ENDOSCOPY

Improved Oral Intake After Palliative Duodenal Stenting for Malignant Obstruction: A Prospective Multicenter Clinical Trial

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OBJECTIVES: **We sought to test the hypothesis that placement of a new nitinol duodenal self-expandable metallic stent (SEMS) for palliation of malignant gastroduodenal obstruction is effective and safe in allowing patients to tolerate an oral diet.**

METHODS: **In a prospective multicenter study, SEMSs (Duodenal WallFlex, Boston Scientific) were placed to alleviate gastroduodenal obstruction in inoperable patients without the ability to tolerate solid food. The primary study end point was improvement in oral intake monitored according to the 4-point Gastric Outlet Obstruction Scoring System (GOOSS) up to 24 weeks after stent placement.**

RESULTS: **Forty-three patients received SEMSs, which were successfully deployed on the first attempt in 41 cases (95%) and the second attempt in two (5%). Within 1 day and 7 days after SEMS placement, 52% and 75% of patients, respectively, benefited from a GOOSS increase ≥1. Resumption of solid food intake (GOOSS 2–3) was attained by 56% of patients within 7 days and 80% by 28 days. Of the patients attaining GOOSS 2–3, 48% remained on solid food until death or last follow-up. Device-related adverse events included stent occlusion/malfunction in 9% of patients and perforation in 5% of patients.**

CONCLUSIONS: **Duodenal WallFlex stent placement promptly improves oral intake in a majority of inoperable patients with malignant gastroduodenal obstruction. In approximately half the patients achieving GOOSS 2–3, the capacity for solid food intake endures until death or last follow-up.**

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INTRODUCTION

Malignant gastric outlet obstruction (GOO) is a late complication of gastric, duodenal, and pancreatic carcinoma that can cause significant morbidity through persistent intractable nausea and vomiting, intolerance of oral feeding, and associated weight loss. Patients are at risk of aspiration and pneumonia (1). Obstruction greatly diminishes the quality of life in these patients who have a limited life expectancy (2). Treatment is palliative with the goal of maintaining the best quality of life possible during the terminal phase of the illness.

The standard treatment for GOO has traditionally been surgical gastrojejunostomy. During the last decade, however,

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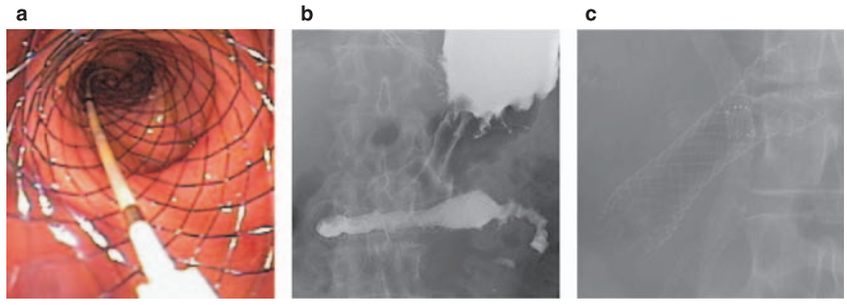

Figure 1. Placement of WallFlex duodenal stent. (**a**) Endoscopic and (**b**, **c**) radiographic views of WallFlex duodenal stent *in situ*.

endoscopically placed self-expandable metallic stents (SEMSs) have been increasingly used as a minimally invasive modality for the palliative treatment of malignant gastroduodenal obstruction. A recent meta-analysis comparing endoscopic stenting with surgical gastroenterostomy for palliation of GOO indicated several benefits of endoscopic stenting, namely, increased clinical success ($P=0.007$), shorter time from the procedure to starting oral intake ($P<0.001$), reduced morbidity ($P=0.02$), lower incidence of delayed gastric emptying ($P=0.002$), and a shorter hospital stay ($P<0.001$) (3).

