

Gastrostomy tube insertion outcomes in South Australian head and neck cancer patients

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> Background: Gastrostomies are important adjuncts in maintaining nutrition in head and neck cancer patients undergoing treatment. This study aims to investigate outcomes in head and neck cancer patients managed with gastrostomies.

> Methods: A retrospective chart review of patients with mucosal head and neck squamous cell carcinoma (SCC) treated with non-surgical therapy, receiving gastrostomies between 2010 to 2015. The primary outcomes were complications following gastrostomy insertion stratified by insertion technique and classified with the Clavien-Dindo classification. Secondary outcomes included re-admission rates, weight changes and gastrostomy dependency.

> Results: A total of 103 patients were identified, consisting of 81% males with a mean age of 58 years. A total of 59 complications occurred in 42% of patients following gastrostomy insertions. Radiological gastrostomies were associated with higher grade complications (15%) requiring surgical intervention under general anaesthesia. Mucositis and acute pain requiring supportive management were the most common indications for readmission. Patients treated with gastrostomies were found to have a median weight loss of 5 kg. Prophylactic gastrostomies demonstrated shorter period of gastrostomy dependency compared to reactive insertions (174 vs. 249 days).

> Conclusions: Radiological gastrostomy insertions were associated with higher grade complications requiring surgical intervention. Higher pre-treatment weights were associated with higher post-treatment weights.

Keywords: Head and neck cancer; gastrostomy; complications; dysphagia; tube dependency

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Introduction

Head and neck cancer is the 6th most common malignancy world-wide, affecting 600,000 patients annually (1). Despite advances in treatment modality, dysphagia is still a common post-treatment morbidity affecting greater than 50% of cancer survivors (2). Gastrostomy tubes are important

adjuncts in maintaining nutrition in patients undergoing treatment for their head and neck cancer and sometimes are a permanent necessity for those suffering from severe long-term dysphagia after treatment of their cancer. There is currently no consensus regarding the role of gastrostomy tube insertions for head and neck cancer patients (3).

Table 1 Prophylactic gastrostomy criteria

T4 or hypopharynx tumours planned for chemoradiotherapy

T3 tumour of the oral cavity

T3 and/or N2 or N3 tumour of the oropharynx or larynx

Bilateral radiotherapy

Major surgery (major flap reconstruction, total glossectomy, or total laryngectomy)

Pre-operative radiotherapy followed by reconstruction with flap, particularly in oropharyngeal area

Significant dysphagia at presentation

Severe malnutrition at presentation

Unintentional weight loss >10% in 6 months

BMI <18.5 or BMI <20 (65 years or older) with unintentional weight loss of 5–10% in 6 months

PG-SGA-C

BMI, body mass index; PG-SGA, patient-generated subjective global assessment.

Treatment options for head and neck cancer currently include surgery, radiotherapy and chemotherapy alone or in combination. However, despite a general trend towards organ-preservation chemo-radiotherapy protocols, dysphagia is still common as it is recognised tissue preservation does not always equal function preservation (4). Dysphagia following non-surgical therapy is usually secondary to mucositis in the acute period and pharyngeal submucosal and muscular fibrosis in the long-term (5-7). These treatments associated side effects lead to hospital readmissions, malnutrition and disruption or delay in treatment.

Gastrostomy tubes can be inserted endoscopically (PEG) or radiologically (RIG) depending on patient factors, institution preference and access to expertise with gastrostomy tubes. Despite improvements in nutritional status of patients following gastrostomy tube insertions, potential complications including stomal site infections, bleeding, tube dislodgement and peritonitis. Thus, the risks associated with gastrostomy insertion must be weighed up against the risks associated with malnutrition and clearly discussed with the patient (8).

This study aims to investigate the nutritional status, readmission rates, gastrostomy dependency and complication rates in patients managed with gastrostomy insertions in two tertiary head and neck cancer centres in South Australia.

Methods

A retrospective chart review was performed on all patients with head and neck cancer treated with non-surgical modality at Flinders Medical Centre and Royal Adelaide Hospital from January 1st 2010 to December 31st 2015 with at least 12 months follow-up data. Inclusion criteria included patients greater than 18 years of age with a histological diagnosis of mucosal squamous cell carcinoma (SCC) in any head and neck subsite treated with primary radiotherapy or chemoradiotherapy aimed at curative intent. Patients managed with palliative intent were excluded.

