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Predictive factors for long-term patency in duodenal stenting for malignant gastric outlet obstruction

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ABSTRACT

Background and study aims Malignant gastric outlet obstruction (GOO) occurs often late during disseminated disease, requiring palliation. Placement of duodenal self-expandable metal stents (SEMS) is a common method for relieving malignant GOO but recurrent obstruction is common, warranting reintervention. The aim of the present study was to identify predictive factors for stent patency at 3 months and survival. Also, stent patency rate and adverse events after duodenal stenting were analyzed.

Patients and methods This was a retrospective observational single-center study including all patients with malignant GOO receiving duodenal SEMS for palliation (2008–2021). Logistic regression for stent patency (3 months) and Cox regression for survival were undertaken.

Results Overall, 198 patients were included. The most common malignancies were pancreatic adenocarcinoma (40%), gastric adenocarcinoma (18%), and cholangiocarcinoma (13%). Uncovered SEMS were used in 88% of patients and the reintervention rate was 44%. The stent patency rate was 63% in 188 patients with clinical success. Predictors of stent patency at 3 months were jaundice, semi- or fully-covered stents, and chemotherapy prior to stenting. Median survival was 81 days (interquartile range 40–241) after stenting. In Cox regression, predictors for overall survival at 6 months were absence of jaundice and stent patency at 3 months. Stent dysfunction was the most common cause of reintervention and was managed by repeated stent (76%) or dilation (11%).

Conclusions Treatment of malignant GOO with duodenal SEMS is effective but the reintervention rate is high. Predictors of stent patency were jaundice, semi- or fully-covered SEMS, and chemotherapy. Survival was impaired by jaundice and stent dysfunction.

Introduction

Malignant gastric outlet obstruction (GOO) is a condition presenting with vomiting and inability to tolerate solid oral intake due to tumor obstruction of the distal stomach and/or duodenum. GOO is usually a late sign of malignancy associated with short survival time requiring palliative treatment [1]. The most common cause in the European context is pancreatic adenocarcinoma, whereas gastric cancer is predominant among the Asiatic population, but several other malignancies can cause GOO due to primary overgrowth or metastatic disease [2, 3].

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Surgical bypass and duodenal self-expandable metal stents (SEMS) have shown similar efficacy in relieving malignant GOO. Endoscopic uncovered (UC) or covered (C) SEMS induce a faster clinical response, fewer complications, and shorter hospitalization [3, 4, 5]. Surgical bypass performed as an open procedure or laparoscopically with a conventional gastrojejunstomy or partial stomach partitioning gastrojejunostomy has a lower rate of re-obstructions/reinterventions, and longer survival [6, 7, 8]. Endoscopic ultrasound (EUS)-guided therapy has recently become a promising option [9, 10].

Several studies have shown that higher performance status (Karnofskys > 50% and World Health Organization [WHO] 1–2) and absence of metastases are associated with longer survival after placement of duodenal SEMS [11]. Several authors have found ascites, peritoneal carcinomatosis, and poor nutritional status adversely associated with clinical outcomes [7]. Other studies have shown conflicting data on the effect of chemotherapy in post-stent survival [12, 13, 14, 15].

It is important to evaluate predictive factors for clinical outcome in order to select the best therapy in this group of patients with an often short life expectancy. The primary aim of this study was to identify factors predicting patency at 3 months after placement of duodenal SEMS in malignant GOO. Secondary aims were to assess rate of stent patency, overall survival (OS), and adverse events (AEs).

Patients and methods

This retrospective, single-center study was approved by the Swedish Ethical Review Authority (registration number 2023/01484/01) and was performed in accordance with the Declaration of Helsinki and the Strengthening the Reporting of Observational Studies in Epidemiology guideline [16].

Study population and design

The participants were all adult patients (≥18 years of age) treated with duodenal SEMS for malignant GOO from the period January 1, 2008 to December 31, 2021 at Karolinska University Hospital which is a tertiary referral center for hepato-pancreato-biliary malignancy in Stockholm, Sweden. The last follow-up was on April 1, 2022. None of the patients were candidates for curative surgery.

Patients were identified through the International Classification of Disease (ICD)-procedural code, JDH35 “duodenal stenting” and JDH32 “duodenal dilation”. The reason for the latter was to avoid misclassification because it was probable that in some cases, the stenting procedure would be wrongfully coded as only dilation.

