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Biliary stenting is not a prerequisite to endoscopic placement of duodenal covered self-expandable metal stents

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Abstract
Background Duodenal covered self-expandable metal stent (cSEMS) can be used in malignant or benign gastroduodenal obstruction. The need for biliary stenting in patients with no concomitant biliary stricture, before duodenal cSEMS placement, remains unknown. The aim of this study was to determine whether cSEMS placement is responsible for biliary obstruction.
Methods This is a single-center, retrospective, case-controlled study, including 106 patients with symptomatic gastric outlet obstruction or duodenal fistula who received a covered nitinol duodenal stent by using through-the-scope/over-the-wire placement procedure. The main outcome measurement was the occurrence comparison of jaundice and bilirubin level, between patients with previous or concomitant biliary stenting (cSEMS + BS group), and patients with no biliary stent (cSEMS group) during an observational period of 90 days.
Results Hundred and six patients underwent cSEMS placement between June 2005 and March 2014: 53 in the cSEMS group (58 % male, mean age 66.4 ± 13.3 years) and 53 in cSEMS + BS group (60 % male, mean age 70.4 ± 11.6 years). The obstruction was due to cancer in 45 % in cSEMS group and 87 % in cSEMS + BS group. No case of jaundice was reported in the cSEMS group or in the cSEMS + BS group. In cSEMS group, the mean bilirubin level (μmol/L ± SD) was 8.0 ± 4 at baseline and 8.5 ± 4.6 at day 10, while in the cSEMS + BS group it was 91.4 ± 108 at baseline and 35.3 ± 39 at day 10 ($p < 0.01$). Patients from the two groups were matched on age, gender and bilirubin level at baseline. Evolution of bilirubinemia was +0.98 ± 2.76 μmol/L in experimental group and +0.39 ± 522 μmol/L in the control group ($p = 0.34$). No significant difference was observed between the two groups in term of technical success, clinical effectiveness, migration and other complications.
Conclusions Previous biliary stenting is not required before endoscopic covered duodenal stent placement in patients with no associated biliary obstruction. Prospective studies are needed.

Keywords Gastric outlet obstruction · Duodenal fistula · Covered duodenal stent · Biliary stent · Jaundice · Biliary adverse events

Gastric outlet obstruction (GOO) is a therapeutic challenge. As causation is usually advanced gastric, duodenal or biliopancreatic cancer, relief of GOO symptoms and improvement of oral intake are the primary goals in such advanced malignancies. Endoscopic placement of a duodenal self-expandable metallic stent (SEMS) has emerged as a broadly accepted first-line palliative treatment for patients with advanced malignant gastroduodenal obstruction [1], as the procedure has higher clinical success rates, lower

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morbidity and mortality rates, and shorter length of hospital stay than surgical gastrojejunostomy [2, 3]. Moreover, these patients are mostly poor surgical candidates.

Uncovered SEMS are widely used in these indications despite recurrent obstruction due to tumor ingrowth or hyperplasia [4]. Covered SEMS (cSEMS) have thus been developed in order to prevent tumor ingrowth [5] in malignant gastroduodenal obstruction. Although covered stents are associated with a more frequent rate of migration [6], cSEMS are removable and could represent an alternative to surgery or endoscopic dilation for benign mechanical obstruction such as peptic ulcer, chronic pancreatitis or radiation-induced stenosis [7]. cSEMS placement has been also described as an alternative treatment for duodenal fistula and surgical leakage [8]. However, placement of a cSEMS covering the major papilla may cause bile duct obstruction by mechanical occlusion of the ampulla of Vater. Despite the lack of data, some authors recommend concomitant biliary stenting to guarantee adequate bile outflow before duodenal cSEMS placement in the second duodenum [9–14], whereas other authors have suggested that the rate of biliary adverse events after cSEMS placement is overestimated [15]. It thus remains unknown whether biliary stenting is needed before cSEMS placement in patients without concomitant biliary stricture.

The aim of this study was to compare the occurrence of jaundice after duodenal cSEMS placement in patients with biliary stenting versus patients without biliary stenting.

