Review Article

# Self-expandable metallic stent placement for palliation in gastric outlet obstruction

**Iruru Maetani**

Division of Gastroenterology and Hepatology, Department of Internal Medicine, Toho University Ohashi Medical Center, Tokyo, Japan
*Correspondence to:* Iruru Maetani. 2-17-6 Ohashi Meguro-ku Tokyo, 153-8515, Japan. Email: mtnir50637@med.toho-u.ac.jp.

**Abstract:** Malignant gastric outlet obstruction (GOO) often has a markedly adverse impact on the quality of life (QOL) of patients. Procedures in affected patients should aim to reduce obstructive symptoms and enable oral ingestion. Surgical gastrojejunostomy (GJJ) has been performed as a conventional palliative procedure. Enteral stenting has been increasingly used as an alternative to surgical palliation because of its lower invasiveness. Enteral stents used for GOO are made of a metal alloy mesh in a cylindrical shape, and are termed self-expandable metallic stent (SEMS). Of the two placement techniques, over-the-wire (OTW) and through-the-scope (TTS) deployment, TTS is easier and is now more frequently used. In general, the technical success rate is extremely high, at nearly 100%, and the clinical success rate is about 90%, but complications after placement can occur, most frequently late-developing stent dysfunction due to stent obstruction and migration. Biliary obstruction can occur concurrently with GOO, or before or after GOO, particularly in patients with pancreaticobiliary malignancies. Considering accessibility to the bile duct, biliary stenting should generally be conducted prior to enteral stenting. Transhepatic or transmural biliary stenting may be required if transpapillary stenting is not possible. Because enteral stenting is more commonly associated with late-developing stent dysfunction, it is better suited than GJJ for patients with a short life expectancy and poorer performance score. Chemotherapy may be beneficial in reducing the risk of stent obstruction, despite the possible risk of migration, particularly in patients with GOO due to gastric cancer. Many enteral stents with different structures are now commercially available, but the association between the design and mechanical properties of a stent and clinical outcomes is still poorly understood. Further, no consensus on the benefits of covered SEMS has yet been obtained. Further study to verify which types of SEMS are most suited for GOO is warranted.

**Keywords:** Gastric outlet obstruction (GOO); enteral stent; self-expandable metallic stent (SEMS); palliation

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## Introduction

Even today, many gastrointestinal (GI) malignancies are significantly advanced and incurable at presentation. Unresectable malignancies frequently lead to luminal obstruction, and reobstruction due to local recurrence or lymph node metastasis may occur after surgical resection. Gastric outlet obstruction (GOO) particularly occurs in patients with unresectable peri-ampullary (e.g., pancreatic, ampullary, hepatobiliary cancer) or gastric cancer.

The consequences of GOO can be serious. These include intolerance of oral intake and deterioration of quality of life (QOL), with vomiting, aspiration, bloating and malnutrition. Surgical gastrojejunostomy (GJJ) has been performed as a conventional palliative procedure for GOO, but the disadvantages of this procedure include significant risks of higher morbidity and mortality (1), and a higher incidence of delayed gastric emptying (2). Enteral stenting has been increasingly used as an alternative to surgical palliation thanks to its lower invasiveness and quicker response, and the many articles related to enteral stenting for GOO show a variety of evidence. This review paper overviews the literature on enteral stenting for GOO.

## General outline of gastric outlet obstruction (GOO)

GOO is usually found as a late complication and causes a variety of obstructive symptoms, including nausea, vomiting, or bloating, and usually leads to poor or no oral intake in affected patients. These symptoms tend to lead to dehydration, malnutrition and weight loss, and these are distinguished from cancerous cachexia, which accompanies advanced malignancy. Severe GOO which prevents the passage of gastric juice is often accompanied by electrolyte dehydration as well as dehydration and reflux esophagitis. These symptoms are likely to markedly harm the QOL of affected patients. The goal of palliation of GOO is to resume oral intake and improve obstructive symptoms.

## Treatments for malignant GOO

The conventional palliative management for GOO is GJJ, either open or laparoscopic. This procedure provides an effective reduction in obstructive symptoms and allows the resumption of oral intake. However, enteral stent placement was developed in the early 1990's (3-6) and has been practically available for 15 years now.

