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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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1 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].

8

9 Surgical bypass and duodenal self-expandable metal stents (SEMS) have shown similar efficacy in 10 relieving malignant GOO. Endoscopic uncovered (UC) or covered (C) SEMS induce a faster clinical 11 response, fewer complications, and shorter hospitalization [3,4] [5]. Surgical bypass performed as an 12 open procedure or laparoscopically with a conventional gastrojejunstomy, or partial stomach 13 partitioning gastrojejunostomy has a lower rate of re-obstructions/re-interventions, and longer 14 survival. [6,7] [8]. Endoscopic ultrasound (EUS) guided therapy has recently become a promising 15 option [9,10].

16

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].

22

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).

27 METHODS

28 This retrospective single center study was approved by the Swedish Ethical Review Authority

29 (registration number 2023/01484/01) and was performed in accordance with the Declaration of

30 Helsinki and the Strengthening the Reporting of Observational Studies in Epidemiology guideline

31 [16].

32

33 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.

38

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.

43

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.

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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.

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53

54 Data variables & definitions

55 Data on gender, BMI, American Society of Anesthesiologists - Physical Status (ASA-PS) 56 classification[17], performance status according to WHO/ECOG[18], comorbidity, chemotherapy 57 prior to stenting, presence of jaundice (regardless of previous biliary stenting) at the time of 58 procedure (defined as bilirubin >50mmol/l), prior or concomitant biliary drainage, ascites, carcinosis, 59 CA19-9 level, site of tumor obstruction, cancer type (histological diagnosis), gastric outlet 60 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 61 62 papillary and post-papillary[19]. A stenosis was defined as intrinsic in the presence of gastric, 63 duodenal or ampullary carcinoma, and extrinsic in pancreatic, bile duct, gallbladder, or other 64 cancer[11,20].

65

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 SEMStype were recorded. Overall survival was the number of days from intervention to death.

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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.
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- 82

83 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.

89

90 Procedural details

91 Endoscopic duodenal stenting was performed under propofol sedation or general anesthesia. A 92 therapeutic gastroscope or side-viewing duodenoscope was advanced to the site of obstruction. 93 Then a sphincterotome and guidewire were advanced through the stricture with following contrast 94 injection under fluoroscopy to determine the length of stricture and its position in relationship to the 95 papilla which was also assessed endoscopically. During the study period there were no institutional 96 protocol on type of SEMS to be used. Thus, based on the endoscopist preference uncovered (UC), 97 semi-covered (SC) or fully covered (FC) (SEMS) were used. Diameter of the SEMS was 22 mm and the 98 length varied from 6-12 cm. In most cases an UC WallFlex (Boston Scientific Corporation) but in some 99 cases Hanaro (MI Tech) and Cook SEMS (Cook Medical) have been used as well. Patients receiving 100 multiple stents were recorded. If deemed clinically necessary, primary stent dilation was performed. 101 Technical success was confirmed endoscopically and by fluoroscopy.

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104 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.

112

113 Statistical analyses

114 Covariates with categorical data were compared by using the Pearson's Chi square test or Fisher's 115 exact test when appropriate and presented as percentages and frequencies. Covariates with 116 continuous data were compared by using Mann-Whitney *U* test and presented as medians and 117 interquartile ranges (IQR).

118

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).

126

127 Using the Kaplan-Meier method, predictors for survival in Cox regression were used to estimate 128 survival probability as a function of time. Curves were plotted, and groups were compared using the 129 log-rank test. Unless otherwise stated, all statistical tests were two-sided, and the level of statistical

- 130 significance was set at p<0.05. Data analyses were performed in R version 4.0.2 (Vienna, Austria.
- 131 2020).
- 132
- 133
- 134

137

135 **RESULTS**

136 Demographic data and clinicopathological variables

138 There were 198 eligible patients with malignant GOO who underwent duodenal stenting (Fig. 1).

139 Median age was 68 years (IQR 58-76), similar in female (53%) and male (47%) patients (Table 1).

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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

