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Self-expandable metal stents for malignant gastric outlet obstruction: A pooled analysis of prospective literature

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Data sharing statement: All data in this systematic review were extracted from the original articles and are presented in the literature Table 1. No additional data are available.

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Abstract

AIM: To provide an overview of the clinical outcomes of self-expandable metal stent (SEMS) placement for malignant gastric outlet obstruction (MGOO).

METHODS: A systematic literature search was performed in PubMed of the literature published between January 2009 and March 2015. Only prospective studies that reported on the clinical success of stent placement for MGOO were included. The primary endpoint was clinical success, defined according to the definition used in the original article. Data were pooled and analyzed using descriptive statistics. Subgroup analyses were performed for partially covered SEMSs (PCSEMSs) and uncovered SEMSs (UCSEMSs) using Fisher's exact test.

RESULTS: A total of 19 studies, including 1281 patients, were included in the final analysis. Gastric (42%) and pancreatic (37%) cancer were the main causes of MGOO. UCSEMSs were used in 76% of patients and PCSEMSs in 24%. The overall pooled technical success rate was 97.3% and the clinical success rate was 85.7%. Stent dysfunction occurred in 19.6% of patients, mainly caused by re-obstruction (12.6%) and stent migration (4.3%), and was comparable between PCSEMSs and UCSEMSs (21.2% *vs* 19.1%, respectively, $P = 0.412$). Re-obstruction was more common with UCSEMSs (14.9% *vs* 5.1%, $P < 0.001$) and stent migration was more frequent after PCSEMS placement (10.9% *vs* 2.2%, $P < 0.001$). The overall perforation rate was 1.2%. Bleeding was reported in 4.1% of patients, including major bleeding in 0.8%. The median stent patency ranged from 68 to 307 d in five studies. The median overall survival ranged from 49 to 183 d in 13 studies.

CONCLUSION: The clinical outcomes in this large population showed that enteral stent placement was feasible, effective and safe. Therefore, stent placement

is a valid treatment option for the palliation of MGOO.

Key words: Stents; Gastric outlet obstruction; Stomach neoplasms; Pancreatic neoplasms; Intestinal obstruction; palliative care; Systematic review

Core tip: In this pooled analysis of the prospective literature published since January 2009, we provide an extensive overview of the clinical outcomes of stent placement for malignant gastric outlet obstruction. We analyzed the technical and clinical success, stent dysfunction, stent patency, perforation, bleeding and overall survival in 1281 patients treated with enteral stent placement.

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INTRODUCTION

Gastric outlet obstruction is a syndrome characterized by nausea (90%), vomiting (83%), regurgitation (69%) and abdominal pain (66%)[1]. The majority of patients (> 75%) presenting with malignant gastric outlet obstruction (MGOO) cannot tolerate solids, and approximately 40% of patients have no oral intake at all[1]. Pancreatic cancer is the most common cause of MGOO in Western countries[1-3], while gastric cancer is the leading cause of MGOO in Eastern Asian studies[4-6]. Gastric outlet obstruction is usually a late sign of a locally advanced or metastatic cancer, requiring palliative management. These patients have a poor prognosis with a mean survival of approximately 100 d (3.3 mo)[7], and an impaired quality of life[8,9]. The aim of palliative therapy is to relieve obstructive symptoms and to allow oral intake. Treatment options for MGOO are endoscopic stent placement (Figure 1), surgical bypass by means of a gastrojejunostomy, a percutaneous gastrostomy (PEG) serving for gastric decompressing with subsequent jejunal feeding tube placement, and pharmacological therapy aiming for improvement in gastric emptying, relief of symptoms and comfort[7,10-12]. Comparison of enteral stenting and gastrojejunostomy revealed sooner return to oral intake and shorter hospital stay after stent placement[7,13]. On the long term, however, patients with an enteral stent have more recurrent obstruction and require more re-interventions[9]. Therefore, one might argue that patients with a relatively short survival benefit the most from enteral stent placement.

The stents used for the endoscopic treatment of MGOO are self-expandable metal stents (SEMSs) (Figure 2). They consist of a flexible framework of wire mesh made of nitinol, a metal alloy of nickel and titanium, and are either uncovered or covered by a polytetrafluoroethylene, polyurethane or silicone membrane. Over the past years many studies have been published on the clinical outcomes of enteral stent placement for MGOO. With a pooled analysis of the recent literature we aim to provide an overview of the clinical outcomes of SEMS placement for MGOO, including subgroup analyses for covered and uncovered SEMSs.

MATERIALS AND METHODS

The PubMed database was searched for relevant articles published between January 2009 and March 2015. This period was chosen because during the past years new stent designs have emerged and before 2009 the studies were usually small and retrospective. The search terms used were gastric outlet obstruction, duodenal obstruction, malignant and stents. A single reviewer (van Halsema EE) selected relevant articles by title and abstract. Only prospective studies that reported on the clinical success and safety of stent placement for MGOO were included. Studies with a sample size of less than 10 patients were excluded to avoid pilot studies with experimental stent designs and because the average series in this field usually contains a minimum of at least 30 patients. The search strategy and exclusion criteria are presented in Figure 3. The primary endpoint was clinical success of stent placement. Secondary endpoints were technical success of stent placement, stent dysfunction, stent patency, perforation, bleeding and survival. Clinical success was defined according to the definition used in the original article. These definitions all comprised the ability to tolerate oral intake, improvement in Gastric Outlet Obstruction Severity Score or relief of obstructive symptoms, up to 14 d after enteral stent placement. Stent dysfunction included re-obstruction by tumor in- or overgrowth, stent migration, stent compression by tumor pressure, insufficient expansion after deployment, stent fracture and food occlusion. Technical success was defined as successful stent placement across the obstructing tumor. Perforation and bleeding were analyzed when reported, regardless whether they were thought to be unrelated to enteral stent placement.

