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Review

Use of esophageal stents to relieve dysphagia during neoadjuvant therapy prior to esophageal resection: a systematic review

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SUMMARY. **Esophageal cancer stenting offers symptomatic relief for patients suffering from dysphagia. There are limited data to support their use to relieve dysphagia and improve nutrition during neoadjuvant therapy with some concern that they may negatively impact oncological outcomes. The aim of this systematic review was to quantify the impact of esophageal stents on outcomes prior to resection with curative intent. A literature search was performed using Embase, Medline, PubMed, PubMed Central, the Cochrane library for articles pertaining to esophageal stent use prior to or during neoadjuvant chemotherapy or chemoradiotherapy in patients planned for curative esophagectomy. Data extracted included basic demographics, clinical, nutritional and oncologic outcomes. A total of 9 studies involving 465 patients were included. Esophageal stent use resulted in a significant improvement in mean dysphagia scores in the immediate post stent period but failed to demonstrate any positive changes in weight, body mass index (BMI) or albumin. Only 33% of stented patients ultimately progressed to potential curative surgical resection and stents were associated with reduced R0 resection rates and lower overall survival. This systematic review shows that, although esophageal stenting is associated with improvements in dysphagia during neoadjuvant therapy, their effect on improving patient nutritional status is less clear and they may be associated with poorer long-term oncological outcomes. Stents should be used with caution in patients who are being considered for potentially curative resection of esophageal malignancies and other strategies of nutritional supplementation should be considered.**

KEY WORDS: **esophageal malignancy, neoadjuvant therapy, bridge to surgery.**

INTRODUCTION

Multidisciplinary and modality approaches to the treatment of esophageal cancer has been shown to provide incremental improvements in 5-year survival rates, which now may be as high as 47%.[1] Dysphagia, with subsequent malnutrition, debilitates patients and may compromise long-term prognosis.[2] Malnutrition at the time of diagnosis is associated with a poorer response to chemotherapy, which impacts upon the likelihood of patients undergoing resection with curative intent.[3] Preoperative malnutrition has consistently been shown to increase postoperative morbidity and mortality rates in esophageal cancer patients and, when malnutrition is severe, it may be regarded as a contraindication to surgery.[3, 4]

Neoadjuvant therapy has been shown to provide a survival advantage.[1, 5] Neoadjuvant therapy comes with its own specific nutritional challenges, with potential for a period of prolonged dysphagia and reduced calorie intake prior to surgical resection. Strategies to optimize nutrition in the neoadjuvant and perioperative periods are important to reduce treatment delays and perioperative morbidity associated with malnutrition.[6, 7] Although esophageal stenting is the preferred modality for palliation of dysphagia,[8, 9] its use as a means of improving patient nutrition during neoadjuvant treatment is debated. Relieving dysphagia with an esophageal stent in the hope of improving nutrition prior to, or during, neoadjuvant therapy and surgery may provide prompt symptom relief but also presents challenges. Stent-related adverse events are common and studies have previously reported on their potential negative impact on long-term oncologic outcomes.[9–13]

The purpose of this systematic review was to assess the safety, efficacy, oncological outcomes and survival associated with the use of self-expanding metallic stents (SEMS) and self-expanding plastic stents

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Table 1 Study inclusion and exclusion criteria

Inclusion criteria
Studies involving patients with an esophageal cancer diagnosis undergoing metallic or plastic esophageal stent insertion preintervention as compared with standard care
Original publication (reviews, opinions, letters, protocols and conference proceedings excluded)
Reported outcome measures on at least one of: • morbidity • mortality • readmission/reintervention rates • oncologic outcomes
Exclusion criteria
Studies where biodegradable stents were included
Patients not suitable for operative resection
Postoperative patients
Recurrent esophageal cancer
Papers where data was unavailable or uninterpretable and authors uncontactable
Papers in languages other than English
Nonhuman studies

(SEPS) as a bridge to curative surgery in patients with esophageal cancer.