The curved contour of the duodenum can pose technical challenges in placing stents. Nitinol, a flexible nickel titanium alloy, is a suitable stent material that may allow for better conformance of the stent to the duodenum as compared with stainless steel or other alloys. The present prospective clinical trial was undertaken to test the hypothesis that a newly introduced uncovered nitinol SEMS (WallFlex) placed for palliative treatment of malignant GOO effectively and safely improves the capacity to tolerate an oral diet. This study evaluated patient response to stent placement using the Gastric Outlet Obstruction Scoring System (GOOSS).

METHODS

Patients

This prospective multicenter cohort study was conducted at 10 investigative sites in the United States. Patients ≥18 years of age with gastroduodenal obstruction were eligible if they were not candidates for surgical resection and could tolerate either no oral intake or only liquids. Main exclusion criteria were: imaging evidence of multiple gastric outlet or duodenal lesions that could not be bridged by a single stent or two overlapping stents; gastroduodenal obstruction preventing passage of a guidewire; suspected or impending perforation; and any acute or chronic infection. All participating patients signed an informed consent form before study enrollment, and the Human Research Committee or Investigational Review Board at each of the study sites approved the study protocol.

Stent placement

From January 2005 to November 2005 patients received the WallFlex Enteral Duodenal Stent (Boston Scientific, Natick, Massachusetts), a 22 mm mid-body diameter through-the-scope self-expandable nitinol stent with looped ends. The stent is braided in a tubular mesh configuration with a 27 mm diameter flare at the proximal end. Available in lengths of 60, 90, and 120 mm, the stent is preloaded in a 10F delivery system.

At baseline, the site and length of the obstructions were assessed by computed tomography or barium series. One or more stents of sufficient length in the fully expanded state were selected to extend beyond the estimated length of the stricture by at least 2 cm at each end. During complete expansion, the WallFlex stent undergoes foreshortening by up to 45%.

Stent placement procedures have been described elsewhere (4). The stricture was first traversed using a biliary-type guidewire. The SEMS delivery system was then advanced through the working channel of the endoscope over a stiff guidewire, positioned across the stricture, and deployed under a combination of endoscopic and fluoroscopic guidance (**Figure 1**).

Study end points

The primary study end point was improvement after stent placement in the ability to tolerate an oral diet as assessed by GOOSS (5). On the basis of oral intake a GOOSS value was assigned on a 4-point scale: 0 for no oral intake; 1 liquids only; 2 soft solids only; or 3 low-residue or full diet. Secondary end points were success in accurate stent placement; vomiting frequency; quality of life assessed by Standard Form-36 (SF-36) questionnaire; and reintervention.

Evaluations

Medical history, patient demographics, type of malignancy, current and previous cancer therapy, location of obstruction and the presence of previous biliary stents were recorded at baseline. GOOSS, vomiting frequency, and quality of life were assessed at baseline and follow-up evaluations scheduled for 24 h and 1, 4, 8, 12, 16, 20, and 24 weeks after stent placement, as well as any unscheduled evaluations if feasible. Adverse events and reinterventions during follow-up were documented. Follow-up evaluations were conducted by hospital clinic visit or telephone interview.

Statistical analysis

A sample size of 42 patients was calculated as adequate to provide >90% statistical power in demonstrating a lower 95% confidence limit exceeding 65% for the rate of success in tolerating an

Table 1. Patient data

Characteristic	*n* (%)
Age (years)	
<60	18 (42)
60–69	14 (32)
≥70	11 (26)
Gender	
Male	28 (65)
Female	15 (35)
Malignancy	
Pancreatic adenocarcinoma	21 (49)
Gastric adenocarcinoma	6 (14)
Cholangiocarcinoma	3 (7)
Other[a]	12 (28)
Indeterminate	1 (2)
Location of obstruction[b]	
Pylorus	8 (19)
Duodenum	
Bulb	3 (7)
1st part	10 (23)
2nd part	16 (37)
3rd part	4 (9)
4th part	4 (9)
Anastomosis/surgical outlet	5 (12)
Other[c]	4 (9)
Indeterminate	1 (2)
Previous biliary stent	23 (53)
Chemotherapy	
Previous only	20 (47)
After stent placement	12 (28)
Radiation therapy	
Previous only	8 (19)
After stent placement	4 (9)