Statistical analysis

Data were pooled and analyzed as an intention-to-treat analysis. Pooled data were presented as frequency and proportion. The median in days was used to report the stent patency and overall survival, because the median was reported most frequently in the original articles. Fisher's Exact Test was used to compare two

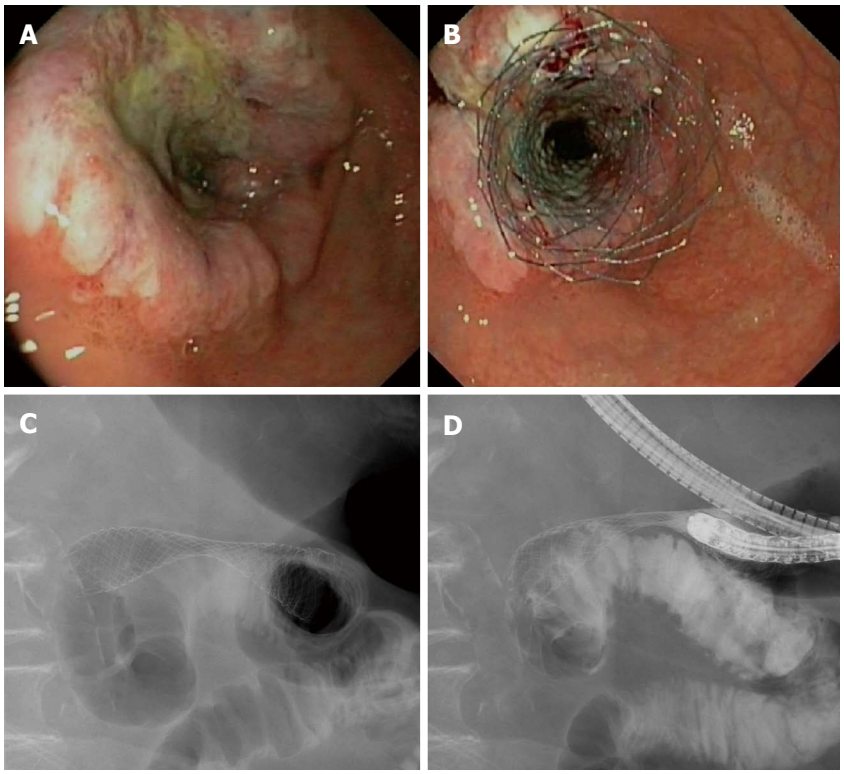

Figure 1 Endoscopic view of a gastric antrum adenocarcinoma involving the pylorus and causing obstructive symptoms (A) for which an uncovered WallFlex stent (Boston Scientific) was placed (B). Fluoroscopic view shows the fully deployed stent across the pylorus (C) with good passage of contrast to the duodenum (D).

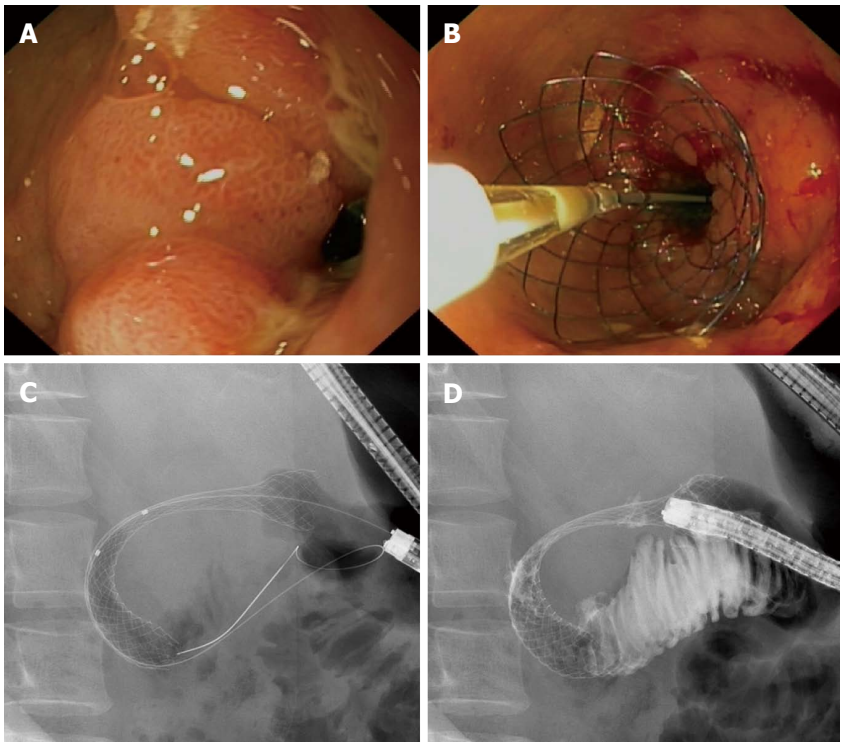

Figure 2 Endoscopic view of an adenocarcinoma of the distal stomach invading the duodenal bulb causing a gastric outlet obstruction (A) for which an uncovered WallFlex stent (Boston Scientific) was placed (B). Fluoroscopic view shows the fully deployed stent in the duodenal bulb (C) with good passage of contrast to the distal duodenum (D).

