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Treatment of malignant gastric outlet obstruction with endoscopically placed self-expandable metal stents

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Abstract

Malignant gastroduodenal obstruction can occur in up to 20% of patients with primary pancreatic, gastric or duodenal carcinomas. Presenting symptoms include nausea, vomiting, abdominal distention, pain and decreased oral intake which can lead to dehydration, malnutrition, and poor quality of life. Endoscopic stent placement has become the primary therapeutic modality because it is safe, minimally invasive, and a cost-effective option for palliation. Stents can be successfully deployed in the majority of patients. Stent placement appears to lead to a shorter time to symptomatic improvement, shorter time to resumption of an oral diet, and shorter hospital stays as compared with surgical options. Recurrence of the obstructive symptoms resulting from stent occlusion, due to tumor ingrowth or overgrowth, can be successfully treated with repeat endoscopic stent placement in the majority of the cases. Both endoscopic stenting and surgical bypass are considered palliative treatments and, to date, no improvement in survival with either modality has been demonstrated. A tailored therapeutic approach, taking into consideration patient preferences and involving a multidisciplinary team including the therapeutic endoscopist, surgeon, medical oncologist, radiation therapist, and interventional radiologist, should be considered in all cases.

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INTRODUCTION

Malignant gastroduodenal obstruction can occur in up to 20% of patients with primary pancreatic, gastric or duodenal carcinomas, with pancreatic cancer being the most common cause^[1]. Obstruction is a late occurrence in patients with advanced disease. Presenting symptoms include nausea, vomiting, abdominal distention, pain and poor oral intake which can lead to dehydration, malnutrition, and poor quality of life.

Traditionally, malignant gastric outlet obstruction has been treated surgically, usually by creating a gastrojejunostomy. More recently, the use of endoscopically placed self-expandable metal stents (SEMS) has become a routine practice^[2].

Radiologists were the first to offer an alternative to surgery by demonstrating the feasibility of stent placement using a peroral or percutaneous approach under fluoroscopic guidance^[3-5], but this approach never gained popularity due to its invasiveness and limited success rate^[4]. Technological advances have led to the development of self-expandable metallic stents that can pass through the operating channel of a therapeutic endoscope, allowing for endoscopic placement with fluoroscopic guidance, first described by Truong *et al*^[6] in 1992. Endoscopic treatment has become more successful as this approach has increased in popularity.

TECHNICAL CONSIDERATIONS

There are limitations in the ability to successfully place metal stents, including the inability to pass the guidewire

Table 1 Outcomes and complications of endoscopic stent placement

Author, yr	No. of patients	Stent used	Technical success (%)	Clinical outcome (%)	Complications, early/late
Cho <i>et al</i> ^[13] , 2009	75	Hanaro and Niti-S, covered and uncovered	98	87	3 (1 pneumonia, 1 perforation, 1 stent kinking)/35 (23 ingrowth, 2 overgrowth, 8 migration, 2 food impactions)
Nassif <i>et al</i> ^[9] , 2003	63	Wallstent (36), Choostent (32)	95	92	9 (1 perforation, 8 stent dysfunction)/18 (1 perforation, 13 obstruction, 4 migration)
Maetani <i>et al</i> ^[20] , 2009	60	Uncovered (31) and covered (29) Ultraflex	100	90.3 (uncovered), 86.2 (covered)	2 (mild pancreatitis)/10 (4 obstructions, 2 migrations, 2 stent fractures, 1 perforation, 1 bleed)
Kim <i>et al</i> ^[14] , 2007	53	NiTi-S Pyloric	100	81.1	5 (tumor ingrowth)/12 (9 tumor ingrowth, 1 tumor overgrowth, 2 migration)
Phillips <i>et al</i> ^[21] , 2008	46	Wallstent (40), Alimaxx (4), Bard (2)	100	91	5 (2 stent migration, 2 delayed-onset obstructive symptoms, 1 stent fracture)/2 (1 duodenal perforation, 1 aortoenteric fistula)
Lopes <i>et al</i> ^[16] , 2008	44	Choostent (14 uncovered, 1 covered), Hanarostent (21 uncovered, 1 covered), uncovered Wallstent (21)	100	Not measured	6 (1 perforation, 1 migration, 3 obstructions, 1 hemorrhage)/11 (8 obstructions, 2 migrations, 1 fistula)
Mosler <i>et al</i> ^[8] , 2005	36	Gianturco Z-stent, Ultraflex, Endocoil, enteral Wallstent	92	75	3 (2 stent migrations, 1 impaction)/13 (5 migrations, 4 tumor ingrowth, 2 erosion/perforation, 2 impactions)

