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Symptom Management and Supportive Care

Evaluation of Quality of Life Following Placement of Self-Expanding Plastic Stents as a Bridge to Surgery in Patients Receiving Neoadjuvant Therapy for Esophageal Cancer

ROBERT C.G. MARTIN II,[a] ROBERT M. CANNON,[a] RUSSELL E. BROWN,[a] SUSAN F. ELLIS,[a] SHARON WILLIAMS,[b] C.R. SCOGGINS,[a] ABBAS E. ABBAS[b]

[a]University of Louisville, Department of Surgery, Division of Surgical Oncology, Louisville, Kentucky, USA; [b]Department of Surgery, Ochsner Medical Center, Ochsner Health Systems, New Orleans, Louisiana, USA

Disclosures of potential conflicts of interest may be found at the end of this article.

Key Words. Esophageal cancer • Esophageal stenting • Quality of life • Neoadjuvant therapy

Learning Objectives

Describe the quality of life changes that can occur during neoadjuvant therapy for esophageal cancer.

Explain the use of esophageal stenting during neoadjuvant therapy for esophageal cancer.

ABSTRACT

Purpose. To determine whether self-expanding plastic stent (SEPS) placement significantly improves quality of life and maintains optimal nutrition while allowing full-dose neoadjuvant therapy (NAT) in patients with esophageal cancer.

Patients and Methods. A prospective, dual-institution, single-arm, phase II (http://ClinicalTrials.gov: NCT00727376) evaluation of esophageal cancer patients undergoing NAT prior to resection. All patients had a self-expanding polymer stent placed prior to NAT. The European Organisation for Research and Treatment of Cancer QLQ-C30 and QLQ-OG25, Functional Assessment of Cancer Therapy–Anorexia, and Functional Assessment of Cancer Therapy–General surveys were administered prior to stenting, within 1 week post-stent placement, and at the completion of neoadjuvant therapy.

Results. Fifty-two patients were enrolled; 3 (5.8%) had stent migrations requiring replacement. There were no instances of esophageal erosion or perforation. All patients received some form of neoadjuvant therapy. Thirty-six (69%) received chemoradiation; 34 (93%) of these patients received the planned dose of chemotherapy, and 27 (75%) received the full planned dose of radiotherapy. There were 16 (31%) patients receiving chemotherapy alone; 12 (74%) of patients in the chemotherapy-alone group completed the planned dose of therapy.

Conclusion. Placement of SEPS appears to provide significant improvement in quality of life related to dysphagia and eating restriction in patients with esophageal cancer undergoing neoadjuvant therapy. Consideration of SEPS instead of percutaneous feeding tube should be initiated as a first line in dysphagia palliation and NAT nutritional support. ***The Oncologist*** 2014;19:259–265

Implications for Practice: Malnutrition is a major difficulty encountered by patients with resectable esophageal cancer and the physicians who care for them. Malnutrition is well established as a significant risk factor for the intolerance to essential neoadjuvant therapy and subsequent surgical postoperative morbidity and mortality. Because of these concerns, maintenance of nutritional support remains essential in the management of patients with esophageal cancer. Placement of self-expanding plastic stents provides significant improvement in quality-of-life-related symptoms of dysphagia in patients with esophageal cancer undergoing neoadjuvant therapy. Consideration of self-expanding plastic stents instead of percutaneous feeding tube should be initiated as a first line in dysphagia palliation and neoadjuvant therapy nutritional support.

INTRODUCTION

Malnutrition is a major difficulty encountered by patients with resectable esophageal cancer and the physicians who care for them. Rates of malnutrition and cachexia associated with this disease have been reported to be as high as 85% at the time of initial diagnosis [1, 2]. Malnutrition is well established as a significant risk factor for the intolerance to essential neoadjuvant therapy and subsequent surgical postoperative morbidity and mortality [3, 4]. Because of these concerns, maintenance of nutritional support remains essential in the management of patients with esophageal cancer.