Materials and methods

Patients and study design

The study was performed in accordance with the Declaration of Helsinki, good clinical practice and all applicable regulatory requirements. The local Clermont-Ferrand Institutional Review Board approved this clinical trial (IRB #00008526/Ref: 2014/CE44).

This observational study reviewed medical records of all patients who consecutively underwent endoscopic duodenal SEMS placement in our facility between June 2005 and March 2014. All patients presented either malignant or benign gastroduodenal stenosis with obstructive symptoms, i.e., nausea, vomiting, bloating with no oral intake or liquid-only intake [score $\leq$1 on the gastric outlet obstruction scoring system (GOOSS)], or duodenal fistula. Pyloroduodenal stenoses or fistulas were documented by CT scan, radiological opacification or endoscopy. Patients with uncovered SEMS were first excluded. Then, among patients with a covered SEMS, we excluded those in whom the papilla was not covered by the stent, those with nonfunctional previous biliary drainage and those with a temporary 7-day duodenal stent placed to access the papilla for a secondary retrograde biliary stent placement.

Patients with a cSEMS alone (cSEMS group) were defined as the experimental group and compared against patients with a cSEMS associated with functional biliary stenting (cSEMS + BS group) defined as the control group. In this control group, biliary stenting (BS) either preceded the duodenal stent or was performed at the same endoscopic time as duodenal stent placement but only when patients presented with associated biliary stricture.

In a second step, we applied a case-control study design to match patients from the two groups on age, gender and bilirubin level at baseline.

Equipment

Through-the-scope (TTS) silicon-covered nitinol Hanarostents (NDC Duodenum/Pylorus or DPC Duodenum/Pylorus, M.I. Tech, Korea) were used in all patients. The NDC stent has a body diameter of 20 mm, a flare diameter of 26 mm at the proximal tip and a length of 60, 90 or 110 mm. Both tips have an 18-mm uncovered bare portion. The DPC stent has a body diameter of 20 mm, a flare diameter of 40 mm at the proximal tip and a length of 90, 110 or 130 mm. Only the large proximal tip is uncovered over 20 mm, with body and distal tips remaining fully covered, the design aim being to prevent distal stent migration. The stents are tightly mounted on a TTS/OTW delivery system with an outer diameter of 10.2F (3.4 mm) and an overall length of 230 cm. They can be resheathed if deployed less than 70 %. Each tip of the stent carries four radiopaque gold marks. Endoscopes used were a side-viewing duodenoscope with a working channel of 4.2 mm (TJF 160, Olympus Tokyo, Japan), a colonoscope with a working channel 3.8 mm (AOI 180, Olympus) or a 2-channel gastroscope with a working channel of 3.7 mm (GIF-2T200, Olympus).

Procedure

Written informed consent was obtained from all patients prior to endoscopic procedures. All procedures were performed with patients in supine position, intubated and sedated with propofol, in an interventional endoscopy room, under endoscopic and fluoroscopic guidance. In a first step, 50 cm^3 of Telebrix 30 ® was injected via the working channel of the endoscope to assess stenosis length and morphology. A guidewire (0.035 inch Dreamwire, Boston Scientific) was passed through the stenosis using an ERCP catheter (Tandem XL 5.5F, Boston Scientific) and advanced to the angle of Treitz. If the gastroduodenal stenosis was difficult to catheterize, the patient was placed in left lateral decubitus to facilitate catheterization. When initial

opacification was unable to assess stenosis length and locate the distal end of the stenosis because it was too tight, opacification had to be performed via the triple lumen catheter advanced over the guidewire. If required, the wire was exchanged with an extra-stiff 430-cm guidewire (Wallstent/Boston Scientific) to enable insertion of the delivery device if the duodenal anatomy presents an angulated distortion. The stent delivery system was then advanced over the guidewire through the stricture, under fluoroscopic guidance. The sheath was slowly withdrawn in continuous motion but frequently repositioning the proximal stent tip due to its tendency to move away from the scope. The stent was deployed from its distal tip, located in the third duodenum, to its proximal tip, through the pylorus, under fluoroscopic and endoscopic control. The stent was at least 4 cm longer than the stenosis (2 cm longer at each end) in order to cover the entire stenosis and anticipate post-procedure stent shortening due to continued radial stent expansion. Balloon dilation before or after stent placement was not performed as suspected to increase risk of perforation. Adequacy of stent placement and stent performance was assessed after stent deployment by endoscopy and fluoroscopy using a contrast injection through the scope (Fig. 1). In all patients with concomitant biliary stricture, a biliary metal stent was inserted by endoscopic retrograde, EUS-guided or percutaneous antegrade route if ERCP failed. When a biliary metal stent had already been placed before duodenal obstruction, this stent was left in place.

