Gastrostomy in the Era of Minimally Invasive Head and Neck Cancer Surgery

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Objectives: Minimally invasive transoral robotic surgery (TORS) is less likely to necessitate gastrostomy tube (GT) following resection of head and neck lesions versus conventional open procedures. However, the incidence of and indications for GT after TORS has not been reported in detail. This study defines the incidence of intra- and postoperative gastrostomy following robotic resection of advanced head and neck disease. It seeks to clarify the relevance of GT after TORS.

Design: Adult patients undergoing TORS and neck dissection (ND) from 2008-2014 were identified in the New York Statewide Planning and Research Cooperative System (SPARCS) all-payer administrative database.

Methods: Demographic data and timing of GT in relation to surgery were recorded. Emergency Department (ED) visits and inpatient readmissions were compared with multivariable logistic analysis.

Results: Of the 441 included patients, immediate, delayed and total GT incidence within the first postoperative year was 9.5%, 11.6% and 21.1%, respectively. GT complications resulted in 4.5% of 30-day ED visits, 3.3% of 30-day readmissions, and 3.5% of 90-day readmissions. Thirty-nine percent of 90-day readmissions were linked to poor postoperative oral intake. Delayed GT status was associated with an increase in 30-day ED visits, and 30 or 90-day readmissions attributable to poor oral intake ($p=0.10$, $p<0.0001$, 0.002, respectively).

Conclusions: Even in the era of minimally invasive transoral robotic surgery, impaired oral intake is a significant postoperative burden to head and neck cancer patients with advanced disease. Attention to patient risk factors combined with a complicated hospital course may identify patients benefiting from early GT.

Key word: gastrostomy, PEG, g-tube, TORS, cancer **Level of Evidence:** 2c

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Introduction

Gastrostomy tubes (GT) provide necessary alimentation for many patients with advanced head and neck cancer who require chemotherapy, radiation and/or surgical treatment. They avoid nutritional deficits in patients recovering from morbid operations and in those patients with impaired postoperative functional outcomes, such as dysphagia. However, GT can also negatively impact patient quality of life, and placement is not without risk or complications.[1] The procedure should not be employed without calculation of the benefits versus the risks.

Prior to the emergence of minimally invasive surgical techniques, gastrostomy was routine for at-risk patients undergoing head and neck cancer therapies. Open resection of difficult-to-reach head and neck neoplasms frequently requires GT. High-risk patients undergoing definitive chemoradiotherapy often receive prophylactic gastrostomy.[2, 3] However, the development of transoral robotic surgery (TORS) by the University of Pennsylvania (Philadelphia, PA) in 2004 shifted this paradigm.[4] Fewer TORS patients require gastrostomy than similar patients undergoing non-surgical therapy or open resection.[5, 6] Gastrostomy is not routine for TORS.[7]

There is a paucity of data regarding indications for gastrostomy in TORS, particularly in locally advanced Stage III or IV (M0) disease. TORS is FDA approved for resection of smaller (T1 and T2) malignancies, however it is becoming increasingly utilized for more advanced lesions (up to T4a oropharyngeal), which may lead to greater nutritional challenges in the perioperative period.[8-10] Current reports on gastrostomy incidence in TORS have small numbers, are often institution-based, and have a high proportion of early stage disease. The purpose of this study is to clarify the relevance of GT placement in the new era of minimal invasive TORS.

Methods

Study Design

Following Institutional Review Board approval, the New York Statewide Planning and Research Cooperative System (SPARCS) all-payer administrative database was used to identify all TORS.[7] Patients were tracked with a unique patient identifier. ND and robotic procedures (ICD-9 17.41-17.45, 17.49 or CPT S2900) were identified through ICD-9/CPT codes. Patients who were <18 years, had multiple resections (n=2) or had procedures staged with >6 month intervals (n=19) were excluded. Patient characteristics, including age, gender, race/ethnicity, region, facility type, payer, concurrent versus staged ND, surgical site, and comorbidities were identified. Inpatient complications, readmissions and Emergency Department (ED) visits were evaluated. Inpatient complications were defined as occurring during surgical admission, not readmission. Readmissions were evaluated 30 and 90 days following surgery. For patients with GT, only those placed during or after TORS + ND were considered (n=98). Patients receiving GT within the first postoperative year were further analyzed (n=93). Surgeon volume was considered. Low volume surgeons (LVS) performed an average of ≤5 TORS/year over nonzero years.[8] High volume surgeons (HVS) performed >5 TORS/year. Diagnosis codes for readmission and ED visits were analyzed. GT complications were identified (ICD-9 536.4). Patient records demonstrating a GT complication without record of GT placement (n=3) were included for the purpose of calculating overall GT complication rates, but these patients were excluded from further subgroup analyses. Frequency of diagnoses attributable to poor oral intake (ICD-9 276, 536.2, 783, 787.0, 787.2) were compared between no GT, immediate and delayed GT groups.

