Predictive Factors for Preoperative Percutaneous Endoscopic Gastrostomy Placement: Novel Screening Tools for Head and Neck Reconstruction

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Objective: The treatment of head and neck cancer has varying impact on postoperative recovery and return of swallowing function. The authors aim to establish screening tools to assist in preoperatively determining the need for gastrostomy tube placement.
Methods: The authors prospectively assessed all patients undergoing complex head and neck reconstructive surgery during a 1-year study period. Only patients tolerating an oral diet, without preoperative gastrostomies, were enrolled for study. Eight parameters were assessed including: body mass index (BMI), prealbumin, albumin, smoking history, comorbidities [including coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD), and diabetes mellitus (DM)], age, use of microvascular reconstruction, and type of defect. Two specific screening tools were assessed. In the first, a multivariate logistic regression model was employed to determine factor(s) that predict postoperative gastrostomy tube. In a second screening tool, the 8 parameters were scored between 0 to 1 points. The total score obtained for each patient was correlated with postoperative gastrostomy placement.
Results: Out of the 60 study patients enrolled in the study, 24 patients (40%) received a postoperative gastrostomy. In the logistic regression model, albumin level was the only factor that was significantly associated with need for postoperative gastrostomy ($P < 0.0023$). A score of 4 or greater was determined to have a sensitivity of 83% and specificity of 61% for postoperative gastrostomy.
Conclusions: Patients with a score of 4 or more with this screening scoring system or those patients with an albumin level <3.5 g/dL were at high risk for postoperative feeding tube placement.

Key Words: Head and neck reconstruction, percutaneous endoscopic gastrostomy tube, preoperative nutrition

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Received June 6, 2015.
Accepted for publication August 8, 2015.
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Presentation: Oral presentation at the 2014 American Society of Plastic Surgeons (ASPS) Annual Meeting, Chicago, IL, October 11, 2014.
Level of Evidence: Level II (Prognostic/Risk Studies).
Neil Tanna is a scientific consultant at Acelity. The remaining authors report no conflicts of interest.

ISSN: 1049-2275
DOI: 10.1097/SCS.0000000000002132

(*J Craniofac Surg* 2015;26: 2124–2127)

Head and neck cancers are predicted to comprise 3.2% of all new cancers in the United States.[1] These patients face the difficult task of maintaining their nutritional status in the face of the metabolic demands of the malignancy, the potential physical obstruction and pain associated with the tumor, and the potential of a baseline nutritional deficiency.[2] As a result, a considerable proportion of this patient population presents with dysphagia and difficulty maintaining their weight preoperatively.[3] Patients undergoing surgical treatment have the added challenge of postoperative healing and recovery in the setting of a surgical site that can further affect their ability to eat.[2,4] Not surprisingly, malnutrition was reported in 34% of all head and neck cancer patients.[5] Malnutrition in this population was shown to decrease survival and increase the rate of complications.[6] In addition, proper nutrition is a well-recognized, critical factor in wound healing that should be optimized in these patients.[7]

Currently, there is no consensus on the prevention and treatment of malnutrition in head and neck reconstruction. Oral dietary supplements, nasogastric (NG) tube feeds, and/or percutaneous endoscopic gastrostomy (PEG) are commonly used.[8] An NG tube is well suited for short-term nutrition following reconstruction and at the authors' center; patients that have undergone pharyngeal reconstruction will rely on this method of feeding for the 7 to 10 days after the procedure. Although effective, NG tubes may become blocked, cause nasopharyngeal irritation, reduced mobility, and may become dislodged.[9] A dislodged NG tube after a pharyngeal reconstruction can create a dilemma with the potential of endangering the suture inset with the passing of a new tube.

Dysphagia and aspiration are known complications following reconstruction of the upper aerodigestive tract defects.[10] During the postoperative period, patients may have a swallow study that demonstrates these conditions. As such, a gastrostomy tube may be warranted. Placing a PEG, however, may not be feasible at this time, whether it is due to the recent pharyngeal inset or patient trismus. This may require an open or laparoscopic gastrostomy tube placement exposing the patient to a new set of risks and another episode of general anesthesia.