In addition to stent placement and bypass surgery, other palliative procedures include chemotherapy, radiotherapy, insertion of a decompression tube (e.g., nasogastric or gastrostomy tube), and administration of somatostatin analogue. These have been used independently or in combination with stent placement or GJJ. Nevertheless, the only effective management which allows the resumption of oral intake is surgical GJJ and stent placement; in the absence of either, patients are usually unable to ingest food orally, and often require placement of a decompression tube.

Surgical palliation carries significant risks of morbidity and mortality (1), and frequently causes delayed gastric emptying (2). In addition, many patients with GOO are poor surgical candidates, because of their debilitated condition and malnutrition due to significantly advanced cancer. Against this background, stent placement is both effective in palliating GOO and minimally invasive, and is now widely used in these patients.

## Types of enteral stents

Enteral stents used for GOO consist of a metal alloy (e.g., nitinol) mesh in a cylindrical shape, and are termed self-expandable metallic stent (SEMS). Most SEMS used in the gastroduodenal region have a knitted or braided wire structure. Several types of SEMS which differ with regard to mesh structure and properties (radial force, axial force, etc.) are now commercially available from various manufacturers. SEMSs can be flared at the proximal or both ends, and may be covered with a polyurethane or polytetrafluoroethylene membrane to help prevent tumor ingrowth.

For insertion, the stent is constrained and loaded into the delivery system, most of which are designed for through-the-scope (TTS) deployment. This delivery system is about 10-Fr, which allows passage through the working channel of therapeutic endoscopes. However, SEMSs with a larger introducer sheath designed for over-the-wire (OTW) deployment are also available in some countries (7). OTW deployment is usually performed by radiologists.

## Placement procedure

Before the development of dedicated devices, anatomical difficulties made stent placement for GOOs a difficult and challenging procedure (3-6). The development of dedicated stents and TTS placement have markedly facilitated placement, however, even in long, tortuous strictures.

Currently, stent placement is mostly performed with the TTS deployment technique because of its significant ease of use (8) (*Figure 1*). In addition, TTS deployment technique has an advantage enabling simultaneous placement of two stents without second insertion of endoscope (*Figure 2*). However, the diameter of the delivery catheter is 10-10.5 Fr, requiring a therapeutic endoscope with a large working channel. The procedure is performed under conscious sedation and analgesia. The prone position is optimal because it avoids aspiration and allows an ideal X-ray image to be taken. The X-ray tube of the C-arm should be appropriately rotated so that side view of the stenosis can be obtained. A therapeutic endoscope with a large working channel is inserted and the stenosis is observed. It is not necessary to traverse the stenosis with the endoscope if the stenosis is tight. Negotiation of the stricture is performed using a biliary guidewire (usually "0.035" in diameter) with an ERCP catheter. Once the guidewire can be passed through the stricture, sufficient contrast is injected to define the length of the stenosis. Withdrawing the catheter/guidewire from the distal to the proximal end of the stenosis, or use of a measuring guidewire, is helpful in determining the precise length. An appropriate length of stent (usually at least 2 cm longer than the measured stricture at each end) is then chosen according to the length

 