[a]Two cases of gastric cancer and one each of: colon, gallbladder, liver, papillary serous ovarian, signet ring cell and unspecified adenocarcinoma; bladder cancer; esophageal cancer; malignant melanoma; and primitive neuroectodermal tumor. [b]Multiple obstruction sites present in some patients. [c]One each of antrum, efferent limb (jejunum), ligament of Treitz, and post pyloric.

oral diet on the assumption of an 82% success rate. Time to event data was analyzed by the Kaplan–Meier product limit method. Events evaluated by this method were: (a) death; (b) first GOOSS increase ≥1; (c) first attainment of solid diet intake (GOOSS 2–3); (d) first failure to maintain an initial GOOSS increase ≥1; and (e) first failure to maintain a previously achieved GOOSS 2–3. When the event rate exceeded 50%, the median time to event was calculated together with its 95% confidence interval (CI). Rates of GOOSS increase ≥1 and attainment of GOOSS 2–3 at specific time points were calculated as the Kaplan–Meier estimated fractions for those time points. The significance of difference in time to event resulting from administration of chemotherapy after stent placement or the occurrence of serious device-related adverse events was determined by exact log-rank test. Analyses were performed using R version 2.6.2 (The R Foundation for Statistical Computing, Vienna, Austria) and StatXact 7.0 (Cytel Software, Cambridge, MA) statistical software.

RESULTS

Fifty patients were enrolled, of whom seven received no WallFlex stent. In two of the seven patients, the existence of a duodenal stricture could not be confirmed, and in two patients the obstructions were too severe to allow stent or guidewire passage. In the remaining three cases stent placement was precluded by: unacceptable migration risk based upon easy endoscope passage through the stricture; previously undiagnosed perforation discovered on endoscopy; and patient withdrawal of consent before treatment.

The characteristics of the 43 treated patients are summarized in **Table 1**. Their mean age was 61 years. The most common type of malignancy was pancreatic cancer. The most frequent sites of obstruction were the second part of the duodenum (37% of patients) and the first part (23%). Over half the patients were previous recipients of biliary stents. At study entry, 14 patients (32%) were receiving some form of cancer therapy.

Stent placement

The 43 treated patients received a total of 47 WallFlex stents: one each in 39 patients and two each in 4. Median stricture length was 32 mm (range 3–120 mm). Thirteen stents (27%) were 60 mm long, 23 (50%) were 90 mm and 11 (23%) 120 mm. Stent deployment was successful on the first attempt in 41 patients (95%) and the second attempt in two (5%). In the two patients requiring a second attempt, the first stent failed to deploy properly and was successfully withdrawn before placement of the second stent. The median stent deployment time was 33 min (range, 9–95 min). Stent expansion immediately after placement was <50% in 25 patients (58%), 50–75% in 6 (14%) and >75% in 12 patients (28%).

Survival

Twenty-four patients (56%) died during the study, 17 from progression of their underlying disease, five from respiratory dysfunction and two from sepsis. One of the two deaths from sepsis was the only death classified as device-related. Median survival for the study population was 49 days (**Figure 2**). Survival was not affected by the administration of chemotherapy after stent placement ($P = 0.21$) or the occurrence of serious device-related adverse events ($P = 0.54$).