Exclusion criteria were duodenal stenting for non-malignant cause, i. e. chronic pancreatitis, duodenal fistulas and perforations, altered surgical anatomy, possible curative surgery, lack of follow up data, and age <18 years.

Patients were referred by their oncologist, primary health physician or via the Emergency Department due to GOO symptoms. All patients underwent computed tomography (CT) scan and malignant GOO was confirmed endoscopically.

Data variables and definitions

Data were collected on gender, body mass index, American Society of Anesthesiologists - Physical Status (ASA-PS) classification [17], performance status according to WHO/Eastern Cooperative Oncology Group (ECOG) [18] , comorbidity, chemotherapy prior to stenting, presence of jaundice (regardless of previous biliary stenting) at the time of procedure (defined as bilirubin > 50 mmol/L), prior or concomitant biliary drainage, ascites, carcinosis, CA19–9 level, site of tumor obstruction, cancer type (histological diagnosis), and GOO scoring system (GOOSS score) defined as 0: no oral intake possible; 1: only liquid intake; 2: only soft solid diet; 3: full diet [2]. Site of tumor obstruction was defined as pre-papillary, peri/juxta papillary and post-papillary [19]. A stenosis was defined as intrinsic in the presence of gastric, duodenal or ampullary carcinoma, and extrinsic in pancreatic, bile duct, gallbladder, or other cancer [11, 20].

Time to oral intake after intervention, time to death from intervention, number of SEMS deployed, need for reintervention, time to reintervention, and type of reintervention needed as well as SEMS type were recorded. OS was the number of days from intervention to death.

Clinical success was defined as improvement in GOOSS score with ≥ 1; remaining patients experienced initial clinical failure. Stents were considered as patent if no need for reintervention or readmission for GOO had occurred. Stent patency was measured in days. Stent patency (days) was defined as no need for reintervention or admission for GOO. Stent dysfunction was diagnosed at time of reintervention by assessment of the endoscopist, confirmed stent dysfunction (including the cause of stent failure). There are no data on relative impairment of oral intake without endoscopic diagnosis, i. e. clinical stent failure.

Minor AEs (nausea, vomiting, mild abdominal pain) were not registered. Major AEs were defined as perforation, bleeding in need of intervention, cholangitis, or pancreatitis. Reinterventions performed due to suspected stent failure (early or late) were considered as AEs.

Outcome measures

The primary objective was to investigate predictive factors for stent patency at 3 months (comparing patients with clinical success without reintervention for recurrent GOO with those having clinical failure or developing confirmed stent failure) after duodenal stenting. Secondary objectives were to analyze rate of stent patency, OS, and AEs. Clinical success, stent patency time, and cause of reintervention after duodenal stent deployment were also evaluated.

Procedure details

Endoscopic duodenal stenting was performed under propofol sedation or general anesthesia. A therapeutic gastroscope or side-viewing duodenoscope was advanced to the site of obstruction. Then a sphincterotome and guidewire were advanced through the stricture with following contrast injection under fluoroscopy to determine stricture length and position in relationship to the papilla, which was also assessed endo-

scopically. During the study period, there were no institutional protocols on type of SEMS to be used. Thus, based on endoscopist preference, uncovered (UC-SEMS), semi-covered (SC-SEMS), or fully-covered (FC-SEMS) were used. The diameter of the SEMS was 22 mm and the length varied from 6 to 12 cm. In most cases, an UC WallFlex (Boston Scientific Corporation) but in some cases Hanaro (MI Tech) and Cook SEMS (Cook Medical) have been used as well. Patients receiving multiple stents were recorded. If deemed clinically necessary, primary stent dilation was performed. Technical success was confirmed endoscopically and by fluoroscopy.

Follow-up

Patients were discharged early from the hospital when oral intake (GOOSS ≥ 1) was possible. A higher GOOSS score could have been achieved later on (after full stent expansion); however, such data were not available. Follow-up was performed by oncologists, primary care physicians, or palliative care physicians. If signs of GOO recurred or jaundice developed, patients were readmitted. CT scan was repeated and, if warranted, endoscopy was performed confirming stent dysfunction. Patients receiving care at palliative units who developed clinical signs of recurrent GOO may have been considered unsuitable for readmission. Thus, clinical or confirmed stent dysfunction may have been undiagnosed.