Statistical Methods

A Chi-square test with exact P-values based on Monte Carlo simulation was used to compare categorical variables among patients having immediate GT, delayed GT and not having a GT. Logistic regression models were used to compare differences in readmission or ED visits. Any GT, as well as variables which were significant in the univariate analysis at the significance level of 0.1 were further included in the multivariable regression models while applying the forward selection process considering the number of events per variable issue.[11] All analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC), and statistical significance was set at 0.05. SPARCS restricts reporting cell size <6.

Results

There were 441 patients who underwent TORS + ND from 2008 through 2014. In this group, 9.5% of patients underwent immediate GT (n=42) and 90.5% did not undergo immediate GT (n=399). Of those patients who did not receive an immediate GT, 12.8% required delayed GT placed within the first postoperative year (n=51). The average time to delayed GT was 62±59 days. At one year, the total incidence of having had a GT placed was 21.1% (n=93). No significant differences existed between patients with and without GT in terms of age, gender, race, ND timing, or surgeon volume (Table 1). Medicare/Medicaid patients had slightly higher GT rates than commercially insured patients (p=0.06). The patient factors that were associated with need for and timing of GT included fluid and electrolyte disorder or weight loss (FED), liver disease, alcohol abuse, paralysis and hypertension. Inpatient GT complications occurred in 2.4% (n=1) of the immediate GT group. GT complications resulted in 4.5% (n=4) of 88 ED visits within 30 days, 3.3% (n=2) of 61 readmissions within 30 days, and 3.5% (n=4) of 114 readmissions within 90 days.

A minority of patients harbored the diagnosis of FED preoperatively (4.8%, n=21). Of the 21 patients with preoperative FED, 61.9% (n=13) did not receive an immediate gastrostomy. However, patients with preoperative FED were more likely to receive a GT within one year of surgery (FED, 52.4% vs. no FED, 19.5%, p<0.001). At the time of postoperative discharge, 36 patients carried a diagnoses of FED, but only 50% (n=18) had or subsequently received a GT.

Immediate GT placement was most frequently associated with a complicated hospital course. All patients with an immediate GT (n=42) experienced at least one complication throughout their operative hospital course, compared to 70.6% of patients with a delayed GT (n=36) and 57.5% patients without GT (n=200, p<0.0001). However, the delayed GT group had the highest rates of ED visits and readmission within 30 days and 90 days when compared to immediate GT and no GT groups (p=0.03, <0.01, <0.0001, respectively) (Table 2).

Thirty and 90-day readmissions and 30-day ED visits occurred overall in 12.2% (n=54), 19.3% (n=85), and 14.1% (n=62) of patients. Reasons for ED visits and readmission were then reviewed, comparing immediate or delayed GT and no GT groups (Table 3). Twenty-seven percent of total ED visits (n=23) were linked to poor postoperative oral intake. Thirty-six percent of 30-day readmissions (n=22) and 38.6% of 90-day readmissions were linked to poor postoperative oral intake. Delayed GT status was associated with an increase in 30-day ED visits attributable to poor oral intake, however this was not statistically significant (p=0.10). Delayed

GT status was significantly associated with an increase in 30 and 90-day readmissions attributable to poor oral intake (p<0.0001, 0.002, respectively) (Figure 1).