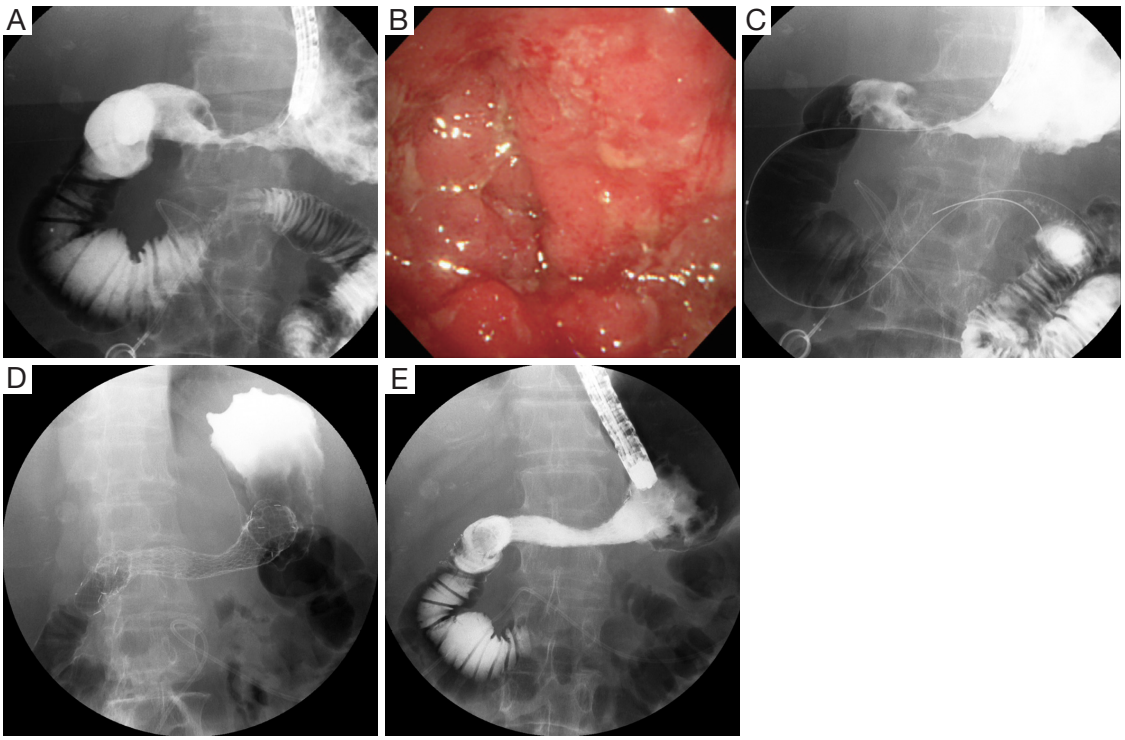


**Figure 1** Stent placement in a patient with antral cancer. (A) Contrast study showing obstruction of the gastric antrum; (B) endoscopy showing gastric cancer which bleed easily; (C) a guidewire has been passed across the obstruction; (D) the stent is successfully placed at the optimal position; (E) final radiogram confirmed good passage within the stent.

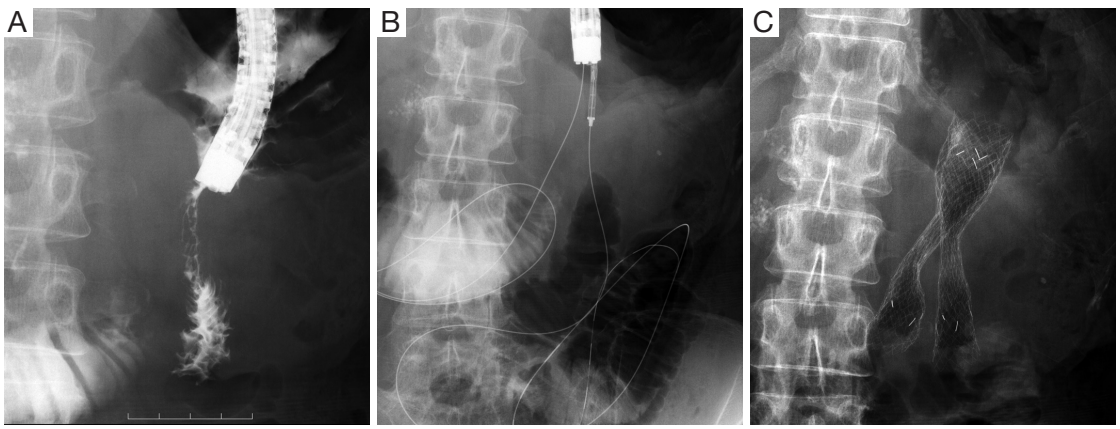


**Figure 2** Stent placement for occluded palliative gastrojejunostomy. (A) Contrast study showing tumor-related obstruction of a gastrojejunostomy created for unresectable gastric cancer; (B) two guidewires have been inserted through the stricture into the afferent and efferent loops; (C) the final radiograph indicates successful placement of stents for both the afferent and efferent loops.

of the stenosis to prevent tumor overgrowth. The stent delivery system is inserted along the guidewire through the working channel of the endoscope. The stent is deployed at the stenotic region in consideration of the foreshortening ratio of the stent, which varies with stent type. The stent should be gradually deployed, with adjustment for position. After deployment, proper positioning is confirmed by a waist within the SEMS. Further, passage is determined by contrast injection via the endoscope. An abdominal plain X-ray film is taken daily to confirm stent positioning and the degree of expansion. Full expansion is usually obtained within three days.

