09, 0.36%		None vs Pre: −0.61, p = 0.54 None vs

Table 3 (*continued*)

Predictor	No G-Tube	Pre-operative G-Tube	Post-operative G-tube	Overall P value (adjusted R^2, where appropriate)	Any G tube (pre- or post-): n (%), P value, adjusted R^2, where appropriate	Odds ratio [95% Confidence interval], p value	T Test
							Post: −1.7, p = 0.09 Pre vs Post: −0.41, p = 0.67
Discharge Location	SNF: 20 (4%) Rehab: 2 (0.38%)	SNF: 12 (19%) Rehab: 1 (1.5%)	SNF: 31 (16%) Rehab: 1 (0.50%)	p < 0.0001	SNF: 43 (16%), p < 0.001 Rehab: 2 (0.76%), p < 0.001		
Wound Care	124 (24%)	24 (38%)	100 (50%)	p < 0.0001	124 (47%), p < 0.0001		

The model for predicting length of ICU time included reconstruction type ($p < 0.0001$), pre-operative weight loss ($p = 0.0001$), tracheostomy placement ($p = 0.0002$), age ($p = 0.0002$), tumor stage ($p = 0.005$), tobacco use ($p = 0.05$), heavy alcohol use ($p = 0.13$). For reconstruction type, primary closure and split thickness skin graft reconstruction spent 1.2 days less in the ICU compared to free flap and pedicled rotation flap reconstruction. Patients without pre-operative weight loss spent 0.92 days less in the ICU as compared to those with pre-operative weight loss.

See Table 7 for the complete ICU time predictive model.

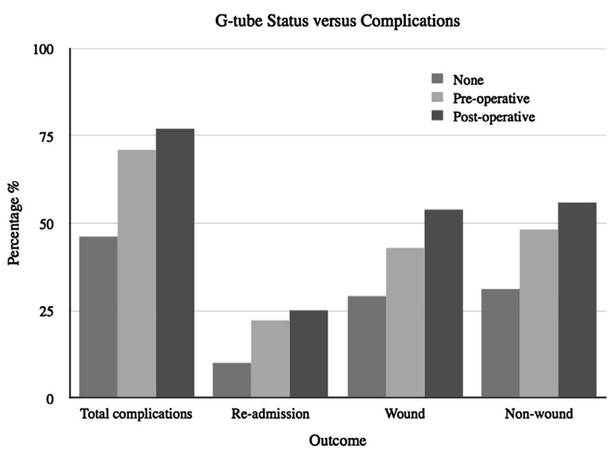

Fig. 1. G-tube status versus complications. We provide a display of each of our main complications and the differentiation between G-tube groups: no G-tube placement, G-tubes placed pre-operatively, and G-tubes placed post-operatively.

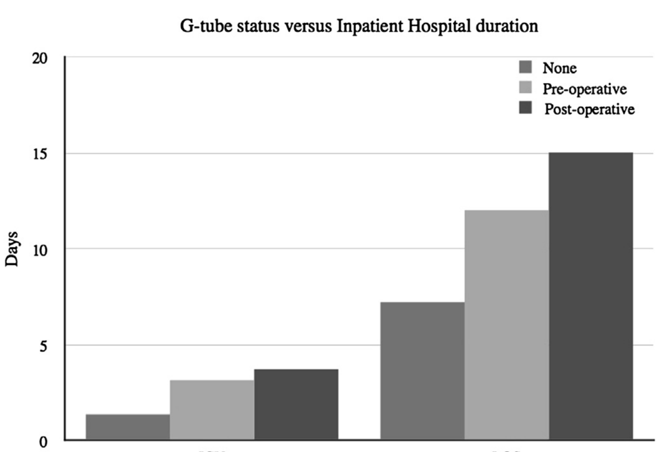

Fig. 2. G-tube status versus inpatient hospital duration. We provide a display of our measures of inpatient hospital duration and the differentiation between G-tube groups: no G-tube placement, G-tubes placed pre-operatively, and G-tubes placed post-operatively.