46 was the most common diagnosis (40%) dominating in peri/juxta-papillary (53%), and post-papillary

148 when the obstruction was pre-papillary (94%) (p<0.001). Extrinsic tumors (76%) were more common

involvement (10%) while gastric carcinoma (accounting for 18% of diagnosis) was more frequent

- 149 in peri/juxta papillary (68%), and post-papillary (91%) (p<0.01). Biliary drainage was performed
- 150 before (26%) or at the index procedure (19%). In post-papillary obstructions, the bile duct never
- 151 needed to be drained (p<0.001). When comparing the stricture site origin, the presence of ascites
- 152 (49%) was similar but carcinosis (46%) was more frequent in post-papillary obstructions (73%)
- 153 (p<0.001). Chemotherapy prior to stenting (52%) did not differ between the groups (Table 1, Table
- 154 2).
- 155
- 156 Therapeutic outcome

157 Most SEMS were UC (88%). Of the 23 C-SEMS only two were FC. Clinical success was noted in 158 188/198 (95%) of patients, not depending on site of obstruction, median hospital stay was 3 days 159 (IQR 1-10), and the majority resumed oral intake the first day after intervention. In our cohort of 198 160 patients, 118 patients (60%) had patent stents, and among those with clinical success (118/188 161 [63%]) stents were patent until end of follow up or death. Totally, confirmed stent failure was 162 demonstrated in 70/188 (37%) among patients with clinical success. Overall, stents failed in 80/198 163 (40%) of patients. The median stent patency time was 48 days (IQR 20-132), in 53% of patients 164 stents were patent at three months, and not depending on location of obstruction. Median survival 165 was 81 days (IQR 40-241) with a 36% 90-day mortality that was not related to site (Table 2). 166

167 Adverse events and reinterventions

168 Major AEs were noted in 88/198 (44%) of patients, the dominating cause was confirmed stent failure 169 in 70. Ingrowth/overgrowth dominated (61), followed by migration (7), and perforation (2). 170 Ingrowth/overgrowth occurred in 51/175 (29%) UC-SEMS, and 10/23 (43%) SC/FC. Stent migration 171 was documented in 4/175 (2%) UC-SEMS, and 3/23 (14%) SC/FC (p<0.05). AEs were not depending 172 on obstruction site. There were five bleedings requiring reintervention, two perforations but no 173 procedural related death (Table 2). There were seven cases of suspected cholangitis, one of which 174 had biliary stent occlusion while the remaining only required antibiotics. No patient was diagnosed 175 with pancreatitis.

176

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).

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- 182

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.

189

190 Predictors for survival at six months according to multivariable logistic regression analysis was 191 jaundice (OR 0.37, Cl 0.15-0.81, p=0.019) and using multivariable Cox regression analysis jaundice 192 (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). 193 Stent type, chemotherapy (prior to stenting), and predictors for stent patency at three months, were 194 however not predictors for survival (p=0.804 and p=0.962 respectively). The median survival in the 195 group of patients with jaundice not undergoing biliary intervention was 52 days (IQR 36-123). 196 Kaplan-Meier survival analyses with log rank test also showed that jaundice and stent patency at 197 three months significantly affected overall survival (p=0.018 and p<0.0001 respectively) (Figure 2a 198 and b). 199 200 DISCUSSION 201 202 This single center study investigated treatment of malignant GOO with duodenal SEMS. The clinical 203 success was high (95%), with a stent patency rate at three months of 53%. Presence of jaundice, the 204 use of covered stents and chemotherapy prior to stenting were associated with improved stent

205 patency. Stent function was not related to the site of obstruction, presence of ascites or peritoneal

206 carcinosis. Except for stent failure there were few AEs.