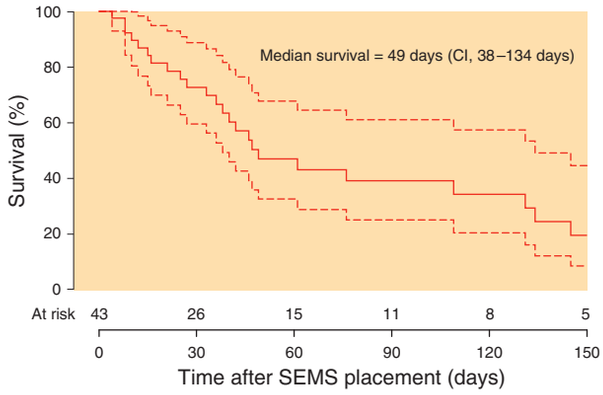

Figure 2. Survival after SEMS placement. Dashed lines depict CI. Numbers at risk shown above the abscissa. CI, 95% confidence interval; SEMS, self-expandable metallic stent.

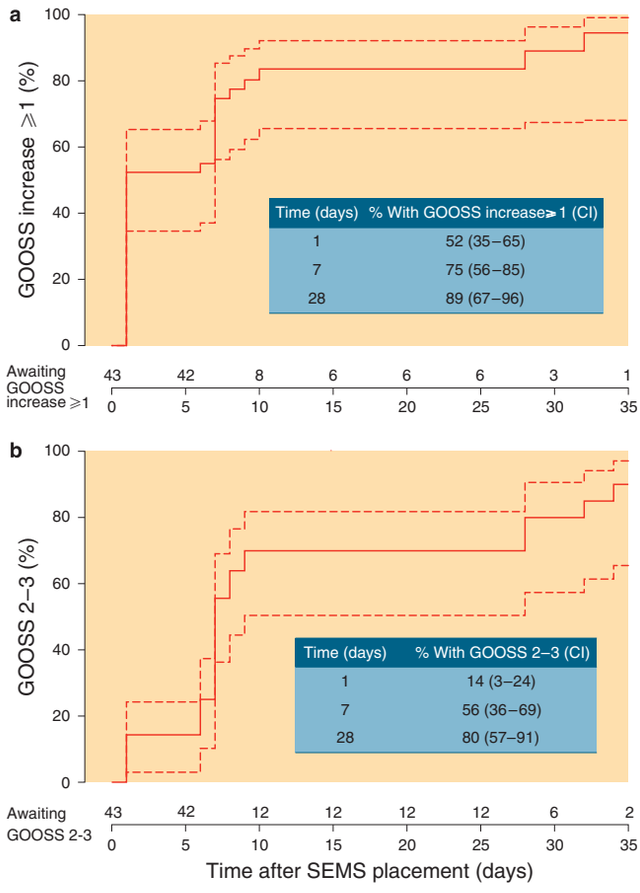

Figure 3. GOOSS scores. Percentages of patients attaining (**a**) GOOSS increase ≥1 and (**b**) GOOSS 2–3 after SEMS placement. Dashed lines depict CI. Numbers awaiting event shown above the abscissa. CI, 95% confidence interval; GOOSS, Gastric Outlet Obstruction Scoring System; SEMS, self-expandable metallic stent.

Oral intake

At baseline, 31 patients (72%) were incapable of any oral intake (GOOSS = 0), whereas 12 (28%) could tolerate liquids only (GOOSS = 1). By the day after WallFlex stent placement 52% of