Preoperative PEG placement can have many benefits, including eliminating the need for nasogastric tubes and decreasing postoperative trauma and surgical site disruption. In addition, a prophylactic PEG can aid in preoperative nutrition optimization. This is critical to successful reconstruction, because it was shown that a decreased preoperative prealbumin level is associated with an increased rate of free flap failure.[11] Placing a PEG in every patient undergoing head and neck reconstruction, however, is also not warranted, because some of these patients never require one.

Consideration for preoperative feeding tube placement is increasingly being observed in head and neck cancer treatment protocols.[8,9,12] There, however, is a paucity of studies examining the predictive factors, indications, and outcomes of patients with preoperative PEG tube placement. In light of this, the authors set out to create an evidence-based, preoperative scoring system to aid in determining which patients undergoing major head and neck reconstruction would benefit from prophylactic PEG placement.

METHODS

The authors prospectively evaluated all patients undergoing major reconstructive surgery for head and neck defects. All patients received either free flap or pedicled pectoralis major muscle flap head and neck reconstruction. All reconstructions were performed by the same extirpative and reconstructive team. The prospective study period was defined as 1 year.

Patients tolerating oral diet, without preoperative gastrostomies, were included for study. Exclusion factors included any patients with a preoperative PEG, incomplete neoplasm extirpation (determined at the time of oncologic resection), postoperative inpatient mortality, or age less than 18 years. All patients included in the study would receive postoperative radiographic evaluation (ie, swallow study) and assessment by a certified speech language pathologist. Need for postoperative PEG was preoperatively defined when the patient failed postoperative swallow evaluation.

A comprehensive literature review of nutrition in the setting of head and neck cancer was performed.[1–12] Based on this, 8 specific parameters were prospectively included for study. These included: body mass index, prealbumin, albumin, smoking history, presence of comorbidities [including coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD), and diabetes mellitus (DM)], age, use of microvascular reconstruction, and location of defect (cervicofacial, skull base, oral cavity, oromandibular, and pharyngoesophageal).

Screening Factors

Each of the 8 factors underwent univariate analyses using the χ^2test or Fisher exact test, as deemed appropriate, for categorical variables and the 2-sample *t*-test for continuous data was used to compare patients with and without postoperative PEG placement. Those factors that appeared to be associated with the outcome measure in the univariate analysis ($P < 0.25$) were considered in the building of the multivariate logistic regression model.

A receiver operating characteristic (ROC) curve was constructed to look at the model's ability to predict the PEG placement. A numerical measure of the accuracy of the model was obtained from the area under the curve (AUC), where an area of 1.0 signifies near perfect accuracy, whereas an area close to 0.5 indicates that the model is no better than random chance.

A result was considered statistically significant at the $P < 0.05$ level of significance. All analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC).

Screening Score

Based on the results of the screening factor analysis, a screening score was devised. The rationale was to include only significant factors in an easy-to-use, clinical scoring system. For each of the parameters, a patient received a score ranging from 0 to 1 points (Table 1). The total score obtained for each patient was correlated with postoperative PEG placement to determine the validity. Sensitivity and specificity for each were calculated to determine the optimal cutoff point.

RESULTS

During the 1-year study period, defined from August 2012 to July 2013, 60 patients were enrolled in the study. All patients were preoperatively tolerating a diet by mouth. Consistent with the exclusion criteria, none of the patients had a preoperative PEG.

TABLE 1. For Each of 8 Specific Parameters, a Patient Received a Score Ranging From 0 to 1 Points

	0 Point	1 Point
BMI (kg/m^2)	≥20.5	<20.5
Prealbumin (mg/dL)	≥15	<15
Albumin (g/dL)	≥3.5	<3.5
Smoking (pack/year)	≥25	<25
Comorbidities (CAD, DM, and COPD)	≤1	>1
Age (years)	<70	≥70
Microvascular free flap	No	Yes
Type of defect	Skull base, cervicofacial	Oral cavity, oropharyngeal, or pharyngoesophageal

CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus.

The average age of the study participant was 64.7 years old (range, 39–88). Mean body mass index (BMI) of included patients was 26.6 (range, 14.26–41.7). Approximately 42.6% (26/60 patients) were smokers. Comorbidities were present in 53% of patients. The average preoperative prealbumin and albumin were 13.55 and 3.55, respectively. The defects ranged in variety including 17 oral cavity, 14 oromandibular, 12 cervicofacial, 1 skull base, 11 pharyngoesophageal, and 5 patients with combined pharyngoesophageal and oral cavity defects. Out of the 60 patients, 31 (51.6%) underwent reconstruction with a free microvascular flap.