Correspondence: Robert C.G. Martin II, M.D., Ph.D., University of Louisville, Department of Surgery, Division of Surgical Oncology, 315 East Broadway, #312, Louisville, Kentucky 40202, USA. Telephone: 502-629-3355; E-Mail: Robert.Martin@louisville.edu Received August 23, 2013; accepted for publication November 22, 2013; first published online in ***The Oncologist*** *Express* on February 24, 2014.
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Historic modalities for nutritional support include total parenteral nutrition, enteral nutrition via various access methods, and orally. Because of the known complications associated with total parenteral nutrition, enteral and oral methods are preferred [5]. Enteral access via jejunostomy or percutaneous endoscopic gastrostomy (PEG) tubes has traditionally been the mainstay for nutritional support in the neoadjuvant therapy esophageal cancer population. Although these therapies allow for appropriate nutritional supplementation, they do nothing to address the patient's inability to tolerate oral intake due to dysphagia, which can have substantial quality of life implications. Recently, the use of a removable self-expanding plastic stent (SEPS) has been introduced as a means to allow for continued oral intake during neoadjuvant therapy prior to planned surgical resection [6–8]. A more recent study from Bower et al. [9, 10] confirmed that esophageal SEPS in the neoadjuvant setting offers improved results compared with feeding tubes both in maintaining preoperative nutrition and in tolerance of neoadjuvant chemoradiotherapy. We have also recently reported on the safety of SEPS prior to neoadjuvant therapy, demonstrating no difference in surgical dissection, morbidity, or anastomotic leak rates [11]. The current study was undertaken to provide a more detailed evaluation of the ability to give full-dose neoadjuvant therapy and maintain nutritional parameters and quality of life in this study population, particularly as it relates to dysphagia and restrictions on oral intake. Our hypothesis was that placement of self-expanding plastic stents would provide significant improvement in quality of life for these patients and would allow for successful administration of neoadjuvant therapy.

Patients and Methods

Study Description

A prospective, phase II study (http://ClinicalTrials.gov: NCT00727376) of the safety and efficacy of a removable SEPS placed prior to the initiation of neoadjuvant therapy in patients with potentially resectable (American Joint Committee on Cancer clinical stage IIIB or less) adenocarcinoma or squamous cell carcinoma of the esophagus was conducted. We report our findings according to the CONSORT (CONsolidated Standards of Reporting Trials) Statement (supplemental online Fig. 1). The study was performed at the University of Louisville and Ochsner Health System. The study conformed to the Declaration of Helsinki, and institutional review board approval was obtained at each participating institution. Further inclusion criteria were age 18 years or older, ability and willingness to provide informed consent, biopsy-confirmed esophageal cancer of the mid or distal esophagus, ability to dilate the stricture to at least 15 mm, and ability to place a Polyflex (Boston Scientific, Natick, MA, http://www.bostonscientific.com) stent of at least 18 $\times$ 23 mm in diameter and 120 mm in length. Exclusion criteria were contraindication for esophagoscopy, previous esophageal stent placement, disease burden greater than T3, and presence of metastatic (M1) disease.

Stent Placement and Neoadjuvant Therapy

Details of stent placement have been previously published [11]. Briefly, Polyflex stents were placed under continuous fluoroscopic guidance with either a pediatric or diagnostic endoscope. Procedures were performed using either i.v. conscious sedation or general anesthesia at the discretion of the attending surgeon and anesthesiologist. All procedures were performed by one of the two senior authors (A.A., R.M.). Further radiographic investigations for stent-related complications were performed when indicated by patient symptoms.

Decisions related to neoadjuvant therapy regimens were made with multidisciplinary input from thoracic surgery, surgical oncology, medical and radiation oncology, gastroenterology, and radiology. Patients were scheduled to undergo either chemotherapy alone or chemoradiation based on disease histology and patient comorbidities. Chemotherapy was most commonly 5-fluorouracil and cisplatin based, and radiotherapy most commonly consisted of three-dimensional conformal radiation with high-dose photons. Alterations of the initially planned regimen were allowed in the case of intolerance of either chemotherapy or radiotherapy. At the completion of neoadjuvant therapy, patients were restaged with either computed tomography or positron emission tomography. Restaging was performed earlier in the event that disease progression was suspected.

Quality of Life Measures

Quality of life (QOL) was assessed using the Functional Assessment of Cancer Therapy (FACT)–General, FACT–Esophageal, FACT–Anorexia, and European Organisation for Research and Treatment of Cancer QLQ-OG25 and QLQ-C30 at baseline and then at every 2-week interval until completion of therapy. The QLQ-C30 version 3.0 [12] was used because it is a validated, cancer-specific instrument designed for prospective clinical trials. The QLQ-C30 evaluates five functions (physical, role, cognitive, emotional, and social), nine symptoms (fatigue, pain, nausea and vomiting, dyspnea, loss of appetite, insomnia, constipation, diarrhea, and financial difficulties), and the global health status QOL. This questionnaire adequately covers the main problems and symptoms presented by patients with esophageal adenocarcinoma [4].