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208 Most studies evaluating duodenal SEMS treating malignant GOO are retrospective, and meta-209 analyses have also been performed. However, comparison between studies is hampered by applying 210 different outcome measures (technical success, clinical success, stent patency, overall survival, GOO-211 symptom free survival, AEs), and including a variety of contributing factors (ascites, carcinosis, 212 chemotherapy, scoring systems, level of stenosis, bile duct stenting). Different definitions of clinical 213 success have also been applied; authors have used any improvement in GOOSS score, achieving 214 defined levels (e.g. GOOSS >2, >3) or achieving 85-90% clinical success [11,15,21-23]. Patient 215 selection to duodenal stenting, choice of stent, referral patterns, follow-up policy, and case-mix, 216 between-study heterogeneity (meta-analyses) may also be varying [13-15,19,20,24-26]. In the 217 present study, by using a more "liberal" definition of clinical success (improvement in GOOSS >1) 218 than some other studies, 95% of the patients experienced clinical success. After the early discharge 219 from hospital in our series a further improvement in GOOSS could be expected but such data was 220 not available.

221

222 Given the high rate of clinical success treating malignant GOO with duodenal SEMS, the seemingly 223 most important outcome is to achieve a high rate of long stent patency, thus, obviating need for 224 reintervention in this group of patients with short life expectancy. Unlike other studies we chose to 225 evaluate predictive factors for stent patency (clinical success without reintervention for recurrent 226 GOO confirming stent failure) at three months, which is a clinically relevant objective. We compared 227 patients with persistent stent patency to those who developed stent failure or had initial clinical 228 failure (assessing factors contributing to both these causes of failed therapy, although the underlying 229 mechanisms may be different).

230

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

234 endoscopist, and only few C-SEMS were used. The efficacy of UC and C-SEMS has been evaluated in 235 several studies, including meta-analyses showing similar rates of clinical success, stent patency 236 (some indications in favor of C-SEMS), complications, and reinterventions[26,27]. The increased 237 migration risk of C-SEMS is balanced by a higher occlusion rate in UC-SEMS. In the present study 238 migration was more common in C-SEMS while ingrowth/overgrowth occurred at a similar rate 239 regardless type of SEMS. Jung et al. [23] demonstrated a higher migration rate in FC- than SC-SEMS 240 but this was not confirmed in a meta-analysis[26]. It is not clear how jaundice could affect stent 241 patency. It may be that biliary stenting counteracts migration and the shorter survival time in 242 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].

245

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].

252

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 daysand 39 days.

261

262 The median survival time in the present study (81 days) was similar to others but the variation is 263 large (54-180 days)[11,13-15,23,24,30]. In our study, overall survival was negatively impacted by 264 presence of stent dysfunction. Possibly, an aggressive tumor behavior may contribute to stent 265 failure apart from a negative impact on survival in general. Similarly, clinical success has been 266 associated with better outcome[23]. However, Hodo et al.[14] found no relation between stent 267 patency and survival, perhaps a short survival time in general precludes detection of differences. As 268 reported by others, we found no influence of diagnosis on survival[14,15] but in a pooled analysis 269 studies dominated by pancreatic cancer had a worse outcome[1].

270

271 Data regarding other factors predicting survival is conflicting, e.g. performance status 1-2, age, 272 chemotherapy, absence of ascites and carcinosis often have been associated with better outcome 273 but were not confirmed in our series[11,12,14,15,31]. In our study receiving chemotherapy had not 274 improved survival, probably reflecting that GOO is a late event in the malignant disease, although it 275 may slow disease progression[1]. Interestingly, although presence of jaundice indeed was a predictor 276 for stent patency at three months - that in turn was positively associated with survival - jaundice 277 was concurrently also a predictor for death. This may be caused by local tumoral characteristics 278 favoring stent patency but systemic tumoral characteristics suggesting dissemination and ensuing 279 death after some months.

280

281

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].

291

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]
.