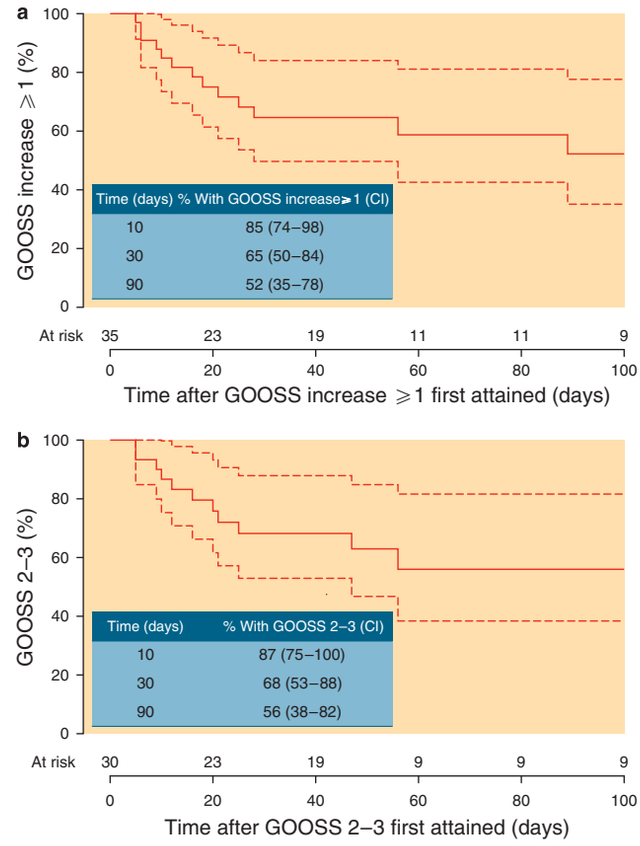

Figure 4. GOOSS scores. Percentages of patients maintaining (**a**) GOOSS increase ≥1 and (**b**) GOOSS 2–3. Dashed lines depict CI. Numbers at risk shown above the abscissa. CI, 95% confidence interval; GOOSS, Gastric Outlet Obstruction Scoring System.

patients had achieved a GOOSS increase ≥1 (**Figure 3a**). After 7 days 75% of patients had attained a GOOSS increase ≥1, and after 28 days 89%. The median time to GOOSS increase ≥1 was 1 day (CI, 1–7 days).

By 7 days over half the patients (56%) had been able to resume solid food (GOOSS 2–3), a proportion that increased to 80% by 28 days (**Figure 3b**). The median time to resumption of solid food was 7 days (CI, 7–9 days). At 7 days, 31 of 36 evaluable patients (86%) were free of vomiting.

Among the 35 patients who achieved a GOOSS increase ≥1, the increase endured for at least 30 days in 65% and for at least 90 days in 52% (**Figure 4a**). The increase persisted until death or last follow-up in 45% (CI, 27–74%). Similarly, of the 30 patients able to resume solid food a GOOSS of 2–3 was maintained in 68% for at least 30 days and in 56% for at least 90 days (**Figure 4b**). Solid food intake continued until death or last follow-up in 48% (CI, 30–78%) of those patients. Chemotherapy after stent placement exerted no effect on maintenance of either a GOOSS increase ≥1 ($P = 0.80$) or a GOOSS of 2–3 ($P = 0.97$). Among the 24 patients followed until death combined with the three patients who completed the 24-week study, the median final GOOSS was 2 with an interquartile range (IQR) of 0–3 compared with a median of 0 (IQR, 0–1) at baseline.

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Table 2. Device-related adverse events

Type	*n* (%)
Stent occlusion/malfunction	4 (9)
Vomiting[a]	4 (9)
Duodenal perforation	2 (5)
Sepsis	1 (5)
Cholangitis	1 (2)
Gastrointestinal hemorrhage	1 (2)
Nausea[b]	1 (2)
Abdominal pain	1 (2)

[a]Associated in one patient each with: early tissue intrusion, tissue ingrowth, inadequate stent expansion, and stent obstruction. [b]Associated with tissue ingrowth.

The observed improvements in oral intake were not accompanied by detectable changes in overall quality of life, as measured by the SF-36 score. SF-36 physical and mental scores displayed only minor fluctuations over the course of the study.

Adverse events

Ten patients (23%) experienced a total of 15 device-related adverse events, all classified as serious (**Table 2**). Five of the events occurred in a single patient, two in another and one each in the remaining eight patients. The most frequent device-related adverse event types were stent occlusion/malfunction and vomiting, accounting for four events each. No case of stent migration was encountered.