 

## Indications and contraindications

Placement of an enteral stent is indicated in patients with documented malignant obstruction of the pylorus and/or duodenum caused by unresectable tumors. Stent placement is frequently employed in patients who are poor surgical candidates with shortened life expectancy, poor performance status, significant comorbidities and anesthetic risk (9,10).

Contraindications of this procedure are evidence of GI perforation and documentation of multiple distal obstructions, particularly in the small bowel. Peritoneal carcinomatosis may induce multiple distal obstructions, but a study found that a diagnosis of carcinomatosis only should not be considered a contraindication to SEMS placement in patients with malignant GOO (11).

## Efficacy

This procedure with TTS deployment is not difficult, and has a technical success rate of 90% to 100% (12-20). A review of 1,046 published cases reported a technical success rate of 96% (21). The most common causes of technical failure were unsuccessful transit of the guidewire through the stenosis, failed placement of the SEMS at the proper position, and migration of the SEMS during the procedure.

Clinical success, defined as the relief of obstructive symptoms and improvement in oral intake, is obtained in 58% to 92% of patients (12-20). The above review article indicates a clinical success rate of 89% (21). The discrepancies between technical success and clinical success might be attributable to underlying GI dysmotility with or without neural involvement by the tumor, distal obstruction secondary to peritoneal carcinomatosis, or general deconditioning and anorexia caused by advanced malignancy (9). A study which assessed whether stent location alters efficacy revealed that efficacy was not altered by location of the stent across the pyloric valve or within the duodenum (22).

Oral intake is most frequently assessed using the Gastric Outlet Obstruction Scoring System (GOOSS), with 0= no oral intake, 1= liquid only, 2= soft solids, and 3= low-residue or full diet (23). Many articles suggested that GOOSS score is significantly improved following stent placement (14,15,18,19,21,24-27). Most patients can continue oral intake until death. A recent study revealed that 95.9% of patients continued oral intake for the rest of their lives and that 78.4% required no further intervention until death (24). This study also revealed that many patients can resume solid food intake (GOOSS 2 or 3), with a cumulative average of 74%, ranging from 56% to 80% (15,16,24,27,28). In addition, approximately two-thirds of patients continued solid food intake until death (24). A study evaluating predictive factors of solid food intake showed that a Karnofsky performance score of 50% or less and the presence of ascites are independent poor predictive factors of ability to ingest solid food (29).

According to a functional evaluation study (30), almost 80% of patients studied had a significant improvement in gastric emptying rate. Nevertheless, another study using radionuclide scanning indicated that gastric emptying function in patients one week after stenting was significantly poorer than in healthy subjects (31).

## Quality of life (QOL)

A prospective randomized trial comparing duodenal stenting versus laparoscopic GJJ by Mehta and colleagues (32) showed a significant improvement in physical health score at one month (P<0.01), but no change in pain score or mental health score at this time. No improvement in any QOL parameter was seen in the laparoscopic GJJ group. Another comparative study conducted under a retrospective design indicated that an improvement in Karnofsky performance score was more frequent in the stent group than in GJJ group (65% *vs.* 26.3%, P=0.0248) (33). Further, the median difference in performance score before and after the procedure was significantly greater in the stent group than in the bypass group (15 *vs.* –10; P=0.0149) (33). A UK study by Lowe and colleagues reported similar results, with an increase in Karnofsky score from 44/100 to 63/100 post-procedure (34). A prospective study with the WallFlex stent by van Hooft and colleagues indicated a significant improvement in post-procedural WHO performance score between the pre-stenting score and mean score up to death (14).

