

Oesophageal Stents for Potentially Curable Oesophageal Cancer – A Bridge to Surgery?

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Accepted: 12th of October 2017

Provenance: externally peer-reviewed

ABSTRACT

For oesophageal cancer patients with potentially curative disease, treatment usually comprises neoadjuvant chemoradiotherapy followed by surgery. Several methods are currently used for nutritional support while patients are undergoing neoadjuvant treatment but these do not relieve dysphagia. Stenting as a bridge to curative surgery has been explored in several case series and a case control study. This is a review of the current literature on the topic. Some small series have shown it to be safe and effective in relieving dysphagia and malnutrition without adverse effect on surgical outcomes, perioperative complications or delay in surgical resection post neoadjuvant therapy. However, there are sufficient concerns about its adverse impact on oncological outcomes such as a reduction in the R0 resection rates, median time to recurrence and 2 - 3 year overall survival, to not currently recommend its routine use in resectable cancers.

INTRODUCTION

For patients with potentially curative oesophageal cancer, there is a risk that a compromised nutritional state can extend through the period of tumour staging to the commencement of neoadjuvant treatment, leading to treatment delays, poorer response and an adverse impact on the long term prognosis and surgical outcome¹.

Several methods are currently used for nutritional support. These include enteral feeding via nasogastric or nasojejunal tubes, percutaneous gastrostomy (PEG) and jejunostomy (PEG-J) tubes, parenteral nutrition via central venous access, as well as aggressive oral supplementation under dietetic review¹⁻⁴. All of these methods have significant limitations as they do not relieve dysphagia, which decreases quality of life. In addition, there is the risk of aspiration pneumonia, surgical compromise of the stomach, dislodgement and risk of central line infection and thrombosis, thrombophlebitis, liver failure and prohibitive cost of parenteral nutrition².

The concept of employing stents (partially or fully covered self-expanding metal stents (SEMS) or plastic/biodegradable) as a 'bridge' to curative surgery has been explored in several case series and a case control study⁵⁻⁸. The principle is that the stent will relieve or improve dysphagia allowing an increase in oral intake, an improvement in nutritional status and possibly

surgical outcome. There is a general reluctance to stent operable candidates, possibly due to poor knowledge about outcome, which is why we decided to review the literature.

METHODS

We included only articles on the use of oesophageal stents in operable cancer in the main discussion, though references have been occasionally made to others when there was no relevant information available. Scientific papers published between 1990 and 2015 were searched for in PubMed, EMBASE, Cochrane Library and Medline; the key words were (o)esophageal stent, surgery, resectable cancer and (o)esophageal cancer. In addition, a search of the references within papers was made to identify other studies. English and non-English sources were reviewed, though the relevant studies included were all in English. Manual searching was also done. Grey literature including non-indexed journals, proceedings and posters from international meetings were also included in the initial review. Two independent reviewers (TCKT and JEJT) scrutinised all the studies with regards to the inclusion criteria and quality. The overall results were assessed by all authors for their robustness and conclusions were discussed to avoid any bias before arriving at a consensus.

RESULTS

We identified 15 studies that evaluated the role of stents as a bridge to surgery^{3-5,9-21}. Three systematic reviews were also available. There are several key questions to be addressed with regards to oesophageal stents being used as a bridge. We have tried to critically review these studies and discuss each question in this context.

WHAT IS THE EFFICACY OF OESOPHAGEAL STENTING IN RELIEVING DYSPHAGIA?

Dysphagia is the commonest indication for stenting this subgroup of patients, being the predominant indication in up to 95% of patients in some studies⁵. It is important to evaluate

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the efficacy of stenting from the point of view of procedural success, and relief of dysphagia. Most of the studies discussed below included subjective scoring of dysphagia at initial presentation, ranging from no dysphagia through solid, mixed and liquid dysphagia to total dysphagia.

Alder et al, conducted a prospective non-randomised study of 13 patients who underwent EUS (endoscopic ultrasound) followed by stent placement¹⁵. The dysphagia scores significantly improved post stent insertion. The study concluded that oesophageal stent insertion was safe and permitted adequate oral feeding though at the cost of risk of migration (6 in 13 patients, 43%). Martin, et al performed a small prospective study of 5 patients who received oesophageal stents prior to receiving neoadjuvant chemotherapy¹⁶. Stent placement was successful in all 5 cases (100%) with optimal caloric needs met within 2 hours.

Siddiqui et al performed a retrospective, non-randomised study of 6 patients with malignant strictures who underwent oesophageal stent placement before receiving neoadjuvant chemo radiation²¹. Of the 6 patients, stent placement was successful in 5 (83%). Pellen et al conducted a study of 16 patients who received a self-expanding removable metal stent (SERMS) during neoadjuvant therapy¹⁰. There was a significant fall in mean dysphagia score from 2.5 (range 1-4) to 1.1 (range 0-3) immediately preoperatively.