Questionnaires were to be completed at baseline before random assignment and every 2 weeks until progression. Questionnaires were completed in the clinic before interaction with health care personnel [13]. Because of the multitude of QOL evaluations, we simplified the number of observations to calculate compliance to include baseline prior to stent, 1, 3, 5, 7, and 9 weeks post stent.

This measure was chosen on the basis of its previous validation for use in patients with cancer of the esophagus and esophagogastric junction [11]. The survey consists of 25 questions that are rated on a four-point Likert scale (1, not at all; 2, a little; 3, quite a bit; 4, very much). Within the survey, questions are divided into six separate scales: dysphagia, eating restriction, reflux, odynophagia, pain and discomfort, and anxiety. Scores for these scales are obtained through a linear transformation of the responses to the individual questions composing the scales, giving a score from 0 to 100. Lower scores indicate lesser symptoms. We had the a priori hypothesis that esophageal stenting would provide the greatest benefit in terms of ability to maintain adequate oral intake; therefore, focus was primarily given to the dysphagia and eating restriction components of the survey. Surveys were administered by a trained clinical trials nurse at baseline prior to stenting and neoadjuvant therapy, within 1 week post-stent placement, and periodically throughout follow-up until stent removal at the

completion of neoadjuvant therapy [14]. Patients recorded daily caloric intake using a standard caloric calculator and recorded the number of calories from liquid and solid nutrition.

Statistical Methods

Quality of life responses are reported as medians because of the ordinal nature of the data, with differences at various time points compared using the signed rank test or McNemar's test, where appropriate. Otherwise, continuous and categorical covariates are summarized as means or counts (percentages) and compared using the paired *t* test and chi-square test, respectively. All statistical analysis was performed using SAS version 9.3 (SAS Institute, Cary, NC, http://www.sas.com) or SPSS version 16 (SPSS Software, IBM Corp., Armonk, NY, http://www-01.ibm.com/software/analytics/spss/). We set significance at $p < .05$.

Results

Nutritional Parameters, Neoadjuvant Therapy, and Performance Status

There were 52 patients included in the study; 3 (5.8%) had stent migrations requiring replacement. Table 1 shows patient characteristics. There were no instances of esophageal erosion or perforation. All patients received some form of neoadjuvant therapy. Of these, 36 (69%) received chemoradiation. Chemotherapy regimens in the chemoradiation group included 5-fluorouracil/cisplatin ($n = 26$, 72%), 5-fluorouracil/carboplatin ($n = 4$, 11.1%), 5-fluorouracil/cisplatin/taxol ($n = 4$, 11%), and 5-fluorouracil/cisplatin/carboplatin ($n = 2$, 5.9%). Thirty-four (94%) of these patients received the planned dose of chemotherapy. The median number of chemotherapy cycles received was two (range, 1–6). Radiotherapy consisted of three-dimensional conformal radiation in all cases, with a median planned dose of 5,040 (4,500–6,600) cGy. Twenty-seven (75%) received the full planned dose of radiotherapy. One patient received radiotherapy alone, consisting of 5,040 cGy. For all radiotherapy patients, the median received dose was 4,860 (2,080–6,600) cGy.

There were 16 (31%) patients receiving chemotherapy alone. Regimens in the chemotherapy-alone group included 5-fluorouracil alone ($n = 1$, 6.3%), 5-fluorouracil/cisplatin ($n = 2$, 12.6%), 5-fluorouracil/oxaliplatin ($n = 2$, 12.6%), 5-fluorouracil/cisplatin/taxol ($n = 6$, 38%), 5-fluorouracil/cisplatin/epirubicin ($n = 3$, 18.8%), and 5-fluorouracil/cisplatin/epirubicin/taxotere ($n = 2$, 12.6%). The median number of cycles received was three (range, 1–6). Twelve (75%) patients in the chemotherapy alone group completed the planned dose of therapy. Dosing of individual chemotherapy agents and the number of patients receiving them for the chemotherapy-alone and chemoradiation groups are presented in Table 2.