through severely narrowed stenoses, anatomic difficulties such as a dilated stomach which may lead to significant looping, or complicated post-surgical anatomy that limits passing of the endoscope or the guidewire to the site of obstruction^[7]. It may be useful to obtain imaging of the obstructed area, such as performing an upper GI barium study, to try to assess the patient's anatomy, the stricture length, and degree of obstruction, if possible.

After administering conscious sedation, the area of stenosis is reached using a therapeutic upper endoscope. If the length of the stenosis is not known, then this can be determined by advancing the endoscope through the stenotic area or, if the stricture is not traversable, then it can be measured fluoroscopically. A guidewire is then advanced through the working channel of the endoscope and passed at least 20 cm distal to the obstructing area. The stent length should be at least 3-4 cm longer than the stenosis to allow for an adequate stent margin after placement. Next, the SEMS delivery system is passed over the guidewire through the working channel of the endoscope and aligned so that the ends of the undeployed stent overlies both ends of the stenosis equally. Once the alignment is correct, the stent is then deployed distal end first, followed by the proximal end. Next, the stent placement and luminal patency are confirmed endoscopically and fluoroscopically.

Patients with malignant gastric outlet obstruction often have coexistent biliary obstruction, which may present before or after the symptoms of gastric outlet obstruction. Placement of a metal biliary stent should be considered prior to duodenal stenting in patients with existent or impending biliary obstruction. Once the duodenal stent is in place, access to the biliary tree becomes extremely limited and a percutaneous transhepatic approach is usually required^[7].

confirmed presence of an unresectable malignancy or malignant recurrence at an anastomotic surgical site causing symptomatic gastric outlet or duodenal obstruction, a single stenotic region, and an expected short survival period (usually less than six months). The presence of free perforation with signs of peritonitis and tension pneumoperitoneum are contraindications to endoscopic stent placement^[7]. The desired outcomes after placement of a SEMS include relief of obstructive symptoms, return to a normal diet with improved nutritional status and improvement in the patient's quality of life. No studies have shown any evidence of survival benefit associated with the relief of malignant obstruction.

Efficacy of endoscopic stent placement in most studies is defined by two measures: technical and clinical success. Technical success is defined by accurate stent placement with adequate expansion of the stent and evidence of luminal patency post-procedure, usually evaluated by performing a water-soluble or barium contrast study. Clinical success is determined by resolution of the patient's obstructive symptoms and the ability to resume a regular diet after stent placement and maintain adequate oral intake during follow-up. The results of the studies evaluating the use of SEMS in malignant gastric outlet obstruction are summarized in Table 1.

The reported technical success rates for endoscopically placed SEMS range from 92%-100%. Mosler *et al*^[8] reviewed outcomes in 36 patients who had undergone SEMS placement for malignant gastric outlet or proximal small bowel obstruction over a 13-year period. Initial stent placement was successful in 33/36 patients (92%); two patients had immediate stent migration and one stent impacted into the duodenal wall. The authors felt that their technical success rate was not as high as more recent studies since their retrospective review extended from January 1991 to March 2003 and a variety of SEMS types were used during the earlier years that were not specifically designed for enteral use, leading to a higher rate of

EFFICACY AND OUTCOMES

Indications for the placement of a SEMS include the

early complications. Nassif *et al*^[9] also reported a high technical success rate with 60/63 patients (95%) obtaining immediate radiographic evidence of luminal patency. It is mentioned that three patients required hydrostatic stent dilation during the initial procedure for insufficient expansion, however it is unclear if these three patients were included in the unsuccessful category. In the other studies with 100% technical success, this was determined based on achieving the technical goals in one endoscopic session, whether that required placement of several overlapping stents due to a long stricture site, adjustment of a migrated stent by realignment using forceps or complete removal with new stent placement, or using hydrostatic dilation to ensure adequate expansion^[10-16].