Radiographic swallow and clinical assessment by a certified speech language pathologist was performed in all 60 patients. Out of these, 24 patients (40%) failed this evaluation, thereby requiring postoperative gastrostomy tube placement.

Screening Factors

Three variables identified from the univariate analysis were included in the multivariate regression model: BMI <20.5, complex surgery (use of microsurgery), and albumin <3.5 (Table 2). Ultimately, albumin ($P < 0.0023$) was the only variable that was significantly associated with postoperative PEG placement in the multivariate model. Patients with an albumin level <3.5 were almost 13 times more likely to have a postoperative PEG as compared with patients with albumin ≥3.5 (Table 2). An ROC curve was constructed based on this model (Fig. 1). The resulting AUC was 0.76. The ideal cutoff point yielded a sensitivity of 63% and a specificity of 88% but correlated with the values of BMI <20.5, albumin ≥3.5, and presence of complex (microvascular) surgery.

Screening Score

A simple scoring system was devised, assigning a value of 0 or 1 to each of the 3 variables used in the multivariate model. The ideal cutoff value of 2, yielded a sensitivity of 79% and a specificity of 64%. Although promising, the authors realized that a sensitivity of 79% was too low to be valuable as a screening tool. Despite the lack of a robust univariate correlation and the poor performance of the multivariate regression, the original 8 variables were incorporated into the scoring system because of previous work showing their association with malnutrition.[2,9,11,13–17] The ideal cutoff of the full screening tool was determined to be greater than or equal to 4, which yielded a sensitivity of 83% and specificity of 61%. The positive predictive value (PPV) of this tool is 59% and the negative predictive value is 84%.

TABLE 2. Body Mass Index, Complex Surgery, and Albumin Were Included in the Logistic Regression Model

Parameter	β	Standard Error	Odds Ratio	95% Confidence Interval		*P*-Value
Intercept	−1.13	0.58				0.0517
BMI (<20.5 versus ≥20.5)	0.88	0.72	2.40	0.58	9.90	0.2246
Albumin (<3.5 versus ≥3.5)	2.56	0.84	12.96	2.49	67.47	0.0023
Complex surgery (Use of microvascular surgery)	0.80	0.65	2.22	0.63	7.88	0.2166

*Hosmer and Lemeshow goodness-of-fit test ($\chi^2 = 2.88$, df = 5, $P < 0.718$). BMI, body mass index.

DISCUSSION

Nutrition management in patients with cancer of the head and neck is a clinical problem under active investigation. In patients undergoing radiation and/or chemotherapy, numerous studies have shown the benefits of early PEG placement.[6,18–20] There, however, is no consensus on the optimization of nutrition or the timing of PEG placement. This results in highly variable criteria and guidelines among many centers treating these patients.[13,14,15,21] Extirpation and reconstruction of these malignancies adds another layer of complexity and the evaluation of prophylactic gastrostomy placement in these patients is just beginning.[8,9]

The scoring system proposed here was developed in response to the significant need for postoperative enteral nutritional support among patients undergoing head and neck reconstruction. In addition, the authors believe that a considerable fraction of these patients may have preoperative malnutrition or dysphagia. Recognizing the need for preoperative gastrostomy tube may not only optimize the patient preoperatively, but also may obviate the need to place a PEG in the early postoperative period.

The need for postoperative gastrostomy tube placement was considerable in this prospective study. Secondary to dysphagia or aspiration risk, 40% of patients required postoperative PEG placement. Postoperative gastrostomy tube placement is not without risk. It exposes patients to additional procedural morbidity and in some patients, can disrupt the reconstructive site. In addition, it can delay hospital discharge, adjuvant therapy, and recovery.