Discussion

Our study is the first to consider the clinical impact of potential GT under-utilization in minimally invasive TORS patients with locally advanced head and neck cancer. We clearly identify a subpopulation of TORS patients treated for Stage III or IV disease who fail to thrive in the immediate postoperative period and ultimately require GT. We uniquely propose an aggressive early GT strategy aimed to minimize the delayed GT subset of the studied population. Their poor oral intake is a common cause of both readmission and return to the ED following TORS + ND. Postoperative readmission rates are increasingly used as proxy indicators of surgeon performance and hospital system quality. Targeting nutrition with or without GT in these patients could significantly improve surgeon operative outcomes and hospital reimbursement.

Other studies have considered post-TORS GT rates and potential predisposing factors.[12-16] GT rates are generally low for TORS. For early stage disease, few, if any, patients require GT.[17] Not surprisingly, more complicated TORS patients may have higher GT rates. Iseli *et. al.* demonstrate T4 primary site disease is an independent predictor of GT after TORS.[18] Al-Khudari *et al.* sites that salvage TORS or TORS plus free flap have 50% and 80% GT rates, respectively.[14] However, Weinstein *et al.* showed that most Stage III or IV TORS + ND patients do not require long-term GT.[9] Given the published data to date, our observation that approximately one-third of patients undergoing TORS for advanced disease may derive benefit from short-term perioperative improvements in nutrition – a benefit which appears unexpected and ultimately resulted in GT – is of clear value.

The delayed GT patients in this study utilize significantly greater health care resources postoperatively. Paradoxically, however, they have a less complicated initial hospital course than immediate GT patients. It is unexpected for patients with a more benign hospital course to experience increased rates of fluid and electrolyte disruption, weight loss, failure to thrive, dysphagia and inability to tolerate oral feeding. Future studies that are prospective, randomized, and that utilize clinical nutritional and functional outcomes data may better elucidate the nuances of why this discrepancy is observed in our study. Given that delayed GT patients represent a minority (11.5%) of the patients in this study, a refined, rather than an overarching, risk-screening strategy should be used to identify patients benefiting from early GT in minimally invasive robotic resection of advanced head and neck cancers.

Evidence-based guidelines to predict the need for gastrostomy exist, but high-quality evidence to support specific timing and screening criteria for tube feeds is lacking.[19] It is generally accepted that demographics, tumor site and staging, nutritional status, and the presence of dysphagia play a role in risk stratification. Brown *et al.* describes a validated high-risk stratification protocol for head and neck cancer patients undergoing chemotherapy and radiation in which patients meet gastrostomy criteria if they exhibit >10% unintentional weight loss or BMI <20 with 5-10% weight loss in past 6 months, or they meet other criteria for severe malnutrition as judged by a dietician.[3] The findings of this study suggest that perioperative fluid and electrolyte disorders, weight loss, liver disease, alcohol abuse, paralysis, hypertension and the presence of any perioperative complication contribute a high risk nutritional status following TORS, and these patient characteristics could be included in future rubrics.

The benefit of early GT with respect to head and neck surgery is controversial. Specifically, for TORS, 26.7% of surveyed surgeons routinely do not place either nasogastric or gastrostomy feeding access, and only 2.2% of surgeons routinely place a PEG.[7] Chandler *et al.* outlines a preoperative scoring system to predict gastrostomy specific to head and neck reconstruction, with emphasis on low preoperative albumin as a major risk factor for postoperative complications.[20] Mays *et al.* found that perioperative GT with respect to head and neck tumor resection suggests a high risk patient with a complicated hospital stay, but also that preoperative GT can protect against poor postoperative outcomes, such as prolonged hospital length of stay, wound complications, and weight loss.[21] Our data also suggests that postoperative outcomes can be improved by aggressive nutritional screening and early GT in appropriate candidates undergoing robotic primary head and neck tumor resection.

This study is subject to the inherent limitations of a retrospective observational study, particularly surgeon selection bias when deciding on GT timing. The data are dependent on an administrative database, and thus are not clinically rich with tumor staging, histology, intraoperative details or postoperative laboratory data. This data is specific to the SPARCS database, which only includes patients within New York State. Data may not be extrapolated for the remainder of the United States, where trends may be different.