METHODS

Search strategy and study selection

The present review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses.[12] We conducted a comprehensive review of original articles published in English containing data on clinical, oncological and nutritional outcomes in patients with esophageal cancer undergoing esophageal stenting as a bridge to surgery during neoadjuvant therapy. An electronic search of five major databases (Embase, Medline, PubMed, PubMed Central and Cochrane library) was performed for relevant original articles up to and inclusive of November 2018. The following Boolean search terms were employed: esophageal stent OR metallic OR plastic stent AND esophagectomy OR esophageal resection and the search strategy was inclusive of the alternative European spelling of 'oesophagus'. In addition to the primary electronic search, the bibliographies of selected articles were manually reviewed to identify other studies for inclusion and an additional review of the 'related citations' in PubMed was also performed. Data extraction from selected studies was based on strictly defined criteria as shown in Table 1. Exclusion criteria were case reports, review articles and studies reporting on the efficacy of biodegradable stenting where the outcomes of metallic and plastic stenting could not be separated. Studies focussing on palliative stenting in esophageal malignancy, postoperative patients or patients with recurrent disease were also excluded.

Data collection and statistical analysis

Two independent reviewers applied the stated inclusion and exclusion criteria to retrieve citations and selected full papers for analysis. When two publications were believed to involve potentially duplicated or overlapping patient populations (based on authors, institutions and study years), only the most recent and most comprehensive cohort was included to avoid double-counting subjects and discrepancies were agreed upon by consensus. All search results were combined in a reference manager database (Endnote X8) and duplicates were removed. For each study, data on author institution, country, study period and methodology, total number of patients, patient sex, cancer histology, oncologic staging, type of stent and operative morbidity and mortality were extracted. Basic descriptive statistics were used to summarize patient and study characteristics and weighted mean values were recorded. Given the paucity of data on this topic, any measure of survival (median, 1, 3 or 5-year survival) was extracted. Continuous variables were compared using unpaired *t*-tests. Association of categorical variables (differences for dichotomous variables between groups) was assessed using a chi-square (X^2) test. A significance level of 0.05 was used for all analyses and all p values reported are two-tailed. Study methodological quality was assessed by applying the Methodological Index for Non-Randomized Studies (MINORS).[13]

RESULTS

After the initial screening of titles and abstracts regarding metallic or plastic stenting as a bridge to surgery in esophageal malignancy, 788 duplicates were excluded and 2861 studies were reviewed. Of these, 2811 records were deemed irrelevant and excluded after title and abstract analysis for failing to meet the inclusion criteria. Upon review of the remaining 50 publications in full, a further 39 were excluded for including palliative cases only in their analysis, and 2 studies were rejected for uninterpretable data.