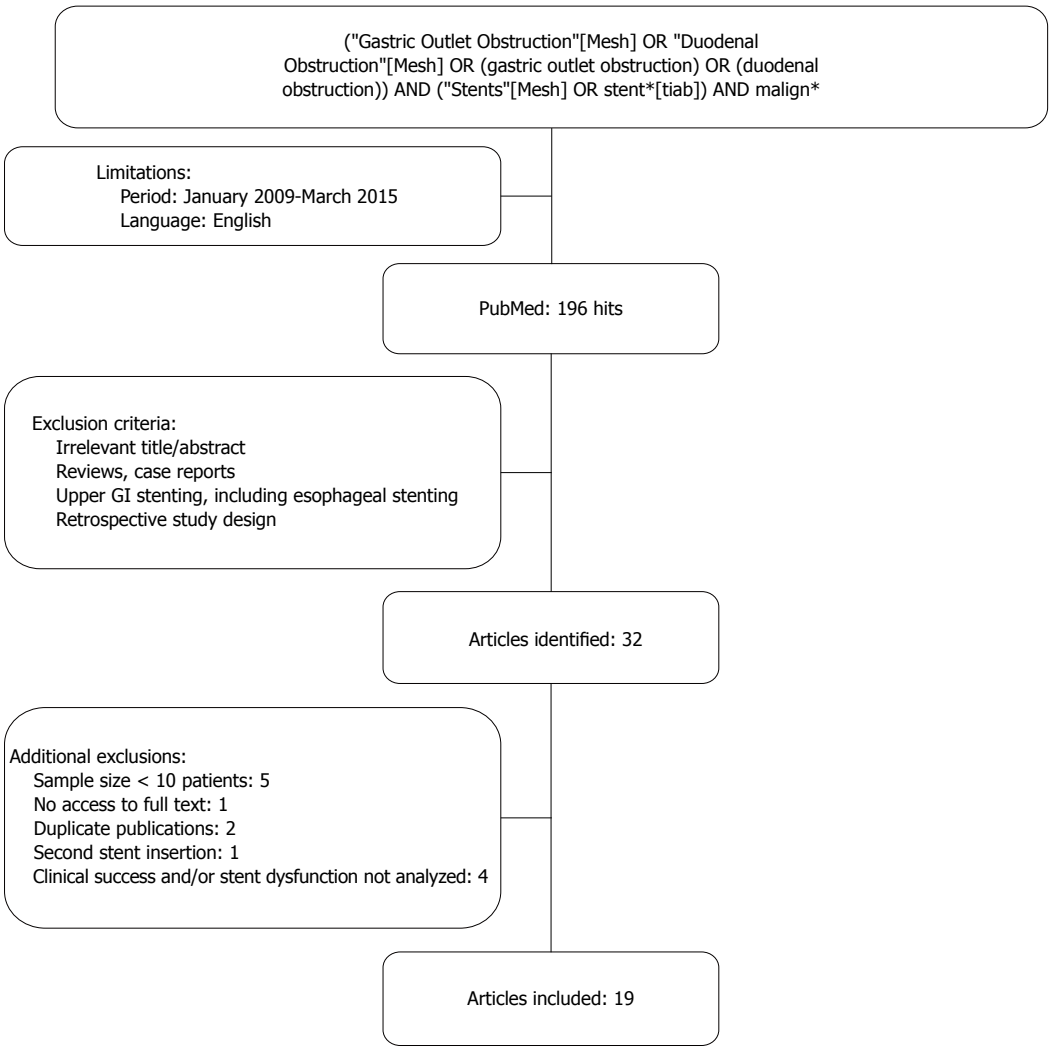

Figure 3 PubMed search. GI: Gastrointestinal.

proportions using WinPepi, Version 11.26, freeware computer programs for epidemiologists[14]. Two-sided *P* values < 0.05 were considered statistically significant.

RESULTS

Thirty-two relevant prospective studies were identified. Figure 3 shows the results of the literature search. Thirteen articles were excluded because of the following reasons: the sample size was insufficient (*n* = 5)[30-34], the primary endpoint as defined before was not analyzed (*n* = 4)[8,35-37], second stent insertion was analyzed (*n* = 1)[38], the full text was not accessible (*n* = 1)[39] or because of duplicate publication (*n* = 2)[40,41]. Nineteen prospective studies, including four randomized controlled trials (RCTs), were included in the final analysis (Table 1[1,2,5,9,15-29]). A total of 1281 patients underwent enteral stent placement for MGOO. Gastric cancer (42%) was the most common indication for stent placement, followed by pancreatic cancer (37%). Uncovered SEMSs (UCSEMS) were used in 75.7% of patients and partially covered SEMSs (PCSEMS) in 24.3%. The majority of patients (93.5%, 692/740) received a single stent during the initial procedure and 6.5% (48/740) required two stents. The baseline characteristics are summarized in Table 2.

Technical and clinical success

Technical success was achieved in 97.3% (range 89.1%-100%) of patients and was significantly higher for PCSEMSs in comparison with UCSEMSs: 99.4% *vs* 96.6% (*P* = 0.008). The main reasons for technical failure were the inability to pass the guidewire across the stenosis (1.0%), stent migration during deployment (0.3%) and insufficient deployment (0.3%). Technical failure due to a procedure-related perforation was reported in one case (0.1%)[25]. The overall clinical success rate was 85.7% (range, 57.8%-97.4%). PCSEMSs had a significantly higher clinical success rate than UCSEMSs: 92.3% *vs* 83.6% (*P* < 0.001). Four studies compared the clinical outcomes of PCSEMSs and UCSEMSs[5,15,16,24]. In those comparative studies, the pooled clinical success rates of PCSEMSs and UCSEMSs were 94.3% (164/174) and 93.6% (175/187), respectively (*P* = 0.829). Further details are summarized in Table 3.

Table 1 Literature table

Ref.	Design, patients, indication	No. of stents[1], biliary obstruction	Stent type	Technical success	Clinical Success, definition	Adverse events	Stent dysfunction	Stent patency, median (range)	Survival, follow-up, median (range)
Maetani *et al*[15] 2014 Japan	RCT, *n* = 62 GC: *n* = 27 PC: *n* = 26 BDC: *n* = 7 OT: *n* = 2	No. of stents: 1: *n* = 58 2: *n* = 4 Biliary drainage: Yes: *n* = 24 No: *n* = 38	UCSEMS: -Niti-S PCSEMS: -Niti-S Comvi	100% (62/62)	90.3% (56/62) -UCSEMS: 93.5% (29/31) -PCSEMS: 87.1% (27/31) ⩾ 1 grade of improvement in GOOSS at any visit compared to baseline	Perforation: 1.6% (1/62) -PCSEMS: 3.2% (1/31) Major bleeding: 1.6% (1/62) -UCSEMS: 3.2% (1/31)	Overall: 22.6% (14/62) -UCSEMS: 29.0% (9/31) -PCSEMS: 16.1% (5/31) Re-obstruction: 9.7% (6/62); -UCSEMS: 19.4% (6/31) -PCSEMS: 0% (0/31) Migration: 4.8% (3/62) -UCSEMS: 3.2% (1/31) -PCSEMS: 6.5% (2/31) Fracture: 4.8% (3/62) -UCSEMS: 6.5% (2/31) -PCSEMS: 3.2% (1/31) Insufficient expansion: 3.2% (2/62) -UCSEMS: 0% (0/31) -PCSEMS: 6.5% (2/31)	PCSEMS: 68 d UCSEMS: 88 d (*P* = 0.70)	PCSEMS: 73 d UCSEMS: 93 d (*P* = 0.34) FU: 83.5 d; until death
Shi *et al*[16] 2014 China	RCT, *n* = 65 GC: *n* = 65	No. of stents: 1: *n* = 65 Biliary obstruction: NR	UCSEMS: -Micro-Tech PCSEMS: -Micro-Tech (tailored cup- or funnel-shaped)	96.9% (63/65) -UCSEMS: 96.9% (31/32) -PCSEMS: 97.0% (32/33)	93.7% (59/63) -UCSEMS: 93.5% (29/31) -PCSEMS: 93.8% (30/32) Resolution of symptoms and the ability to restart a low residue diet after stent placement	Mild bleeding: 20% (13/65) -UCSEMS: 6.3% (2/32) -PCSEMS: 33.3% (11/33) Mild abdominal pain: 21.5% (14/65) -UCSEMS: 3.1% (1/32) -PCSEMS: 39.4% (13/33)	Overall: 18.5% (12/65) -UCSEMS: 25% (8/32) -PCSEMS: 12.1% (4/33) Re-obstruction: 12.3% (8/65) -UCSEMS: 21.9% (7/32) -PCSEMS: 3.0% (1/33) Migration: 3.1% (2/65) -UCSEMS: 0% -PCSEMS: 6.1% (2/33) Food impaction: 3.1% (2/65) -UCSEMS: 3.1% (1/32) -PCSEMS: 3.0% (1/33)	NR	Tailored PCSEMS: mean 231 (30-387) d Standard UCSEMS: mean 212 (43-267) d FU: until death
Tringali *et al*[1] 2014 Italy, Netherlands, Australia, Czech Republic, Canada, United States	Pros, *n* = 108 PC: *n* = 58 GC: *n* = 14 BDC: *n* = 7 GBC: *n* = 7 DC: *n* = 5 APC: *n* = 3 OT: *n* = 14	No. of stents: 1: *n* = 106 2: *n* = 2 Biliary obstruction: Yes: *n* = 56 No: *n* = 52	UCSEMS: -Evolution	99.1% (107/108)	84.5% (82/97) Relief of symptoms and/or improvement of oral intake at 14 d	Overall: 32.4% (35/108), including 19.4% (21/108) stent-related Perforation: 1.9% (2/108) Bleeding: 4.6% (5/108) No intervention required Abdominal pain: 1.9% (2/108) Other GI events: 15.7% (17/108)	Overall: 17.6% (19/108) Re-obstruction: 15.7% (17/108) Migration: 1.9% (2/108)	Estimated patency rates: -At 14 d: 94.6% (88/93) -At 60 d: 86.2% -At 180 d: 63.4%	Patients who completed 6 mo follow-up (11/108): 182 (178-195) d Patients who died before 6 mo follow-up: 52 (9-180) d FU: until 6 mo, death or re-intervention
Shi *et al*[17] 2013 China	Pros, *n* = 37 GC: *n* = 37	No. of stents: 1: *n* = 35 2: *n* = 2 Biliary obstruction: NR	PCSEMS: -Micro-Tech (cup- or funnel-shaped)	97.3% (36/37)	94.4% (34/36) Relief of obstructive symptoms	Mild bleeding: 40.5% (15/37) Major hemorrhage: 2.7% (1/37) Abdominal pain: 37.8% (14/37) Perforation: 0%	Overall: 5.4% (2/37) Food impaction: 5.4% (2/37) Migration: 0% Re-obstruction: 0%	NR	Mean 232 (28-387) d FU: until death