Conclusion

More than one-third of 30 and 90-day readmissions in TORS and neck dissection for advanced head and neck cancer in NY are related to impaired PO intake. A disproportionate number of these readmissions occur in patients with delayed GT. Patient risk factors combined with a complicated hospital course can identify patients benefiting from early GT, enhancing postoperative resource utilization. Future prospective studies are needed to evaluate the true benefit of early GT in appropriate head and neck cancer surgical candidates, and how improved risk-stratification for this intervention may effect postoperative outcomes. An improved understanding of the benefits of GT in this population can assist surgeons during informed consent, and help them to balancing quality of life decisions versus potentially avoidable hospital readmissions.

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Conflict of Interest Disclosures

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Table 1. Characteristics and Comorbidities of Patients Undergoing Gastrostomy

		Total, n	No GT, n(%)	Delayed GT n(%)	Immediate GT n(%)	P-value
Age	<55	138	116 (33.3)	11 (21.6)	11 (26.2)	0.3
	55-75	288	207 (59.5)	33 (64.7)	24 (57.1)	
	>75	39	25 (7.2)	7 (13.7)	7 (16.7)	
Gender	Male	345	269 (77.3)	43 (84.3)	33 (78.6)	0.54
	Female	96	79 (22.7)	8 (15.7)	9 (21.4)	
Race	Caucasian	338	266 (76.4)	42 (82.4)	30 (71.4)	0.88
	African American	29	23 (6.6)	<6	<6	
	Spanish/ Hispanic	24	18 (5.2)	<6	<6	
	Other	50	41 (11.8)	<6	<6	
Insurer	Medicaid	10	6 (1.7)	<6	<6	0.14
	Medicare	126	92 (26.4)	19 (37.3)	15 (35.7)	
	Commercial	302	247 (71.0)	31 (60.8)	24 (57.1)	
	Other	<6	<6	0	0	
Surgery Type	Concurrent	349	281 (80.8)	37 (72.6)	31 (73.8)	0.28
	Staged	92	67 (19.2)	14 (27.4)	11 (26.2)	
Surgeon Volume	Low	180	149 (42.8)	16 (31.4)	15 (35.7)	0.24
	High	261	199 (57.2)	35 (68.6)	27 (64.3)	
FED	Absent	405	330 (94.8)	45 (88.2)	30 (71.4)	**0.0001**
	Present	36	18 (5.2)	6 (11.8)	12 (28.6)	
Comorbidity	Congestive heart failure	7	<6	<6	<6	1.00
	Valvular disease	18	13 (3.7)	<6	<6	0.63
	Peripheral vascular disease	11	6 (1.7)	<6	<6	0.09
	Chronic pulmonary disease	62	44 (12.6)	9 (17.7)	9 (21.4)	0.23
	Diabetes, uncomplicated	51	39 (11.2)	<6	7 (16.7)	0.50
	Hypothyroidism	23	18 (5.2)	<6	<6	0.50
	Renal failure	16	10 (2.9)	<6	<6	0.17
	Liver disease	10	<6	<6	<6	**<0.01**
	Obesity	43	34 (9.8)	<6	<6	0.81
	Paralysis	<6	<6	<6	<6	**0.03**
	Alcohol abuse	27	14 (4.0)	<6	9 (21.4)	**<0.0001**
	Depression	27	22 (6.3)	<6	<6	0.95
	Hypertension	215	156 (44.8)	35 (68.6)	24 (57.1)	**<0.01**

P < 0.05 is highlighted. Data <6 suppressed due to small cell size publication restrictions. FED = Fluid and electrolyte or weight loss disorder.

Table 2. GT Status and Postoperative Hospitalization				
	GT Status, n (%)			P-Value
	None	Immediate	Delayed	
Any 30-day ED visit	41 (11.8)	9 (21.4)	12 (23.5)	**0.03**
More than one ED visit	12 (3.4)	<6	7 (13.7)	**0.05**
Any 30-day readmission	34 (9.8)	6 (14.3)	14 (27.5)	**<0.01**
Any 90-day readmission	51 (14.7)	9 (21.4)	25 (49.0)	**<0.0001**
More than one 90-day readmission	<6	<6	10 (19.6)	**<0.001**

GT = Gastrostomy tube. ED = Emergency department. P<0.05 is highlighted. Values <6 suppressed due to cell size restrictions.