3.8. *Weight change between pre- and post-operative periods*

Seventy-seven percent of patients lost weight, 18% gained weight, and 5% had no weight change between the pre-operative and post-operative periods. For those patients that never received G-tubes, they lost an average of 7.2 pounds or 3.7% of total body weight. Patients with pre-operative G-tubes lost an average of 5 pounds or 2.2% body weight, compared to 9 pounds or 5% of body weight for the post-operative G-tube group ($p = 0.03$). There was

Table 4
Total complications predictive model.

Variable	Odds ratio and 95% confidence interval	P value
Tumor stage	T1 vs T2: 2.4 [1.5–3.6][a] T1 vs T3: 3.8 [2.3–6.3][a] T1 vs T4: 2.5 [1.6–3.8][a] T2 vs T4: 0.96 [0.62–1.5][b] T3 vs T4: 1.5 [0.95–2.5][b]	<0.0001
Tracheotomy placement	2.2 [1.5–3.1]	<0.0001
Reconstruction type	0.53 [0.36–0.77]	0.0004
ASA class	Class 2 vs Class 3: 2.1 [1.4–3.2][c] Class 2 vs Class 4: 1.9 [1–3.6][c] Class 3 vs Class 4: 1.1 [0.64–1.9][d]	0.003
Dysphagia	1.5 [1.1–2.1]	0.016
Gender	0.70 [0.49–0.99]	0.05

[a] T1 was used as the reference level.
[b] T4 was used as the reference level.
[c] ASA 2 was used as the reference level.
[d] ASA 4 was used as the reference level.

Table 5
Hospital re-admission predictive model.

Variable	Odds ratio and 95% confidence interval	P value
Radiation	2.4 [1.5–3.6]	0.039
Tumor Stage	T1 vs T2: 2.9 [1.4–6.0][a] T1 vs T3: 4.6 [2.2–9.7][a] T1 vs T4: 3.7 [1.8–7.4][a] T2 vs T4: 0.80 [0.47–1.3][b] T3 vs T4: 1.2 [0.74–2.1][b]	<0.0001
ASA class	Class 2 vs Class 3: 2.8 [1.2–6.2][c] Class 2 vs Class 4: 2.1 [0.78–5.9][c] Class 3 vs Class 4: 1.3 [0.66–2.6][d]	0.0005

[a] T1 was used as the reference level.
[b] T4 was used as the reference level.
[c] ASA 2 was used as the reference level.
[d] ASA 4 was used as the reference level.

Table 6
LOS predictive model.

Variable	Coefficient	P value
Tumor stage[a]	T1 vs T4: −4.1[b] T2 vs T4: −1.4[b] T3 vs T4: −1.1[b]	<0.0001
Tracheostomy	3.7	<0.0001
Pre-operative weight loss	3.3	<0.0001
Age	0.088	<0.0001
Reconstruction type	−2.5	0.0002
Tobacco use	1.8	0.01
Dysphagia	1.9	0.002

[a] The 'score' variable was the most significant variable for prediction of length of stay however the other variables were allowed to enter the model, the variable 'score' fell out of the model.
[b] T4 was used as the reference level.

no significant difference in weight change between those that never had G-tubes and those that had any G-tube ($p = 0.35$).

3.9. Wound care

31% of patients required wound care at discharge. Of those patients that never required a G-tube, 24% required wound care compared to 38% and 50% for the pre-operative and post-operative G-tube groups, respectively ($p < 0.001$). Those patients that required any G-tube were twice as likely to require wound care at discharge as compared to those that never required G-tubes (24% versus 47%, $p < 0.001$).

3.10. G-tube predictive score

The predictive probabilities of G-tube placement were 17%, 53%, and 038% for the never, pre-operative, and post-operative G-tubes, respectively ($p < 0.001$). The correlation between predictive score and ICU time was $r = 0.28$, $p < 0.001$ and between predictive score and LOS was $r = 0.39$, $p < 0.001$.