van den Berg *et al*[18] 2013 Netherlands	Pros, *n* = 46 PC: *n* = 25 GC: *n* = 5 BDC: *n* = 7 DC: *n* = 3 GBC: *n* = 1 OT: *n* = 5	No. of stents: 1: *n* = 43 2: *n* = 3 Biliary drainage: Yes: *n* = 34 No: *n* = 12	UCSEMS: -Evolution	89.1% (41/46)	71.7% (33/46) Improvement of GOOSS of ⩾ 1 point and/or relief of symptoms after 1 wk	Overall: 56.5% (26/46) *Procedure-related:* -Perforation: 2.2% (1/46) -Pancreatitis: 2.2% (1/46) -Pain: 2.2% (1/46) -Cholangitis: 2.2% (1/46) *Non procedure-related:* -Acute abdomen: 2.2% (1/46) -Cholangitis: 13.0% (6/46) -Jaundice: 4.3% (2/46) -Anemia: 8.7% (4/46) -Pneumonia: 2.2% (1/46) -CVA: 6.5% (3/46) -Ascites: 4.3% (2/46) -Motility disorder: 10.9% (5/46)	Overall: 30.4% (14/46) Re-obstruction: 19.6% (9/46) Stent compression: 4.3% (2/46) Migration: 4.3% (2/46) Food impaction: 2.2% (1/46)	67% for up to 395 d, accounting for death unrelated to stent	87 (IQR 35-237) d FU: until death
Costamagna *et al*[2] 2012 Italy, Czech Republic, South Africa, Canada, Sweden, Brazil, France, Germany, Finland, Spain	Pros, *n* = 202 PC: *n* = 104 GC: *n* = 37 DC: *n* = 18 BDC: *n* = 12 GBC: *n* = 12 APC: *n* = 2 OT: *n* = 17	No. of stents: 1: *n* = 192 2: *n* = 10 Biliary drainage: Yes: *n* = 127 No: *n* = 75	UCSEMS: -WallFlex	98.0% (198/202)	91% (177/195) Relief of obstruction as measured by oral intake	Overall: 20.3% (41/202) Transient periprocedural symptoms: 3.5% (7/202) Bleeding: 3.0% (6/202) -Major: 2.0% (4/202) -Self-limiting: 1.0% (2/202) Perforation: 0.5% (1/202)	Re-obstruction: 12.4% (25/202) Migration: 1.5% (3/202) Food impaction: 0.5% (1/202)	Maintaining GOOS score of 2-3 (*n* = 149): 91 d (95%CI: 87-182)	Survival rate at 9 mo: 28.2% FU: until 9 mo
Isayama *et al*[19] 2012 Japan	Pros, *n* = 50 PC: *n* = 26 GC: *n* = 14 BDC: *n* = 9 OT: *n* = 1	No. of stents: NR Biliary obstruction: Yes: *n* = 30 No: *n* = 20	PCSEMS: -ComVi Niti-S (modified)	100% (50/50)	90% (45/50) Relief of symptoms or improvement in GOOSS after 3 d	Cholangitis: 2% (1/50) Mild pancreatitis: 2% (1/50) Minor perforation: 2% (1/50)	Overall: 18% (9/50) Re-obstruction: 10% (5/50) Stent migration: 6% (3/50) Insufficient expansion: 2% (1/50)	Mean ± SD: 149.8 ± 8.9 d	106 d FU: NR
Moura *et al*[20] 2012 Brazil	Pros, *n* = 15 PC: *n* = 9 GC: *n* = 3 BDC: *n* = 1 OT: *n* = 2	No. of stents: NR Biliary drainage: Yes: 8 No: 7	UCSEMS: -WallFlex	100% (15/15)	80% (12/15) Improvement of GOOSS at 15 d	Removal of foreign body: 7% (1/15)	Re-obstruction: 13% (2/15) Migration: 13% (2/15)	Mean time to first failure to maintain GOOS 2-3: 2.35 mo	NR FU: until 180 d
Dolz *et al*[21] 2011 Spain	Pros, *n* = 77 GC: *n* = 29 PC: *n* = 20 DC: *n* = 5 GBC: *n* = 4 BDC: *n* = 3 APC: *n* = 3 OT: *n* = 6 Unk: *n* = 7	No. of stents: NR Biliary obstruction: NR	UCSEMS: -WallFlex -Wallstent -Ultraflex	92.2% (71/77)	81.7% (58/71) GOOSS 2-3 post-stenting	Pneumonia: 1.4% (1/71) Central catheter infection: 1.4% (1/71) Self-limiting bleeding: 7.0% (5/71) Late perforation: 2.8% (2/71) Intense pain: 2.8% (2/71)	Re-obstruction: 14.1% (10/71) Insufficient expansion: 4.2% (3/71)	NR	91 (9-552) d FU: NR