Table 3. Reasons for Postoperative Hospitalization				
Visit Type	GT Status	Hospital Visits		P-Value
		Total, n	Attributable to Poor Oral Intake, n(%)	
30-Day, Emergency Department	No GT	50*	10 (20.0)	0.10
	Immediate GT	13	4 (30.8)	
	Delayed GT	20	9 (45.0)	
30-Day, Readmission	No GT	36	6 (16.7)	**<0.0001**
	Immediate GT	7	2 (28.6)	
	Delayed GT	18	14 (77.8)	
90-Day, Readmission	No GT	55*	14 (25.0)	**0.002**
	Immediate GT	15	5 (33.3)	
	Delayed GT	42	25 (59.5)	

GT = Gastrostomy Tube. P<0.05 is highlighted. *Three patient records (five ED visits and two 90-day readmission) were excluded. Values <6 suppressed due to cell size restrictions.

Figure Legend

Figure 1. Paradoxical increase in postoperative readmissions despite fewer perioperative complications in patient with delayed GT versus early GT. Delayed GT patients have increased 30-day readmissions attributable to poor oral intake ($p<0.0001$). GT = Gastrostomy tube. $P<0.05$ significant.

Abbreviations:

ND = Neck dissection

SOAR = Surgical Outcomes Analysis Research

SPARCS = Statewide Planning and Research Cooperative

TORS = Transoral Robotic Surgery

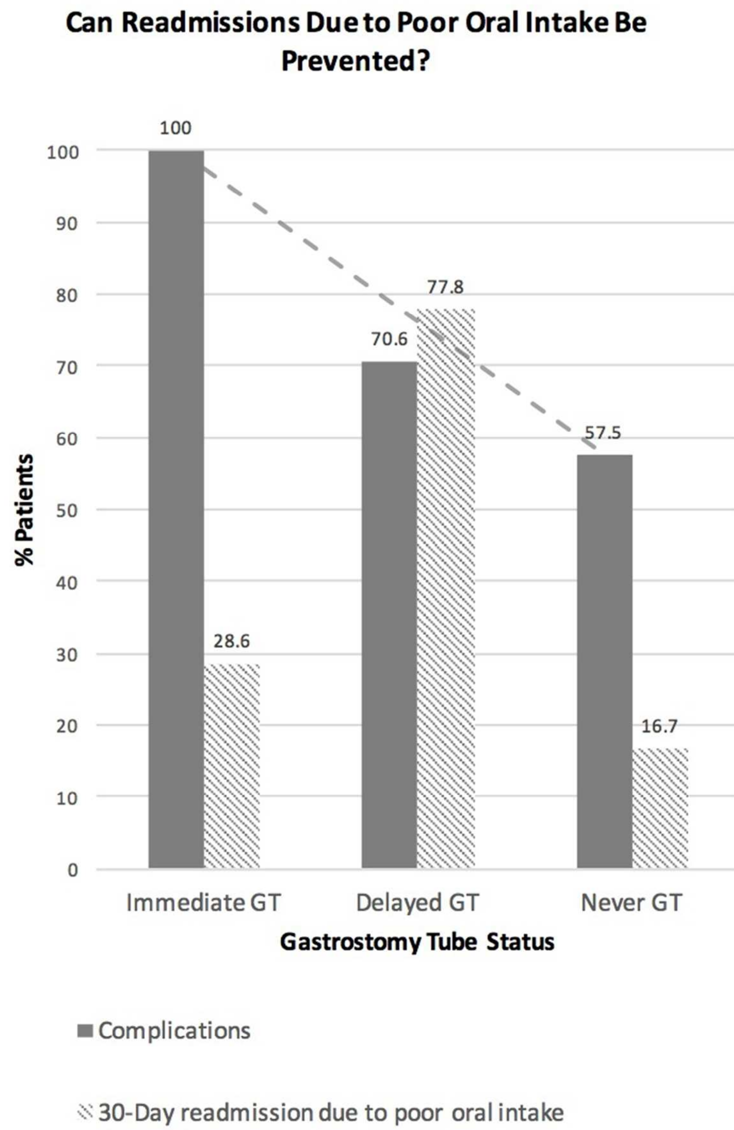
GT = Gastrostomy tube

ED = Emergency department

LVS = Low volume surgeons

HVS = High volume surgeons

FED = Fluid, electrolyte, weight loss disorder



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