295 A possible explanation could be our low threshold for reintervention reflected by 14% of 296 reinterventions being "checks". Cholangitis was rare in our series, nearly half of the patients had 297 biliary stents before or at the index procedure. A similar experience is presented by others, also 298 reporting <1% pancreatitis[11,15,19,22]. However, cholangitis is a serious AE related to clinical 299 failure (GOO), and impaired survival[11,14]. In a meta-analysis cholangitis was not related to if SEMS 300 were covered or not but SEMS traversing the papilla seem to increase the risk[20,24]. Also, 301 pancreatitis remains a serious issue after stenting, and has been reported in 6.9% (12.8% when the 302 stent crossed the papilla)[34] Recurrent GOO may also be caused by motility problems, 17% [24], 303 and in one series inability to oral intake exceeded stent dysfunction by 14% [13]. The present study 304 only analyzed endoscopically confirmed stent failure but there was not data on clinical stent 305 dysfunction.

306

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

311 jaundice also serves as a positive predictor for stent patency at three months. Prognostic scoring 312 systems (Glasgow Prognostic Score, neutrophile-to-lymphocyte ratio) may be helpful in the decision 313 process[12,15]. Currently, also EUS guided gastrojejunostomy has been introduced, combining the 314 endoscopic approach as well as bypassing the diseased area similar to a surgery. EUS placed SEMS 315 may be superior to duodenal SEMS, and have results comparable to surgical bypass regarding clinical 316 success and reintervention frequency[9,10,36]. Hepaticogastrostomy by EUS may be used in 317 jaundiced patients but data is lacking regarding possible influence on duodenal stent patency[34] 318 Limitations of the present study is the retrospective design, lack of standardized allocation to SEMS 319 320 treatment, and non-systematic choice of SEMS type. Comparison of stent failure between studies is 321 hampered by differences in follow-up, definitions, diagnostic procedures, and policy for 322 reintervention. Strengths are the consecutive design, patients handled by the same multidisciplinary

323 team, and complete follow-up.

324

325 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.

