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

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Abstract:
Background: Malignant gastric outlet obstruction (GOO) occurs often late during disseminated disease needing palliation. Placement of duodenal self-expandable metal stents (SEMS) is a common method 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 three months and survival. Also, stent patency rate and adverse events after duodenal stenting were analyzed.
Methods: 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 malignancy was pancreatic adenocarcinoma (40%), gastric adenocarcinoma (18%) and cholangiocarcinoma (13%). Uncovered SEMS were used in 88%, and the reintervention rate was 44%. The stent patency rate was 63% in 188 patients with clinical success. Predictors for stent patency 3 months were jaundice, semi- or fully covered stents, and chemotherapy prior to stenting. Median survival was 81 days (IQR 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%).
Discussion: Treatment of malignant GOO by duodenal SEMS is effective but the reintervention rate is high. Predictors for stent patency were jaundice, semi- or fully covered SEMS, and chemotherapy. Survival was impaired by jaundice and stent dysfunction.

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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]. Most common cause in the European context, is pancreatic adenocarcinoma while gastric cancer is dominating in Asiatic population, but several other malignancies can cause GOO due to primary overgrowth or metastatic disease[2] [3].

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/re-interventions, 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 WHO 1-2) and absence of metastases are associated with longer survival after duodenal SEMS [11]. Several authors have found ascites, peritoneal carcinomatosis, and poor nutritional status adversely associated with the clinical outcome [7]. Other studies have shown conflicting data on the effect of chemotherapy in post-stent survival. [12–15].

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 three months after duodenal SEMS in malignant GOO. Secondary aims were to assess rate of stent patency, overall survival, and adverse events (AEs).

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 & design

All adult patients (≥18 years of age) treated with duodenal SEMS for malignant GOO from the period January 1, 2008 – December 31, 2021, at Karolinska University Hospital which is a tertiary referral center for hepato-pancreato-biliary malignancy in Stockholm, Sweden. Last follow up was on April 1, 2022. None of the patients were amenable 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 since it was probable that in some cases the stenting procedure would be wrongfully coded as only dilation.

The 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 <18 years of age.

Patients were referred from their oncologist, primary health physician or via the emergency department due to GOO-symptoms. All patients underwent CT-scan and malignant GOO was confirmed endoscopically.

Data variables & definitions

Data on gender, BMI, American Society of Anesthesiologists – Physical Status (ASA-PS) classification[17], performance status according to WHO/ECOG[18] , comorbidity, chemotherapy prior to stenting, presence of jaundice (regardless of previous biliary stenting) at the time of procedure (defined as bilirubin >50mmol/l), prior or concomitant biliary drainage, ascites, carcinosis, CA19-9 level, site of tumor obstruction, cancer type (histological diagnosis), gastric outlet obstruction 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 of re-intervention, time to reintervention and type of reintervention needed as well as SEMS-type were recorded. Overall survival was the number of days from intervention to death.

Clinical success was defined as improvement in GOOSS score with ≥1, the remaining patients experienced initial clinical failure. Stents were considered as patent if no need for reintervention or re-admission 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 the time of reintervention by assessment of the endoscopist, confirmed stent dysfunction (including the cause of stent failure). There is 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 three months (comparing patients with clinical success without reintervention for recurrent GOO to those having clinical failure or developing confirmed stent failure) after duodenal stenting. Secondary objectives were to analyze rate of stent patency, overall survival, and AEs. Clinical success, stent patency time, and cause of reintervention after duodenal stent deployment were also evaluated.

Procedural 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 the length of stricture and its position in relationship to the papilla which was also assessed endoscopically. During the study period there were no institutional protocol on type of SEMS to be used. Thus, based on the endoscopist preference uncovered (UC), semi-covered (SC) or fully covered (FC) (SEMS) were used. Diameter of the SEMS was 22 mm and the length varied from 6-12 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 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 was not available. Follow up was performed by oncologists, primary health care or palliative care. 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 developing clinical signs of recurrent GOO may have been considered not suitable 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 three months and overall survival at six months (only using covariates present at decision) were analyzed using logistic regressions. Overall survival (using all covariates) was also analyzed in Cox regression. In all regressions, covariates were assessed uni- 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 (CI).