Kim *et al*[22] 2011 South Korea	Pros, *n* = 50 GC: *n* = 31 PC: *n* = 11 BDC: *n* = 6 GBC: *n* = 2	No. of stents: NR Biliary drainage: Yes: *n* = 17 No: *n* = 33	PCSEMS: -Niti-S Comvi	100% (50/50)	88% (44/50) Ability to tolerate oral food intake without vomiting	Hyperamylasemia: 2% (1/50) Obstructive jaundice: 10% (5/50)	Re-intervention rate: 28% (14/50) Stent migration: 10% (5/50) Re-obstruction: 8% (4/50) Stent compression: 10% (5/50)	Mean 92 (4-238) d	Mean 110 (30-290) d FU: until death
van Hooft *et al*[23] 2011 Netherlands	Pros, *n* = 52 PC: *n* = 32 GC: *n* = 7 BDC: *n* = 10 APC: *n* = 1 DC: *n* = 1 OT: *n* = 1	No. of stents: 1: *n* = 45 2: *n* = 7 Biliary obstruction: NR	UCSEMS: -Niti-S D-Weave	96.2% (50/52)	76.9% (40/52) Relief of symptoms or improvement of GOOSS after 1 wk	Overall complications: 23.1% (12/52) *Procedure-related:* -Pain: 7.7% (4/52) -Cholangitis: 1.9% (1/52) *Non procedure-related:* -Anemia: 3.8% (2/52) -Pneumonia: 1.9% (1/52) -Ascites: 1.9% (1/52) -Gastroenteritis: 1.9% (1/52) -Peritonitis carcinomatosis: 1.9% (1/52) -Bacteremia: 1.9% (1/52)	Overall: 25% (13/52) Re-obstruction: 21.2% (11/52) Migration: 3.8% (2/52)	75% for up to 190 d, accounting for death unrelated to stent	82 (IQR 31-135) d FU: until death
Jeurnink *et al*[9], 2010 Netherlands	RCT, *n* = 21 PC: *n* = 15 GC: *n* = 2 DC: *n* = 3 OT: *n* = 1	No. of stents: 1: *n* = 17 2: *n* = 4 Biliary drainage: Yes: *n* = 12 No: *n* = 9	UCSEMS: -WallFlex	95.2% (20/21)	85.7% (18/21); persistent obstruction within 4 wk in 3/21	Bacterial infection: 4.8% (1/21) Delayed gastric emptying: 14.3% (3/21) Jaundice post stent: 19.0% (4/21) Cholangitis: 4.8% (1/21)	Overall: 19.0% (4/21) Re-obstruction: 9.5% (2/21) Migration: 4.8% (1/21) Food obstruction: 9.5% (2/21) Re-intervention rate: 33% (7/21)	NR	56 d FU: until death
Kim *et al*[24] 2010 South Korea	RCT, *n* = 80 GC: *n* = 80	No. of stents: NR Biliary obstruction: NR	PCSEMS: -Niti-S pyloric -Niti-S Comvi UCSEMS: -Wallstent -WallFlex	100% (80/80)	92.5% (74/80) -PCSEMS: 95% (38/40) -UCSEMS: 90% (36/40) Relief of symptoms or improvement of GOOSS at 3 d	Perforation by migrated stent: 1.5% (1/67) -PCSEMS: 3.2% (1/31) Intestinal obstruction by migrated stent fragment after fracture: 1.5% (1/67) -PCSEMS: 3.2% (1/31)	Re-obstruction: 25.4% (17/67) -PCSEMS: 3.2% (1/31) -UCSEMS: 44.4% (16/36) Migration: 19.4% (13/67) -PCSEMS: 32.3% (10/31) -UCSEMS: 8.3% (3/36) Fracture: 4.5% (3/67) -PCSEMS: 9.7% (3/31) Stent collapse: 1.5% (1/67) -PCSEMS: 3.2% (1/31)	PCSEMS: 14 wk (95%CI: 8.9-19.1) UCSEMS: 13 wk (95%CI: 9.5-16.5)	PCSEMS: 26 wk (95%CI: 11-41) UCSEMS: 19 wk (95%CI: 10-28) FU: until 8 wk
Maetani *et al*[25] 2010 Japan	Pros, *n* = 53 GC: *n* = 29 PC: *n* = 14 BDC: *n* = 5 OT: *n* = 5	No. of stents: 1: *n* = 44 2: *n* = 9 Biliary drainage: Yes: *n* = 17 No: *n* = 36	UCSEMS: -Niti-S	98.1% (52/53)	94.3% (50/53) Ability to tolerate oral intake without vomiting	Procedure-related perforation: 1.9% (1/53) Obstructive jaundice: 1.9% (1/53) Major bleeding: 1.9% (1/53)	Overall: 18.9% (10/53) Insufficient expansion: 3.8% (2/53) Re-obstruction: 13.2% (7/53) Food impaction: 1.9% (1/53) Fracture: 1.9% (1/53) Re-intervention rate: 20.8% (11/53)	NR	88 d FU: until death