332 **REFERENCES**

- 333 [1]Halsema EE van. Self-expandable metal stents for malignant gastric outlet obstruction: A pooled 334 analysis of prospective literature. WJG 2015; 21: 12468. doi:10.3748/wjg.v21.i43.12468 335 [2] Brimhall B, Adler DG. Enteral Stents for Malignant Gastric Outlet Obstruction. Gastrointestinal 336 Endoscopy Clinics of North America 2011; 21: 389–403. doi:10.1016/j.giec.2011.04.002 337 [3] Del Nero L, Sheijani AD, De Ceglie A, et al. A Meta-Analysis of Endoscopic Stenting Versus Surgical 338 Treatment for Malignant Gastric Outlet Obstruction. World J Surg 2023; 47: 1519–1529. 339 doi:10.1007/s00268-023-06944-3 340 [4] Upchurch E, Ragusa M, Cirocchi R. Stent placement versus surgical palliation for adults with 341 malignant gastric outlet obstruction. Cochrane Database Syst Rev 2018; 5: CD012506. 342 doi:10.1002/14651858.CD012506.pub2 343 [5] Jeurnink SM, Steyerberg EW, van Hooft JE, et al. Surgical gastrojejunostomy or endoscopic stent 344 placement for the palliation of malignant gastric outlet obstruction (SUSTENT study): a 345 multicenter randomized trial. Gastrointestinal Endoscopy 2010; 71: 490-499. 346 doi:10.1016/j.gie.2009.09.042 347 [6] Suzuki O, Shichinohe T, Yano T, et al. Laparoscopic modified Devine exclusion gastrojejunostomy 348 as a palliative surgery to relieve malignant pyloroduodenal obstruction by unresectable cancer. 349 Am J Surg 2007; 194: 416-418. doi:10.1016/j.amjsurg.2007.02.011 350 [7] Jang S, Stevens T, Lopez R, et al. Superiority of Gastrojejunostomy Over Endoscopic Stenting for 351 Palliation of Malignant Gastric Outlet Obstruction. Clinical Gastroenterology and Hepatology 352 2019; 17: 1295-1302.e1. doi:10.1016/j.cgh.2018.10.042 353 [8] Kumagai K, Rouvelas I, Ernberg A, et al. A systematic review and meta-analysis comparing partial 354 stomach partitioning gastrojejunostomy versus conventional gastrojejunostomy for malignant 355 gastroduodenal obstruction. Langenbecks Arch Surg 2016; 401: 777–785. doi:10.1007/s00423-356 016-1470-8 357 [9] Chandan S, Khan SR, Mohan BP, et al. EUS-guided gastroenterostomy versus enteral stenting for 358 gastric outlet obstruction: Systematic review and meta-analysis. Endosc Int Open 2021; 09: 359 E496-E504. doi:10.1055/a-1341-0788 [10] Van Wanrooij RLJ, Bronswijk M, Kunda R, et al. Therapeutic endoscopic ultrasound: European 360 361 Society of Gastrointestinal Endoscopy (ESGE) Technical Review. Endoscopy 2022; 54: 310–332. 362 doi:10.1055/a-1738-6780 363 [11] Yamao K, Kitano M, Kayahara T, et al. Factors predicting through-the-scope gastroduodenal 364 stenting outcomes in patients with gastric outlet obstruction: a large multicenter retrospective 365 study in West Japan. Gastrointestinal Endoscopy 2016; 84: 757-763.e6. 366 doi:10.1016/j.gie.2016.03.1498 367 [12] Kobayashi S, Ueno M, Kameda R, et al. Duodenal stenting followed by systemic chemotherapy 368 for patients with pancreatic cancer and gastric outlet obstruction. Pancreatology 2016; 16: 369 1085-1091. doi:10.1016/j.pan.2016.07.007
- [13] Kobayashi S, Ueno M, Nagashima S, et al. Association between time to stent dysfunction and the
 anti-tumour effect of systemic chemotherapy following stent placement in patients with

- 372pancreaticobiliary cancers and malignant gastric outlet obstruction: a retrospective cohort373study. BMC Cancer 2021; 21: 576. doi:10.1186/s12885-021-08336-z
- [14] Hodo Y, Takatori H, Komura T, et al. Prognostic impact of clinical outcome after endoscopic
 gastroduodenal stent placement for malignant gastric outlet obstruction: a multicenter
 retrospective cohort study using a time-dependent analysis. Therap Adv Gastroenterol 2023;
 16: 17562848231156279. doi:10.1177/17562848231156279
- [15] Takamatsu Y, Fujimori N, Miyagahara T, et al. The Glasgow Prognostic Score and stricture site
 can predict prognosis after endoscopic duodenal stent placement for malignant gastric outlet
 obstruction. Sci Rep 2022; 12: 9746. doi:10.1038/s41598-022-13209-x
- [16] von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies
 in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin
 Epidemiol 2008; 61: 344–349. doi:10.1016/j.jclinepi.2007.11.008
- [17] Statement on ASA Physical Status Classification System. . Im Internet:
 https://www.asahq.org/standards-and-practice-parameters/statement-on-asa-physical-status classification-system; Stand: 21.11.2023
- [18] ECOG Performance Status Scale. ECOG-ACRIN Cancer Research Group. Im Internet: https://ecog-acrin.org/resources/ecog-performance-status/; Stand: 21.11.2023
- [19] Mutignani M, Tringali A, Shah SG, et al. Combined endoscopic stent insertion in malignant biliary
 and duodenal obstruction. Endoscopy 2007; 39: 440–447. doi:10.1055/s-2007-966327
- [20] Tamura T, Mamoru T, Terai T, et al. Gastrojejunostomy versus endoscopic duodenal stent
 placement for gastric outlet obstruction in patients with unresectable pancreatic cancer: a
 propensity score-matched analysis. Surg Endosc 2023; 37: 1890–1900. doi:10.1007/s00464 022-09685-x
- [21] Larssen L, Medhus AW, Hauge T. Treatment of malignant gastric outlet obstruction with stents:
 An evaluation of the reported variables for clinical outcome. BMC Gastroenterology 2009; 9:
 45. doi:10.1186/1471-230X-9-45
- 398 [22] Hori Y, Naitoh I, Hayashi K, et al. Predictors of outcomes in patients undergoing covered and
 399 uncovered self-expandable metal stent placement for malignant gastric outlet obstruction: a
 400 multicenter study. Gastrointestinal Endoscopy 2017; 85: 340-348.e1.
 401 doi:10.1016/j.gie.2016.07.048
- 402 [23] Jung K, Ahn JY, Jung H-Y, et al. Outcomes of endoscopically inserted self-expandable metal
 403 stents in malignancy according to the type of stent and the site of obstruction. Surg Endosc
 404 2016; 30: 4001–4010. doi:10.1007/s00464-015-4712-x
- [24] Reijm AN, Zellenrath PA, Bogt RD van der, et al. Self-expandable duodenal metal stent
 placement for the palliation of gastric outlet obstruction over the past 20 years. Endoscopy
 2022; 54: 1139-1146. doi:10.1055/a-1838-5642
- [25] Yoshida Y, Fukutomi A, Tanaka M, et al. Gastrojejunostomy versus duodenal stent placement for
 gastric outlet obstruction in patients with unresectable pancreatic cancer. Pancreatology 2017;
 17: 983–989. doi:10.1016/j.pan.2017.09.011