Statistical analyses

Covariates with categorical data were compared by using the Pearson's Chi square test or Fisher's exact test when appropriate and presented as percentages and frequencies. Covariates with continuous data were compared by using Mann-Whitney *U* test and presented as medians and interquartile ranges (IQR).

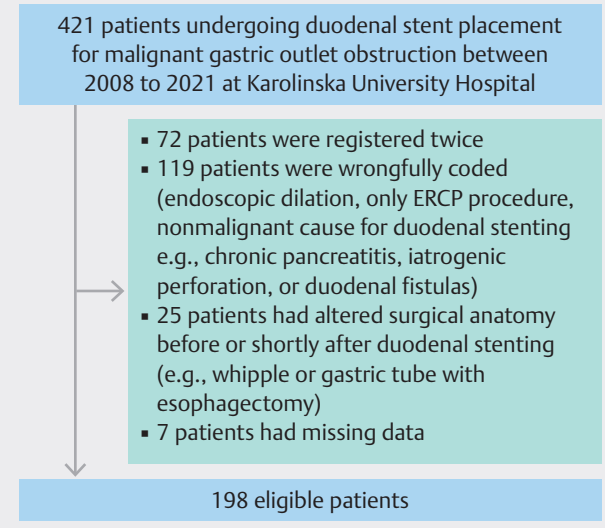
Predictive factors for stent patency at 3 months and overall survival at 6 months (only using covariates present at decision) were analyzed using logistic regression. OS (using all covariates) was also analyzed in Cox regression. In all regressions, covariates were assessed univariably and multivariably using a backwards stepwise selection approach with a threshold set to 10% (P <0.1). The effect of covariates on the outcome was calculated and presented as odds ratio (OR) and hazard ratio (HR) for logistic and Cox regressions, respectively, including 95% confidence intervals (Cis).

Using the Kaplan-Meier method, predictors for survival in Cox regression were used to estimate survival probability as a function of time. Curves were plotted, and groups were compared using the log-rank test. Unless otherwise stated, all statistical tests were two-sided, and the level of statistical significance was set at P <0.05. Data analyses were performed in R version 4.0.2 (Vienna, Austria. 2020).

Results

Demographic data and clinicopathological variables

There were 198 eligible patients with malignant GOO who underwent duodenal stenting (▶ **Fig. 1**). Median age was 68 years (IQR 58–76), similar in female (53%) and male (47%) patients (▶ **Table 1**).



▶ **Fig. 1** Flow chart for patient inclusion and exclusion.

Jaundice was present in 52 patients, 14 had biliary stents prior to duodenal stenting with still some remaining jaundice, 28 received concomitant biliary stents, and in 10 biliary stenting was not performed.

The site of tumor obstruction was pre-papillary (59%), peri/juxta papillary (36%), and post-papillary (5%). Performance status, prevalence of diabetes, and jaundice were similar. Pancreatic carcinoma was the most common diagnosis (40%) dominating in peri/juxta-papillary (53%) and post-papillary involvement (10%), whereas gastric carcinoma (accounting for 18% of diagnoses) was more frequent when the obstruction was pre-papillary (94%) (P <0.001). Extrinsic tumors (76%) were more common in peri/juxta papillary (68%) and post-papillary (91%) (P <0.01). Biliary drainage was performed before (26%) or at the index procedure (19%). In post-papillary obstructions, the bile duct never needed to be drained (P <0.001). When comparing the stricture site origin, presence of ascites (49%) was similar but carcinosis (46%) was more frequent in post-papillary obstructions (73%) (P <0.001). Chemotherapy prior to stenting (52%) did not differ between the groups (▶ **Table 1**, ▶ **Table 2**).

Therapeutic outcome

Most SEMS were UC (88%). Of the 23 C-SEMS, only two were FC-SEMS. Clinical success was noted in 188 of 198 patients (95%), not depending on site of obstruction, median hospital stay was 3 days (IQR 1–10), and the majority resumed oral intake the first day after intervention. In our cohort of 198 patients, 118 patients (60%) had patent stents and among those with clinical success (118/188[63%]) stents were patent until end of follow-up or death. In total, confirmed stent failure was demonstrated in 70 of 188 patients (37%) with clinical success. Overall, stents failed in 80 of 198 patients (40%). Median stent patency time was 48 days (IQR 20–132), in 53% of patients, stents were patent at 3 months, and not dependent on obstruction location.

▶ **Table 1** Descriptive statistics for baseline characteristics.

