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Endoscopic stenting-Where are we now and where can we go?

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Abstract

Self expanding metal stents (SEMS) play an important role in the management of malignant obstructing lesions in the gastrointestinal tract. Traditionally, they have been used for palliation in malignant gastric outlet and colonic obstruction and esophageal malignancy. The development of the polyflex stent, which is a removable self expanding plastic stent, allows temporary stent insertion for benign esophageal disease and possibly for patients undergoing neoadjuvant chemotherapy prior to esophagectomy. Potential complications of SEMS insertion include perforation, tumour overgrowth or ingrowth, and stent migration. Newer stents are being developed with the aim of increasing technical and clinical success rates, while reducing complication rates. Other areas of development include biodegradable stents for benign disease and radioactive or drug-eluting stents for malignant disease. It is hoped that, in the future, newer stents will improve our management of these difficult conditions and, possibly, provide prognostic as well as symptomatic benefit in the setting of malignant obstruction.

Key words: Endoscopy; Stent; Palliation; Bowel obstruction; Malignancy

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INTRODUCTION

Self expanding metal stent (SEMS) insertion has an important role in the management of malignant gastrointestinal obstruction. There are several types and sizes of SEMS on the market. Each has its own characteristics in terms of radial forces exerted, foreshortening on deployment, and flexibility. SEMS are made of either stainless steel [e.g. Z-stent (Cook)] or alloys such as Nitinol [e.g. Ultraflex (Boston Scientific), Alimaxx E (Alveolus)] or Elgiloy [e.g. Wallstent (Boston Scientific)][1]. Stent insertion is also increasingly used in benign esophageal disease, such as non-malignant strictures and anastomotic leaks. The Polyflex stent (Boston Scientific) is a self expanding plastic stent which has been approved for use in the management of benign and malignant esophageal strictures.

Enteral SEMS, i.e. for the duodenum and colon, are generally inserted through the scope (TTS). These are deployed over a guidewire under direct vision, usually with fluoroscopic guidance. Esophageal stents are not TTS and are deployed under fluoroscopic guidance after delineating the margins of the stricture endoscopically.

In this article, we review the current state of play with respect to enteral and esophageal stents, the latest developments, and possible future directions.

ESOPHAGEAL STENTING

SEMS have been in use for malignant dysphagia and trache-esophageal fistulae (TEF) since the early 1990s when they replaced rigid plastic stents. They are relatively easy to deploy, have a high technical success rate and provide rapid relief of dysphagia[2]. However, insertion of SEMS has a complication rate of 26%-52%[3-7] with 1 in 6 requiring further stents[8]. Procedure related mortality is 2%-3%[7,8]. Complications associated with esophageal stent insertion include perforation, bleeding,

stent migration, reflux, chest pain, recurrent dysphagia due to tumour overgrowth or ingrowth, migration, and food bolus impaction. Although SEMS insertion is still the treatment of choice for TEF, it appears not to be the safe, one-off treatment for malignant dysphagia that it was once hoped to be.

Comparisons between SEMS and brachytherapy for esophageal malignancy have shown improved dysphagia scores at 30 d with reduced complications[9] and improvements in quality of life, dysphagia, and eating scales[10] for brachytherapy. It has been suggested that, as stent re-intervention is likely to be increased for those who live longer, SEMS should be considered for those with a poorer prognosis, and chemo/radiotherapy, with temporary stent placement, for those with a longer life expectancy[2]. A Korean group inserted a removable nitinol stent in 47 patients who had concurrent radiotherapy and extracted the stent in 24 patients after 4 wk, leaving the stent in place in the remaining patients[11]. The complication and re-intervention rates were significantly lower in the group in which the stent was extracted, while the dysphagia-progression-free and overall survival rates were significantly longer. No randomized trials have yet been conducted with the Polyflex stent, which is the only removable stent licensed in the USA in this setting. Further randomized trials of SEMS in combination with other treatment modalities would help determine the optimal management strategy in terms of symptom control and overall survival. Drug-eluting and radioactive stents may also have a future role in the management of esophageal malignancy; these have been tested with success in animal models[12,13].