The use of fluoroscopic and endoscopic guidance allows for adequate stent and stenosis visualization to ensure proper stent placement during the procedure and improve technical success overall. However, in the study by Kaw *et al*^[17], successful stent placement was achieved in 32/33 patients (96.9%) due to complete obstruction distal to a previous surgical site with recurrence at the anastomosis and inability to pass the guidewire through the stricture in one patient. Complete obstruction remains a major limitation to endoscopic stent placement and surgical intervention is then required if possible.

Not surprisingly, clinical success rates are usually lower than the technical success, with reports ranging from 79%-91%, depending on the definition of success^[17,18]. Mosler *et al*^[8] defined clinical success as improvement in obstructive symptoms (i.e. nausea, vomiting, abdominal distention, and reflux), which occurred in 29/32 patients (90.6%), with no symptomatic improvement in three patients. Kim *et al*^[10] also used symptomatic improvement as the measure of clinical success in their assessment of outcomes after SEMS placement in 53 patients with gastric outlet obstruction due solely to gastric cancer, in which they reported a success rate of 81.8%.

Adler *et al*^[11] and Lindsay *et al*^[12] specifically studied clinical success, defined as the ability to resume a regular diet after SEMS placement. Adler *et al*^[11] reported the results of endoscopic treatment for malignant gastric outlet obstruction in 36 patients and found an improvement in 31/36 (86%), which was statistically significant ($P < 0.0001$), with 61% being able to consume a solid or soft diet without symptoms of obstruction. Importantly, 58% noted improvement in < 1 d with 86% showing improvement in 3 d or less. Lindsay *et al*^[12] reported an 80% clinical success rate in patients deemed unsuitable for surgical intervention, with a median survival of 7 wk, as 32/40 patients were able to resume a solid or soft diet after stent insertion.

Also looking at the clinical success rate, van Hooft *et al*^[19] reported symptomatic improvement in 51 patients with malignant gastric outlet obstruction followed prospectively at three tertiary referral centers. In this study, clinical improvement was determined by the change in the Gastric Outlet Obstruction scoring system before treatment compared with the score after endoscopic placement of the Wallflex enteral stent. There was a 98% (50/51 patients) technical success

rate and an 84% (43/51 patients) clinical success rate, with a statistically significant ($P < 0.001$) improvement in obstruction symptoms after treatment, as well as improvement in overall performance status ($P = 0.002$). Forty-six patients (90%) were able to resume oral intake within one day of stent placement. This study did not, however, find an improvement in global quality of life.

Masci *et al*^[18] prospectively assessed the duration of symptomatic improvement in a cohort of 38 patients with malignant upper gastrointestinal obstruction treated with endoscopic stent placement. At 30 d, follow-up was available for 34 patients and 79.4% of these patients were able to tolerate a solid or soft diet. At 90 d, 11 patients remained alive and 90.9% remained on a solid or soft diet. At 180 d, only five patients were alive, however all of them were eating a solid or soft diet. Telford *et al*^[15] reported a median duration of oral intake of 146 d after SEMS placement, which increased to 219 d with repeat stenting for recurrent obstruction, in patients with a median survival of 97 d. These articles not only highlight the duration of stent patency but the short survival period in these patients.

Kim *et al*^[14] and Cho *et al*^[13] evaluated clinical factors that contribute to longer durations of stent patency. Kim *et al*^[14] found that patients who received chemotherapy after stent placement were noted to have significantly prolonged stent patency. Cho *et al*^[13] reported similar findings, however they included the use of covered stents, in addition to chemotherapy after stent placement, as a significant prognostic factor contributing to stent patency.

COMPLICATIONS

Complication rates range from 11%-43% and can be reported as immediate, which occur within 24 h after placement of the SEMS, early or late^[9,18]. Each study determines the time frame that differentiates early from late complications, which can vary anywhere from < 96 h to within two weeks to be considered an early complication^[16,18]. Immediate and early complications include problems with sedation, stent obstruction, stent malposition, perforation, aspiration, and bleeding. Late complications include stent obstruction, bleeding, perforation, stent migration, and fistula formation^[7] (Table 1).