Variable	Overall N = 198*	Pre (papillary) n = 116*	Peri (papillary) n = 71*	Post (papillary) n = 11*	*P* value†
Sex					0.406
▪ Female	105 (53)	65 (56)	36 (51)	4 (36)	
▪ Male	93 (47)	51 (44)	35 (49)	7 (64)	
Age	68 (58–76)	67 (58–76)	68 (58–76)	69 (54–80)	0.879
Diabetes	38 (19)	20 (17)	15 (21)	3 (27)	0.513
ASA					0.656
▪ 1–2	104 (53)	64 (55)	35 (49)	5 (45)	
▪ 3–4	94 (47)	52 (45)	36 (51)	6 (55)	
ECOG					0.805
▪ 0–2	175 (88)	104 (90)	61 (86)	10 (91)	
▪ 3–4	23 (12)	12 (10)	10 (14)	1 (9.1)	
Carcinosis	88 (46)	56 (50)	24 (35)	8 (73)	0.026
Ascites	94 (49)	54 (48)	33 (48)	7 (64)	0.594
Jaundice	52 (26)	32 (28)	20 (28)	0 (0)	0.121
CA19–9					0.101
▪ <1000	60 (61)	37 (69)	21 (57)	2 (29)	
▪ ≥1000	38 (39)	17 (31)	16 (43)	5 (71)	
Chemotherapy	102 (52)	57 (49)	40 (56)	5 (45)	0.581
Histology					
▪ Pancreatic	80 (40)	30 (26)	42 (59)	8 (73)	
▪ Gastric	35 (18)	33 (28)	2 (2.8)	0 (0)	
▪ Biliary	26 (13)	22 (19)	3 (4.2)	1 (9.1)	
▪ Duodenal/Ampullary	12 (6.1)	4 (3.4)	7 (9.9)	1 (9.1)	
▪ Other	45 (23)	27 (23)	17 (24)	1 (9.1)	
Histology					0.005
▪ Intrinsic	47 (24)	37 (32)	9 (13)	1 (9.1)	
▪ Extrinsic	151 (76)	79 (68)	62 (87)	10 (91)	

*n (%); median (25%-75%). †Pearson's Chi-squared test; Kruskal-Wallis rank sum test; Fisher's exact test. ASA, American Society of Anesthesiologists; CA19–9, cancer-associated Antigen; ECOG, Eastern Cooperative Oncology Group.

Median survival was 81 days (IQR 40–241) with a 36% 90-day mortality that was not related to site (▶ **Table 2**).

Adverse events and reinterventions

Major AEs were noted in 88 of 198 patients (44%), the predominant cause being confirmed stent failure in 70. Ingrowth/overgrowth dominated (61), followed by migration (7), and perforation (2). Ingrowth/overgrowth occurred in 51 of 175 (29%) UC-SEMS and 10 of 23 (43%) SC-SEMS/FC-SEMS. Stent migration was documented in four of 175 (2%) UC-SEMS and three of 23 (14%) SC-SEMS/FC-SEMS (P <0.05). AEs were not depending on obstruction site. There were five bleeding episodes that required reintervention and two perforations but no procedure-related deaths (▶ **Table 2**). There were seven cases of suspected cholangitis, one of which had biliary stent occlusion whereas the remaining one only required antibiotics. None of the patients were diagnosed with pancreatitis.

Most reinterventions were repeated insertion of SEMS (76%) or stent dilation (11%). A surgical procedure (with or without prior endoscopic reintervention) was performed in seven patients (▶ **Table 2**).

▶ **Table 2** Outcome measures and adverse events.