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).

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%) while gastric carcinoma (accounting for 18% of diagnosis) 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, the 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. Clinical success was noted in 188/198 (95%) of patients, 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. Totally, confirmed stent failure was demonstrated in 70/188 (37%) among patients with clinical success. Overall, stents failed in 80/198 (40%) of patients. The median stent patency time was 48 days (IQR 20-132), in 53% of patients stents were patent at three months, and not depending on location of obstruction. 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 88/198 (44%) of patients, the dominating cause was confirmed stent failure in 70. Ingrowth/overgrowth dominated (61), followed by migration (7), and perforation (2). Ingrowth/overgrowth occurred in 51/175 (29%) UC-SEMS, and 10/23 (43%) SC/FC. Stent migration was documented in 4/175 (2%) UC-SEMS, and 3/23 (14%) SC/FC ($p<0.05$). AEs were not depending on obstruction site. There were five bleedings requiring reintervention, two perforations but no procedural related death (Table 2). There were seven cases of suspected cholangitis, one of which had biliary stent occlusion while the remaining only required antibiotics. No patient was 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).

Predictive factors for stent patency at three months and overall survival

Predictive factors for stent patency at three months (n=68) were according to multivariable logistic regression (Table 3) jaundice (OR 3.03, CI 1.23-7.69, p=0.018), semi- or fully covered 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 for survival at six months according to multivariable logistic regression analysis was jaundice (OR 0.37, CI 0.15-0.81, p=0.019) and using multivariable Cox regression analysis jaundice (HR 0.50, CI 0.32-0.77, p=0.02) and stent patency at three months (HR 2.78, CI 1.89-4.00, p<0.001). Stent type, chemotherapy (prior to stenting), and predictors for stent patency at three months, were however not predictors for survival (p=0.804 and p=0.962 respectively). The 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 three months significantly affected overall survival (p=0.018 and p<0.0001 respectively) (Figure 2a and b).

DISCUSSION

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

Most studies evaluating duodenal SEMS treating 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, overall survival, 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 85-90% clinical success [11,15,21–23]. Patient selection to duodenal stenting, choice of stent, referral patterns, follow-up policy, and case-mix, between-study heterogeneity (meta-analyses) may also be varying[13–15,19,20,24–26]. In the present study, by using a more "liberal" definition of clinical success (improvement in GOOSS≥1) than some other studies, 95% of the patients experienced clinical success. After the early discharge from hospital in our series a further improvement in GOOSS could be expected but such data was not available.

Given the high rate of clinical success 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 other studies we chose to evaluate predictive factors for stent patency (clinical success without reintervention for recurrent GOO confirming stent failure) at three 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, the 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 since the choice of stents was at the preference and discretion of the

endoscopist, and only 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 of C-SEMS is balanced by a higher occlusion rate in UC-SEMS. In the present study migration was more common in C-SEMS while ingrowth/overgrowth occurred at a similar rate regardless type of SEMS. Jung et al.[23] demonstrated a higher migration rate in FC- 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 is 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. Similarly, 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 sized multicenter study dominated by gastric cancer diagnosis was not related to stent dysfunction[22] .

In the present series stent failure was observed in 70/188 (37%) of patients 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 a 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 68-307 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.