The third part of the duodenum, the fourth part, or both were obstructed in six patients; however, only one of those (17%) developed a serious device-related adverse event, and in that patient obstruction was also present in the first and second parts of the duodenum. Thus, there was no evidence that stricture location in the third or fourth parts of the duodenum increased the risk of serious device-related adverse events.

In 6 of the 10 patients, the device-related adverse events occurred within 1 week of stent placement. The patient with five events, namely vomiting, stent occlusion, duodenal perforation, abdominal pain and sepsis, was a 63-year-old man with pancreatic cancer who received a 90 mm WallFlex stent. Multiple episodes of emesis ensued, and at endoscopy 6 days after placement the distal portion of the stent was positioned at right angle to the normal contour of the duodenum, and this misalignment had resulted in obstruction. A second WallFlex stent of length 120 mm was placed through the original stent, and the emesis resolved. Six days after placement of the second stent, severe abdominal pain, distension, vomiting, and free air on x-ray prompted a diagnosis of perforation. A nasogastric tube was placed and the patient was hospitalized. Two days after the perforation was diagnosed, the patient developed sepsis and died.

Early stent occlusion/malfunction occurred in two patients. In one of those, invasive tumor angulation at the ligament of Treitz led to stent collapse and folding, necessitating removal 5 days after insertion. The stent of the other patient became partially occluded 6 days after placement due to tissue intrusion and incomplete stent expansion. In both patients Wallstent placement allowed uneventful recovery.

One patient developed severe abdominal pain and pneumoperitoneum immediately after stent placement and required emergency exploratory laparotomy. Duodenal perforation was suspected but could not be confirmed. The patient underwent a loop gastrojejunostomy and a combined gastrostomy-jejunostomy tube was placed. Vomiting 1 day after stent placement was the adverse event in two patients. In one of the two, early tissue intrusion was demonstrated by endoscopy and fluoroscopy. A 60 mm Wallstent was placed through the original WallFlex stent. The initial stent of the second patient failed to expand fully. Another WallFlex stent was placed through the original stent, and the patient maintained a liquid diet until death approximately 5 weeks later.

In the remaining four patients, the device-related adverse events were encountered more than 1 week following stent placement. One of these was a patient experiencing two events, i.e., nausea and vomiting, 52 days after stent placement. The events were attributable to tissue ingrowth. The patient then received a 90 mm Wallstent overlapping the original WallFlex stent and recovered without sequelae. In another patient the stent became occluded by the jejunal wall 8 days after placement. That patient recovered uneventfully following Wallstent placement. A third patient experienced gastrointestinal bleeding 37 days following stent placement, and upper endoscopy revealed a duodenal stricture due to tumor overgrowth of the metal stent. The fourth patient was hospitalized with ascending cholangitis judged to be possibly stent-related 18 days after stent placement. Percutaneous transhepatic biliary drainage was performed with placement of a biliary stent.

Adverse events judged not to be device-related led to withdrawal of six patients. These events consisted of tumor ingrowth in three patients and new distal gastric outlet obstruction, impaction, and partial stent obstruction in one patient each. In five of these patients the events were managed by placing another stent.

DISCUSSION

Unless treated, GOO is highly detrimental to quality of life in patients with unresectable malignant disease and limited life expectancy, leading to nausea and vomiting, abdominal distension, weight loss, dehydration, electrolyte imbalance, malnutrition and, ultimately, starvation. Chief objectives of palliative treatment are amelioration of the obstructive symptoms and resumption of oral intake.

While both open and laparoscopic gastrojejunostomy have been standard treatments, patients commonly present with poor nutritional and general health status, and many are poor

surgical candidates. The rigors of recovering from major surgery impose added burdens on these already compromised patients with advanced cancer and relatively short expected survival (3). In recent years, SEMSs have provided an attractive alternative to surgery for palliative treatment of GOO (6). A number of comparative studies on gastrojejunostomy and enteral stents have documented the advantages of stenting (2,7–14). Two recent meta-analyses comparing enteral stent placement with gastrojejunostomy have also confirmed the high technical and clinical success rates of stent placement and indicated favorable short-term outcomes with stenting (3,15).