Prior to treatment, patients were examined clinically and with a panendoscopy under general anaesthesia. Radiological examination consisted of computed tomography (CT) neck and chest and positron emission tomography (PET) scans where indicated. Tumour staging was based on the TNM classification of International Union Against Cancer (UICC) 7th edition (9). All cases were discussed in a multidisciplinary meeting where a decision was made regarding treatment modality. Decision on gastrostomy tube insertion was based on institution preference and pre-defined criteria (*Table 1*). Prophylactic gastrostomy insertion was defined by the multidisciplinary team (MDT) decision to insert the tube prior to treatment, whereas reactive tube insertion was defined as gastrostomies inserted after initiation of treatment.

The Human Research Ethics Committee at Flinders Medical Centre and Royal Adelaide Hospital granted ethics approval. All patients were identified through the electronic theatre management system (ORMIS) with a search query consisting of "percutaneous endoscopic gastrostomy", "radiologically inserted gastrostomy", "PEG" and "RIG" conducted between 2010 and 2015.

Medical records for all identified patients were reviewed to collect patient demographic details, clinical, radiology, pathology and treatment data. Patient demographics collected included age, gender, malignancy stage, completion of treatment, pre-treatment weight, post-treatment weight, duration of gastrostomy, complications from gastrostomy and readmissions. The aim of this study was to review the outcomes in patients treated with gastrostomy tubes. The primary outcomes were complication rates. These were grouped by gastrostomy insertion technique and stratified according to the Clavien-Dindo classification (*Table 2*) (10). Secondary outcomes included interruption to treatment, readmission rates, weight changes and gastrostomy dependency. Readmissions were stratified into readmissions to hospital within one

Table 2 Clavien-Dindo classification of surgical complications

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Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions; acceptable therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications; blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anaesthesia
Grade IIIb	Intervention under general anaesthesia
Grade IV	Life-threatening complication (including CNS complications) requiring ICU management
Grade IVa	Single organ dysfunction
Grade IVb	Multi organ dysfunction
Grade V	Death

CNS, central nervous system; ICU, intensive care unit.

year following treatment, 30-days following gastrostomy insertion or during active treatment. Weight loss defined as decrease in post-treatment weight compared to pretreatment weight. All readmissions were within one year following treatment.

Statistical analysis

Statistical analysis was performed utilizing the SPSS version 24. Parametric statistical analysis was performed (chi-squared tests, Fisher's exact test) comparing patient demographic and complications between the PEG and RIG groups. As there was only one patient treated with surgical gastrostomy, they were excluded from the statistical analysis. Repeated measures ANOVA was used to investigate the changes in weight between time points. Spearman's rho correlation analysis was conducted to find associations between repeated measures weights and gastrostomy dependence.

Results

Patient demographics

A total of 103 patients were identified as having received gastrostomy tube insertions over a 5-year period; 54 (52%) patients had a percutaneous approach, 48 (47%) patients had a radiological approach (*Table 3*). One patient with a T4bN0M0 hypopharynx SCC underwent a surgical gastrostomy. The majority of patients had prophylactic

gastrostomy insertions compared to reactive insertions, 88 (85%) and 15 (15%), respectively. PEG's were commonly employed in patients with prophylactic gastrostomy tubes, whereas RIG's were utilized more commonly in patients with reactive gastrostomy tubes. The oropharynx was the most commonly involved subsite, consisting of 77 (75%) patients. All patients with T1 disease had at least N2a disease with overall stage 4a. No patients had delay in treatment secondary to malnutrition.

Gastrostomy complications

A total of 59 complications occurred in 44 (42%) patients following their gastrostomy tube insertions, of which 17 (16%) had PEG's, 26 (26%) had RIG's and 1 (1%) had surgical gastrostomy insertion. Four PEG patients and two RIG patients suffered two or more complications. The majority of the complications were minor complications such as excessive granulation tissue around the tube site or superficial skin infections (Table 4). This study found that grade IIIb complications all occurred in the RIG group, requiring surgical intervention under general anaesthetic for the treatment of peritonitis, intra-abdominal bleed and gastrostomy site fistula (Table 5). No patients died from gastrostomy complications during this study period. Total complications and complications stratified by grade were found to be statistically significant (P=0.027 and P=0.042, respectively). However, there was insufficient data to perform statistical testing for individual complications and grades.