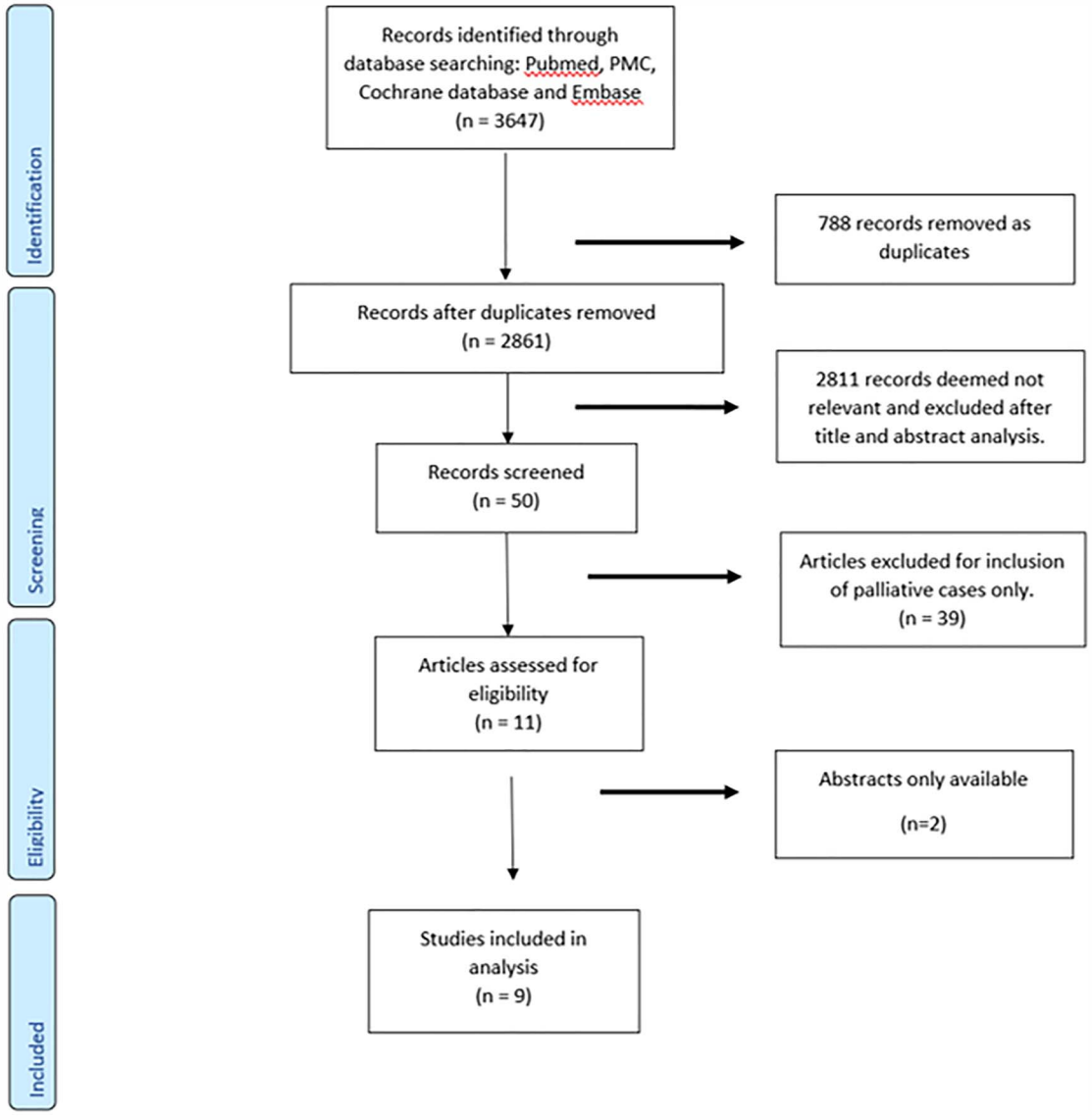

Fig. 1 Inclusion of studies and workflow.

The remaining 9 studies contained sufficient detail to merit inclusion in the extractable and analyzable dataset. The search strategy and outcomes are summarized in Figure 1.

Study characteristics

The dataset consisted of 9 original articles and yielded a total of 465 patients with study groups ranging from 11 to 169 patients.[14–22] Four studies originated from the USA, three were from Europe and the remaining two studies were conducted in Asia. The main characteristics of eligible studies are characterized in Table 2. Four studies were conducted prospectively and all studies included patients undergoing esophageal stenting prior to or during neoadjuvant therapy before a planned curative resection. Three studies included data on a comparative control group whereby data on patients undergoing a gastrostomy feeding tube[16] and a cohort with no stent intervention were included for comparison.[15, 20]

Patient characteristics

The baseline mean age of patients was 62.2 years with an age range of 30–88 years based on data from seven studies.[14, 15, 17, 18, 20–22] Of the 465 patients reviewed in the 9 included studies, 414 were male. Most studies commented on histological subtype with squamous cell carcinomas accounting for 55% of primary malignancies. There was no significant difference in tumor distribution. Tumors were present in the upper, middle and lower esophagus in 15%, 23% and 62%, respectively ($P = 0.12$). Based on the available data of 6 studies, 282 patients had clinical T category of T3 or more.[14–16, 18–20] Esophageal stents were inserted in all patients with a post procedural morbidity rate ranging from 3–55%. Seventy-three patients (21%) required an additional endoscopic