4. Discussion

Malnutrition is a poor prognostic indicator for medical therapy and has been shown to significantly impact survival and overall performance in cancer patients [4–6]. Patients that are nutritionally optimized pre-operatively not only rate their quality of life as better than those that are nutritionally depleted but they also have been shown to have better post-operative outcomes [1]. BMI greater than 25 pre-operatively has also been associated with improved swallow, longer time to disease recurrence and improved survival [7]. Though surgeons have long relied on nasogastric tubes in the immediate post-operative period to supplement nutrition during times of healing, longer term G-tubes are often required if swallowing function does not permit adequate oral intake to sustain life or because the aspiration risk is too great. Further, even those patients that may retain adequate swallowing function post-operatively may experience dysfunction during adjuvant therapy, demonstrated by the fact that 75–80% of patients undergo significant weight loss during chemoradiotherapy [8]. With all this in mind, for a certain subset of head and neck cancer patients, pre-operative G-tube placement is an important consideration in comprehensive treatment planning. We sought to determine any relationship between G-tube placement timing, pre-operative versus post-operative, and post-operative outcomes in order to assess for any potential benefit to placement of a G-tube in the pre-operative period.

Improving outcomes in the post-operative period is a necessary step to ensuring successful oncologic practice. Further, outcomes measures are now being evaluated by health care insurers and our government to determine reimbursement. Hospital re-admission rate is now used as a health care quality indicator though multiple studies have shown that high re-admission rate is not associated with inferior care [9–15]. The Patient Protection and Affordable Care Act of 2010 identified 30-day unplanned hospital re-admissions as a major contributor to Medicare overspending and this has driven the push to penalize facilities with high re-admission rates [14]. This push for quality-based reimbursement was proposed by the Center for Medicare and Medicaid Services and has directed financial penalties for institutions whose quality outcomes, such as re-admission rates and complications, are below acceptable standards [15–17]. Proactive measures on the part of the head and neck surgical team to reduce the incidence of these poor outcomes is now all the more important.

The overall rate of 30 day hospital re-admissions in head and neck surgery patients is roughly 10% [14,15]. Our study is not the first study to evaluate risk factors for re-admission in head and neck cancer patients. In multiple studies, wound complications such as fistula or infection are among the most common reasons for readmission, with an estimate of 51% of re-admissions being related to complications [14,15,18]. Advanced tumor stage (T3-T4) as well as longer length of stay have also been found to be predictors re-admission [13,18]. Interestingly, the presence of a G-tube at discharge was found to have a 3-fold increase in the rate of re-admission, and was also found to predict re-admission for pneumonia [14]. Another study found that pre-operative G-tubes were predictors of re-admission after resection [15]. Despite these findings that suggest a negative effect of G-tubes on outcomes, our findings suggest a potential protective quality of pre-operative G-tubes.

Length of stay during the hospitalization for tumor resection has also been studied in the past, most commonly as it relates to hospital re-admission rates. Prolonged length of stay has been found to be a very significant predictor of hospital re-admission across surgical subspecialties [15,19]. Only one study could be found that quantified the degree of prolonged care, showing that greater than five days demonstrated a 3-fold increased risk of re-admission [14]. Weight loss greater than 10% in the 6 months prior to surgery and high ASA class were found to be significant predictors of prolonged LOS [20]. Despite the prior work that has been done in identifying risk factors for poor outcomes, the authors cannot find another study that directly compares the outcomes of those patients that had G-tubes placed in the pre-operative and post-operative periods.

Our study demonstrates differences between patients that never require G-tubes and those that do require G-tubes, but also between those that have G-tubes placed in the pre-operative and post-operative periods across multiple outcomes. Patients that never required G-tubes had higher pre-operative BMI and

Table 7
ICU Predictive model.