Table 3 Patient demographics

Variable	PEG	RIG	P value
Mean age	58±10 SD	58±11 SD	
Gender			>0.05
Female	9	10	
Male	45	38	
Primary site			0.048
Nasopharynx	1	3	
Oral cavity	2	2	
Oropharynx	46	31	
Supraglottis	0	1	
Hypopharynx	1	6	
Larynx	2	5	
Unknown	2	0	
T-stage			0.004
Х	2	0	
1	5	5	
2	19	5	
3	11	7	
4a	16	23	
4b	1	8	
N-stage			>0.05
0	11	12	
1	4	8	
2a	8	3	
2b	21	15	
2c	9	8	
3	1	2	
M-stage			>0.05
0	54	48	
1	0	0	
Overall staging			>0.05
1 or 2	2	2	
3	7	6	
4	45	40	
Table 3 (continued)			

Table 3 (continued)

Table 3 (continued)

Variable	PEG	RIG	P value
HPV status			0.039
Positive	31	16	
Negative	7	13	
Unknown	16	19	

PEG, percutaneous endoscopic gastrostomy; RIG, radiologically inserted gastrostomy; SD, standard deviation.

Table 4 Absolute number of complications between PEG and RIG

Complication	PEG (%)	RIG (%)	P value
Overgranulation	17 [53]	2 [7]	>0.05
Superficial Infection	7 [22]	10 [37]	
Bleeding	1 [3]	0 [0]	
Leaking	1 [3]	7 [26]	
Dislodged	6 [19]	4 [15]	
Peritonitis	0 [0]	1 [4]	
Fistula	0 [0]	1 [4]	
Balloon rupture	0 [0]	1 [4]	
Intra-abdominal bleed	0 [0]	1 [4]	
Total	32 [100]	27 [100]	0.027

PEG, percutaneous endoscopic gastrostomy; RIG, radiologically inserted gastrostomy.

Table 5 Complications by grade

Grade	DEC (0/)	DIC (0/)	P value
Grade	PEG (%)	RIG (%)	P value
No complications	37	22	0.042
1	0 [0]	0 [0]	
II	25 [78]	12 [44]	
Illa	7 [22]	11 [41]	
IIIb	0 [0]	4 [15]	
IVa	0 [0]	0 [0]	
IVb	0 [0]	0 [0]	
V	0 [0]	0 [0]	

PEG, percutaneous endoscopic gastrostomy; RIG, radiologically inserted gastrostomy.

Table 6 Total readmissions

Readmission indication	Re-admission (%)
Acute airway emergency	7 [6]
Primary site bleed	8 [7]
Mucositis	27 [22]
Febrile illness	16 [13]
Acute pain control requiring supportive care	20 [17]
Gastrostomy complication	18 [15]
Cardiac (APO/MI/AF)	2 [2]
Respiratory (COPD/LRTI/pneumothorax)	8 [7]
Gastrointestinal (SBO)	1 [1]
Urinary retention	1 [1]
Chronic pain	13 [11]

APO, acute pulmonary oedema; MI, myocardial infarction; AF, atrial fibrillation; COPD, chronic obstructive pulmonary disease; LRTI, lower respiratory tract infection; SBO, small bowel obstruction.

Readmissions

A total of 121 readmissions occurred in 73 (70%) patients, of which 36 (35%) patients had multiple re-admissions within one year of treatment (*Table 6*). And 35 (29%) admissions occurred within 30-days of gastrostomy insertion and 57 (47%) admissions occurred during treatment. Mucositis and acute pain requiring supportive care were the most common indications for readmission, accounting for 27 (22%) and 20 (17%) re-admissions respectively. Gastrostomy-related readmissions occurred in 18 (15%) patients.