Table 2 Demographic data of included studies

Author	Year	Country	*N*	Mean age	Study type	Sex% males	Sex% female	Stent type	Progression to surgery in stented patients %
Langer *et al.*[22]	2010	Austria	38	66	Retrospective	68%	32%	SEPS: 13/38 (34%) SEMS: 25/38 (66%)	68%
Lopes *et al.*[19]	2010	USA	11	61	Prospective	91%	9%	FCSEMS	18%
Brown *et al.*[21]	2011	USA	32	61	Prospective	81%	19%	SEPS	63%
Pellen *et al.*[17]	2011	UK	16	63	Prospective	56%	44%	SEMS	63%
Mariette *et al.*[15]	2015	France	38	65	Retrospective	87%	13%	SEMS	100%
Francis *et al.*[20]	2016	USA	28	63	Retrospective	95%	5%	SEMS: 17/28 (61%) SEPS: 11/28 (39%)	29%
Min *et al.*[16]	2017	Korea	169	65	Retrospective	93%	7%	FCSEMS	5%
Smith *et al.*[18]	2017	USA	12	59	Prospective	92%	8%	SEMS	42%
Lu *et al.*[14]	2018	Taiwan	46	59	Retrospective	93%	7%	SEMS	0%

N = number stented in each study.
FCSEMS, fully covered self-expandable metallic stent; SEMS, self-expandable metallic stent; SEPS, self-expandable plastic stent.

Table 3 Procedural outcomes and interventions post SEMS insertion

Author	*N*	Stent morbidity %	% Stent replacement/reintervention
Langer *et al.*[22]	38	42%	13%
Lopes *et al.*[19]	11	55%	9%
Brown *et al.*[21]	32	41%	6%
Pellen *et al.*[17]	16	25%	44%
Mariette *et al.*[15]	38	5%	21%
Francis *et al.*[20]	28	68%	29%
Min *et al.*[16]	169	3%	22%
Smith *et al.*[18]	12	42%	42%
Lu *et al.*[14]	46	–	–

intervention or replacement of a displaced metallic stent (Table 3). Neoadjuvant therapy was explicitly described in 4 studies. In one study, patients received concurrent preoperative chemoradiation therapy combining cisplatin, 5 FU and paclitaxel with radiotherapy dose of 45Gy.[14] In a second study, patients received 5-FU and platinum based chemotherapy with concomitant radiotherapy delivered at 45Gy.[15] A third study administered a combination of cisplatin and paclitaxel or carboplatin and cetuximab with radiotherapy delivered at 50.4Gy.[20] In the last study, patients received preoperative chemotherapy with ECF only.[17]

Dysphagia/nutrition

Dysphagia was graded using the previously validated Mellow–Pinkas scoring system (Table 4).[23] Six studies reported on patient dysphagia and swallowing status prior to and after esophageal stent insertion.[17–22] Overall, there was a significant improvement in mean dysphagia grades from 2.88 to 0.66 ($P < 0.01$) in the immediate post stent period. Weight and albumin measurements constituted nutritional parameters in 5 studies.[14, 16–18, 22] Albumin levels dropped from a mean value of 3.7 g/dL to 3.5 g/dL post stent insertion but failed to achieve statistical significance ($P = 0.43$). There was a mean weight loss of 4.3 kg post stent insertion, however, there was no significant difference on statistical analysis[14, 17, 18, 21] ($P = 0.64$). Pre and post stent BMI was reported in two publications and displayed no significant change in the 54 patients studied (−2.25 kg/m^2).[17, 21] These results are presented in Table 5.

Table 4 Mellow–Pinkas scoring system for dysphagia

Grade	Criteria
0	Able to eat normal diet/no dysphagia
1	Able to swallow some solid foods
2	Able to swallow only semi solid foods
3	Able to swallow liquids only
4	Unable to swallow anything/total dysphagia

Surgery

Of 352 stented patients, 117 were suitable for a potential curative resection. Mariette *et al.* only included patients who underwent potentially curative resection in their study.[15] In the other studies, 79 of 314 patients initially identified as suitable for curative resection progressed to surgery demonstrating an overall potentially curative resection rate of 33% in the stented patient cohort. The most common reason for not proceeding to surgery was disease progression.[17–22] Two studies mention whether SEMS were removed prior to

Table 5 Patient outcomes following stent insertion in potentially curable esophageal cancer