In the study by Cho *et al*^[13], 2/75 (2.6%) patients experienced immediate complications (1 aspiration pneumonia and 1 bowel perforation, which was successfully treated with surgical gastrojejunostomy) and 1 patient had a recurrence of obstructive symptoms due to tumor ingrowth within 1 wk of stent placement (1.3%), which was treated with repeat stenting. Late complications in this study included stent migration in 8/75 patients (6 treated with repeat stenting, 1 treated with palliative gastrojejunostomy, and 1 was asymptomatic so received no further treatment) and recurrence of obstructive symptoms in 25/75 (33.3%) due to tumor ingrowth in 23 and tumor overgrowth in 2 (14 treated with repeat stenting, 1 with palliative radiotherapy, no further intervention in the other 10 patients either due to mild

symptoms, poor condition or patient preference).

In the study by Kim *et al*^[10], restenosis occurring at less than 4 wk after stent placement was found in 5/43 patients (11.6%), which was successfully treated with placement of covered stents in the new stenotic area. Stent-related problems requiring treatment occurred in 17 patients (32.1%) during the follow-up period (mean 145 d, range 4-718 d). Two patients (3.8%) had recurrence of symptoms due to distal stent migration (both successfully treated with placement of a second stent overlapping the first), stent overgrowth occurred in one patient (1.9%) at 331 d after deployment, tumor ingrowth occurred in 14 patients (26.4%) at a mean of 78.4 d after stent placement. In this study the mean survival was 145 d and the median stent patency time was 187 d.

Ten early complications were reported in the study by Nassif *et al*^[9]. Eight patients (12.7%) had a primary duodenal stent dysfunction (treated with insertion of a second stent or with hydrostatic dilation), 1 patient who had previously undergone duodenal dilation for papillary cannulation experienced a duodenal perforation 24 h after stent placement (successfully treated with surgical bypass), and one patient developed mild post-endoscopic retrograde cholangiopancreatography (ERCP) acute pancreatitis after undergoing biliary stenting (which resolved with medical management). Eighteen patients (28%) experienced late complications in this study, with the majority due to stent obstruction secondary to tumor ingrowth (in 12 patients) or due to impaction of the proximal end of the stent into the duodenal bulb (in 1 patient). These were treated with repeat stenting (in 9 patients), surgical bypass (in two patients) and conservative management (in two patients). Stent migration occurred in four patients (6.3%); two patients were treated with repeat stenting and the other two patients were asymptomatic and required no further intervention. There was one case of peritonitis due to duodenal wall perforation that occurred 1 mo after stent placement in a patient who was being treated with chemotherapy and radiation for duodenal invasion by a Hodgkin's lymphoma, which was treated with surgical bypass.

Lopes *et al*^[16] assessed complications associated with endoscopic stenting for palliative treatment of malignant esophageal, gastroduodenal, and colonic obstruction. In their study population of 153 patients, 44 patients underwent duodenal stent placement, 84% for neoplastic obstruction and 16% for extrinsic compression. In this group of patients there were 6 (12%) procedure-related complications, including 1 perforation, 1 stent migration, 3 obstructions and 1 hemorrhage, which were all successfully treated endoscopically. The group of patients with gastroduodenal obstruction had a higher procedure-related complication rate than the esophageal (8.8%) or colonic (7.5%) stenting groups, primarily due to early obstruction. Eleven (22%) late complications were reported, including 8 due to obstruction from tumor ingrowth or overgrowth, 2 due to migration and 1 fistula, which were all treated with endoscopic placement of new stents; however one patient with late stent migration was treated with supportive care only.

More recently, Maetani *et al*^[20] compared the outcomes, complication rate and reintervention rate in patients who received uncovered (31 patients) *vs* covered (29 patients) stents for malignant gastric outlet obstruction. There was a 100% technical success rate in both groups and no significant difference in clinical success. In each group, there was one patient who experienced mild pancreatitis within 1 wk of stent placement, which was managed medically in both instances. In the uncovered stent group, late complications included one stent fracture, which did not require any additional intervention; one stent obstruction due to hyperplasia, which required repeat stent placement for treatment; one case of bleeding, which ceased spontaneously; and 1 fatal perforation that occurred during chemoradiation therapy 39 d after stent placement. In the covered stent group, late complications included 1 stent fracture that occurred after ERCP for management of biliary stent dysfunction, 3 stent obstructions (2 due to tumor overgrowth, 1 due to hyperplasia), and 2 stent migrations; all were treated with repeat endoscopic stent placement. This study concluded that reintervention is more commonly required after covered stent placement for management of complications.