Weight changes between prophylactic and reactive gastrostomy

The prophylactic gastrostomy group consisted of 88 patients with a median pre-treatment weight of 75 kg (range: 41–133). The reactive gastrostomy group included 15 patients with a median pre-treatment weight of 71 kg (range: 36–93). Immediately post treatment, patients in both groups were found to have a median weight loss of 5 kg. The weight remained stable between immediate post-treatment and 12 months post treatment for both groups. Pre-treatment weights were found to correlate with the different time points (*Figure 1*, P<0.05). There was no correlation with weights to duration of gastrostomy *in situ*.

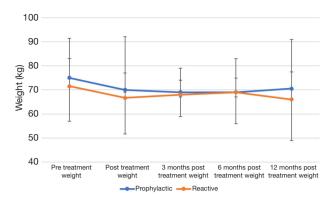


Figure 1 Prophylactic vs. reactive weight changes.

Gastrostomy tube removal

Prophylactic gastrostomy tubes remained *in situ* for a median 174 days (SD 292.4) compared to reactive gastrostomy tubes which remained *in situ* for median of 249 days (SD 204.8). There was no statistically significant difference due to the small group of reactive gastrostomy patients (P=0.41).

Discussion

This multi-institutional retrospective chart review examines the use of gastrostomy tubes in 103 head and neck cancer patients treated with primary non-surgical therapy in two South Australian tertiary head and neck centres. The use of gastrostomy tubes in the maintenance of nutrition in head and neck cancer patients during treatment is a controversial topic. Current literature demonstrates conflicting results with different institutions adopting varying protocols and treatment regimes (3,11,12). The decision for prophylactic insertion of a gastrostomy tube was made at our multi-disciplinary meetings, based on patient and treatment factors, before the patient began treatment of their cancer. Despite these issues, there was found to be no delay in treatment.

This study demonstrated overall complication rates for PEG and RIG insertions were 16% and 26% respectively. RIG insertions were found to have a greater number of grade III complications compared to the PEG group. Grade II complications occurred in 24% of patients, requiring pharmacological intervention. Grade III complications occurred in 18% of patients requiring surgical management. Brown *et al.* demonstrated minor and major complication rates of 40% and 10% respectively in Australian head and

neck cancer patients (13). It was difficult to compare these results due to differing classifications of complications and 93% of Brown's patients having PEG insertions. This study had comparable results to the systematic review conducted by Grant et al. demonstrating PEG and RIG complication rates of 19% and 24% respectively (8). Although no mortalities were present in this series, the current literature demonstrates fatality rates following PEG and RIG insertions of 2.2% and 1.8% respectively (8). Our results demonstrate lower rates of overall and serious complications with PEG's. The choice of employing a PEG or RIG is dependent on patient factors, such as oral access (mouth opening, obstructive aerodigestive tract mass), previous abdominal surgeries, co-morbidities, institution and operator expertise. These results bring into question the use of nasogastric tube feeding as a safer alternative for shortterm nutrition. Systematic reviews by Wang et al. and Paleri et al. demonstrated equivalent weight maintenance between the PEG's and nasogastric feeding (14,15). Additionally, PEG's were associated with increased incidence of pain and delay in return to oral diet compared to nasogastric tubes. Alternatively, patients with nasogastric feeds experienced altered body image with increased inconvenience compared to their PEG counterparts.

Readmissions to hospital were found to be due to acute pain management requiring supportive care secondary to mucositis. Mucositis affects up to 60% of patients receiving radiation therapy to the head and neck region, with a significant rise in incidence to greater than 90% when utilized on conjunction with chemotherapy (5). The significant pain associated with mucositis commonly leads to severe dehydration and malnutrition associated with hospital readmissions. Capuano et al. found reduced rates of hospital readmissions with stable maintenance of weight in patients with prophylactic gastrostomy insertions (16). Patients with prophylactic gastrostomies readmitted with dehydration could be due to non-compliance with gastrostomy use. Patient education and motivation on gastrostomy use must be considered prior to insertion; however, this was outside the scope of this study.