Paper	Number of patients	Swallow (Mellow–Pinkas score)	Weight	Albumin	BMI	Progression to surgery	Positive margins
Langer *et al.*[22]	Stents: 38	Baseline: 3.0 Post stent: 0.6	N/A	Baseline: 4 g/dl Post stent 3.9 g/dl	N/A	26/38 (68%)	N/A
Lopes *et al.*[19]	Stents: 11	Baseline: 3.36 6 months: 0.8	N/A	N/A	N/A	2/11 (18%)	N/A
Brown *et al.*[21]	Stents: 32	Baseline: 2.1 48 hours: 0.6	Baseline: 84.8 kg Post stent: 77.3 kg	Baseline: 4 g/dl Post stent: 3.6 g/dl	Baseline: 28.1 kg/m^2 Post stent: 24.9 kg/m^2	20/32 (63%)	0/20
Pellen *et al.*[17]	SEMS: 38 Control: 152	Baseline: 2.5 2/3 months: 1.1	Baseline: 69.6 kg 2/3 months: 67.4 kg	Baseline: 3.28 g/dl 2/3 months: 3.2 g/dl	Baseline: 24.5 kg/m^2 2/3 months: 23.2gkg/m^2	10/16 (63%)	2/10 (20%)
Mariette *et al.*[15]	SEMS: 38	N/A	SEMS: −0.61 kg	SEMS: −0.39 g/dL	N/A	Only included patients undergoing surgery (100% both groups)	SEMS: 11/38 (28.9%)
	Control: 152		PG: −0.36 kg	PG: −0.15 g/dL			Control: 22/152 (14%)
Francis *et al.*[20]	Stents:28 Control: 75	N/A	N/A	N/A	N/A	8/28 (29%)	N/A
Min *et al.*[16]	SEMS: 169 PG: 64	Baseline: 2.5 3 months: 1.1	Baseline: 69.6 kg 3 months: 67.4 kg	Baseline: 32.8 g/dL 3 months: 32.0 g/dL	Baseline: 24.5 g/dL 3 months: 23.2 g/dL	SEMS: 8/169 (5%) PG: 13/64 (20%)	N/A
Smith *et al.*[18]	Stents: 12	Baseline: 3.4 2 months: 0.11	Baseline: 79.8 kg 2 months: 76.0 kg	Baseline: 36 g/dL 2 months: 34 g/dL	N/A	5/12 (42%)	N/A
Lu *et al.*[14]	Stents: 8	N/A	SEMS baseline: 55.5 kg. SEMS 3 months: 51.5 kg	N/A		SEMS: 0/8 (0%)	N/A
	Control: 38		Control baseline: 58.5 kg Control 3 months: 56.5 kg			Control: 13/38 (34%)	

PG, percutaneous gastrostomy; SEMS, self-expanding metal stent.

surgery, with removal taking place in 6/15 cases.[17, 18] SEPS were removed at the time of tumor resection in 41/70 patients in 2 further studies.[21, 22] Mariette *et al.* reported a no significant difference in postoperative mortality in the stent group when compared to the control group (13.2% vs 8.6%, $P = 0.37$).[15] This was described as in-hospital mortality with the time period not explicitly defined. There were one postoperative death[20] and no stent-related mortalities in the other 8 studies. The postoperative complication rate ranged from 10% to 63.2%.[15, 17]

Oncological outcomes

Surgical margin status was assessed in 3 papers.[15, 17, 21] The rate of margin positivity (R1 or R2) was 29%, 20% and 0% in these studies.[15, 17, 21] Mariette *et al.* showed that the rate of R1 or R2 resection was significantly greater in those with preoperative stenting as compared with a group who had percutaneous enteral feeding preoperatively. Furthermore, the rate of circumferential resection margin positivity is higher in those who had pre-operative stent placement.[15] Data on recurrence rates were only available in one study and demonstrated a significantly shorter interval in the SEMS group.[15] Brown *et al.*[21] reported no positive margins in the 20 patients who progressed to surgery in their study.

Survival data

The average duration of follow up was reported in 3 studies,[15, 16, 19] from which the weighted mean follow up post stent insertion was 18.2 months

(range 2.4–143.3 months). Overall survival data were available for 4 studies (median OS: range 10–96 months)[14–16, 20] and 3-year survival data was available for 1 study. Survival was significantly superior in a comparative gastrostomy group[16] in one study ($P = 0.007$) and a control group[14, 15, 20] of nonstented patients in the remaining 3 studies ($P = 0.026$,). Three-year survival was significantly reduced in a SEMS group of 38 patients when compared to the no stent group (28% vs 44%, $P = 0.043$).[15] No study compared survival data between SEMS and SEPS.