A study which objectively evaluated QOL score before and after stenting using the EORTC QLQ-C30 instrument to assess functional status and cancer-related symptoms and the QLQ-STO22 instrument to assess gastric-specific symptoms found that among QLQ-C30 parameters, role functioning, physical functioning, global health status, and nausea/vomiting improved after stenting, although the difference was statistically significant only for global health status (P=0.010) and nausea/vomiting (P=0.001). In contrast, however, no change was seen in other QLQ-C30 parameters, including emotional, cognitive, and social functions, or other symptoms (35). In addition, enteral stenting was associated with a significant improvement

 

**Table 1** Comparison of three prospective studies using different stents

| | Study name, authors, year | | |
|---|---|---|---|
| | DUOFLEX (14), van Hooft *et al*. 2009 | DUONITI (18), van Hooft *et al*. 2011 | DUOLUTION (25), van den Berg *et al*. 2013 |
| Stent used | WallFlex | Niti-S | Evolution |
| No. pts | 51 | 52 | 46 |
| Tech. success [%] | 50 [98] | 50 [96] | 41 [89] |
| Clin. success [%] | 43 [84] | 40 [77] | 33 [72] |
| Complications [%] | 14 [27] | 18 [35] | 18 [39] |
| BMI | Decr (P<0.001) | NS | NS |
| WHO-PS | Improv (P=0.002) | NS | NS |
| EQ-VAS | NS | NS | Improv (P=0.005) |
| QL2 | NS | Improv (P=0.001) | Improv (P<0.0001) |

Decr, decrease; Improv: improvement; NS, not significant.

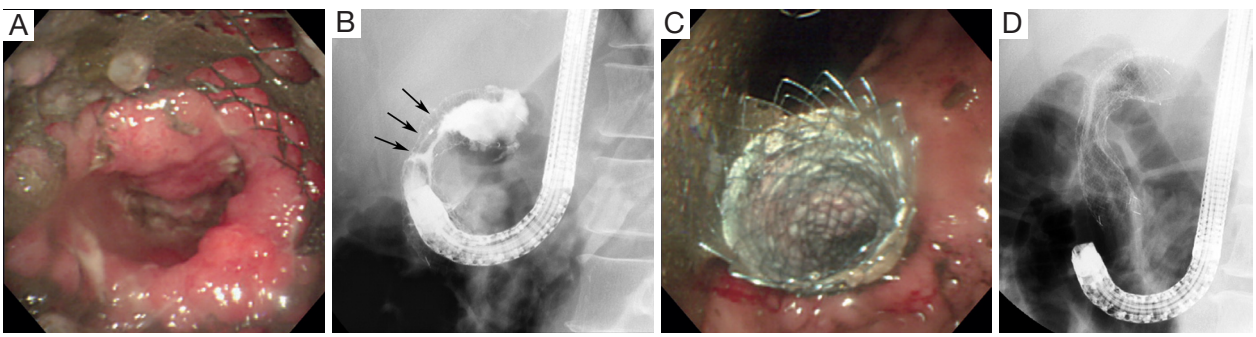


**Figure 3** Placement of a second stent for occluded pre-existing SEMS due to tumor ingrowth. (A) Endoscopy reveals stent occlusion due to tumor ingrowth; (B) contrast study using endoscopy showing tumor ingrowth (arrows); (C) a covered SEMS was placed within the occluded uncovered SEMS; (D) radiograph immediate after deployment showing two overlapping SEMSs and the waist of the second SEMS. SEMS, self-expandable metallic stent.

in dysphagia (P=0.001), eating restrictions (P=0.010), dry mouth (P=0.029), and reflux (P=0.040), as assessed by the QLQ-STO22 instrument (35).

One group has recently reported three prospective studies of three different SEMSs, namely the DUOFLEX (WallFlex stent) (14), DUONITI (Niti-S stent) (18) and DUOLUTION (Evolution stent) (25) studies. The QOL score results of the three studies differed, but it is unclear whether this was due to the different structures of the stents (*Table 1*).