Variable	Coefficient	P value
Reconstruction type	−1.2	<0.0001
Pre-operative weight loss	0.92	0.0001
Tracheostomy	0.99	0.0002
Age	0.03	0.0002
Tumor stage	T1 vs T4: −1.1[a] T2 vs T4: −0.40[a] T3 vs T4: −0.31[a]	0.005
Tobacco use	0.54	0.05
Heavy alcohol use	0.42	0.13

[a] T4 was used as the reference level.

statistically significant lower overall complications, re-admissions, ICU/LOS time, and wound care needs. Much of this can reasonably be explained by the assumption that those patients that never require G-tubes are able to retain enough swallow function to maintain adequate nutrition in the pre-operative and post-operative periods. Sustaining a higher BMI and swallow function should predispose these patients to a nutritionally optimized state. This is a plausible explanation for these patients overall better outcomes. Though the aim of this study was to demonstrate a possible protective quality to pre-operative G-tubes, it is important to recognize that though patients with pre-operative G-tubes do better than post-operative, they still have worse outcomes than those that never required G-tubes. Certainly G-tubes can be avoided in low risk patients, i.e. those that retain adequate swallow function and weight, but for that subset of patients that are high risk and will likely require G-tubes at some point during their care, we recommend close attention and consideration of pre-operative placement.

Though studies have shown that nutritional optimization in the pre-operative period improves post-operative outcomes, no prior studies have demonstrated a clear advantage to pre-operative G-tube placement [1]. In fact, other studies have shown a negative impact of G-tubes on outcomes [14,15]. We show in this study that patients with pre-operative G-tubes have statistically significant shortened length of stay, less weight loss, and less wound care needs than those that received G-tubes post-operatively. However, even though the differences did not reach statistical significance, patients with pre-operative G-tubes also had less complications overall (both wound and non-wound in nature), fewer re-admissions, and shorter ICU time when compared to those that received G-tubes post-operatively. Patients with G-tubes placed post-operatively had worse outcome scores in all categories, expect pre-operative BMI. Certainly some of these outcomes are correlated. For example, patients develop wound complications, such as fistulas, in the immediate post-operative period and due to the need for prolonged NPO time for healing of these complications, we elect to place G-tubes prior to discharge. This lengthens the hospital stay and may affect other variables such as probability of re-admission after discharge. However, the fact that patients with G-tubes placed post-operatively had worse outcome scores in nearly all categories suggests a potential protective quality to early G-tube placement in high risk patients.

In looking at variables that were common predictors of post-operative outcomes, several variables were found to play a more significant role. Tumor stage was the only variable to enter the predictive model for each of our main post-operative outcomes. Advanced tumor stage (T3-T4) was found to predict longer hospital stay and ICU time, as well as increased complications and re-admissions. Though pre-operative nutritional optimization may be protective against poor outcomes, our data also suggests that tumor characteristics in and of themselves can predict poor outcomes. Prior studies that found that advanced tumor stage predicts overall outcomes [13,18]. Further, prior studies have suggested that advanced tumors (T3-T4), and most consistently those of the hypopharynx, oral cavity and oropharynx are most likely to require G-tubes when treated with primary surgery or chemoradiation [3,21–23]. This need is intuitive in the surgical group given the greater volume of tissue excised with larger tumors and the need for larger and potentially more bulky reconstructions. In advanced tumor stage patients, this may suggest that pre-operative G-tube placement for nutritional optimization may be all the more beneficial.

Other common variables for prediction of poor outcomes were tracheotomy placement, reconstruction type, and pre-operative weight loss. Tracheotomy placement at the time of the resection and reconstruction type were also common predictors of poor outcomes. Similarly, tracheotomy tube at discharge has previously been found to predict hospital re-admission previously [14]. No prior studies were found that studied reconstruction type in the context of outcomes. Pre-operative weight loss was also a common predictor in our models. It was found to predict longer ICU and hospital stay. In the primary chemoradiation literature, patient with G-tubes placed prophylactically lost less weight and reported higher quality of life than those placed reactively [24,28]. They were also found to limit post-treatment dysphagia and had a faster return to normal diet [24]. Our findings further support our premise that measures to prevent weight loss, i.e. G-tube placement, prior to definitive therapy can protect against untoward post-operative courses. We point out these other variables that are predictive of poor outcomes to demonstrate that certainly overall outcomes have multifactorial influences, however also to point out that our predictive model [3] incorporates many of these variables into the predictive algorithm and may be used as a surrogate predictive model for predicting poor outcomes.