The mean weight at baseline was 84.5 kg, with a body mass index of 28.1, which decreased to 81.3 kg ($p = .057$) and 26.9 ($p = .091$), respectively, at completion of neoadjuvant therapy. One patient required placement of a feeding jejunostomy tube. Albumin decreased from a mean of 4.0 g/dL at baseline to 3.9 g/dL ($p = .3$) at completion of neoadjuvant therapy. Karnofsky performance status at baseline was 90.0, compared with 94.4 ($p = .170$) at the completion of neoadjuvant therapy. The median daily caloric intake of the patients was 1,900 calories (range, 800–2,800 calories), with an even distribution of both liquid calories (51%) and solid calories (49%).

Table 1. Baseline characteristics of all patients enrolled

Variable	Value
Patients enrolled, *n*	52
Male, *n* (%)	42 (81)
Female, *n* (%)	10 (19)
Median age, yr (range)	61 (39–82)
Histology, *n* (%)	
Adenocarcinoma	43 (83)
Squamous cell carcinoma	9 (17)
Tumor location	
Distal third or gastroesophageal junction	43 (83)
Middle third	9 (17)
Initial weight, kg	
Mean (SD)	79.5 (20.3)
Median (range)	81.2 (38.5–131.1)
Initial body mass index, kg/m^2	
Mean (SD)	26.5 (5.9)
Median (range)	26.5 (13.7–42.7)
Comorbidities, *n* (%)	
Coronary artery disease	7 (13)
Chronic obstructive pulmonary disease	7 (13)
Tobacco use	20 (38)
Diabetes	10 (19)
Weight loss at diagnosis, kg	
Mean (SD)	12.7 (7.9)
Median (range)	11.4 (2.3–36.4)
Mean (SD) serum albumin at diagnosis, mg/dL	3.8 (0.7)

Overall OG25 Measures

Of the 52 patients in the study, all completed the OG25 survey prior to the initiation of stenting and neoadjuvant therapy. All patients completed a survey within 1 week of stenting in addition to the baseline survey, as well as a follow-up survey after stenting and during their therapy. The median duration of survey follow-up was 9 weeks (range, 6–14 weeks). At the time of the initial survey within 1 week post-stent placement, statistically significant improvements were noted in terms of dysphagia, eating restriction, and pain and discomfort (Table 3). At the time of the final survey, statistically significant improvements were also present in these same three categories (Table 3). This improvement in swallowing-dysphagia QOL was seen immediately, with a consistent statistically improved swallowing QOL throughout the follow-up period ($p = .001$) (Fig. 1).

Quality of Life Component

In a review of all patients related to their FACT QOL, there was a worsening of physical QOL during the patients' neoadjuvant therapy, but this was not significant, with an improvement of QOL from week 5 to week 9 (Fig. 2). All of the patients' social QOL remained the same during their neoadjuvant therapy. All patients' emotional QOL became worse at week 3, with the

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Table 2. Dosing of individual chemotherapy agents

Agent	No. of patients receiving	Median dose (mg/m^2)	Range of doses
5-Fluorouracil	45	1,000	200–2,040
Cisplatin	24	75	75–190
Taxol	9	112.5	75–150
Carboplatin	6	300	75–341
Epirubicin	6	50	50
Taxotere	1	150	n/a

Abbreviation: n/a, not applicable.

Table 3. Comparison of QLQ-OG25 survey components during follow-up

Survey component	Baseline survey	1-week survey	*p*	Final survey	*p*
Dysphagia score	66.6	11.1	**<.001**	11.1	**<.001**
Eating restriction score	79.2	33.3	**.002**	41.7	**.012**
Reflux score	33.3	16.7	.368	0	.241
Odynophagia score	41.6	16.7	.154	33.3	.074
Pain and discomfort score	33.3	0	**.024**	0	**.005**
Anxiety score	33.3	33.3	.135	33.3	.412

All *p* values represent comparison with the baseline survey. Values presented are medians. Bold type indicates a statistical value of significance.