Looking at the long term results and complications of enteral stent placement for unresectable cancer, Phillips *et al*^[21] reviewed the outcomes of 46 patients with malignant gastric outlet obstruction. All patients had successful stent placement and 42 patients (91%) showed clinical improvement. There were 5 early complications (defined as occurring in ≤ 30 d) including stent migration in 2 patients, both treated with endoscopic removal of the initial stent and stent replacement; 2 patients with delayed-onset obstructive symptoms with patent SEMS, both treated with percutaneous endoscopic gastrojejunostomy placement; and 1 patient with stent fracture, treated with stent removal and endoscopic dilation. Late complications consisted of 1 patient with a duodenal perforation, treated with emergent surgical repair, and 1 patient who developed an aortoenteric fistula from stent erosion in the setting of a previous pancreaticoduodenectomy, which was treated with an endovascular aortic stent followed by definitive repair. There were 4 patients who developed stent obstruction and recurrence of obstructive symptoms due to local tumor ingrowth. In this study, unlike most others, this was not included as a procedural complication as it was due to progression of the underlying primary disease and not a result of the intervention.

TYPES OF STENTS

Studies have evaluated the use of different stent designs, covered and uncovered, to try to determine which stent is best for different patient populations. Since recurrent obstruction due to tumor ingrowth with uncovered stents is common^[22-24] and the migration rate of covered stents used for malignant gastric outlet obstruction was found to be unacceptably high (21% and 26% in two small studies^[25,26]), Kim *et al*^[27] examined the rate of stent restenosis in 49 patients with malignant gastric outlet

obstruction in an effort to identify characteristics that would predict early restenosis. In all patients, uncovered stents were used and there was a 100% technical success. The patients were then divided into two cohorts, one with early restenosis and the other without early restenosis, for retrospective comparison with regard to host-related factors (i.e. age and gender) and lesion-related factors (i.e. primary illness, stenosis site and length). The only statistically significant difference between these groups was the site of stenosis, with early restenosis occurring more frequently at the post-operative anastomotic sites ($P < 0.05$, 95% CI 0.003-0.005). The median follow-up period was 17 wk (range 2-64 wk), median patient survival was 10 wk, while the median stent patency time was 8 wk. Placement of an additional uncovered stent, placement of a covered stent inside an occluded uncovered stent, and use of laser therapy have all been used to treat stent restenosis^[28-30]. A study by Jung *et al.*^[31] reported a decrease in stent migration rate and a decrease in recurrent obstruction caused by tumor ingrowth with coaxial placement of uncovered and covered expandable stents, however, the use of this technique with all patients is cost-prohibitive.

ENDOSCOPY WITH STENT PLACEMENT VS SURGICAL GASTROENTEROSTOMY

Multiple retrospective studies have compared the outcomes of surgical bypass and endoscopic stent placement for the palliative treatment of malignant gastric outlet obstruction. Early studies showed significant morbidity, including delayed gastric emptying post-operatively for up to 31 d, and a mortality of up to 18%, associated with gastrojejunostomy^[32]. More recently, Maetani *et al.*^[33] retrospectively reviewed the outcomes of 20 patients who underwent palliative enteral stenting compared with 19 matched patients who underwent surgical gastrojejunostomy and found that the only statistically significant difference between the groups was an earlier return to an oral diet in the endoscopically treated group at 1 d compared with 9 d in the surgical group ($P < 0.0001$). Otherwise, there was no difference with regard to patient survival, complication rates, technical or clinical success rates, and possibility of discharge. There was a difference in the length of hospital stay (15 d in the endoscopically treated group *vs* 30 d in the surgical group), however, due to the small study population, this difference was not statistically significant. In 2005, Maetani *et al.*^[34] reported another slightly larger comparative study, limited to patients with gastric outlet obstruction due to gastric cancer, and reported similar results with a significant difference in time to resumption of an oral diet as well as a shorter procedure time in the endoscopically treated groups, but no significant difference in the other measured outcomes (possibility of discharge, median post-operative hospital stays, survival periods, complication rates).