Variable	Overall N = 198*	Pre (papillary) n = 116*	Peri (papillary) n = 71*	Post (papillary) n = 11*	*P* value†
Stent type					0.005
▪ Uncovered	175 (88)	96 (83)	69 (97)	10 (91)	
▪ Semi/fully	23 (12)	20 (17)	2 (2.8)	1 (9.1)	
Stent length (mm)					0.023
▪ 60	33 (17)	26 (22)	6 (8.5)	1 (9.1)	
▪ 90	106 (54)	62 (53)	39 (55)	5 (45)	
▪ 100	2 (1.0)	2 (1.7)	0 (0)	0 (0)	
▪ 110	7 (3.5)	6 (5.2)	1 (1.4)	0 (0)	
▪ 120	50 (25)	20 (17)	25 (35)	5 (45)	
Stents deployed					0.648
▪ 1	188 (95)	111 (96)	66 (93)	11 (100)	
▪ 2	9 (4.5)	4 (3.4)	5 (7.0)	0 (0)	
▪ 3	1 (0.5)	1 (0.9)	0 (0)	0 (0)	
Biliary drain					< 0.001
▪ No	109 (55)	71 (61)	27 (38)	11 (100)	
▪ Before	51 (26)	22 (19)	29 (41)	0 (0)	
▪ At index procedure	38 (19)	23 (20)	15 (21)	0 (0)	
▪ Length of stay	3 (1–10)	3 (1–10)	3 (1–10)	2 (2–6)	0.957
▪ Clinical success	188 (95)	110 (95)	67 (94)	11 (100)	>0.999
Stent patency					
▪ 1 month	159 (80)	97 (84)	53 (75)	9 (82)	0.360
▪ 3 months	68 (53)	39 (54)	23 (48)	6 (67)	0.572
▪ Stent failure, confirmed	70 (35)	36 (31)	29 (41)	5 (45)	0.284
▪ Reintervention	88 (44)	49 (42)	33 (46)	6 (55)	0.660
▪ Days to	32 (12–108)	32 (12–112)	27 (14–82)	98 (73–165)	0.394
Cause				0.610	
▪ Growth	61 (70)	30 (61)	26 (81)	5 (83)	
▪ Check	12 (14)	9 (18)	2 (6.2)	1 (17)	
▪ Migration	7 (8.0)	4 (8.2)	3 (9.4)	0 (0)	
▪ Bleeding	5 (5.7)	4 (8.2)	1 (3.1)	0 (0)	
▪ Perforation	2 (2.3)	2 (4.1)	0 (0)	0 (0)	
Type					0.368
▪ Stent	55 (76)	29 (78)	22 (76)	4 (67)	
▪ Dilation	8 (11)	2 (5.4)	5 (17)	1 (17)	
▪ Surgery	7 (9.7)	5 (14)	1 (3.4)	1 (17)	
▪ None	2 (2.8)	1 (2.7)	1 (3.4)	0 (0)	
Survival					
▪ Overall (Days)	80 (40–232)	80 (42–217)	73 (35–269)	124 (96–203)	0.505
▪ 1 month	156 (79)	21 (18)	20 (28)	1 (9.1)	0.195

▶ **Table 2** (Continuation)

Variable	Overall N = 198*	Pre (papillary) n = 116*	Peri (papillary) n = 71*	Post (papillary) n = 11*	*P* value†
▪ 3 months	126 (64)	46 (40)	25 (35)	1 (9.1)	0.126
▪ 6 months	56 (28)	84 (72)	50 (70)	8 (73)	0.964
▪ 12 months	26 (13)	102 (88)	60 (85)	10 (91)	0.825

*n (%); median (25%-75%). †Pearson's Chi-squared test; Kruskal-Wallis rank sum test; Fisher's exact test.

Predictive factors for stent patency at 3 months and OS

Predictive factors for stent patency at 3 months (n = 68) were according to multivariable logistic regression (▶ **Table 3**) jaundice (OR 3.03, CI 1.23–7.69, *P* = 0.018), SC-SEMS or FC- SEMS (OR 11.1, CI 3.03–50.0, *P* <0.001), and chemotherapy (prior to stenting) (OR 3.23, CI 1.49–7.69, *P* = 0.004). WHO/ECOG performance status, carcinosis, stricture site, and need for biliary drainage did not influence stent patency in our analysis.

Predictors of survival at 6 months according to multivariable logistic regression analysis and multivariable Cox regression analysis were jaundice (OR 0.37, CI 0.15–0.81, *P* = 0.019), and jaundice (HR 0.50, CI 0.32–0.77, *P* = 0.02) and stent patency at 3 months (HR 2.78, CI 1.89–4.00, *P* <0.001), respectively. Stent type, chemotherapy (prior to stenting), and predictors for stent patency at 3 months, however, were not predictors of survival (*P* = 0.804 and *P* = 0.962 respectively). Median survival in the group of patients with jaundice not undergoing biliary intervention was 52 days (IQR 36–123). Kaplan-Meier survival analyses with log rank test also showed that jaundice and stent patency at 3 months significantly affected OS (*P* = 0.018 and *P* <0.0001 respectively) (▶ **Fig. 2a** and ▶ **Fig. 2b**).