Shaw *et al*[26], 2010 South Africa	Pros, *n* = 70 GC: *n* = 19 PC: *n* = 34 GBC: *n* = 5 DC: *n* = 2 BDC: *n* = 3 OT: *n* = 7	No. of stents: NR Biliary drainage: Yes: *n* = 35 No: *n* = 35	UCSEMS: -WallFlex	92.9% (65/70)	88.6% (62/70) Resumption of intake that enabled the patient to return home independent of nutritional support	Minor bleeding: 2.9% (2/70) Perforation: 0%	Overall: 7.1% (5/70) Re-obstruction: 4.3% (3/70) Insufficient expansion: 1.4% (1/70) Stent migration: 1.4% (1/70)	NR	1.8 (0.1-19) mo FU: 54 (range 1-570) d; until death
Havemann *et al*[27] 2009 Denmark	Pros, *n* = 45 PC: *n* = 30 GC: *n* = 5 OT: *n* = 10	No. of stents: NR Biliary drainage: Yes: *n* = 11 No: *n* = 34	UCSEMS: -Hanaro	91.1% (41/45)	63.4% (26/41) Improvement in GOOSS by ⩾ 1 point	Procedure-related perforation: 4.4% (2/45) Biliary obstruction: 17.8% (8/45)	Re-obstruction: 8.9% (4/45) Migration: 6.7% (3/45) Re-intervention rate: 13.3% (6/45)	NR	Mean 121 (95%CI: 62-181) d FU: NR
Lee *et al*[5] 2009 South Korea	Pros, *n* = 154 GC: *n* = 122 PC: *n* = 19 GBC: *n* = 3 BDC: *n* = 3 APC: *n* = 4 DC: *n* = 2 OT: *n* = 1	No. of stents: NR Biliary obstruction: NR	UCSEMS: -Niti-S PCSEMS: -Niti-S	100% (154/154)	97.4% (150/154) -PCSEMS: 98.6% (69/70) -UCSEMS: 96.4% (81/84) Relief of vomiting and resumption of diet	No procedure-related complications	Migration: 7.8% (12/154) -PCSEMS: 17.1% (12/70) -UCSEMS: 0% Re-obstruction: 13.6% (21/154) -PCSEMS: 7.1% (5/70) -UCSEMS: 19.0% (16/84) Re-intervention rate: 17.5% (27/154) -PCSEMS: 21.4% (15/70) -UCSEMS: 14.3% (12/84)	UCSEMS: 73 (95%CI: 44-102) d PCSEMS: 75 (95%CI: 47-134) d	UCSEMS: 108 (95%CI: 60-151) d PCSEMS: 115 (95%CI: 80-156) d FU: until death
Piesman *et al*[28] 2009 United States	Pros, *n* = 43 PC: *n* = 21 GC: *n* = 8 BDC: *n* = 3 GBC: *n* = 1 OT: *n* = 9 Unk: *n* = 1	No. of stents: 1: *n* = 39 2: *n* = 4 Biliary drainage: Yes: *n* = 23 No: *n* = 20	UCSEMS: -WallFlex	95.3% (41/43)	81.4% (35/43) GOOSS increase of ⩾ 1 point	Duodenal perforation: 4.7% (2/43) Vomiting: 9.3% (4/43) Cholangitis: 2.3% (1/43) Hemorrhage: 2.3% (1/43) -Endoscopy performed Nausea: 2.3% (1/43) Sepsis: 2.3% (1/43)	Overall: 18.6% (8/43) Re-obstruction: 9.3% (4/43) Malposition: 2.3% (1/43) Stent collapse: 2.3% (1/43) Incomplete expansion: 4.7% (2/43) Occlusion by jejunal wall: 2.3% (1/43) Migration: 0%	GOOS score increase of ⩾ 1 until death or end of follow-up: 45% (95%CI: 27-74)	49 d; At 24 wk: 44.1% (19/43) FU: until 24 wk
Van Hooft *et al*[29] 2009 Netherlands	Pros, *n* = 51 PC: *n* = 35 GC: *n* = 2 BDC: *n* = 3 DC: *n* = 3 GBC: *n* = 2 APC: *n* = 1 OT: *n* = 5	No. of stents: 1: *n* = 48 2: *n* = 3 Biliary drainage: Yes: *n* = 38 No: *n* = 13	UCSEMS: -WallFlex	98.0% (50/51)	84.3% (43/51) Relief of symptoms or improvement of GOOSS after 1 wk	Motility dysfunction: 3.9% (2/51) Intermittent pain: 3.9% (2/51) Cholangitis: 5.9% (3/51) Major bleeding: 3.9% (2/51)	Re-obstruction: 11.8% (6/51) Migration: 2.0% (1/51)	307 d; 75% functional at 135 d, 25% functional at 470 d	62 d; 75% alive at 35 d, 25% alive at 156 d FU: until death

[1]Number of enteral stents inserted at the initial procedure. Pros: Prospective; Retro: Retrospective; RCT: Randomized controlled trial; GC: Gastric cancer; PC: Pancreatic cancer; BDC: Bile duct cancer; GBC: Gallbladder cancer; APC: Ampullary cancer; DC: Duodenal cancer; OT: Other malignancies; UCSEMS: Uncovered self-expandable metal stent; PCSEMS: Partially covered self-expandable metal stent; FU: Follow-up; GOOSS: Gastric outlet obstruction severity score; NR: Not reported; IQR: Interquartile range; GI: Gastrointestinal; CVA: Cerebrovascular accident.

Table 2 Baseline characteristics *n* (%)

Patients with MGOO	1281 (100)
Cause of MGOO	
Gastric cancer	536 (41.8)
Pancreatic cancer	479 (37.4)
Bile duct cancer	79 (6.2)
Duodenal cancer	42 (3.3)
Gallbladder cancer	37 (2.9)
Ampullary cancer	14 (1.1)
Other malignancies	86 (6.7)
Unknown	8 (0.6)
Biliary obstruction[1]	
Yes	432 (52.9)
No	384 (47.1)
Stent type	
Uncovered SEMS	970 (75.7)
Partially covered SEMS	311 (24.3)
No. of enteral stents inserted at initial procedure[2]	
Single stent	692 (93.5)
Two stents	48 (6.5)

[1]Total group: n = 816, no data of 465 patients; [2]Total group: n = 740, no data of 541 patients. MGOO: Malignant gastric outlet obstruction; SEMS: Self-expandable metal stent.

Stent dysfunction

Stent dysfunction occurred in 19.6% (range, 5.4%-42.5%) of patients. There was no difference between the stent dysfunction rate of PCSEMSs and UCSEMSs: 21.2% *vs* 19.1%, respectively (P = 0.412). The main reasons for stent failure were re-obstruction by tumor in- or overgrowth (12.6%) and stent migration (4.3%). Re-obstruction was more common with the use of UCSEMSs compared with PCSEMSs: 14.9% *vs* 5.1% (P < 0.001). The stent migration rate was significantly higher after PCSEMS placement: 10.9% *vs* 2.2% (P < 0.001). Stent compression or collapse by tumor pressure occurred in 0.7% of patients, and was significantly higher for PCSEMSs: 1.9% *vs* 0.3% (P = 0.008). Other reasons for stent dysfunction were insufficient expansion (0.9%), food occlusion (0.7%), stent fracture (0.5%) and other (0.2%) (Table 4).

Perforation and bleeding

The overall perforation rate was 1.2% and was comparable for PCSEMSs and UCSEMSs (Table 4). Perforation within 30 d was reported in 0.7% and late perforations in 0.5% of patients. Six (0.5%) perforations occurred during or immediately after the initial stent placement procedure. A description of the perforation cases is provided in Table 5.

Bleeding was reported in 4.1% of patients and was more frequent in patients treated with PCSEMSs: 8.7% *vs* 2.6% (P < 0.001) (Table 4). Major bleeding, requiring an intervention, occurred in 10 (0.8%) cases.

Stent patency and overall survival

The median stent patency was reported in five studies[2,5,15,24,29], including 549 patients, and ranged from 68 d to 98 d, with exception of one study that reported a median stent patency of 307 d[29].

The median overall survival ranged from 49 d to 183 d in thirteen studies, including 867 patients[1,5,9,15,18,19,21,23-26,28,29]. When the majority (⩾ 50%) of the study sample included patients with pancreatic cancer, the median overall survival ranged from 49 d to 106 d[1,9,18,19,23,26,28,29]. When the majority of the study sample included patients with gastric cancer, the median overall survival ranged from 88 d to 183 d[5,24,25].