## Complications and management

Complications are frequently classified as either early- (≤7 days) or late-stage changes (>7 days). According to a systematic review (21), major early complications, including migration and stent dysfunction, occur in 7%, and major late complications in 18%. The most common causes are stent migration, and obstruction caused by tumor in- or over-growth, hyperplasia, or food impaction. Obstruction (5-21.1%) is more frequent than migration (0-3.8%) (14-16,18,19,34). Tumor-related stent obstructions can be managed by placement of a second stent (*Figure 3*) or ablative procedures (36), while migration is often treated by placement of an additional stent. Minor complications, such as pain, nausea or vomiting, are not frequent (9%) (21), while life-threatening complications like perforation and bleeding are rare (1% or less) (9,37). SEMS with significant flexibility and blunt ends may be helpful in preventing ulcer formation and perforation (13).

## Combination with biliary stent placement

Biliary obstruction can occur concurrently with GOO, or before or after GOO. Both gastroduodenal and biliary

obstructions are classified into three patterns based on timing and location (*Table 2*). Mutignani and colleagues proposed a classification for the duodenal stenosis type in relation to the major papilla, with type I at a level proximal to and without involvement of the papilla; type II affecting the second part of the duodenum with involvement of the papilla; and type III involving the third part of the duodenum distal to and without involvement of the papilla (38).

Biliary obstruction usually occurs in patients with pancreaticobiliary malignancy as the underlying disease, but sometimes also in patients with other etiologies, such as gastric, duodenal or metastatic cancers. Particularly in patients with pancreaticobiliary malignancies, biliary obstruction tends to develop before the occurrence of GOO. One study reported the onset of biliary obstruction before GOO in 56%, concomitantly in 25%, and following the development of GOO in 19% (10,23). Many patients undergoing enteral stenting for GOO thus already have a pre-existing biliary stent to manage a preceding biliary obstruction. In these cases, if the pre-existing biliary stent is a plastic, it should be replaced with a SEMS, given the risk of buckling and inability to retrieve it. In type II patients with preceding biliary SEMS, concern has been expressed about the possible blockage of bile outflow with the use of a covered duodenal SEMS. A study which compared post-procedural bilirubin and alkaline between covered and uncovered SEMSs placed to bridge the papilla concluded that placement of a covered SEMS was not contraindicated (39). Nevertheless, selection of an uncovered SEMS to avoid the endoscopic inaccessibility of the bile duct may be preferable.

**Table 2** Classification of gastroduodenal and biliary obstructions

| |
|---|
| Timing of development of biliary obstruction |
| Preceding GOO |
| Concomitant with GOO |
| Subsequent to GOO |
| Location of gastroduodenal obstruction |
| Proximal to and without involvement of the ampulla (type I*) |
| Adjacent to and with involvement of the ampulla (type II*) |
| Distal to and without involvement of the ampulla (type III*) |

*, classification from type I to III was proposed by Mutignani *et al*. (38); GOO, gastric outlet obstruction.

In cases in which biliary obstruction is concomitant with GOO, simultaneous placement of a biliary stent should be considered when placing an enteral stent for GOO, since the success rate of this procedure is comparable to that of placement of a duodenal stent alone (40). In cases with either simultaneous or two-stage placement, biliary stenting prior to duodenal stenting should be considered (*Figure 4*), because endoscopic biliary stenting is generally impossible when a duodenal stent bridges the papilla. If transpapillary biliary stenting fails even with the use of balloon dilation for duodenal stricture, a percutaneous or EUS-guided transmural approach (41) may be selected (*Figure 5*).

As stated above, development of a biliary obstruction after a duodenal obstruction is least common. Thanks to the pre-existing enteral stent, the duodenoscope can usually reach the level of the major papilla. In cases with an enteral SEMS bridging the papilla, however, a transpapillary approach is often impossible.