Study quality

Four studies out of nine in this review were conducted prospectively and 3 studies reported on a comparative patient cohort. The 9 studies achieved a median MINORS score of 16 (mean score of 15 for the non-comparative studies and 18 for the comparative analyses).

DISCUSSION

The purpose of this review was to examine the efficacy of using esophageal stents in the neoadjuvant setting for resectable esophageal cancer, using up to date evidence. Prior reviews have looked primarily at improvements in dysphagia or stent-related complications.[24] We have looked at outcomes related to dysphagia, nutritional status, chances of progression to surgery and oncological outcomes of surgical resection. Overall, this review suggests that although deploying an esophageal stent may provide symptomatic relief from dysphagia, there is no improvement in markers of nutritional status in the preoperative setting. In addition to offering unclear nutritional benefits, there are no clear oncological benefits and the available data suggests stent use may in fact be detrimental in terms of surgical resection margins.

Esophageal malignancies present very specific challenges in dealing with poor nutritional status, sarcopenia and a patient population who are usually advanced in age. Furthermore, dysphagia is a distressing symptom. Significant malnutrition and weight loss prior to potentially curative surgery is associated with higher rates of perioperative morbidity and mortality.[15] Strategies to support nutritional status and correct malnutrition are essential in the neoadjuvant phase of treatment. Debate remains as to whether re-establishing oral intake, supplementary feeding via naso-enteral tube, percutaneous enteral feeding or total parenteral nutrition provides the best nutritional support for patients. The inherent belief that restoring esophageal patency preoperatively may offer some nutritional advantage offers a logical hypothesis. Our review has shown that stenting does provide symptomatic relief. However, although an esophageal stent may improve dysphagia scores, this does not translate into a consistent nutritional benefit in maintaining weight, BMI or serum albumin concentration. Furthermore, neoadjuvant therapies, both chemotherapy and chemoradiotherapy improve dysphagia in and of themselves.[25] Many patients experience a significant improvement in dysphagia following a single round of chemotherapy, potentially obviating the need for stenting for symptomatic relief.[25] Other feeding adjuncts such as percutaneous enteral feeding may offer improved nutritional outcomes.[16]

Despite the accepted role of stenting in palliation of esophageal cancer, our review raises real concerns regarding the oncological outcomes after the use of esophageal stents in the neoadjuvant setting. It has been shown that there is a significant increase in complications with radiation therapy when stents are used preoperatively, with a reduction in numbers progressing to potentially curative surgery.[20] Stenting appears to be associated with significantly increased toxicities and mucosal scarring with chemoradiation therapy.[9, 20] This may further stimulate the inflammatory cascade, promoting tumor growth. Experimental models have shown that the radial forces associated with stenting can trigger an inflammatory response.[26] A systematic review, which included 12 studies, to determine dysphagia relief and complications with esophageal stents suggested that there may be safety concerns in the neoadjuvant setting.[24] That review of metallic, silicone and biodegradable prostheses found no improvement in weight or albumin levels and reported a complication rate as high as 73%, similar to our analysis.

Rates of progression to surgical resection with curative intent following placement of an esophageal stent vary between studies included in this review but remain low, with an overall rate of 33%. Selecting patients who are candidates for potentially curative surgical resection is essential in treating esophageal malignancies, with at least 50% of patients presenting with advanced disease and hence precluded from a curative pathway.[27–30] Our review has suggested that the use of stents in the neoadjuvant setting may be associated with a reduced likelihood of progressing to surgery, most often due to disease progression. It is far from clear whether esophageal stents can be implicated in tumor progression, or whether the low rate of surgical resection reflects the fact that they are more commonly deployed in locally advanced disease. Within our study, Mariette *et al.* and Lu *et al.*[14] had similar tumor characteristics between those with a stent and without.[15] By contrast, Min *et al.*[16] had more patients with advanced disease undergoing stenting as compared with those who did not, while Francis *et al.* had a slightly higher T-stage but similar N-stage in those undergoing stenting.[16, 20] However, all of these studies showed a poor rate of progression

to surgery. Clearly, these data are heterogeneous and are difficult to draw a definitive conclusion from.