- [26] Tringali A, Costa D, Anderloni A, et al. Covered versus uncovered metal stents for malignant
 gastric outlet obstruction: a systematic review and meta-analysis. Gastrointestinal Endoscopy
- 413 2020; 92: 1153-1163.e9. doi:10.1016/j.gie.2020.06.033
- [27] Hamada T, Hakuta R, Takahara N, et al. Covered versus uncovered metal stents for malignant
 gastric outlet obstruction: Systematic review and meta-analysis. Digestive Endoscopy 2017; 29:
 259–271. doi:10.1111/den.12786
- [28] Miyabe K, Hayashi K, Nakazawa T, et al. Safety and benefits of self-expandable metallic stents
 with chemotherapy for malignant gastric outlet obstruction: SEMS and chemotherapy for
 MGOO. Digestive Endoscopy 2015; 27: 572–581. doi:10.1111/den.12424
- [29] Kim C, Park S, Choi I, et al. Effect of chemotherapy on the outcome of self-expandable metallic
 stents in gastric cancer patients with malignant outlet obstruction. Endoscopy 2012; 44: 807–
 812. doi:10.1055/s-0032-1309893
- [30] Grunwald D, Cohen J, Bartley A, et al. The location of obstruction predicts stent occlusion in
 malignant gastric outlet obstruction. Therap Adv Gastroenterol 2016; 9: 815–822.
 doi:10.1177/1756283X16667893
- [31] Mendelsohn RB, Gerdes H, Markowitz AJ, et al. Carcinomatosis is not a contraindication to
 enteral stenting in selected patients with malignant gastric outlet obstruction. Gastrointestinal
 Endoscopy 2011; 73: 1135–1140. doi:10.1016/j.gie.2011.01.042
- [32] Wei T-H, Ye B-W, Wu P-S, et al. Outcomes of patients with malignant duodenal obstruction after
 receiving self-expandable metallic stents: A single center experience. PLoS ONE 2022; 17:
 e0268920. doi:10.1371/journal.pone.0268920
- [33] Jang JK, Song H-Y, Kim JH, et al. Tumor Overgrowth After Expandable Metallic Stent Placement:
 Experience in 583 Patients With Malignant Gastroduodenal Obstruction. American Journal of
 Roentgenology 2011; 196: W831-W836. doi:10.2214/AJR.10.5861
- [34] Yamashige D, Hijioka S, Nagashio Y, et al. Incidence and factors associated with stent
 dysfunction and pancreatitis after gastroduodenal stenting for malignant gastric outlet
 obstruction. Endosc Int Open 2024; 12: E367–E376. doi:10.1055/a-2261-2833
- [35] Jue TL, Storm AC, Naveed M, et al. ASGE guideline on the role of endoscopy in the management
 of benign and malignant gastroduodenal obstruction. Gastrointestinal Endoscopy 2021; 93:
 309-322.e4. doi:10.1016/j.gie.2020.07.063
- [36] Oliveira JF de, Franco MC, Rodela G, et al. Endoscopic ultrasound-guided gastroenterostomy
 (gastroenteric anastomosis). International Journal of Gastrointestinal Intervention 2022; 11:
 112–118. doi:10.18528/ijgii220024
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FIGURE AND TABLE LEGENDS