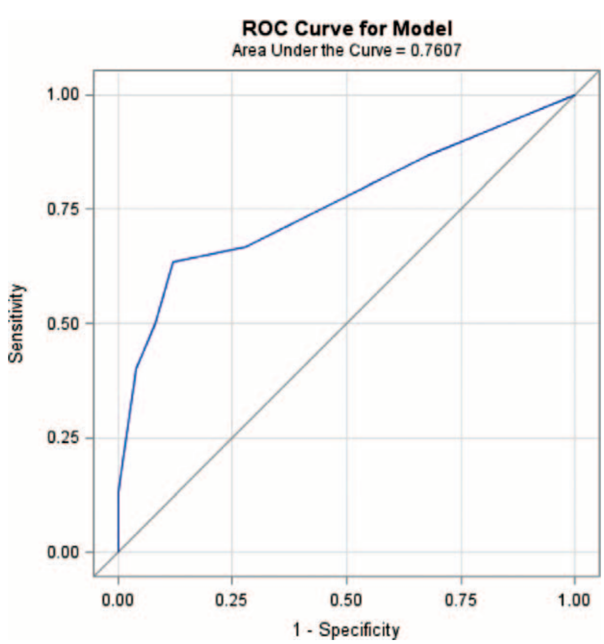

FIGURE 1. A numerical measure of the accuracy of the model was obtained from the area under the curve, where an area of 1.0 signifies near perfect accuracy, whereas an area close to 0.5 indicates that the model no better than random chance. The arrow denotes the optimal cutoff point; sensitivity 63%, specificity 88%.

At present, the need for prophylactic PEG is based on individual physician judgment, experience, and preference. The scoring system, proposed by the authors, aims to identify the patients who will eventually need a PEG during their recovery so that prophylactic placement can be discussed and recommended before reconstruction. This tool uses routinely available clinical information and is simple to score, which makes it convenient to use at all levels of care. In addition, the criteria do not require interpretation, eliminating the problem of inter-rater reliability. Finally, the sensitivity and NPV are relatively high, signifying that this test is appropriate for screening.

An interesting result in the multivariate analysis is the preoperative albumin level as the only statistically significant predictor of the need for a postoperative PEG. Albumin is a commonly used indicator of nutritional status and is included in many algorithms and scoring systems that predict or diagnose malnutrition.[16] Its significance in this study is not surprising. It, however, is the lack of significance of the other variables that is notable, because they are also commonly used in malnutrition studies. One possible reason for this is a relatively small sample size. This is a recognized limitation of this study. Although a larger sample size would have led to a more robust result, the clinical need for developing a scoring system and the time needed to accumulate a sufficient number of patients was prohibitive. In addition, other studies in this area have used a similar number of patients.[8,9] Ongoing studies by the authors are focused on continuing data collection as well as prospectively validating the model with measured outcomes, such as hospital length of stay and body mass index maintenance.

There are other limitations to this study. Similar to many nutrition scoring systems in general, is the assumption that predicting which patients will experience a certain clinical outcome without intervention will be useful for predicting future outcomes once interventions are in place.[22] Clinical outcomes are used because there is no "gold standard" for predicting or diagnosing malnutrition. Similarly, preoperative need for a PEG has no "gold standard." Further study and prospective validation of the proposed scoring system will address these concerns.

Finally, this study did not account for the planned use of adjuvant chemo- and radiotherapy. As described above, patients undergoing these treatment modalities can have a difficult time maintaining their weight and body composition. Prophylactic PEGs, although not universally used, have been shown to assist in maintaining nutrition in this population. Jack et al[8] included the need for radiotherapy in their model for prophylactic PEG placement in head and neck reconstruction and the authors propose including this factor in further study. If a patient is likely to receive a PEG in preparation for future radiotherapy, one could be placed before the reconstruction, which would allow for earlier nutritional optimization.

CONCLUSIONS

Head and neck reconstruction requires a coordinated multidisciplinary treatment approach to achieve a successful functional result. As part of this process, nutritional optimization is paramount to success. With the use of the preoperative scoring system designed in this study, practitioners can better assess which patient will likely require surgical gastrostomy placement in the postoperative period. Prophylactic placement of a PEG, before reconstruction in patients that will likely require them later, may allow for optimization of nutrition in the preoperative and immediate post-operative period. This may ultimately translate to less morbidity, faster healing, shorter length of stay, and a decrease in adjuvant treatment delays.