Definitions

Technical success was defined as successful stent deployment through the stricture with established patency confirmed by a good path of contrast medium through the stent and downstream under fluoroscopic guidance.

Clinical success was defined as relief of symptoms and resumption of diet (GOOSS $\geq$ 2) and duodenal fistula closure confirmed by endoscopic opacification after stent removal. Stent occlusion by tumor ingrowth or overgrowth was defined as recurrence of obstructive symptoms and evidence of GOO on endoscopy or barium radiography.

Stent migration was defined as gastric, small bowel or colon location of a cSEMS on endoscopy, fluoroscopic examination or CT scan.

Follow-up and study endpoint

Data were collected from medical records of clinical follow-up visits with the endoscopist or oncologist at day 30, 60 and 90 or from hospital records when patients were still hospitalized. When data were missing from the medical records, we contacted the primary care physician and appropriate medical laboratories.

Follow-up was 90 days. All cSEMS in patients with benign indications were removed within this 90-day follow-up window. In these patients, if the stenosis was not calibrated after stent removal, another covered stent was placed until duodenal calibration was obtained. In patients with malignant disease, the covered stent was removed intraoperatively if the patient underwent surgery after initial stent placement, or left in place otherwise.

Primary endpoint was the occurrence of jaundice after cSEMS placement. Secondary endpoints were bilirubinemia at baseline compared to day 10, technical success, clinical success, migration rate and other adverse events including pancreatitis, stent occlusion, perforation, gastrointestinal bleeding and peritonitis.

Statistical analysis

Data were collected and managed using REDCap [16] electronic data capture tools hosted at Clermont-Ferrand University Hospital. Baseline characteristics are expressed as mean $\pm$ standard deviation. Categorical variables were compared between groups using a Chi-squared test (or Fisher's exact test when necessary). Quantitative variables were compared using the Student's *t* test (or Kruskal–Wallis test). Intra-group comparisons of bilirubin levels at baseline and after stent placement were performed using the paired Student's *t* test. Survival and adverse event-free survival were assessed using the Kaplan–Meier method. Between-group comparisons were carried out without adjustment using the log-rank test and with adjustment using the Cox model. Propensity score matching was performed to correct the bias associated with use of biliary stenting. A

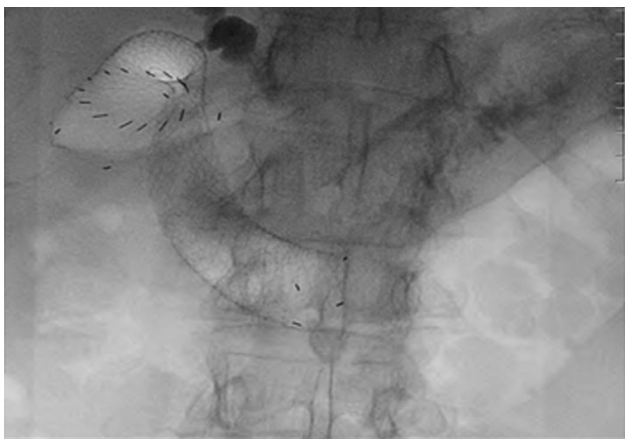

Fig. 1 Covered duodenal stent without biliary stenting: fluoroscopic view

propensity score was generated for each patient by running a logistic regression with technique as dependent variable and age, gender and initial bilirubin included as covariates. Patients were propensity score-matched using radius matching, no replacement and 0.1 caliper width. A two-tailed p value < 0.05 was considered statistically significant. Statistical analyses were performed using STATA v12 (Stata Corp, College Station, Texas, USA). Data were analyzed according to Strengthening the Reporting of Observational Studies in Epidemiology guidelines for reporting observation studies.