Ideally patients would be comprehensively restaged following neoadjuvant treatment. This is limited by the placement of metal stents which will interfere with computerized tomography, making locoregional assessment difficult. This is further limited by the fact that CT and PET-CT in fact have poor sensitivity and specificity for restaging esophageal cancers, even without the presence of a stent.[31]

Overall, this review has suggested a high rate of margin positivity when stents are used, up to 29.8% for R1 and R2 resections.[32] This is a predictor of poor long-term survival.[32] In their propensity-score matched analysis, Mariette *et al.*[15] only included patients who underwent an operation with curative intent of their esophageal malignancy. They directly compared a cohort with SEMS to those who had a percutaneous tube feeding placed preoperatively. Concerningly, patients who had a stent inserted during neoadjuvant therapy fared significantly worse in terms of R0 resection rates, overall survival and 3-year locoregional disease recurrence.[15] Whether the use of stents leads to fewer patients progressing to surgery and impaired oncologic outcomes needs further definitive evaluation.

Data on the impact of esophageal stent insertion on patient survival are limited. Few papers explicitly examine the issue of long-term survival, with only four papers providing adequate data on long-term outcomes.[14–16, 20] Again, it is difficult to distinguish whether this is simply a reflection of these patients having more advanced disease or whether stenting plays a significant role.

There is considerable heterogeneity in reporting of outcomes relating to stents and many studies combine results for SEMS and SEPS.[14, 20–22] There is a correlation between SEMS usage and the development of serious complications during neoadjuvant radiation therapy.[24, 32] One potential solution may be the use of biodegradable stents. Unfortunately, data regarding the role of biodegradable stents to relieve dysphagia as a bridge to surgery are limited to small case series.[33, 34] In other malignancies, such as colorectal cancer, the utility of pre-operative stenting remains a source of debate. The European Society of Gastrointestinal Endoscopy recommends that stents should not be placed routinely as a bridge to surgery for left sided colorectal cancers due to concerns over oncological safety, although in highly selected cases they may be of benefit.[9, 35] There is no consensus on whether stents should be removed preoperatively. The authors feel that if technically feasible, stents should be removed preoperatively to facilitate surgery; however, in cases where there is tumor overgrowth or significant inflammatory reaction, this may not be possible.

Although extrapolating from small volume publications is not ideal, the consensus from all articles included in this review is that stents during neoadjuvant therapy are associated with worse outcomes in esophageal cancer patients. The results demonstrate that metallic and plastic stenting offers no obvious nutritional or oncological benefit in malignant dysphagia when used as a bridge to surgery and may negatively impact progression to resection with curative intent. A recent population-based study from Scandinavia showed a trend toward increased mortality postoperatively with pre-operative stent placement. Although they did not give data on oncological safety, this raises further safety concerns.[11]

Our study is limited by the quality of the studies available for inclusion, heterogeneity of reported results and the lack of sufficient comparative analyses with control groups. No quality of life measurements were available to interpret, despite four of the selected studies being prospective. No randomized studies on stenting during neoadjuvant therapy as a bridge to potentially curative resection exist and a void in the literature is apparent. The evidence base for the utility of SEMS and SEPS during chemoradiation is poor at present with most guidelines reliant on the clinical acumen of specialist centers, small volume case series or reviews combining the effects of metallic, biodegradable and various polyflex prostheses.

CONCLUSION

This systematic review has shown that although esophageal stents are associated with improvements in dysphagia during neoadjuvant therapy, they do not improve nutritional markers in the preoperative setting and may be associated with poorer long-term oncological outcomes. Stents should not be routinely used in patients who are being considered for resection with curative intent for esophageal malignancies. Instead nutritional needs can be met using total parenteral nutrition, naso-enteral feeding or percutaneous enteral feeding. Although these have no effect on dysphagia, they may be more likely to meet the nutritional requirements of patients without the possibility of compromising oncological outcomes.[6, 36] Direct comparison of these strategies would be beneficial in a well-designed randomized controlled trial.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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