Langer et al conducted a study of 38 patients, who had stents inserted, before undergoing neo-adjuvant chemo radiotherapy¹⁴. 37 of 38 (97.4%) patients had immediate dysphagia relief. Brown et al prospectively evaluated the use of self-expanding plastic stents (SEPS) during neoadjuvant therapy¹². Lopes et al conducted a study of 11 patients who received SEMS prior to neoadjuvant therapy¹³. Dysphagia significantly improved compared to baseline in both these studies.

Griffiths, et al¹⁷ evaluated a cohort of 22 patients who received biodegradable oesophageal stents (BD SX –ELLA) of whom 9 had oesophageal malignancy. The insertion was successful in 21/22 (96%) of their patients with a significant improvement in dysphagia scores at a median of 47 days.

Park, et al¹⁹ evaluated the clinical efficacy of temporary placement of a retrievable expandable metallic stent during preoperative neoadjuvant chemoradiotherapy. Stent placement was technically successful in all patients with 24 of 25 (96%) showing symptomatic improvement. Stents were removed electively 32 days after starting neoadjuvant chemoradiotherapy or after stent migration and exit through the anus. The dysphagia score improved from 3.1 by 3 days after stent placement to 1.3 and was maintained up to 1 month after stent removal.

Van den Berg, et al²⁰ included 10 patients who underwent biodegradable stent placement (BD – ELLA) before neoadjuvant chemoradiotherapy. Technical and clinical success rates were 100% each. Mean dysphagia score improved significantly, 3 to 1.13 pre and post stent insertion, $p < 0.001$.

A systematic review and meta-analysis conducted by Nagaraja, et al²² found a substantial decrease in dysphagia scores (standard error 0.15, 95% CI, -1.1 to -0.51). This review included nine of our fifteen studies.

Are oesophageal stents effective in management of malnutrition?

Van den Berg et al showed that although biodegradable stent placement as a bridge to surgery prior to neoadjuvant treatment resulted in improved dysphagia scores, it appeared to hamper oral intake, resulting in significant weight loss, needing additional nutritional interventions²⁰. In contrast Siddiqui, et al⁴ showed that albumin levels and weight increased significantly with both plastic stent (PS) and surgical jejunostomy (JT). There were no significant differences between groups in the procedural success rates (PS 92% vs. JT 100%, $P = 0.33$), complication rates (PS 22% vs. JT 4%, $P = 0.11$), mean increase in weight (PS 4.4 kg vs. JT 4.2 kg, $P = 0.59$), and mean increase in serum albumin (PS 0.62 g/dL vs. JT 0.44 g/dL, $P = 0.05$). In a review of a prospective database by Bower, et al, the silicone stent group demonstrated greater mean improvement in albumin levels (0.14 g/dL vs. -0.39 g/dL vs. -0.45 g/dL, $P < .001$) and less percentage body weight loss (1.5% vs. 4.2% vs. 5.5%, $P < .001$) compared with the groups with feeding tubes and oral nutrition.

Nagaraja et al conducted a meta-analysis of the literature. They found a substantial increase in weight (SE 0.434, 95% CI, -0.261 to 1.442) and albumin (SE 0.271, 95% CI, -0.181 to 0.881) standard difference in means²².

WHAT ARE THE COMPLICATIONS OF STENTING RESECTABLE OESOPHAGEAL CANCER?

Stent migration varied from 20% in the study by Martin, et al (removed without complication at the time of operation¹⁶ to 60% in the study by Siddiqui, et al (all successfully removed endoscopically or at the time of surgery)²². Stent-related morbidity occurred in 4/16 (25%) patients and migration occurred in 7/16 (44%) in the study by Pellen, et al, though all were resolved endoscopically with no stent-related mortality¹⁰. A meta-analysis of stents for resectable oesophageal cancer concluded that stent migration occurred in 1 patient causing jejunal perforation (2.6%), tracheo-oesophageal fistula in 2 (5.2%) and significant bleeding 1 (2.6%); delayed complications occurred in three (7.89%) ie tracheo-oesophageal fistula and recurrent dysphagia²².

Griffiths, et al reported of 9 patients who had biodegradable stents, one (11%) required reinsertion of a self expanding metal stent at 2 months and 2 (22%) required supplementary feeding via jejunostomy and a fine bore nasojejunal tube within 12 weeks of stenting. Van den Berg, et al²⁰ used biodegradable stents, with an adverse event rate of 70%. Retrosternal pain developed in 6 patients and persisted for a median of 12 days. Stent obstruction occurred in one patient because of necrotic tissue.