DISCUSSION

This pooled analysis of 1281 patients identified from the prospective literature, showed that palliative SEMS placement for MGOO is feasible, effective and safe. Stent placement can therefore be regarded as a good alternative for surgery in the palliative setting. The clinical success rate was high (85.7%) and although stent dysfunction was frequently encountered (19.6%), it could usually be managed endoscopically by additional stent placement. Large, recently published, retrospective studies, each including more than 125 patients, reported comparable results[4,42,43].

In subgroup analysis, the technical and clinical success rates of PCSEMS placement were significantly higher than those of UCSEMSs. The reasons for technical failure (Table 3) were rather procedure-related than stent-related. The higher technical success rate of PCSEMSs can therefore not be easily explained. The higher clinical success rate of PCSEMSs is a notable finding, suggesting that these stent models have more capacity in relieving MGOO, for instance by a higher radial force than UCSEMSs. However, the validity of this finding may be questioned because of heterogeneity, such as the difference in definitions of clinical success between the included studies. To exclude this heterogeneity, a subgroup analysis was performed of the four studies that compared the outcomes of PCSEMSs and UCSEMSs, showing similar pooled clinical success rates for PCSEMSs and UCSEMSs. In addition, a meta-analysis of comparative studies found no difference in technical and clinical success between covered and uncovered SEMSs[44]. The data were insufficient and the samples would be too small to analyze the outcomes of the eleven different stent models, including modified and patient-tailored stents, used in the 19 included studies.

Several factors have been identified as predictors for the outcomes of stent placement for MGOO. One prospective cohort study, including 71 patients, found a significantly lower clinical success rate for stents placed in the gastric antrum (29%) compared with success rates of stent placement in the duodenum (70%) or at the gastrojejunal anastomosis (87%)[21]. The authors speculated that antral tumors have to be larger to cause obstruction, resulting in more antral rigidity[21]. The two main indications for enteral stent placement in our pooled analysis were obstruction

Table 3 Technical and clinical success of enteral stent placement *n* (%)

	Overall (*n* = 1281)	UCSEMS (*n* = 970)	PCSEMS (*n* = 311)	*P* value[1]
Technical success	1246 (97.3)	937 (96.6)	309 (99.4)	0.008
Reasons for technical failure				
Inability to pass guidewire	13 (1.0)	13 (1.3)	0	
Looping/buckling of delivery system	2 (0.2)	0	2 (0.6)	
Stent malposition	1 (0.1)	1 (0.1)	0	
Stent migration during deployment	4 (0.3)	4 (0.4)	0	
Insufficient deployment	4 (0.3)	4 (0.4)	0	
Colonic stent inserted	1 (0.1)	1 (0.1)	0	
No stenosis at endoscopy	1 (0.1)	1 (0.1)	0	
Procedural perforation	1 (0.1)	1 (0.1)	0	
Not specified	8 (0.6)	8 (0.8)	0	
Clinical success	1098 (85.7)	811 (83.6)	287 (92.3)	< 0.001

[1]Comparison of UCSEMS and PCSEMS using Fisher's exact test. UCSEMS: Uncovered self-expandable metal stents; PCSEMS: Partially covered self-expandable metal stents.

Table 4 Adverse events *n* (%)

	Overall (*n* = 1281)	UCSEMS (*n* = 970)	PCSEMS (*n* = 311)	*P* value[1]
Stent dysfunction	251 (19.6)	185 (19.1)	66 (21.2)	0.412
Re-obstruction by tumor growth	161 (12.6)	145 (14.9)	16 (5.1)	< 0.001
Stent migration	55 (4.3)	21 (2.2)	34 (10.9)	< 0.001
Stent compression by tumor pressure	9 (0.7)	3 (0.3)	6 (1.9)	0.008
Stent fracture	7 (0.5)	3 (0.3)	4 (1.3)	0.064
Insufficient expansion	11 (0.9)	8 (0.8)	3 (1.0)	0.734
Food occlusion	9 (0.7)	6 (0.6)	3 (1.0)	0.460
Other	2 (0.2)	2 (0.2)	0	-
Perforation	15 (1.2)	12 (1.2)	3 (1.0)	1.000
Bleeding	52 (4.1)	25 (2.6)	27 (8.7)	< 0.001
Major bleeding requiring intervention	10 (0.8)	9 (0.9)	1 (0.3)	0.466

[1]Comparison of UCSEMS and PCSEMS using Fisher's exact test. UCSEMS: Uncovered self-expandable metal stents; PCSEMS: Partially covered self-expandable metal stents.

Table 5 Details on the perforation cases

No.	Description	Day of onset	Treatment
1	Jejunal perforation at distal end of the stent[15]	173	Surgical closure
2	Intraprocedural perforation while the stricture was crossed with the catheter and guidewire[1]	0	Successfully treated with covered SEMS
3	Duodenal perforation after biliary stent placement[1]	82	Laparotomy, abdominal drainage and duodenal covered SEMS
4	Acute abdomen[18]	42	Refused treatment
5	Guidewire perforation[18]	0	Conservative treatment with antibiotics
6	Perforation likely due to stent-induced ischemia[2]	15	Surgical suture and gastrojejunostomy
7	Minor perforation after balloon dilation because of insufficient stent expansion[19]	7	Recovered without surgery
8	Late perforation, not related to dilatation[21]	NR	NR
9	Late perforation, not related to dilatation[21]	NR	NR
10	Late intestinal perforation by migrated stent[24]	NR	Surgical intervention
11	Perforation while pushing the delivery system across the initially placed stent[25]	0	Surgical closure and gastrojejunostomy
12	Perforation by the guidewire and/or ERCP catheter with subsequent misplacement of the stent[27]	0	Surgical suture, bowel patch and gastroenteric bypass
13	Perforation by the guidewire and/or ERCP catheter with subsequent misplacement of the stent[27]	0	Surgical suture, bowel patch and gastroenteric bypass
14	Abdominal pain and pneumoperitoneum immediately after stent placement[28]	0	Loop gastrojejunostomy and combined gastrostomy-jejunostomy tube placement
15	Abdominal pain, distension, vomiting, and free air on x-ray 6 d after second stent placement[28]	12	Nasogastric tube placement and hospitalized; died two days later of sepsis

SEMS: Self-expandable metal stent; NR: Not reported; ERCP: Endoscopic retrograde cholangiopancreatography.