Discharge location and need for post-operative wound care needs were also found to differentiate between G-tube groups. Those patients that never required G-tubes were more likely to be discharged home and required the least wound care needs. Patients with G-tubes placed post-operatively had the highest wound care needs however those patients with G-tubes placed pre-operatively were more likely to require discharge to a skilled facility or rehabilitation facility, though this difference did not reach statistical significance. Prior studies found that discharge location was a predictor of re-admission, in that those that went to skilled nursing facility had a 5-fold increased risk of re-admission as compared to those that were discharged home [15]. Also, those that required home health services, as is often necessary for continued wound care at discharge, had a 3-fold increased risk of re-admission [15]. Efforts to reduce wound complications requiring wound care needs, such as dressing changes, and increase ability to discharge patients to home versus outside facilities should improve overall outcomes measures, such as re-admission rates. Again we have shown in this study that pre-operative G-tubes may protect against these untoward outcomes.

We recognize that in radiation oncology, there is literature that recommends delaying G-tubes in patients to protect inherent swallowing function [2], and here we suggest that placement of G-tubes may in fact be protective. We justify these differences in recommendations because we have thought of these as two separate patient populations: a primary radiation population and a primary surgical population. For the primary radiation population there are no large alterations in tissue bulk or structure, nor violation to normal tissue planes, as with surgical patients. Therefore the types of potential treatment-related complications differ amongst these two populations. While a radiation patient's greatest risk might be of post-treatment dysphagia or weight loss, a surgical patient's greatest risk may be incision breakdown or flap loss. We agree that in certain patients the risk of post-operative dysphagia after surgery is limited and therefore we agree that avoiding gastrostomy tubes and encouraging oral intake to protect swallowing function is appropriate. However we suggest that in certain patients, with characteristics as laid out in our predictive model [3], the probability of need for enteral access is so high that the risk of delaying G-tube (wound breakdown, prolonged hospital course, etc) is greater than the risk of prolonged time without swallow retraining.

Despite their inherent benefits to patients, G-tubes are not without complications themselves. Placement has been associated with a complication rate of 5–10%, including tube migration, leakage, and bleeding [25,26]. It is also associated with mortality and increased health care costs [2]. Further, there is also the potential for seeding of a tumor to the gastrostomy site or other abdominal sites with placement of percutaneous G-tubes (PEG) [27]. The proposed mechanism is most likely secondary to tumor implantation induced by trauma during PEG placement. With this in mind, we recommend either open/laparoscopic G-tube placement or placement intra-operatively at the time of the resection, after tumor has been removed. After the primary tumor has been resected, the oncologic surgeon could guide the endoscope through the defect site to the stomach for placement of G-tube by general surgery team. Despite the risks of the procedure, G-tube placement can offer significant benefits, including potential protection against poor post-operative outcomes. In order to reduce cost and patient burden for those that require pre-operative G-tubes, in our practice we recommend placement of G-tube at a facility convenient to the patient or in conjunction with other procedures, such as pre-resection tracheotomy or biopsy.

In a prior study, our group developed a model to predict G-tube placement in head and neck cancer patients [3]. We attempted in this study to show that the predictive score developed from the model differentiated between those patients that either did or did not receive G-tubes, but also did the predictive score have any relationship with any of our main outcomes. We found that the predictive score was actually the most predictive variable in predicting length of stay. As stated previously, we believe that the predictive model may be able to be used as a stand alone predictive variable to ultimately predict overall risk. We also found that the score differentiated between the three G-tube status groups with statistical significance, in that those patients that never received G-tubes had the lowest predictive score. Interestingly, the score also found that those that received pre-operative G-tubes had the highest predictive score, suggesting that those patients that received them were higher risk than even those that received them in the post-operative period. This implies that the predictive score can identify those patients that are higher risk in the pre-operative period, in that their physician team elected to place the G-tubes in the pre-operative period, making the predictive model all the more valuable. Further, given that this study demonstrated that it is important to differentiate between low risk (never G-tube group) and high risk groups (any G-tube group) to protect those people that should never need G-tubes, this predictive model becomes even more useful to the clinician.