In cases where the distal margin of the stent crosses the gastro-esophageal (GE) junction there are now SEMS available with an anti-reflux mechanism. Survival has been shown to be reduced in patients in whom the stent crossed the GE junction[14]. A study which compared an open stent with the Z-stent with Dua antireflux valve found that 96% of patients with the open stent had reflux symptoms, compared with 12% with the antireflux mechanism[15]. Several other SEMS with antireflux mechanisms have been manufactured. Further work will be required to determine the overall efficacy and complication rates of these stents for distal esophageal and cardia tumours.

Many of the available SEMS are covered to reduce the risk of tumour in-growth and to seal TEF. As the risk of stent migration is higher with covered stents, many have flared ends and uncovered segments at both ends to anchor on to the tissue. Fully covered SEMS may prove useful in benign disease as they are potentially removable but further experience in this area is required.

The Polyflex stent is the only stent currently licensed for benign disease but there has been an interest in the development of biodegradable stents. These would theoretically exert their effect before slowly breaking down and subsequent stent extraction, which can be stressful for the patient and physician, is avoided. A small case series from Japan had promising results when a biodegradable stent constructed from poly-l-lactic acid monofilaments was used to treat benign esophageal stenoses[16].

GASTRIC OUTLET OBSTRUCTION (GOO) AND DUODENAL STENTING

Stent placement for GOO was first described in 1992[17]. Patients with GOO are generally very ill and in the terminal phase of a malignant process. Gastrojejunostomy (GJJ) has traditionally been the procedure of choice for GOO. However, insertion of a SEMS for GOO offers a relatively safe and much less invasive alternative to gastrojejunal bypass. Most trials comparing GJJ with SEMS insertion for GOO are prospective or retrospective comparative studies or case series evaluating either SEMS insertion or GJJ. A summary of the prospective and larger retrospective case series is given in Table 1. A more recent comprehensive review of stent insertion *versus* GJJ for GOO included a total of 1046 patients undergoing stent insertion and 297 undergoing GJJ[39]. There was no difference between SEMS insertion and GJJ in terms of technical success (96% *vs* 100%), early (7% *vs* 6%) and late (18% *vs* 17%) major complications, or persisting symptoms (8% *vs* 9%). Initial symptom relief was higher for SEMS (89% *vs* 72%). Recurrent obstructive symptoms were higher for SEMS (18% *vs* 1%) but hospital stay was shorter (13 d *vs* 7 d) with a mean survival of 105 d after stent placement and 164 after GJJ. These results suggest that stent placement may be the preferred option for patients with a shorter life expectancy but GJJ is preferable for patients with a more favourable prognosis.

Several stents are available for gastroduodenal use including the Wallstent Enteral, Wallflex Enteral Duodenal (Boston Scientific), Choo stent (Solco Intermed Co. Ltd. and Mi Tech Co. Ltd), and the Song stent (Stentech). The aim of stent manufacturers is to produce a SEMS which is easy to insert, is clinically effective and carries a low complication and migration rate. The use of the new Nitinol Wallflex stent was investigated by Van Hooft *et al*[40] who inserted a total of 66 Wallflex stents in 62 patients. with a clinical success rate of 85%. Median hospital stay was 6 d, and 10 of 60 patients (17%) who had follow up data for 30 d developed complications. They concluded that the new stent was effective and relatively safe.

Other recently developed stents include the Niti-S enteral stent (Taewoong Medical Co.) which has a woven rather than the usual braided design, leading to improved flexibility and reduced foreshortening and, it is hoped, reduced migration, as well as dual stents (e.g. Niti-S Comvi, Taewoong Medical Co., and the dual expandable nitinol stent, S&G Biotech). These have a covered layer to reduce tumour ingrowth and an uncovered layer to reduce migration. These newer stents have shown promising results in case series[32,33,37] but randomized comparisons with conventional stents are required to further assess their efficacy.