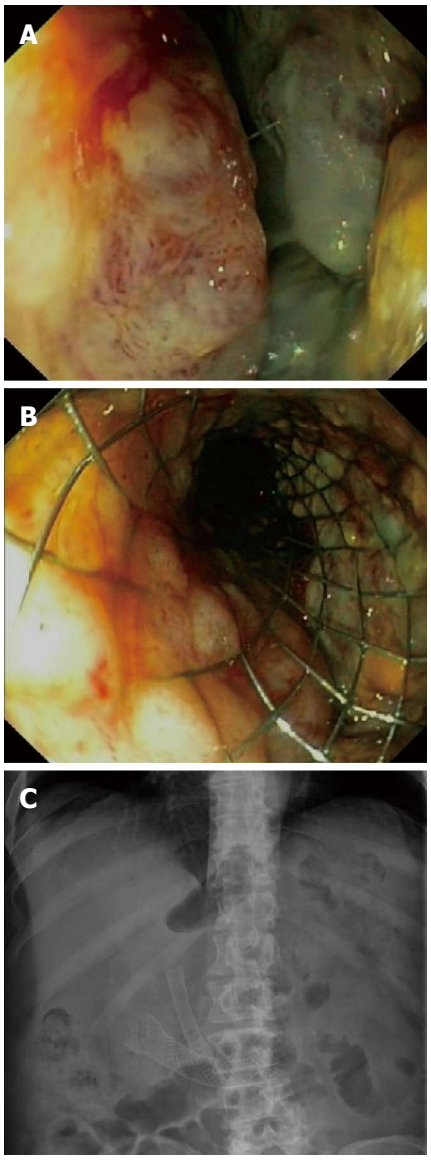

Figure 4 Endoscopic view of an ulcerative, obstructing gastrointestinal stromal tumor of the peri-ampullary region of the duodenum (A) for which an uncovered WallFlex stent (Boston Scientific) was placed (B). Fluoroscopic view shows the fully deployed duodenal stent overlapping the previously placed biliary SEMS (C).

by gastric (42%) and pancreatic (37%) cancer. Unfortunately, the data were insufficient to analyze the clinical outcomes according to cause and site of obstruction. However, other retrospective and prospective studies never identified type of cancer and site of obstruction as predictors for success of enteral stent placement[4,42,45-47]. The main factors associated with a poor stent outcome in the literature are a poor performance status and peritoneal dissemination with ascites[4,36, 37,43,48].

One fifth of the patients experienced stent dysfunction, mainly because of re-obstruction by tumor in- or overgrowth and stent migration. PCSEMSs were associated with the occurrence of stent migration, while re-obstruction was more frequently seen with the use of UCSEMSs. The overall stent dysfunction rates were comparable between both stent types, which is consistent with a recently published meta-analysis[44]. The fact that stent covering precludes tumor ingrowth, but provokes stent migration, has already been demonstrated[44]. A large retrospective analysis, including 583 patients with MGOO mainly caused by gastric cancer (57%), found that duodenal lesions, a shorter stricture length and longer survival time were associated with the occurrence of re-obstruction by tumor overgrowth[49]. Also short time to progression has been identified as a predictor for re-obstruction, while administration of first line chemotherapy was protective against re-stenosis[50]. Regarding the occurrence of stent migration, chemotherapy after stent placement was associated with migration in two studies, although only in univariate analysis[50,51]. In a prospective pilot study of 25 patients with MGOO, covered SEMSs were anchored into the mucosa by three endoscopic clips at the proximal end of the stent to prevent stent migration[41]. No cases of stent migration occurred, suggesting that endoscopic clipping may prevent stent migration[41]. Regarding the stent patency, one of the included studies estimated with a Kaplan-Meier analysis that 63% of the stents were patent at six months[1]. Another prospective cohort reported that the GOOS score increase persisted until death or end of follow-up in 45% (95%CI: 27%-74%) of patients[28].

Perforation and major bleeds were rare, both occurring in approximately 1% of patients. Seven of the 15 perforations were procedure- or balloon dilatation-related. A recently published, retrospective study reported perforation in 3.4% (10/292) of patients treated with SEMSs for MGOO[42]. The perforation rate according to the cause of obstruction was 4.6% (9/196) for pancreatic cancer and 1.0% (1/96) for nonpancreatic cancer[42], suggesting that the cause of obstructing may be associated with the occurrence of perforation after enteral stent placement. However, data are lacking to support this assumption. Minor bleeding was more frequently seen in patients treated with PCSEMSs, mainly contributed by two studies from the same institution that reported 56% (29/52) of bleedings using tailored, funnel- and cup-shaped, PCSEMSs[16,17]. Therefore, these tailored PCSEMSs may not be directly comparable with the other PCSEMS designs used in the literature. Nevertheless, the overall major bleeding rate in our pooled analysis was only 0.8%.

This analysis of the prospective literature has several limitations. Heterogeneity between the included studies is the main limitation. As mentioned before, the causes of MGOO, the definitions used for clinical success and the stent designs differed between the included studies. Furthermore, the included prospective studies are prone to selection-by-indication, since only one RCT was included that compared surgical gastrojejunostomy with enteral stent placement[9]. The patients included in the

remaining articles therefore represent a selected population, because it was decided upfront that stent placement was indicated. This may overestimate the outcomes of enteral stent placement. Another issue is the clinically relevant question whether duodenal stent placement should be preceded by biliary stenting to maintain biliary drainage (Figure 4). However, that question was beyond our literature search.

In conclusion, this pooled analysis of the recently published, prospective literature provides an extensive overview of the clinical outcomes of stent placement for MGOO. In this large population enteral stent placement was feasible, effective and safe. Therefore, stent placement is a valid option for the palliation of MGOO.

COMMENTS

Background

Gastric outlet obstruction is usually a late sign of a locally advanced or metastatic cancer, requiring palliative management. Endoscopic self-expandable metal stent placement to relieve obstructive symptoms and allow oral intake, is a well-established treatment option in patients with malignant gastric outlet obstruction.

Research frontiers

Comparison of enteral stenting and gastrojejunostomy revealed sooner return to oral intake and shorter hospital stay after stent placement. On the long term, however, patients with an enteral stent have more recurrent obstruction and require more re-interventions.

Innovations and breakthroughs

To improve the long term patency of self-expandable metal stents, many different stent designs have been developed to reduce the risk of stent migration and re-obstruction by tumor ingrowth. In this systematic review, the authors provide an extensive overview of the prospective literature published since January 2009 on the clinical outcomes of stent placement for malignant gastric outlet obstruction.

Applications

This pooled analysis may be helpful for the endoscopist in the decision-making on the indication for duodenal stent placement and also to inform the patient on the risks and benefits of stent therapy.

Terminology

Gastric outlet obstruction is an obstruction at the level of the pylorus (gastric antrum, pylorus, duodenal bulb) causing problems with the passage of food into the small intestine. Self-expandable metal stents consist of a flexible framework of wire mesh made of nitinol, a metal alloy of nickel and titanium, and are either uncovered or covered by a polytetrafluoroethylene polyurethane or silicone membrane.

Peer-review

Interesting study, well written and deeply described.

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