Discussion

This single-center study investigated treatment of malignant GOO with duodenal SEMS. Clinical success was high (95%), with a stent patency rate at 3 months of 53%. Presence of jaundice, use of C-SEMS, and chemotherapy prior to stenting were associated with improved stent patency. Stent function was not related to obstruction site, presence of ascites, or peritoneal carcinosis. Except for stent failure, there were few AEs.

Most studies evaluating duodenal SEMS for treatment of malignant GOO are retrospective, and meta-analyses have also been performed. However, comparison between studies is hampered by applying different outcome measures (technical success, clinical success, stent patency, OS, GOO symptom-free survival, AEs), and including a variety of contributing factors (ascites, carcinosis, chemotherapy, scoring systems, level of stenosis, bile duct stenting). Different definitions of clinical success have also been applied; authors have used any improvement in GOOSS score, achieving defined levels (e. g. GOOSS >2, >3), or achieving 85% to 90% clinical success [11, 15, 21, 22, 23]. Patient selection for duodenal stenting, choice of stent, referral patterns, follow-up policy, case-mix, and between-study heterogeneity (meta-analyses) may also vary [13, 14, 15, 19, 20, 24, 25, 26]. In the present study, by using a more "liberal" definition of clinical success (improvement in GOOSS ≥1) than some other studies, 95% of patients experienced clinical success. After early discharge from hospital, in our series, further improvement in GOOSS could be expected but such data were not available.

Given the high rate of clinical success in treating malignant GOO with duodenal SEMS, the seemingly most important outcome is to achieve a high rate of long stent patency, thus obviating need for reintervention in this group of patients with short life expectancy. Unlike in other studies, we chose to evaluate predictive factors for stent patency (clinical success without reintervention for recurrent GOO confirming stent failure) at 3 months, which is a clinically relevant objective. We compared patients with persistent stent patency to those who developed stent failure or had initial clinical failure (assessing factors contributing to both these causes of failed therapy, although the underlying mechanisms may be different).

In the present study, use of C-SEMS (SC or FC), presence of jaundice, and received chemotherapy (prior to stenting) were independently associated with improved stent patency. Our findings must be taken with caution because choice of stents was at the preference and discretion of the endoscopist, and only a few C-SEMS were used. The efficacy of UC and C-SEMS has been evaluated in several studies, including meta-analyses showing similar rates of clinical success, stent patency (some indications in favor of C-SEMS), complications, and reinterventions [26, 27]. The increased migration risk for C-SEMS is balanced by a higher occlusion rate in UC-SEMS. In the present study, migration was more common with C-SEMS whereas ingrowth/overgrowth occurred at a similar rate regardless of SEMS type. Jung et al. [23] demonstrated a higher migration rate with FC-SEMS than SC-SEMS but this was not confirmed in a meta-analysis [26]. It is not clear how jaundice could affect stent patency. It may be that biliary stenting counteracts migration and the shorter survival time in jaundiced patients makes stent failure less likely to occur.

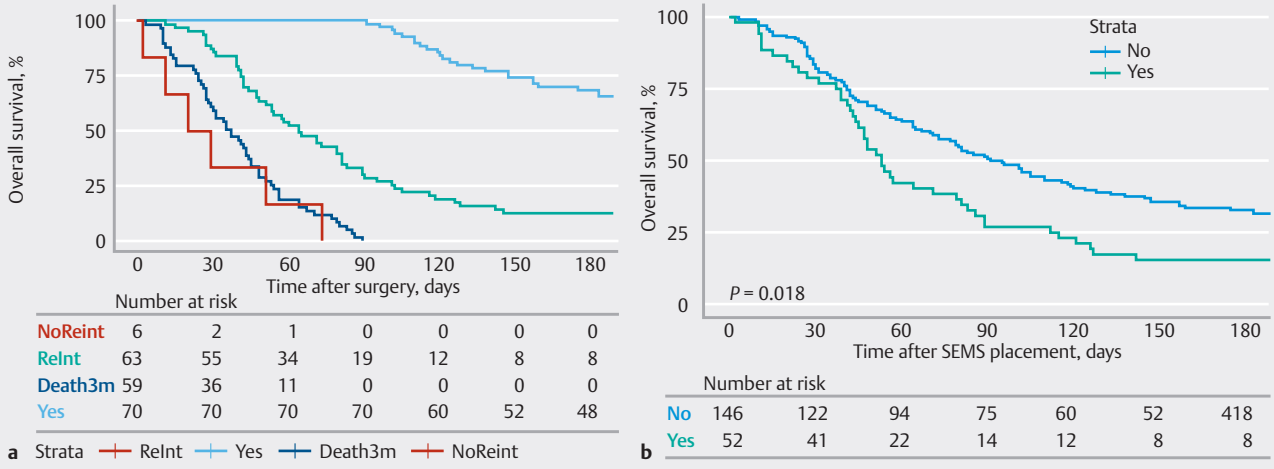
In the present study, chemotherapy (prior to stenting) impacted stent patency positively, but there are conflicting data in the literature, e. g. effect on stent migration and restenosis [13, 26, 28, 29].