The median survival time in the present study (81 days) was similar to others but the variation is large (54-180 days)[11,13–15,23,24,30]. In our study, overall survival was negatively impacted by presence of stent dysfunction. Possibly, an aggressive tumor behavior may contribute to stent failure apart from 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, perhaps a 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 is conflicting, e.g. performance status 1-2, age, chemotherapy, absence of ascites and carcinosis often have been associated with better outcome but were not confirmed in our series[11,12,14,15,31]. In our study receiving chemotherapy had not improved survival, probably reflecting that GOO is a late event in the malignant disease, although it may slow disease progression[1]. Interestingly, although presence of jaundice indeed was a predictor for stent patency at three months – that in turn was positively associated with survival – jaundice was concurrently also a predictor for death. This may be caused by local tumoral characteristics favoring stent patency but systemic tumoral characteristics suggesting 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 the location of obstruction is diverging. 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 of 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 of stent dysfunction, associated with a high rate of ingrowth in UC-SEMS. According to Takamatsu et al. [15] site was not predictive for clinical success but obstruction in the third part of 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 adverse events were common in our series (44%), mostly performed for stent dysfunction. A lower rate has been reported by others (16-28%), similar in UC- 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, nearly half of the 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 if SEMS were covered or not but SEMS traversing the papilla seem to increase the risk[20,24]. Also, pancreatitis remains a serious issue after stenting, and has been reported in 6.9% (12.8% when the stent crossed the papilla)[34] Recurrent GOO may also be caused by motility problems, 17% [24], and in one series inability to oral intake exceeded stent dysfunction by 14% [13]. The present study only analyzed endoscopically confirmed stent failure but there was 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 six months. In our study, the presence of jaundice was a predictor for 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 for stent patency at three months. Prognostic scoring systems (Glasgow Prognostic Score, neutrophile-to-lymphocyte ratio) may be helpful in the decision process[12,15] . Currently, also EUS guided gastrojejunostomy has been introduced, combining the endoscopic approach as well as bypassing the diseased area similar to a surgery. EUS placed SEMS may be superior to duodenal SEMS, and have results comparable to surgical bypass regarding clinical success and reintervention frequency[9,10,36].Hepaticogastrostomy by EUS may be used in jaundiced patients but data is lacking regarding possible influence on duodenal stent patency[34]

Limitations of the present study is 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 adverse events 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.

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445 **FIGURE AND TABLE LEGENDS**

446 **Figure 1.** Flow chart for patient inclusion and exclusion.

447 **Figure 2.** Kaplan-Meier analysis presenting overall survival depending on stent patency at 3 months.
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449 **Table 1.** Descriptive statistics of baseline characteristics.

450 **Table 2.** Outcome measures and Adverse Events

451 **Table 3.** Univariable and multivariable logistic regression analysis of factors predicting stent patency
452 at 3 months.
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Table 1. Descriptive statistics of baseline characteristics

Variable	Overall N = 198[1]	Pre (papillary) n=116[1]	Peri (papillary) n=71[1]	Post (papillary) n=11[1]	p-value[2]
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)	

[1] n (%); Median (25%-75%)

[2] Pearson's Chi-squared test; Kruskal-Wallis rank sum test; Fisher's exact test

CA19-9, Cancer-associated Antigen, ASA, American Society of Anesthesiologists, ECOG, Eastern Cooperative Oncology Group

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Table 2. Outcome Measures and Adverse Events

Variable	Overall N = 198[1]	Pre (papillary) n= 116[1]	Peri (papillary) n =71[1]	Post (papillary) n=11[1]	p-value[2]
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
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

[1] n (%); Median (25%-75%)

[2] Pearson's Chi-squared test; Kruskal-Wallis rank sum test; Fisher's exact test

[1] n (%); Median (25%-75%)

[2] Pearson's Chi-squared test; Kruskal-Wallis rank sum test; Fisher's exact test

Table 3. Uni- and multivariable logistic regression analysis of factors predicting stent patency at 3 months

Univariable				Multivariable	
Characteristic	**OR[1]**	**95% CI[1]**	**p-value**	**OR[2]**	**95% CI[1]**
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	—	—			
SemiFully	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**		

OR, Odds Ratio, CI, Confidence Interval
CA19-9, Cancer-associated Antigen, ASA, American Society of Anesthesiologists,
ECOG, Eastern Cooperative Oncology Group