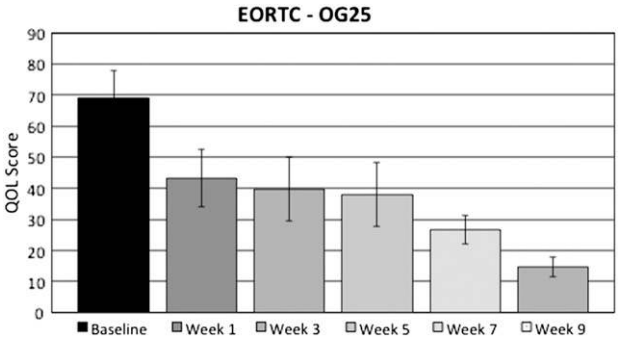

Figure 1. EORTC-OG25. Swallowing/dysphagia QOL scores, in which a lower score indicates better overall QOL, showed a significant improvement in QOL at week 1 and consistency in maintaining that improved QOL to week 9.

Abbreviations: EORTC, European Organisation for Research and Treatment of Cancer; QOL, quality of life.

remaining time demonstrating an improvement in their QOL back to baseline. All patients' functional QOL was worse at weeks 3 and 5 from baseline, with an improvement after weeks 7 and 9 (Fig. 2).

Dysphagia Component

The median baseline physician assessment dysphagia score for all 52 patients was 3 (range, 2–4), with a week 1 dysphagia score of 1 (range, 0–1) ($p < .001$), an improvement in median score on week 3 to 0 (range, 0–1) ($p < .001$), and maintenance of that dysphagia score throughout neoadjuvant therapy. This physician score was further validated by the FACT swallowing QOL, which demonstrated a significant improvement in swallowing QOL at weeks 1 ($p < .001$), 3 ($p < .001$), and 5 ($p < .001$), and maintenance of that QOL for weeks 7 and 9 (Fig. 3). At the time of the final survey, a statistically significant number of patients had maintained improvement over baseline in dysphagia to solids and liquidized/soft foods, whereas the improvement in dysphagia to liquids was not maintained in a statistically significant manner.

Eating Restriction Component

The median responses for trouble enjoying meals, early satiety, taking a long time to complete meals, and difficulty eating at baseline were 4, 4, 4, and 4, respectively. Median responses to these items at the initial survey and final survey were, respectively, 2 ($p = .004$) and 2 ($p = .111$) for trouble enjoying meals, 2 ($p = .012$) and 2 ($p = .001$) for early satiety, 3 ($p = .016$) and 2 ($p = .449$) for taking a long time to complete meals, and 2 ($p = .015$) and 1 ($p = .002$) for difficulty eating. Changes in symptom severity in individual patients for each of the eating restriction component items from baseline to 1 week post-stenting and from baseline to the final survey are presented in Table 4. In all cases, the majority of patients had either improved or unchanged severity of their symptoms.

Global QOL Evaluation

In contrast, when all of the patients' global quality of life scores were evaluated by the QLQ-C30, there were statistical differences seen in overall QOL during neoadjuvant therapy (Fig. 4). There was a consistent reduction in overall quality of life not related to dysphagia in all patients treated with neoadjuvant therapy, with the most significant drop occurring from week 5 to week 7 (Fig. 4A) ($p = .003$). In an evaluation of the questions "How would you rate your overall health during the past week?" and "How would you rate your overall quality of life during the past week?" both measured on a seven-point scale, there was a significant loss of overall QOL from week 5 to week 7 (Fig. 4B) ($p = .002$).