TABLE: SUMMARY OF THE RESULTS OF THE USE OF SELF EXPANDING STENTS AS A BRIDGE TO SURGERY IN OESOPHAGEAL CANCER

SEMS = Self expanding metal stent; SEPS = Self expanding plastic stent, BDS = Biodegradable stent, REMS = Retrievable expandable metallic stent

Author	Year	Type of stent	Number of patients	Number who had surgical resection (%)	Number of stent related complications (%)
Mariette ⁵	2014	SEMS	38	38 (100%)	Not reported
Krokidis ⁴	2013	SEPS	11	1 (9%)	5 (45%)
Pellen ¹⁰	2012	SEMS	16	10 (63%)	8 (50%)
Siddiqui ¹¹	2012	SEMS	55	8 (15%)	19 (35%)
Brown ¹²	2011	SEPS	32	20 (63%)	10 (31%)
Lopes ¹³	2010	SEMS	11	2 (18%)	5 (45%)
Langer ¹⁴	2010	SEMS-25, SEPS-13	38	20 (53%)	18 (47%)
Adler ¹⁵	2009	SEPS	13	3 (23%)	6 (46%)
Bower ³	2009	SEPS	25	14 (56%)	6 (24%)
Martin ¹⁶	2009	SEPS	5	Not reported	1 (20%)
Siddiqui ⁴	2009	SEPS	12	Not reported	4 (33%)
Griffiths ¹⁷	2012	BDS	9	3 (33%)	3 (33%)
Kjaer ¹⁸	2016	SEMS	63	All R0 (this was the group from which the patients who had stents were identified)	Not reported
Park ¹⁹	2015	REMS	25	Not reported	Not reported
Van den Berg ²⁰	2014	BDS	10	7 (70%)	7 (70%)
Siddiqui ²¹	2007	SEPS	6	100%	3 (60%)

The systemic review by Nagaragi et al noted the incidence of major adverse events including stent migration as 32% and chest discomfort as 51.4%²². The authors in this review recommend stents for dysphagia prior to or during neoadjuvant chemotherapy but seem to underestimate the impact of the complications and did not adequately assess the disadvantages of stenting preoperatively as they considered stent migration not to be a disadvantage but rather an indicator of tumour reduction. A review by Jones and Griffiths²³ came to the conclusion that there can be significant complications in a small proportion of patients which can compromise opportunity for curative surgery.

HAS STENTING BEEN COMPARED TO STANDARD OPTIONS SUCH AS NASOGASTRIC OR NASOJEJUNAL FEEDING AND GASTROSTOMY OR JEJUNOSTOMY?

Only two studies to date have compared stenting to standard treatments. Bower, et al conducted a retrospective study comparing nutritional support methods in patients undergoing neoadjuvant chemo radiotherapy³. This study compared the outcomes of oesophageal stenting, feeding tubes and oral diets. 25 patients received stents, 19 patients had feeding tubes inserted and 14 patients were maintained on oral diet only. The group of patients who received oesophageal stents had a lower rate of interruption of chemo radiotherapy (8% vs. 29% vs. 47%, $P=0.011$), greater mean improvement of albumin (0.14 g/dL vs. -0.39 g/dL vs. -0.45 g/dL, $P<0.001$),

less percentage body weight loss (1.5% vs. 4.2% vs. 5.5%, $P<0.001$) and a reduction in major operative complications (20% vs. 47% vs. 43% among stent, feeding tube, and oral nutrition respectively ($P=0.130$)). As mentioned earlier, Siddiqui, et al showed that plastic stents were a safe and effective alternative to surgical jejunostomy for maintaining nutrition in this subset of patients undergoing neoadjuvant chemo radiotherapy⁴.

DOES STENTING COMPROMISE SUBSEQUENT SURGERY AND ONCOLOGICAL OUTCOMES?

Studies have shown that interval disease progression as a direct consequence of SEMS could adversely affect the treatment plan of 30 to 85%.^{3,12,14} Mariette et al conducted a retrospective study of 2944 patients in a multicentre European cohort, who underwent oesophageal resection over a period of ten years⁵. They evaluated the oncologic impact of covered SEMS when used as a bridge to surgery. A total of 38 patients had SEMS inserted. SEMS insertion was complicated by perforation in 2 cases. The study also found that postoperative mortality (13.2% vs 8.6%) and morbidity rates (63.2% vs 59.2%) were increased in the SEMS group compared to the control group respectively. They found a significant reduction in the R0 resection rate (71% vs 85.5%; $p=0.041$), median time to recurrence (6.5 vs 9 months) and the 3-year overall survival (25% vs 44%) in the SEMS group compared to the control.