REFERENCES

1. Felekis D, Eleftheriadou A, Papadakos G, et al. Effect of perioperative immuno-enhanced enteral nutrition on inflammatory response, nutritional status and outcomes in head and neck cancer patients undergoing major surgery. *Nutr Cancer* 2010;62:1105–1112
2. Alshadwi A, Nadershah M, Carlson ER, et al. Nutritional considerations for head and neck cancer patients: a review of the literature. *J Oral Maxillofac Surg* 2013;71:1853–1860
3. Siegel R, Naishadham D, Jemal A. Cancer statistics, 2013. *CA Cancer J Clin* 2013;62:1105–1112
4. Sheth CH, Sharp S, Walters ER. Enteral feeding in head and neck cancer patients at a UK cancer centre. *J Hum Nutr Diet* 2013;26:421–428
5. Guo CB, Ma DQ, Zhang KH, Hu XH. Relation between nutritional state and postoperative complications in patients with oral and maxillofacial malignancy. *Br J Oral Maxillofac Surg* 2007;45:467–470
6. Rutter CE, Yovino S, Taylor R, et al. Impact of early percutaneous endoscopic gastrostomy tube placement on nutritional status and hospitalization in patients with head and neck cancer receiving definitive chemoradiation therapy. *Head Neck* 2011;33:1441–1447
7. Kavalukas SL, Barbul A. Nutrition and wound healing: an update. *Plast Reconstr Surg* 2011;127(Suppl 1):38S–43S
8. Jack DR, Dawson FR, Reilly JE, et al. Guideline for prophylactic feeding tube insertion in patients undergoing resection of head and neck cancers. *J Plast Reconstr Aesthet Surg* 2012;65:610–615
9. Wermker K, Jung S, Hüppmeier L, et al. Prediction model for early percutaneous endoscopic gastrostomy (PEG) in head and neck cancer treatment. *Oral Oncol* 2012;48:355–360
10. Schoeff SS, Barrett DM, Gress CD, et al. Nutritional management for head and neck cancer patients. *Pract Gastroenterol* 2013;37:43–51
11. Shum J, Markiewicz MR, Park E, et al. Low prealbumin level is a risk factor for microvascular free flap failure. *J Oral Maxillofac Surg* 2014;72:169–177
12. Schweinfurth JM, Boger GN, Feustel PJ. Preoperative risk assessment for gastrostomy tube placement in head and neck cancer patients. *Head Neck* 2001;23:376–382
13. Locher JL, Bonner JA, Carroll WR, et al. Gastrostomy tube placement and use in patients with head and neck cancer. *Head Neck* 2012;34:422–428
14. Dechaphunkul T, Martin L, Alberda C, et al. Malnutrition assessment in patients with cancers of the head and neck: a call to action and consensus. *Crit Rev Oncol Hematol* 2013;88:459–476
15. Talwar B, Findlay M. When is the optimal time for placing a gastrostomy in patients undergoing treatment for head and neck cancer? *Curr Opin Support Palliat Care* 2012;6:41–53
16. Gupta D, Lis CG. Pretreatment serum albumin as a predictor of cancer survival: a systematic review of the epidemiological literature. *Nutr J* 2010;9:69
17. Van bokhorst-de van der schueren MA, Lonterman-monasch S, De vries OJ, et al. Prevalence and determinants for malnutrition in geriatric outpatients. *Clin Nutr* 2013;32:1007–1011
18. Atasoy BM, Yonal O, Demirel B, et al. The impact of early percutaneous endoscopic gastrostomy placement on treatment completeness and nutritional status in locally advanced head and neck cancer patients receiving chemoradiotherapy. *Eur Arch Otorhinolaryngol* 2012;269:275–282
19. Assenat E, Thezenas S, Flori N, et al. Prophylactic percutaneous endoscopic gastrostomy in patients with advanced head and neck tumors treated by combined chemoradiotherapy. *J Pain Symptom Manage* 2011;42:548–556
20. Silander E, Nyman J, Bove M, et al. Impact of prophylactic percutaneous endoscopic gastrostomy on malnutrition and quality of life in patients with head and neck cancer: a randomized study. *Head Neck* 2012;34:1–9
21. Langius JA, Zandbergen MC, Eerenstein SE, et al. Effect of nutritional interventions on nutritional status, quality of life and mortality in patients with head and neck cancer receiving (chemo)radiotherapy: a systematic review. *Clin Nutr* 2013;32:671–678
22. Elia M, Stratton RJ. An analytic appraisal of nutrition screening tools supported by original data with particular reference to age. *Nutrition* 2012;28:477–494