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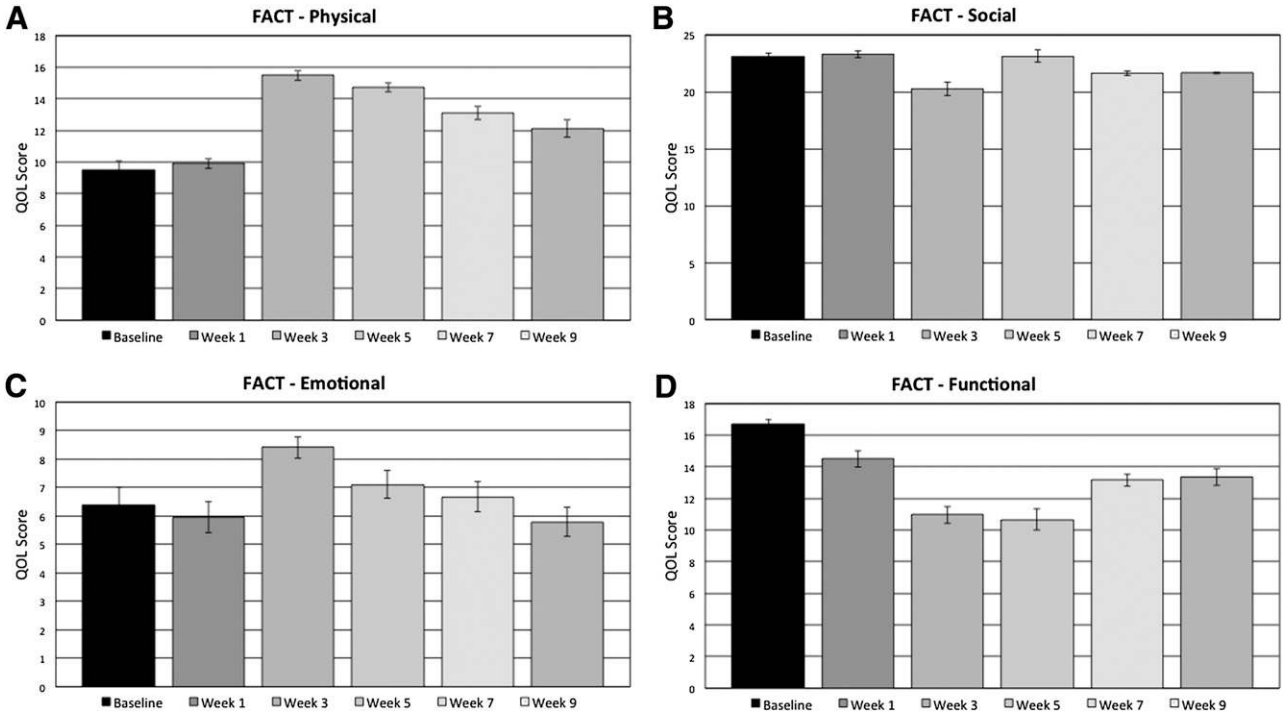

Figure 2. FACT QOL scales from baseline to 9 weeks in all patients undergoing neoadjuvant therapy after esophageal stenting. **(A):** Physical (higher score is worse QOL). **(B):** Social (higher score is better QOL). **(C):** Emotional (higher score is worse QOL). **(D):** Functional (higher score is better QOL).

Abbreviations: FACT, Functional Assessment of Cancer Therapy; QOL, quality of life.

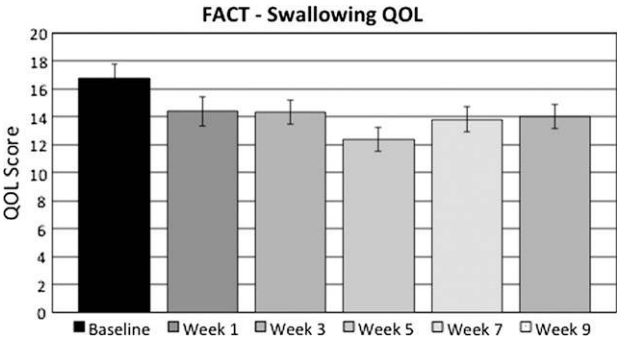

Figure 3. FACT QOL score (lower score is better) showed an immediate QOL improvement related to swallowing, which was maintained through the neoadjuvant course.

Abbreviations: FACT, Functional Assessment of Cancer Therapy; QOL, quality of life.

Discussion

Although enteral access modalities are able to provide adequate nutritional support, they suffer from a number of drawbacks that make their use less than ideal. Nasogastric and nasojejunal tubes are uncomfortable and not socially acceptable outside of the hospital and thus are not well tolerated in the outpatient setting for prolonged use. PEG tubes risk damage to the gastric conduit, particularly the right gastroepiploic artery, which can make subsequent surgical resection more difficult [15]. Furthermore, PEG and jejunostomy tubes have been associated with delays in initiating neoadjuvant therapy, particularly when there is a complication from the procedure [16, 17]. Furthermore, there is the reported risk that such percutaneous procedures can lead to abdominal wall metastases [18], as well as the fact that approximately 30% of patients present with radiographic metastatic disease after their planned neoadjuvant therapy and do not wish to live with a feeding tube [10]. Finally, the above enteral access methods do nothing to address the patient's underlying dysphagia.