Results

From June 2005 to March 2014, 280 patients underwent 367 duodenal SEMS placement procedures. Of these, 127 patients with uncovered SEMS were excluded. Of the remaining 153 patients who underwent a covered SEMS placement procedure, we excluded nine patients with a stent that did not bridge the papilla, 28 patients who underwent a temporary 7-day stent in order to secondarily access the papilla and 10 patients with a nonfunctional previous biliary stent (Fig. 2).

Thus, 106 patients were finally included: 53 in the cSEMS group (58 % male, mean age 66.4 ± ± 14.6 years) and 53 in the cSEMS + BS group (60 % male, mean age 70.4 ± 11.6 years). Gastroduodenal obstruction was due to malignant disease in 24 patients (45 %) in the cSEMS group and 46 patients (87 %) in the cSEMS + BS group. Among the cSEMS + BS group patients, 26 (49 %) had previous biliary stenting and 27 (51 %) required concomitant biliary stenting due to associated biliary tract stenosis. Patient characteristics are reported in Table 1.

Technical success was achieved in 100 % of patients in both groups. Clinical success was achieved 88 % of cSEMS group patients and 90 % of cSEMS + BS group patients, without significant difference ($p = 0.73$). No cases of jaundice or cholangitis were reported in either the cSEMS or cSEMS + BS groups during the 90-day follow-up period. In the cSEMS group, mean bilirubin level (±SD) was 8.0 ± 4 μmol/L at baseline rising to 8.5 ± 4.6 μmol/L at day 10 ($p = 0.43$). In the cSEMS + BS group, mean bilirubin level was 91.4 ± 107.8 μmol/L at baseline and then fell significantly to 34.7 ± 40.8 μmol/L at day 10 ($p < 0.001$). Pre- versus post-procedure difference in bilirubin levels was +0.5 ± 3.5 μmol/L in the cSEMS group and −56.7 ± 82.7 μmol/L in the cSEMS + BS group ($p < 0.001$). There were 27 (25 %) cases of stent migration: 15 (28 %) in the cSEMS group and 12 (22 %) in the cSEMS + BS group ($p = 0.50$). Two patients (2 %) presented with cSEMS occlusion: one (2 %) in the cSEMS group and one (2 %) in the cSEMS + BS group ($p = 1$).