In 2002, Adler and Baron (5) introduced the GOOSS scale for grading the clinical degree of outlet obstruction both before and after treatment, and that scale is being increasingly adopted. A number of studies have demonstrated improved GOOSS results after stent placement (14,16–21). In this study, improvement in GOOSS score was the primary end point. Within 7 days of stent placement 75% of patients had attained a GOOSS increase ≥1, and 56% had resumed solid food intake. Of patients attaining an initial GOOSS increase of ≥1 and an absolute GOOSS score of 2–3, respectively 65 and 68% maintained those improvements for 30 days and 52 and 56% for 90 days, despite progressive disease in many patients.

The present GOOSS findings are consistent with those in previous studies. In a European multicenter retrospective study of 62 patients who received the WallFlex enteral stent, all of the 56 patients evaluable at 1 week had resumed some type of oral intake, consisting of liquids only in seven patients, soft foods in 17 and a low-residue or full diet in 32 (22). GOOSS score also improved ($P < 0.001$) over the course of a prospective study involving 51 patients receiving WallFlex enteral stents at two Dutch centers (23).

In a retrospective study of 95 patients comparing stent placement with open gastrojejunostomy for GOO, patients could tolerate soft solids within 3.6 days of stent placement compared with 10.1 days after surgery (14). No difference was seen in the mean GOOSS score between the stent and surgery groups at 20 days after treatment. Clinical success, defined in that study as oral intake of at least soft solids, was 75%. In this study, 80% of patients were able to resume at least soft solids by 28 days.

In a prospective evaluation of 36 patients with successful stent placement, 34 patients showed an improvement in the level of oral intake (21). GOOSS improved significantly from a median of 0 before stent placement to a median of 3 afterward. It is uncertain whether those highly favorable results predominantly reflected the impact of the stent itself, dietary factors, or the relatively intensive chemotherapy and radiation therapy administered to those patients (6). Chemotherapy and radiation therapy likely helped decrease tumor burden and may have slowed the rate of tumor growth as well, and hence those additional treatments could have significantly promoted maximal stent expansion and prolonged patency. In a retrospective study of 176 patients receiving Wall stents for palliation of malignant GOO, chemotherapy after stent placement was associated with prolongation of oral intake (24). In this study, with a substantially smaller patient population, no effect could be detected of chemotherapy after stent placement on persistence of improvements in oral intake. Chemotherapy after stent placement has also been shown to prolong SEMS patency in a prospective study of 213 patients with malignant duodenal obstructions (25).

In other studies the reported median GOOSS increase after stent placement has been 2 (17–20). By contrast, in another study GOOSS increased by a median of 1 at 4 weeks after SEMS placement (16).

In a previous prospective study, patients experienced an improvement in both SF-36 physical and mental health scores at 1 month after stent placement, and the increase in the physical component was statistically significant (2). However, the wider applicability of this finding is uncertain, because only seven patients who received a stent completed the survey at the 1-month evaluation. Over the course of this study, only minor fluctuations were observed in the overall quality of life as measured by the SF-36 questionnaire. One possible explanation might be the relatively high burden of disease in the study population, as reflected by the median survival of 49 days. Despite improved oral intake, continuing pain, deterioration in physical condition, and mental distress in such severely ill patients may make improvement in global quality of life scores difficult to demonstrate. Another recent study of the WallFlex stent showed significant GOOSS increase without a corresponding effect on global quality of life score (23).