Table 1 Summary of case series of SEMS placement for gastric outlet obstruction (%)

Authors	Yr	Study design	*n*	Technical success	Clinical success	Major complications (early and late)
de Baere *et al*[18]	1997	Prospective	10	100	94	28
Bethge *et al*[19]	1998	Prospective	6	100	100	33
Jung *et al*[20]	2000	Prospective	19	95	100	26
Pinto Pabon *et al*[21]	2001	Prospective	31	100	90	10
Kim *et al*[22]	2001	Prospective	29	90	96	29
Lopera *et al*[23]	2001	Prospective	16	94	81	19
Profili *et al*[24]	2001	Prospective	15	100	93	14
Lee *et al*[25]	2001	Prospective	11	87	82	0
Espinel *et al*[26]	2001	Prospective	6	100	100	0
Jung *et al*[27]	2002	Prospective	39	97	95	36
Jeong *et al*[28]	2002	Prospective	18	100	94	28
Schiefke *et al*[29]	2003	Prospective	20	100	100	nr
Holt *et al*[30]	2004	Prospective	28	93	93	21
Huang *et al*[31]	2007	Prospective	14	100	86	14
Kim *et al*[32]	2007	Prospective	213	94	94	21
Lee *et al*[33]	2007	Prospective	11	100	91	18
Lowe *et al*[34]	2007	Prospective	87	97	87	10
Maetani *et al*[35]	2007	Prospective	37	97	94	19
Song *et al*[36]	2004	Retrospective	102	99	84	9
Telford *et al*[37]	2004	Retrospective	176	97	84	9
Bessoud *et al*[38]	2005	Retrospective	72	97	90	15

nr: Not reported.

Increasingly innovative techniques for stent insertion are also being pioneered. The development of double balloon enteroscopy has allowed us to perform therapeutic procedures in areas that were previously beyond our reach. Ross *et al* successfully inserted a SEMS in the distal duodenum for a patient with metastatic lung cancer using double balloon enteroscopy[41]. This raises the possibility of stent insertion in patients with a single point of malignant small bowel obstruction that is beyond the reach of conventional endoscopes.

COLONIC STENTING

The use of SEMS in the palliation of malignant colonic obstruction was first described in 1991[42]. The current stents available are uncovered but there have been reports on the use of uncovered and covered esophageal stents in the colon. Overall technical success rates are generally in excess of 95% with relief of obstructive symptoms in 85%-90% for palliative stenting[1]. In a comprehensive review of 58 publications on colorectal stent publications from 1990 to 2000[43] stent insertion was successful in 551 of 598 cases (92%). There was a 4% rate of perforation, 10% migration rate and 10% re-obstruction rate. Stent migration was associated with laser pre-treatment, concurrent chemotherapy, covered stent use, and benign disease. The perforation rate was higher in the studies in which balloon pre-dilation was performed (10% *vs* 2%), suggesting that this should not be performed routinely. A variety of stents were used in the different studies but most of them were uncovered. One study, which used partially or fully covered stents, had a migration rate of 22%[44].

Many earlier series used esophageal stents for colonic stenting and it is hoped that specifically designed colorectal stents will have lower rates of migration. For example, in a prospective study with 44 patients[45] the nitinol Ultraflex precision colonic stent migrated in one patient (2%) who had commenced chemotherapy shortly after stent insertion. There was a technical success rate of 95% and a 6 mo clinical success rate of 81%. There have been very few comparisons between different stent types. A small retrospective study comparing the Ultraflex stent and the Wallstent found that they both provided adequate relief of obstruction but the Ultraflex had a significantly lower rate of delayed complications, need for re-intervention, and a non-significant reduction in early migration and occlusion[46].

In recent years there has been a move towards SEMS insertion as a "bridge" to surgery for patients who present with acute malignant obstruction. In the event that a patient is subsequently deemed unsuitable for a curative resection, the stent provides palliation. 10%-30% of patients with colonic cancer present with obstructive symptoms[47] and in many centres surgical decompression remains the primary management option for such patients, either due to local preference or resources. Morbidity and mortality rates have been quoted at 32%-64% and 15%-34%, respectively, for patients who undergo emergency surgery[48-52]. Up to 40% of these patients are left with a permanent colostomy[53]. For those patients who are subsequently found to have operable disease they then need a second surgical procedure. Stent insertion is appealing as it allows these patients to have adequate rehabilitation and preparation before an elective procedure, while avoiding invasive surgery for palliative patients.