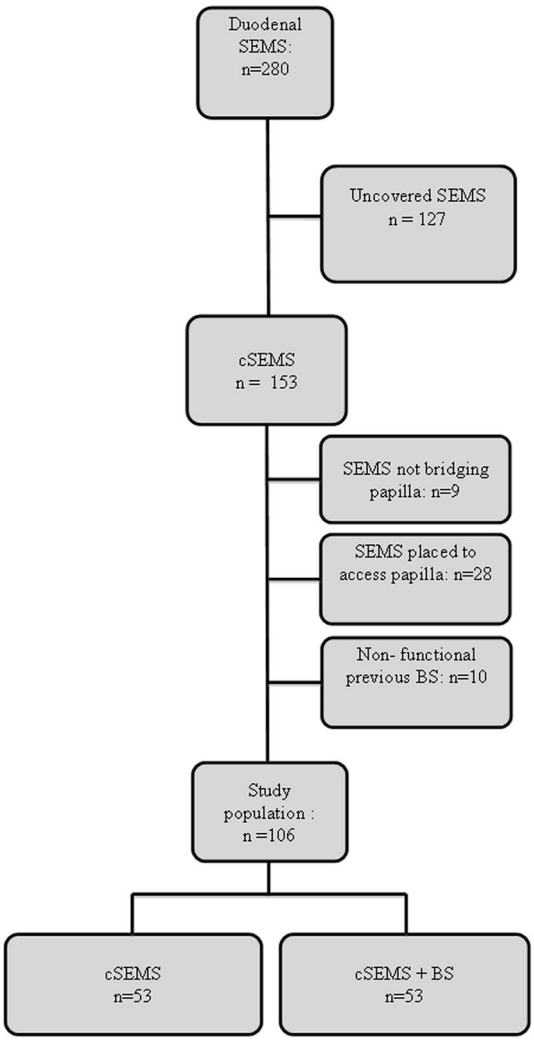

Fig. 2 Patients selection

Gastrointestinal bleeding occurred in two cases (2 %): one (2 %) in the cSEMS group and one (2 %) in the cSEMS + BS group, on days 2 and 30, respectively, after cSEMS placement. Both bleeding episodes were related to an ulcer located at the upper cSEMS tip and were treated successfully with medical therapy (proton-pump inhibitor). One case of duodenal perforation occurred in the cSEMS + BS group (2 %), none in cSEMS group ($p = 1$). One case (2 %) of biliary peritonitis was reported in the cSEMS + BS group after EUS-guided biliary drainage. Only the best supportive care was offered to both these patients, who presented with terminal illness and died at days 26 and 7 post-procedure, respectively. There were no reported cases of stent incarceration. We found one case (2 %) of edematous pancreatitis after stent retrieval in a patient with no biliary stenting *vs* no cases in the cSEMS + BS group ($p = 1$). Death was recorded in seven (13 %) cSEMS group patients and in 14 (26 %) cSEMS + BS group patients. All deaths were related to

Table 1 Patients characteristics at baseline

	All $n = 106$	cSEMS group $n = 53$	cSEMS + BS group $n = 53$	p value
Male gender	63 (59)	30 (58)	32 (60)	0.84
Age (years old)	68.4 ± 13.3	66.4 ± 14.6	70.4 ± 11.6	0.17
Indication *n* (%)				
Malignant disease	70 (66)	24 (45)	46 (87)	<0.001
Pancreatic adenocarcinoma	39 (36)	13 (25)	26 (49)	
Cholangiocellular carcinoma	5 (5)	1 (2)	4 (8)	
Ampullary carcinoma	7 (7)	0 (0)	7 (13)	
Gastric cancer	6 (6)	6 (11)	0 (0)	
Gallbladder cancer	2 (2)	0 (0)	2 (4)	
Duodenal adenocarcinoma	3 (3)	1 (2)	2 (4)	
Other cancer	8 (8)	3 (6)	5 (9 %)	
Benign disease	36 (34)	29 (55)	7 (13)	<0.001
Radiation-induced stenosis	4 (4)	3 (6)	1 (2)	
Stenosis due to duodenal ulcer	7 (7)	7 (13)	0 (0)	
Stenosis due to acute pancreatitis	3 (3)	3 (6)	0 (0)	
Stenosis due to chronic pancreatitis	15 (14)	10 (19)	5 (9)	
Caustic stenosis	1 (1)	1 (2)	0 (0)	
Duodenal fistula	6 (6)	5 (9)	1 (2)	
Bilirubin level at baseline (μmol/L) ± SD	53.4 ± 88.5	9.3 ± 5.8	90.3 ± 106.9	<0.001

cSEMS covered self-expandable metal stent, *BS* biliary stenting

advanced course of malignant disease. Outcomes of the 106 procedures are reported in Table 2.

In a second investigation, patients from both groups were matched on age, gender and bilirubin level at baseline (Table 3), enabling us to compare 19 patients in the experimental group (cSEMS alone) against 15 patients in the control group (cSEMS + BS). Outcomes after the matching procedure are reported in Table 4. There were no cases of jaundice in either the experimental group or the control group during the 90-day follow-up period. Evolution of bilirubinemia was 0.98 ± 2.76 μmol/L in the experimental group and 0.39 ± 522 μmol/L in the control group, without statistically significant difference between groups ($p = 0.34$) (Fig. 3).