In a study by Mittal *et al.*^[35], 16 patients who had open gastrojejunostomy, 14 patients who had laparoscopic

gastrojejunostomy, and 16 patients who underwent endoscopic stenting were all matched for age, sex, ASA grade and level of obstruction in order to compare treatment outcomes, including time to starting free oral fluids and a light diet, length of hospital stay and patient survival. They found that oral intake could be tolerated in 6 d in the open gastrojejunostomy group, in 4 d in the laparoscopic gastrojejunostomy group, and on the same day following endoscopic stenting ($P < 0.001$). In addition they found a higher rate of complications in both surgical groups compared with the endoscopically treated group ($P = 0.016$). There were no differences in the total length of stay between the groups, which was attributed to a delay in referral for endoscopic stenting, however the length of stay after procedure was significantly less in the endoscopic stenting group at 2 d compared with 7 d in the laparoscopic gastrojejunostomy group and 10 d in the open gastrojejunostomy group ($P < 0.001$). Interestingly, survival was noted to be shortest in the endoscopically treated group, which was likely due to patient selection as patients with more advanced disease are referred for the least invasive treatment. In addition to confirming similar findings regarding outcomes in endoscopically *vs* surgically treated patients, this study highlights the lack of difference between open and laparoscopic gastrojejunostomy, the latter of which was previously felt to be superior.

In a prospective, randomized trial of 18 patients referred for treatment of malignant antro-pyloric strictures, patients were randomly assigned into two treatment groups consisting of endoscopic stenting or gastroenterostomy and were followed for 3 mo. Endoscopic treatment was found to have a significantly shorter operative time, with an earlier restoration of oral intake and shorter hospital stay, consistent with previously reported outcomes. There were no differences noted between the groups with regards to delayed gastric emptying, morbidity, mortality, and clinical outcomes at the 3-mo follow-up^[36]. Jeurnink *et al.*^[37] reviewed the outcomes of 95 patients who underwent gastrojejunostomy (42 patients) or endoscopic stent placement (53 patients), including resumption of an oral diet, persistent and recurrent obstructive symptoms, re-interventions, complications, hospital stay and survival. As with previous studies, there was a significantly shorter hospital stay ($P < 0.001$) and shorter time to resuming an oral diet ($P = 0.01$) with endoscopic treatment. This study, however, also found a significantly shorter time to late major complications ($P = 0.004$), shorter time to recurrent obstructive symptoms ($P = 0.002$), and shorter time to re-intervention ($P = 0.004$) in the patients who underwent endoscopic treatment. This study points out that there are benefits and limitations with each treatment option.

The one indisputable difference between these treatment options is cost. In 2001, Yim *et al.*^[38] compared the costs of palliative treatment with endoscopic enteral stenting *vs* gastrojejunostomy in patients with malignant gastric outlet obstruction due to pancreatic cancer and found the cost of endoscopic treatment was \$9921 *vs* \$28173 for surgical bypass. Adler *et al.*^[11] also conducted a cost analysis, including procedural and hospitalization

costs, comparing 10 patients who underwent endoscopic stenting with 10 patients who had surgical bypass for the treatment of malignant gastric outlet obstruction and found the median cost of endoscopic treatment was \$5970 compared to \$13445 in the surgical group ($P < 0.0001$). Mittal *et al*^[35] included a cost comparison in their study comparing three treatment groups and, as expected, found the surgical treatment options to be more expensive than endoscopic treatment with the cost of open gastrojejunostomy to be NZ\$13256, laparoscopic gastrojejunostomy to be NZ\$10938, and endoscopic stenting costing NZ\$5736. It has been consistently shown in these studies that surgical intervention is more costly than endoscopic treatment strategies.

CONCLUSION

In summary, endoscopic placement of SEMS is a safe, minimally invasive, and cost-effective option for palliation of malignant gastric outlet obstruction. SEMS can be successfully deployed in the majority of patients. Stent placement appears to lead to a shorter time to symptomatic improvement, shorter time to resumption of an oral diet, and shorter hospital stays as compared with surgical options. There is, however, a potential for the development of recurrence of the obstructive symptoms, most often due to stent obstruction from tumor ingrowth or overgrowth, which can, in the majority of cases, be successfully treated with repeat endoscopic stent placement. Both endoscopic stenting and surgical bypass are considered palliative treatments and, to date, no improvement in survival with either modality has been demonstrated. A tailored therapeutic approach, taking into consideration patient preferences and involving a multidisciplinary team including the therapeutic endoscopist, surgeon, medical oncologist, radiation therapist, and interventional radiologist, should be considered in all cases.

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