Maintenance of weight and nutrition is an important aspect in the treatment of patients with head and neck cancer. Patients treated in both prophylactic and reactive gastrostomy groups were found to lose a median weight of 5 kg during treatment, which stabilised by 12 months following treatment. These findings are similar to the study by Kramer *et al.* demonstrating no significant difference in rates of weight loss between patients

with prophylactic or reactive gastrostomy tubes (11). Additionally, our study identified that pre-treatment weight was strongly correlated with post-treatment weight at all time points, demonstrating the importance of pre-treatment nutritional status on weight maintenance. These findings demonstrate the importance of optimising head and neck patient nutritional status prior to treatment. Capuano *et al.* and Paccagnella *et al.* demonstrated early nutritional intervention to be associated with improved weight maintenance, decreased infections, early mortality, survival, treatment tolerance and decreased readmissions (16,17). Isenring *et al.* demonstrated early nutritional supplementation resulted in improvement with global quality of life and physical function with reduction in treatment-associated morbidity (18).

Prophylactic gastrostomy tubes were found to be in situ in the patient for a shorter period compared to reactive gastrostomy tubes, being 174 and 249 days respectively. Brown et al. demonstrated median time to tube removal in prophylactic gastrostomy insertions ranging from 100 to 110 days (13). Additionally, they found 87% of patients were completely dependent on enteric feeds for their full nutritional needs at the completion of treatment. This rate dropped to 66% and 29% at one- and threemonths post-treatment. The extend of gastrostomy usage was outside the scope of this study. The prolonged gastrostomy dependence present in the reactive group may demonstrate progressive swallowing impairment secondary to treatment with poor nutritional status. This group of patients may have had impaired swallowing prior to treatment predisposing them to increased incidence of failing oral feeding during treatment compared to patients completing chemoradiotherapy without gastrostomy feeds, this was outside the scope of this study. The increased gastrostomy dependence in these patients is likely secondary to the effects of chemoradiotherapy such as late oesophageal strictures, muscular fibrosis and disuse atrophy of pharyngeal muscles (12,19,20). Additionally, prolonged gastrostomy dependency has been associated with adverse effects on quality of life (15). The shorter gastrostomy dependency within the prophylactic group could be due to that group of patients having minor swallowing difficulties. There is evidence to support maintenance of swallowing function during and after treatment to prevent the deterioration of swallowing function (21,22). The speech pathology and dietetic departments in our institutions routinely see the patients during treatment to aid in swallowing therapy, gastrostomy education and monitoring

nutritional status. Patients were encouraged to continue with oral intake and swallowing exercises during treatment despite having a gastrostomy in situ.

The retrospective nature of this study leads to a source of several potential biases. Firstly, there was a difference in population size between the PEG and RIG groups. There was heterogeneity with malignancies of differing stages and head and neck subsites in this study. Advanced staged tumours are associated with higher levels of dysphagia, and thus would be expected to have a longer duration of gastrostomy dependency. However, despite these potential biases, there was no significant difference in weight changes between patients with different stages. It was difficult to draw conclusions regarding weight changes and gastrostomy dependency between prophylactic and reactive gastrostomy patients as the reactive gastrostomy group did not include all head and neck cancer patients treated without gastrostomy tube insertions.

Gastrostomy use in head and neck cancer is an important and controversial topic among clinicians. The results from our study indicate optimisation of nutritional status prior to treatment is useful for patient's weight maintenance and minimising weight loss post treatment. Protocol-based approach may be advantageous for patients with advanced malignancies due to greater potential for long-term dysphagia, however, patients with lower stage malignancy may not require gastrostomy tube insertion. The risks need to be stratified as these patients may benefit from a "watch and wait" approach with gradual escalation to short-term nasogastric feeds prior to gastrostomy tube insertion as nasogastric feeds have also been demonstrated to be a safe alternative for short-term dysphagia (15). Institution expertise, patient factors and preference must be taken into consideration prior to tube insertion.

Conclusions

- Gastrostomy insertions are important adjuncts in the maintenance of nutrition in head and neck cancer patients undergoing treatment.
- RIG tubes are associated with higher grade complications compared to percutaneous endoscopically inserted gastrostomy tubes.
- Prophylactic gastrostomy tube insertions were associated with shorter periods of gastrostomy dependency.
- Pre-treatment nutritional optimisation is important in the maintenance of higher post-treatment weight.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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