In previous clinical studies of duodenal stent placement, median survival has ranged from 49 to 195 days (7,10,11,13, 14,18,20,21,23–27). In 7 of the 13 previous studies, median survival was 70 days or less, and the median values in those 7 studies were 49 (26), 51 (18), 56 (10), 59 (11), 62 (23), 65 (13) and 70 (14) days. Thus, the median of 49 days in this study was at the low end of the range, but nevertheless not inconsistent with the often short median survival in other similar studies.

In this study, the new nitinol WallFlex stent was successfully deployed in 95% of patients on the first attempt. No stent migrations occurred. Device-related adverse events included one confirmed and one suspected perforation. After receiving a second WallFlex stent to replace one that had become misaligned, the patient with a verified perforation developed sepsis and died. Another recent report has appeared of stent-related perforation resulting in sepsis and death (27). In a recent study of 62 patients receiving WallFlex stents, one stent-related perforation was described (22). No perforation occurred in a prospective study of 51 patients with malignant GOO who received WallFlex duodenal stents for palliation (23) or in a retrospective study that included eight such patients (28). On the other hand, a randomized trial of palliation in patients with stage IV left-sided colorectal cancer was prematurely halted due to perforations among recipients of WallFlex colonic stents (29). In that trial 3 of 11 patients (27%) suffered stent-related perforations, and the investigators raised the possibility that the design of the WallFlex stent may have contributed to this. Such

a conjecture is not supported, however, by a prospective study of stenting for malignant colonic obstruction in which only one patient experienced perforation of 23 receiving colonic WallFlex stents for palliation and none of 19 as a bridge to surgery (30).

Tumor ingrowth is a recognized potential complication of uncovered SEMS placement occurring over a time frame of weeks or months. In this study, tissue intrusion into the lumen of the stent was observed after 4 days in one patient and 6 days in another. It is highly unlikely that tissue ingrowth could have occurred so rapidly. Plausibly, these cases of early tissue intrusion may have resulted from a "cheese-cutter" effect of the expanding stent on relatively friable adjacent stricture tissue. One other case of early tissue intrusion after WallFlex stent placement has recently been noted (22). Such early intrusion might be related to the wider mesh spacing of the WallFlex stent compared with Wallstent. With the two early tissue intrusion cases excluded, four study patients experienced tumor ingrowth prompting placement of another stent at 19, 20, 33 and 42 days.

In this study, duodenal stenting improved oral intake and allowed most patients to resume solid food ingestion. In the context of a study population with limited life expectancy, these benefits proved to be durable in the majority of cases. Over a time span equaling the median survival of the study population (49 days), 66% of patients did not require any reintervention. Firm conclusions concerning the comparative performance of the WallFlex stent vs. other available stents would require controlled clinical studies, in which the contribution of stent type to outcome could be differentiated from that of other variables such as primary malignancy, administration of chemotherapy and radiation, and baseline GOOSS.

CONFLICT OF INTEREST

Guarantor of the article: David L. Carr-Locke, MD, FRCP, FASGE. He accepts full responsibility for the conduct of the study. He has had access to the data and control of the decision to publish.

Specific author contributions: All authors participated in planning and conducting the study and collecting and interpreting data. Carr-Locke, Piesman, and Kozarek participated in drafting the article. All authors have approved the final draft submitted.

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Potential competing interests: Pleskow and Slivka are consultants to Boston Scientific Corp. The other authors have no potential competing interests to disclose.

Study Highlights

WHAT IS CURRENT KNOWLEDGE

- ✓ Malignant gastric outlet obstruction can cause significant morbidity and intolerance of oral feeding.
- ✓ Major objectives of palliative treatment for malignant gastroduodenal obstruction are symptom relief and oral nutrition.
- ✓ Self-expandable metallic stents have gained increasing acceptance as a minimally invasive palliative option.

WHAT IS NEW HERE

- ✓ A new uncovered nitinol self-expandable metallic stent allowed most patients to resume oral intake.
- ✓ Approximately half those patients maintained an oral diet until death or last follow-up.

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