In this current study, we demonstrated a significant improvement in quality of life following SEPS placement in a number of categories. When comparison is made to the mean dysphagia and eating restriction scores of 29 and 40, respectively, obtained in the study by Lagergren et al. to validate the QLQ-OG25, we note that the patient population in the current study was highly symptomatic [19]. Despite the initial high degree of symptoms, within 1 week following stent placement, there were significant improvements seen in the dysphagia, eating restriction, and pain and discomfort components of the QLQ-OG25 quality of life survey. There was no significant improvement in reflux, odynophagia, and anxiety. This finding was not unexpected as these factors are influenced by a number of factors unrelated to the partial obstruction of the esophagus that stents are intended to address. Odynophagia, for example, may be a product of mucositis and esophagitis that can be potentially induced by chemotherapy and/or radiation [20].

As expected, the primary benefit of SEPS in this study was in the immediate relief of dysphagia. The most profound effect was in the reduction of dysphagia to solid foods. Whereas the majority of patients in the study experienced dysphagia to solid foods "very much" at baseline, the 1 week post-stenting survey indicated that the dysphagia occurred "not at all" or "a little" after stent placement. A similar benefit was seen in terms of reduction in dysphagia to liquidized/soft foods. These improvements would appear to be clinically relevant patient benefits

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Table 4. Number of patients (percentage) reporting change in severity of symptoms as rated by the eating restriction items in the QLQ-OG25 survey

	Baseline to 1 week survey			Baseline to final survey		
Question	**Improved**	**No change**	**Worse**	**Improved**	**No change**	**Worse**
Have you had trouble enjoying your meals?	11 (50.0%)	10 (45.5%)	1 (4.6%)	15 (62.5%)	4 (16.7%)	5 (20.8%)
Have you felt full up too quickly after beginning to eat?	10 (45.6%)	8 (36.4%)	4 (18.2%)	10 (41.7%)	8 (33.3%)	6 (25.0%)
Has it taken you a long time to complete your meals?	11 (50.0%)	9 (40.9%)	2 (9.1%)	12 (50.0%)	9 (37.5%)	3 (12.5%)
Have you had difficulty eating?	13 (59.1%)	8 (36.4%)	1 (4.6%)	14 (58.3%)	8 (33.3%)	2 (8.3%)

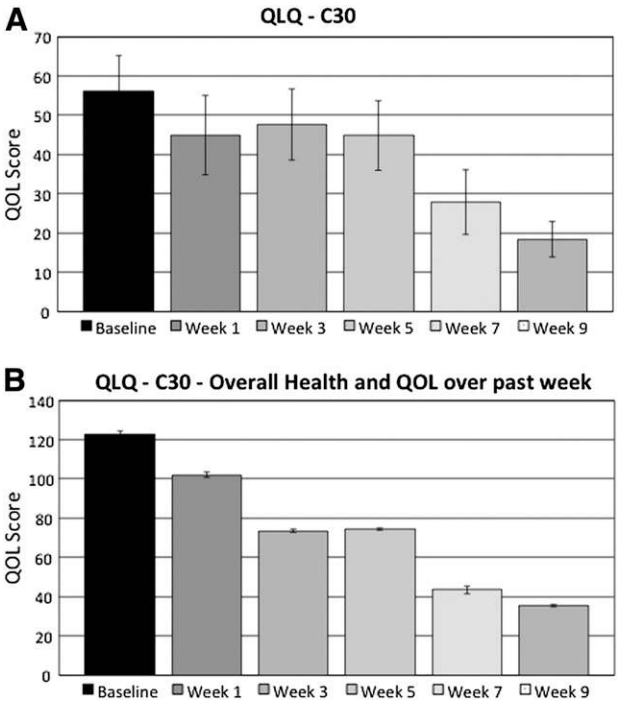

Figure 4. Global QOL evaluation. **(A):** QLQ-C30 scores over 9 weeks of neoadjuvant therapy demonstrating a decrease in overall QOL. **(B):** Overall health over the past week, demonstrating a decline in QOL over neoadjuvant therapy.

Abbreviation: QOL, quality of life.

rather than just statistically significant differences. That there was no statistically significant benefit in reducing dysphagia to liquids is likely due to the fact that this symptom indicates a more advanced local tumor and was less commonly present at baseline.

Eating restriction was also significantly improved by stent placement, although to a lesser extent than the improvement seen in dysphagia. A majority of patients reported improvement in having difficulty eating in the week following stent placement, with lesser improvements in meal enjoyment, early satiety, and time to complete meals. Again, these three symptoms were affected by a number of factors other than relief of esophageal obstruction, so stent placement was not expected to provide as great a benefit in these areas.