Griffiths, et al¹⁷ found that in nine patients who had biodegradable stents, 6 (66%) did not proceed to surgery; 1 (11%) because of disease progression, two (22%) because of failure to gain weight and three (33%) because they became unfit for surgery. The additional 3 (33%) did progress to surgery but were not resected due to the recognition of disseminated disease. In the other biodegradable stent study by van den Berg²⁰, 4 of 10 patients did not undergo surgery because of fatal pneumonia, liver metastases, poor performance status and insertion of a self expanding metal stent for a post radiation stricture, respectively.

A retrospective cohort study from a prospectively maintained national database in Denmark identified all patients treated without neoadjuvant therapy that had an R0 resection¹⁸. Of these 63 patients had a stent as a bridge to surgery. The outcomes from these patients were compared to 211 who did not have a stent. The median survival in the stent group was significantly lower than the non-stent group by 11.6 months and 21.3 months respectively. Non-stent group exhibited a significantly better two year survival with a median recurrence free survival of 9.1 months for the stent group compared with 15.2 months for the non-stent group.

ARE THERE ANY DIFFERENCES DEPENDING ON THE TYPES OF STENTS USED?

Krokidis, et al conducted a prospective study to evaluate the use of biodegradable oesophageal stents in malignant oesophageal strictures as a bridge to surgery⁹. In this study 11 patients had a woven polydioxanone degradable oesophageal stent inserted. Stent deployment was successful in all patients. However, early complications occurred in 3 patients that resulted in failure to restore oral nutrition. Stent dysfunction occurred in 5 of 8 patients (62.5%). In 2 of the 5 patients this was due to a local inflammatory reaction and in the remaining 3, this was due to tumour ingrowth. Subsequently a new metallic stent was inserted in 4 of the 5 patients. At the end of follow-up only 3 of 8 oesophageal stents were patent. This study demonstrates that biodegradable oesophageal stents do not appear to have benefit in malignant strictures. Two other studies on biodegradable stents^{17,20} also do not show good outcomes in terms of surgical resection and stent related complications.

Five studies have evaluated self-expanding plastic stents (SEPS)^{3,4,15,16,21} and three studies^{10,11,13} have evaluated self-expanding metal stents (SEMS). One study combined both SEPS and SEMS¹⁴. There did not appear to be any differences in outcomes although there are no studies comparing these two. Two studies looked at the concept of removing stents prior to surgery with self expanding plastic stents^{19,21} but there was no clear benefit.

WHAT ABOUT COST-EFFECTIVENESS?

To date, no studies have evaluated cost effectiveness as a bridge to neoadjuvant therapy and surgery in oesophageal cancers.

DISCUSSION

In summary, although stents are effective in relieving dysphagia in resectable tumours, significant complications are common such as perforation and fistula, with one study showing increased postoperative mortality and morbidity.

Although a systematic review²² found that stents before neoadjuvant therapy result in an increase in weight and albumin, biodegradable stents appear to hamper oral intake resulting in weight loss needing additional nutritional interventions²⁰.

Stent insertion before surgery was found to be a predictor of poor prognosis after adjusting for confounding factors in the study by Mariette, et al⁵. The reasons suggested include peri-stent fibrosis secondary to expansive radial forces, compromising the normal planes of dissection and therefore the resectability^{24,25}; fixating spurs causing micro perforations and dissemination²⁶; inability to accurately restage tumours after stent insertion making it difficult to identify the tumours that progress and become unresectable. However this study has limitations. This retrospective study did not evaluate patients who underwent stent insertion and did not benefit from surgery due to tumour progression or stent-related fistula. In addition, it is a small study with only 38 cases of SEMS insertion. The findings from this study are supported by a larger similar study from Denmark¹⁸ of 63 patients who underwent stenting prior to surgery. In this study, only patients who underwent an R0 resection were selected. They too found that the two year survival and recurrence-free survival was decreased in the stent group compared with those who did not have a stent.

Although stents appear to be effective in relieving dysphagia prior to surgery, there are major concerns about its adverse impact on oncological outcomes. The European Society of Gastrointestinal Endoscopy (ESGE) clinical guidelines²⁸ for the use of oesophageal stenting in benign and malignant disease do not recommend the use of stent placement as a bridge to surgery or prior to preoperative chemo-radiotherapy due to a high incidence of adverse events and the availability of safer feeding options²⁹. The review by Jones and Griffiths²³ also came to the same conclusion.

CONCLUSION

With the limited available data on this topic, we can conclude that although stenting appears to be effective in relieving dysphagia and addressing malnutrition prior to surgery, there are currently sufficient concerns about its adverse impact on oncological outcomes, to not recommend its routine use in resectable patients. Well-designed randomised prospective trials are required but are unlikely to happen because of concern about adverse oncological outcome. In our opinion, the use of oesophageal stents as a bridge to surgery should be confined to patients with dysphagia who cannot tolerate tube feeding or where a feeding gastrostomy or jejunostomy is contraindicated or not possible, or in the context of a clinical trial evaluating its role.



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