- **Figure 1.** Flow chart for patient inclusion and exclusion.
- **Figure 2.** Kaplan-Meier analysis presenting overall survival depending on stent patency at 3 months.
- 448449 Table 1. Descriptive statistics of baseline characteristics.
- **Table 2.** Outcome measures and Adverse Events
- **Table 3.** Univariable and multivariable logistic regression analysis of factors predicting stent patency452 at 3 months.

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Table 1. Descriptive statistics of baseline characteristics

Variable	Overall	Pre	Peri (papillar	Post (papillar	p-
	$N = 198^{1}$	(papillary) n=116 ¹	y) n=71 ¹	(papinal y) $n=11^{1}$	e 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)	
Duodenai/ 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

Table 2. Outcome Measures and Adverse Events

Variable	Overall	Pre	Peri	Post	p-
	$N = 198^{1}$	(papillary) n= 116 ¹	(papillary) n =71 ¹	(papillary) n=11 ¹	
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)	
					<0.00
Biliary drain	100 (55)			11 (100)	1
No	109 (55)	71 (61)	27 (38)	11 (100)	
Before	51 (26)	22 (19)	29 (41)	0(0)	
procedure	38 (19)	23 (20)	15 (21)	0 (0)	
Length of	3 (1-10)	3 (1-10)	3 (1-10)	2 (2-6)	0.957
Clinical	100 (OE)	110 (05)	67 (04)	11 (100)	>0.99
success	188 (95)	110 (95)	07 (94)	11 (100)	9
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	70 (25)	26 (21)	20 (41)		0.004
failure, confirmed	/0 (35)	36 (31)	29 (41)	5 (45)	0.284
Reinterventi on	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)	

Туре					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 ¹ n (%); Median	26 (13) (25%-	102 (88)	60 (85)	10 (91)	0.825

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

Univariable 473		95%		Multivariable	
Characteristic Sex Female			p-value	OK ²	95% CI [⊥]
Male	0.93	0.46,	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		1.40			

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

No	—				
Yes	0.95	0.47, 1.91	0.876		
Jaundice No	_	_			1 0 0
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,	0.002	11.1	3.03, 50.0
Stricture site Pre	_	_			5010
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, Cl, Confidence Interval CA19-9, Cancer-associated Antigen, ASA, American Society of Anesthesiologists, ECOG, Eastern Cooperative Oncology Group					

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- 72 patients were registered twice
- 119 patients were wrongfully coded (Endoscopic dilation, only ERCP procedure, nonmalignant cause for duodenal stenting e.g., Chronic pancreatitis, iatrogenic perforation, or duodenal fistulas)
- 25 patients had altered surgical anatomy before or shortly after duodenal stenting (e.g., Whipple or gastric tube with esophagectomy)
- 7 patients had missing data.