Tamura et al. [20] demonstrated that UC-SEMS may have a lower rate of dysfunction in extrinsic tumors. In our study dominated by pancreatic carcinoma followed by gastric cancer, there was no difference in stent patency related to tumor origin. Si-

▶ **Table 3** Univariate and multivariable logistic regression analysis of factors predicting stent patency at 3 months.

Univariable				Multivariable	
Characteristic	**OR** *	**95% CI** *	***P* value**	**OR**†	**95% CI** *
Sex					
▪ Female	–	–			
▪ Male	0.93	0.46, 1.87	0.839		
Age	1.05	1.02, 1.08	0.003		
Diabetes					
▪ No	–	–			
▪ Yes	0.97	0.39, 2.43	0.954		
ASA					
▪ 1–2	–	–			
▪ 3–4	0.88	0.44, 1.76	0.710		
ECOG					
▪ 0–2	–	–			
▪ 3–4	1.29	0.39, 4.56	0.683		
Carcinosis					
▪ No	–	–			
▪ Yes	0.73	0.36, 1.48	0.390		
Ascites					
▪ No	–	–			
▪ Yes	0.95	0.47, 1.91	0.876		
Jaundice					
▪ No	–	–			
▪ Yes	2.17	0.94, 5,26	0.074	3.03	1.23–7.69
CA19–9					
▪ <1000	–	–			
▪ ≥1000	0.68	0.26, 1.77	0.437		
Stent type					
▪ Uncovered	–	–			
▪ Semi/fully	7.69	2.38, 33,3	0.002	11.1	3.03–50.0
Stricture site					
▪ Pre	–	–			
▪ Peri/post	0.88	0.44, 1.76	0.710		
Chemotherapy					
▪ No	–	–			
▪ Yes	2.78	1.37, 5.88	0.005	3.23	1.49–7.69
Biliary drainage					
▪ No	–	–			
▪ Before	1.00	0.42, 2.37	0.993		
▪ Index	0.43	0.16, 1.08	0.076		

ASA; American Society of Anesthesiologists; CA19–9, cancer-associated antigen; CI, confidence interval; ECOG, Eastern Cooperative Oncology Group; OR, odds ratio.



▶ **Fig. 2** **a** Kaplan-Meier analysis presenting overall survival depending on stent patency at 3 months. **b** Kaplan-Meier analysis presenting overall survival depending on the presence of jaundice.

milarly, Yamao et al [11] reported in a multicenter study of 278 patients with 31% having gastric cancer that intrinsic disease did not influence clinical efficacy. Also, in another similar-size multicenter study dominated by gastric cancer, diagnosis was not related to stent dysfunction [22].

In the present series, stent failure was observed in 70 of 188 patients (37%) with initial clinical success obtaining a median patency time of 48 days. As in other studies, inability to detect stent failure is a problem (i. e. underdiagnosed). In relevant studies, there is wide variation in rates of stent dysfunction (12%-35%), and patency time ranges (median 39–242 days) [13, 22, 26, 30]. In a pooled analysis, van Halsema et al. [1] reported 19.6% stent dysfunction, and median patency times of included studies ranging from 68 to 307 days. Reijm et al. [24] analyzed two time periods, finding recurrent GOO in 56% and 59%, respectively. Corresponding median patency times were 28 days and 39 days.

Median survival time in the present study (81 days) was similar to others but the variation is large (54–180 days) [11, 13, 14, 15, 23, 24, 30]. In our study, OS was negatively impacted by presence of stent dysfunction. Possibly, aggressive tumor behavior may contribute to stent failure apart from having a negative impact on survival in general. Similarly, clinical success has been associated with better outcome [23]. However, Hodo et al. [14] found no relation between stent patency and survival, so perhaps short survival time in general precludes detection of differences. As reported by others, we found no influence of diagnosis on survival [14, 15], but in a pooled analysis, studies dominated by pancreatic cancer had a worse outcome [1].