The early benefit of stent placement was found to be sustained throughout the duration of follow-up in most cases. The ability to attribute these longer-term improvements solely to stent placement, however, is not so clear. Neoadjuvant therapy alone is known to result in tumor shrinkage and a concomitant reduction in dysphagia for a significant portion of patients [21–23]; therefore, the late reduction of dysphagia symptoms in our patient population is almost certainly attributable at least partially to the effects of chemotherapy/chemoradiation. In our earlier report on the safety of stenting in this study, we noted eight cases of stent migration (although only two required stent replacement) [11]. Because stent migration is primarily a consequence of tumor shrinkage, this finding provides evidence of the efficacy of neoadjuvant therapy in achieving measurable local tumor response. To see such a benefit, however, often requires weeks of treatment; therefore, the early symptom improvements noted in this study can be fairly attributed primarily to stent placement.

The current study corroborates the findings of several previous studies of SEPS as a bridge to surgery during neoadjuvant therapy. In a study of 12 patients undergoing SEPS versus 24 patients undergoing jejunostomy tube placement, Siddiqui et al. found that dysphagia scores significantly improved in the SEPS patients but not in the patients treated with jejunostomy [6]. In a single-center study of 13 patients, Adler et al. found significant improvement in dysphagia scores at 1, 2, 3, and 4 weeks after SEPS placement [8]. Finally, in what to our knowledge is the largest study of the use of SEPS as a bridge to surgery during neoadjuvant therapy, Langer et al. found instant relief of dysphagia in 37 of 38 patients studied [7]. Our results also refute the bias that these types of patient will not eat. When provided with effective palliation of dysphagia and with appropriate nutrition education, these patients will eat and will obtain an appetite before and during their neoadjuvant therapy.

Although these quality of life improvements are important, the use of SEPS would not be justified if it were not a safe procedure. In our previous report, we noted no instances of stent-related esophageal erosion or perforation, nor was there any reported difficulty with stent removal or surgical dissection in the 20 patients who went on to surgical resection of their cancer [11]. This represents an improved safety record compared with the other studies in the literature. In the study by Langer et al., for example, there was one case each of esophageal perforation, mediastinitis, bleeding, and jejunal perforation by a migrated stent, and there were two reports of tracheoesophageal fistula [7]. In contrast, there were no major stent-related complications or perforations in the studies performed by Siddiqui et al. [6] and Adler et al. [8]. On the whole, these data suggest that placement of self-expanding plastic stents is a safe procedure in the setting of neoadjuvant therapy, albeit with only a small number of cases reported in the literature.

This is the largest study to report a combined relief of dysphagia and neoadjuvant QOL assessment with the use of

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SEPS as a bridge to surgery using the validated QLQ-OG25 survey. Furthermore, we believe that the current study meets the criteria for robustness specified by Efficace et al. [24]. The primary limitations of this study are related to its small sample size and the proportion of patients who did not complete all surveys. There is the possibility that the patients who did not complete all surveys represented a more sickly population (and thus less likely to have experienced improvements in their symptoms), which could introduce bias into the study results. With these caveats in mind, we believe that the current study provides preliminary evidence as to the efficacy of SEPS in improving patient quality of life while undergoing neoadjuvant therapy for esophageal cancer. Further studies with a greater number of patients will be needed to determine whether SEPS is indeed a more optimal method for maintenance of nutritional support than the more commonly used enteral access modalities.

Author Contributions

Conception/design: Robert C. G. Martin II, Abbas E. Abbas
Provision of study material or patients: Robert C. G. Martin II, Russell E. Brown, Susan F. Ellis, Sharon Williams, C.R. Scoggins
Collection and/or assembly of data: Robert C. G. Martin II, Abbas E. Abbas, Russell E. Brown, Susan F. Ellis, Sharon Williams, C.R. Scoggins
Data analysis and interpretation: Robert C. G. Martin II, Abbas E. Abbas, Robert M. Cannon, Russell E. Brown, Susan F. Ellis, C.R. Scoggins
Manuscript writing: Robert C. G. Martin II, Abbas E. Abbas, Robert M. Cannon, C.R. Scoggins
Final approval of manuscript: Robert C. G. Martin II, Abbas E. Abbas, Robert M. Cannon, Russell E. Brown, Susan F. Ellis, Sharon Williams, C.R. Scoggins

Disclosures

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