Martinez-Santos *et al*[50] performed a prospective study investigating the results of colonic stenting *versus* emergency surgery in 72 patients presenting with left

sided malignant colorectal obstruction. Forty-three patients had preoperative stent insertion followed by elective surgery (if necessary) and 29 had emergency surgical treatment. Surgical resection was subsequently found not to be indicated in 18 of the patients who had SEMS insertion and in 3 from the control group. SEMS insertion was clinically successful in 41 cases (95%). Of those patients with colonic stents who proceeded to surgery 85% had a primary anastomosis, compared to 41% in the non-stent group ($P = 0.0025$), with a lower need for a colostomy (15% *vs* 59%). There were also significantly reduced severe complications, re-intervention rates, total hospital stay, and ICU stay. Overall, stent placement prevented 17 of 18 (94%) unnecessary operations. In a long-term follow up study there was no difference in 3 years (48% *vs* 50%) and 5 years (40% *vs* 44%) survival in the SEMS and emergency surgery groups respectively, but post-operative complications were significantly lower in the stent group[51]. Therefore, stent insertion as a bridge to surgery is technically and clinically successful, relatively safe, and cheaper than emergency surgery for patients who present with malignant left sided obstruction.

SEMS insertion is not currently approved for benign disease of the colon, primarily because of high failure and complication rates, as well as an inability to remove the stent endoscopically[54]. In one study there was a failure rate of 63% for 8 patients[55]. In the largest series to date 23 patients had an SEMS placed for benign colonic disease[56]. There was a 100% technical success rate and 95% (22/23) clinical success rate. Eight of the 23 patients (38%) had major complications, 7 of which (87%) occurred within the first week. Sixteen of the 19 patients who underwent a colectomy were successfully converted from an emergency procedure to an elective one; 8 patients did not require a colostomy. SEMS insertion should probably not be considered as a definitive treatment option for benign colonic strictures, in view of the high rate of complications in the limited published data available. However, in the setting of colonic obstruction it may be appropriate as a temporary measure to facilitate decompression with subsequent elective surgery, rather than proceeding to emergency colectomy.

CONCLUSION

Endoscopic stenting remains an important tool in the management of malignant conditions of the esophagus, gastric outlet, and colon. As newer stents are developed, randomised trials are required to determine which provides the most benefit. For esophageal malignancy the evidence suggests that SEMS insertion may be appropriate for patients with a poorer prognosis, with temporary SEMS and chemoradiotherapy for those with a longer life expectancy. However, further trials are required to clarify the optimum management of these patients. For patients undergoing neo-adjuvant therapy prior to esophagectomy, a small retrospective trial reported favourable results for temporary placement of the Polyflex stent[57]. The Polyflex stent is being increasingly used for benign esophageal strictures and has also been used with success in the management of post-operative esophageal leak[58]. Another novel use for temporary esophageal stent placement was in the management of acute esophageal variceal bleeding[59]. Although the findings of this small study were positive, a large comparative trial would be required before SEMS could replace the current therapy for bleeding varices.

Colonic stenting should be considered for palliation in malignant obstruction and as a bridge to surgery in the setting of acute obstruction. The results of further randomized controlled trials, such as the Dutch Stent-in 2 study[60], are awaited to bolster the existing evidence. Covered stents and pre-deployment dilatation appear to increase the complication rate. The development of stents with longer delivery systems will hopefully make the right colon more accessible also. Double balloon enteroscopy may also allow stent insertion in areas that were previously beyond our reach.

As stenting devices and our skills develop, endoscopic capabilities will continue to expand. Bioabsorbable stents may allow a safe and effective method of temporary stent placement, without the need for a further procedure. Radioactive and drug-eluting esophageal stents have already been trialled in animal models; it is hoped that such stents in the future will have prognostic as well as symptomatic benefit for patients with malignant obstruction. We await these new developments with anticipation.

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