## Stent placement versus gastrojejunostomy (GJJ)

Many studies, including three randomized studies, have

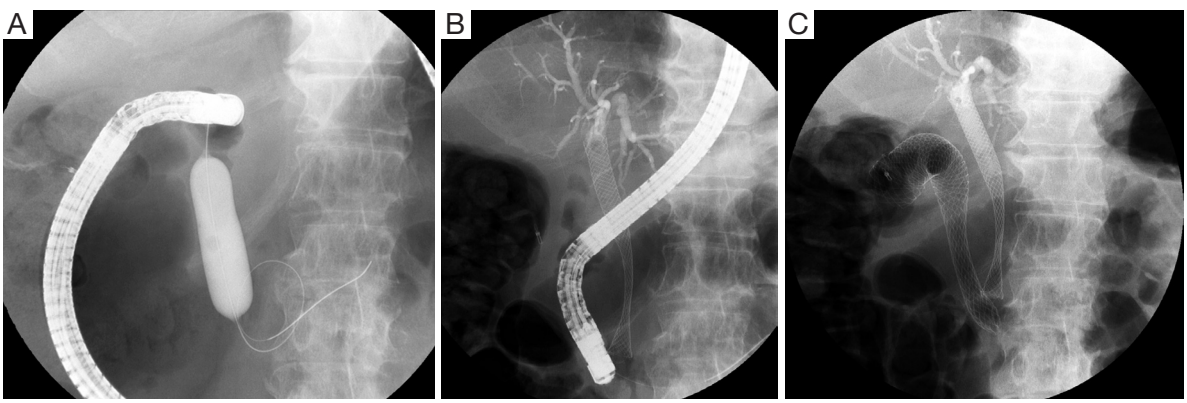


**Figure 4** Stent placement for both biliary and duodenal obstruction. (A) Initially, duodenal obstruction (Pars II) was dilated with a balloon dilator; (B) next, transpapillary biliary stent placement was performed; (C) the duodenal SEMS was then placed during the same procedure. SEMS, self-expandable metallic stent.

 

compared enteral stenting and GJJ (32,33,42-55). Most have suggested the superiority of enteral stenting, particularly with regard to short-term outcomes such as a shorter hospital stay and faster resumption of oral intake. The most recent systematic review reported similar results (56). Another systematic review, however, found that although stenting had a higher clinical success rate and fewer minor complications, it had a higher rate of recurrence of obstructive symptoms, suggesting that stenting may be more favorable in patients with a relatively short life expectancy, while GJJ is preferable in those with a longer prognosis (21).

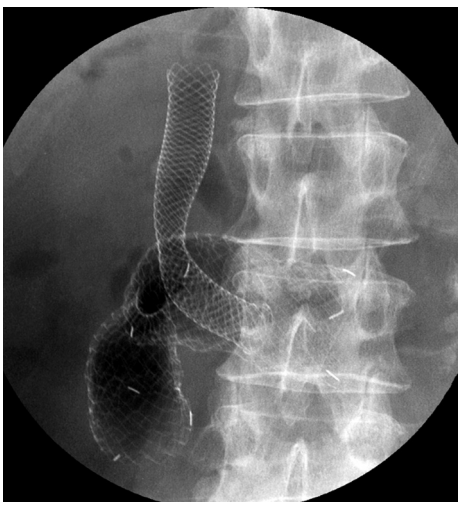

**Figure 5** EUS-guided biliary stent placement in a patient with indwelling duodenal SEMS. Transpapillary biliary stenting failed because the papillary orifice was not identified due to the duodenal SEMS crossing the papilla. The EUS-guided biliary was placed through the interstices of the duodenal stent. SEMS, self-expandable metallic stent.

These authors also conducted the largest randomized study to date (53), the results of which were consistent with their previous systematic review (21). This study showed that enteral stenting was associated with poorer long-term results, with more major complications (6 *vs.* 0 cases; P=0.02) and a higher incidence of recurrent obstructive symptoms (8 *vs.* 1; P=0.02) and reinterventions (10 *vs.* 2; P<0.01), versus a better short-term outcome, with more rapid improvement of oral intake (5 *vs.* 8 days; P<0.01) and a shorter hospital stay (7 *vs.* 15 days; P=0.04) (53). There was no difference in median survival or QOL scores (53). The authors again proposed that enteral stenting should be considered in patients with a short life expectancy (less than two months). In their subsequent study evaluating possible predictors of survival, WHO score was the only significant predictor of survival in patients with malignant GOO (57). They proposed that patients with WHO score of 0-1 should be considered for GJJ, whereas those with a WHO score of 3-4 should be considered for enteral stenting (57). Similar results were reported in a recent study comparing outcomes between enteral stenting and GJJ only in patients with gastric cancer but a good performance status. That study concluded that enteral stenting was associated with more frequent late adverse events (44.4% *vs.* 12.2%; P<0.001) and reinterventions (43% *vs.* 5.5%; P <0.001), and shorter patency (125 *vs.* 282 days; P=0.001) and survival (189 *vs.* 293 days; P=0.003) (55), suggesting that enteral stenting is likely favorable in patients with a poor performance status and/or short life expectancy. However, patients with malignant GOO have a limited median survival time (49-99 days) even in many recent literatures (12,14-16,18,19,25,28,58), so many patients have a very short life span and are better served by stents.