Data regarding other factors predicting survival are conflicting, e. g. performance status 1–2, age, chemotherapy, absence of ascites, and carcinosis often have been associated with better outcomes but were not confirmed in our series [11, 12, 14, 15, 31]. In our study, receiving chemotherapy did not improve survival, probably reflecting that GOO is a late event in malignant disease, although it may slow disease progression [1]. Interestingly, although presence of jaundice indeed was a predictor of stent patency at 3 months, that in turn was positively associated with survival; jaundice was concurrently also a predictor of death. This may be caused by local tumor characteristics favoring stent patency, but systemic tumor characteristics suggest dissemination and ensuing death after some months.

In the present series there was no influence of obstruction site on stent patency or survival. The impact of obstruction location is divergent. In one study, a higher clinical success was noted if the location was in the peri-pyloric region but with similar patency time [23] and a sequential increase in stent occlusion more distally has been reported [30]. Contrarily, according to Hori et al. [22] a pyloric site of obstruction was the only predictive factor for stent dysfunction, associated with a high rate of ingrowth in UC-SEMS. According to Takamatsu et al. [15], site was not predictive of clinical success but obstruction in the third part of the duodenum was related to improved survival. Stricture length may have a negative impact on survival and stent function, but we have no such data [32, 33].

Reinterventions for AEs were common in our series (44%), mostly performed for stent dysfunction. A lower rate has been reported by others (16%-28%), similar for UC-SEMS and C-SEMS [11, 15, 26]. A possible explanation could be our low threshold for reintervention, reflected by 14% of reinterventions being “checks”. Cholangitis was rare in our series and nearly half of patients had biliary stents before or at the index procedure. A similar experience is presented by others, also reporting <1% pancreatitis [11, 15, 19, 22]. However, cholangitis is a serious AE related to clinical failure (GOO) and impaired survival [11, 14]. In a meta-analysis, cholangitis was not related to whether SEMS were covered or not, but SEMS traversing the papilla seem to increase risk [20, 24]. Also, pancreatitis remains a serious issue after stenting, and has been reported in 6.9% of patients (12.8% when the stent crossed the papilla) [34]. Recurrent GOO may also be caused by motility problems in 17% [24], and

in one series, impaired oral intake exceeded stent dysfunction by 14% [13]. The present study only analyzed endoscopically confirmed stent failure but there were not data on clinical stent dysfunction.

In recent American Society for Gastrointestinal Endoscopy (ASGE) guidelines [35], a surgical procedure has been suggested if predicted survival exceeds 6 months. In our study, presence of jaundice was a predictor of death at 6 months, making surgical bypass questionable in patients with a large tumor burden or a low performance score. This decision can be reinforced by the fact that jaundice also serves as a positive predictor of stent patency at 3 months. Prognostic scoring systems (Glasgow Prognostic Score, neutrophile-to-lymphocyte ratio) may be helpful in the decision-making process [12, 15]. Currently, EUS-guided gastrojejunostomy also has been introduced, combining the endoscopic approach as well as bypassing the diseased area, similar to surgery. EUS-guided placement of SEMS may be superior to duodenal SEMS, and produce results comparable to surgical bypass regarding clinical success and reintervention frequency [9, 10, 36]. Hepaticogastrostomy guided by EUS may be used in jaundiced patients, but data are lacking regarding the possible influence on duodenal stent patency [34].

Limitations of the present study are the retrospective design, lack of standardized allocation to SEMS treatment, and non-systematic choice of SEMS type. Comparison of stent failure between studies is hampered by differences in follow-up, definitions, diagnostic procedures, and policy for reintervention. Strengths are the consecutive design, patients handled by the same multidisciplinary team, and complete follow-up.

Conclusions

Treatment with duodenal SEMS is a feasible option in patients with malignant GOO with short hospitalization, rapid resumption of oral intake, and few AEs apart from predictable problems with stent patency, which remains a major concern. The short survival time is further curtailed in jaundiced patients and if SEMS are non-patent. In non-jaundiced patients eligible for chemotherapy, surgical or EUS-guided gastrojejunostomy may be more appropriate than duodenal SEMS.

Conflict of Interest

The authors declare that they have no conflict of interest.

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