Though the goal of this study was to show that pre-operative G-tubes are protective, we must also point out potential health care costs savings of G-tube placement in the pre-operative period. A cost analysis was outside the primary scope of this study, however intuitively any measure that decreases hospital length of stay, complications, re-admissions, and wound care needs i.e. home nursing services or need for skilled nursing facility, will likely save our health care system dollars. In our ever changing and more cost-efficient health care climate, physicians must recognize areas of potential cost-savings and in demonstrating all of these characteristics of the pre-operative G-tube group, we recommend careful consideration of pre-operative G-tubes in the high risk head and neck cancer population.

The strengths of this study include that it was performed on a large patient population cared for in a multi-surgeon practice at a large tertiary care facility. It included multiple facets of outcomes including surgical outcomes, like wound complications, but also objective outcomes like hospital stay duration. We performed a comprehensive multifactorial assessment which allowed us to differentially control for confounding factors and more clearly define true predictors. Further, we were able to further validate the accuracy of our predictive model [3] that was originally developed to be easily utilized in otolaryngology practices in the pre-operative setting to assess risk in head and neck cancer populations.

There are several limitations of this study. Our data was largely reliant on the accuracy and completeness of clinic notes, not all of which may have described the presence or extent of symptoms such as dysphagia or weight loss. With numerous providers involved in pre-operative clinical evaluation, there was certainly variability in the standard patient pre-operative evaluation. Further, we relied on patient report or outside records to alert us to complications or re-admissions that occurred outside our facility. If patients did not report these at their routine follow-up appointments or we did not receive these outside records, these would not have been included. Those that died within 3 months of resection were also excluded as we were not able to determine if they would have received G-tubes. Though only a few of our patients died during that interval, certainly the complications that led to their death may have been valuable to our analysis. We also did not include quantification of the number of complications as part of the analysis. Patients that had one complication were coded the same as those that had multiple complications. Additionally, we excluded patients whose notes clearly stated that a G-tube was being placed in anticipation of worsening function due to upcoming adjuvant chemoradiotherapy. If this concern was the main factor in the decision to refer a patient for a G-tube but was not documented in the record, then these patients were not excluded, but likely would have been excluded with better documentation.

Despite having a predictive algorithm and clinical data to suggest that a patient may be at risk for poor post-operative outcomes, good clinical judgment is invaluable. The goal of this study was to identify factors that make a patient high risk for poor outcomes and to assess for any protection inherent with pre-operative placement of G-tubes in a high risk population. We recommend a careful pre-operative assessment very early in treatment planning, and use of the predictive model, in order to determine need for pre-operative G-tube placement with the ultimate goal being optimized post-operative outcomes.

Further studies are warranted to analyze cost savings in those patients receiving pre-operative G-tubes, compared to those performed in the post-operative period. Analysis of survival outcomes over 5 and 10 year periods between G-tube groups would also be helpful. We also plan to reproduce the predictive model in a larger, new patient sample in other high-volume centers to further stratify high and low risk patients based on score. In order to determine the most beneficial time of pre-operative G-tube placement (weeks prior or intra-operative), future studies including pre- and post-operative nutrition labs such as pre-albumin to objectively identify nutritional optimization in G-tube groups are planned.

5. Conclusion

Post-operative complications and prolonged hospital care can be predicted based on patient characteristics available to the physician in the pre-operative period. Though having enteral access in the form of a G-tube at any point suggests a more high risk patient, having a G-tube placed in the pre-operative period may protect against poor post-operative outcomes. A comprehensive predictive model exists to predict need for G-tube placement in the head and neck cancer patient.

Author contribution

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Contributions: conception and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript, statistical analysis. Study design, data collection, statistical analysis, manuscript preparation.

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Contributions: conception and design, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript, supervision. Study design, manuscript preparation.

Conflict of interest

No conflicts of interest or financial disclosures to report.

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I, Ashley Mays, as the corresponding author had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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