The two modalities are compared in *Table 3*.

**Table 3** Comparison between ES and GJJ

| | |
|---|---|
| Technical success | No difference |
| Clinical success | Meta-analysis (5) indicates higher clinical success with ES, despite some reports showing no difference |
| Time to diet | Shorter time to diet by ES is a clinical consensus |
| Hospital stay | Shorter hospital stay by ES is a clinical consensus |
| Early complications | GJJ are associated with more frequent early complications, mostly related to surgery (e.g., wound infection, respiratory infection) |
| Late complications | ES are associated with more frequent later developing complications, mostly related to stenting procedure (e.g., stent obstruction, migration) |
| 30-day mortality | No difference |
| Survival | No difference |

ES, enteral stenting; GJJ, gastrojejunostomy.

## Role of chemotherapy

Some reports have shown that chemotherapy is associated with a lower risk of reobstruction and more frequent migration (12,59). However, a retrospective study comparing clinical outcomes by stent type and chemotherapy for GOO due to gastric cancer revealed that patency rates are significantly improved by combining the use of an uncovered stent with follow-up chemotherapy treatment, because chemotherapy significantly lowered re-intervention rates, particularly with uncovered stents (60). According to a recent study investigating the association between the response to chemotherapy and pyloric stent outcome in patients with gastric cancer, a long time-to-progression (adjusted hazard ratio, 0.29; 95% CI, 0.13-0.67) and first-line chemotherapy (adjusted hazard ratio, 0.45; 95% CI, 0.22-0.93) were significant protective factors against reobstruction, whereas response to chemotherapy was not associated with stent migration or reobstruction (61).

## Comparison between stents

Few reports have compared stent outcomes between stent types. In a retrospective study comparing Niti-S with Ultraflex, the former SEMS could be placed by a simpler and faster method, but was more frequently reobstructed (62). Although many enteral stents with different structures are now commercially available, the association between the mechanical properties of stent design and clinical outcome is still poorly understood.

Aside from stent structure or properties, several types of covered SEMS have been developed to reduce the potential risk of stent obstruction due to tumor ingrowth or mucosal hyperplasia. Five studies have compared covered or uncovered SEMS (58,63-66) (RCT, 2; prospective cohort, 1; retrospective cohort, 2). Two Korean studies showed similar results, namely less frequent reobstruction and more frequent migration for covered stents (63,65). However, a retrospective study of covered and uncovered Ultraflex stents showed that covered SEMS were associated with a higher reintervention rate despite similar outcomes in reobstruction and migration (64). A retrospective study with various covered or uncovered SEMSs in patients with pancreaticobiliary malignancies concluded that the use of uncovered SEMS may be preferable for duodenal obstruction secondary to pancreaticobiliary malignancy, since these were effective in preventing stent migration and tended to have a longer patency than covered stents (66). The most recent prospective randomized trial reported that use of a triple-layered covered SEMS was associated with less frequent stent dysfunction at more than four weeks after stenting, despite similar short-term outcomes (58). These conflicting results may be due to differences in patient demographics, stent types, or patient survival period. In any case, they mean that a consensus on the benefit of covered SEMS has yet to be obtained. A larger randomized study is warranted.

## Summary

GOO can dramatically detract from QOL. Enteral stenting is beneficial in obtaining a rapid improvement in obstructive symptoms and can be performed with a high success rate. However, it carries a higher risk of late-developing complications than surgical palliation and is therefore likely more favorable in patients with a short life expectancy. Follow-up chemotherapy may significantly lower reintervention rates, particularly with uncovered SEMSs. A consensus regarding the most suitable stent type for GOO and the significance of the use of covered SEMS has yet to be obtained.

## Acknowledgements

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