Discussion

Currently, covered duodenal stenting can be performed in several situations in benign and malignant diseases. In cases of malignant obstruction, temporary cSEMS placement with perioperative stent removal is useful in patients scheduled for surgery, as it can enable preoperative oral feeding or enteral feeding by nasojejunal tube placement and surgical pylorus preservation in resection by the Whipple procedure. Similarly, cSEMS are useful in patients with unknown resectable status and in patients pending histological proof, especially in emergency procedures. In cases of benign gastroduodenal obstruction, cSEMS placement could prove useful after unsuccessful endoscopic dilation or as an alternative to surgery. Indeed, temporary stent placement in peptic ulcer stenosis can be expected to be beneficial, as dilation in the stenotic portion is more gradual and sustained than endoscopic dilation [17–20]. In cases of paraduodenal pancreatitis, cSEMS placement could be useful after unsuccessful medical treatment, associating Taylor's method and subcutaneous injections of somatostatin analogs. Moreover, a growing number of GOO cases involve radiation-induced stenosis of the duodenum, and our own institution is increasingly using chemoradiotherapy after initial disease control under chemotherapy in patients treated for locally advanced pancreatic adenocarcinoma, in line with the GERCOR protocol [21]. Moreover, temporary 7-day cSEMS placement could also be useful to access the ampulla of Vater 7 days later and achieve secondary retrograde biliary drainage in patients with failed ERCP due to an initial duodenal stenosis. This explains the exclusion of 28 patients who underwent cSEMS placement in this indication (Fig. 2). Most recently, case studies have suggested the potential efficiency of cSEMS in the treatment of gastrointestinal fistula or postsurgical leakage [8].

Table 2 Main outcomes

	All $n = 106$	cSEMS group $n = 53$	cSEMS + BS group $n = 53$	p value
Jaundice or cholangitis	0	0	0	1
Bilirubin levels (μmol/L) ± SD				
Bilirubin at baseline	53.4 ± 88.5	9.3 ± 5.8	90.3 ± 106.9	<0.001
Bilirubin at day 10	23.6 ± 32.9	8.5 ± 4.6	35.3 ± 39.9	<0.001
Evolution	−31.6 ± 68.1	0.5 ± 3.5	−56.2 ± 82.7	<0.001
Technical success	106 (100)	53 (100)	53 (100)	1
Clinical success	94 (93)	46 (88)	48 (91)	0.73
Other adverse events				
Migration	27 (25)	15 (28)	12 (23)	0.5
Gastrointestinal bleeding	2 (2)	1 (2)	1 (2)	1
Duodenal perforation	1 (1)	0 (0)	1 (2)	1
Stent obstruction	2 (2)	1 (2)	1 (2)	0.86
Biliary peritonitis	1 (1)	0 (0)	1 (2)	1
Acute pancreatitis after stent retrieval	1 (1)	1 (2)	0 (0)	0.5
Death (all causes)	21 (20)	7 (13)	14 (26)	0.09

cSEMS covered self-expandable metal stent, *BS* biliary stenting

Table 3 Patient characteristics after the matching procedure

	All $n = 34$	cSEMS group $n = 19$	cSEMS + BS group $n = 15$	p value
Male gender	21 (62 %)	12 (63 %)	9 (60 %)	0.85
Age (years old)	71 ± 12	71 ± 11	71 ± 13	0.93
Indication				
Malignant disease	22 (65 %)	11 (58 %)	11 (73 %)	0.35
Benign disease	12 (35 %)	8 (42 %)	4 (27 %)	0.35
Bilirubin level at baseline				
(μmol/L) ± SD	9.8 ± 6.36	9.47 ± 5.66	10.17 ± 7.00	0.38

cSEMS covered self-expandable metal stent, *BS* biliary stenting, *SD* standard deviation

Table 4 Outcomes after the matching procedure

	All: $n = 34$	cSEMS group: $n = 19$	cSEMS + BS group: $n = 15$	p value
Jaundice or cholangitis	0	0	0	1
Evolution in bilirubin level (μmol/L) ± SD	0.69 ± 4	0.98 ± 2.76	0.39 ± 5.22	0.34
Technical success	34 (100 %)	19 (100 %)	15 (100 %)	1
Clinical success	31 (93 %)	18 (95 %)	13 (87 %)	0.2
Other adverse events				
Migration	9 (26 %)	4 (21 %)	5 (33 %)	0.46
Gastrointestinal bleeding	1 (2.94 %)	1 (5.26 %)	0 (0 %)	1
Stent obstruction	2 (5.88 %)	1 (5.26 %)	1 (6.67 %)	1
Death	5 (14.71 %)	2 (10.53 %)	3 (20 %)	0.43

cSEMS covered self-expandable metal stent, *BS* biliary stenting, *SD* standard deviation

Biliary stricture is associated with malignant gastroduodenal obstruction in only 60 % of cases [22]. In benign condition, associated biliary stricture is rare and occurs mostly in patients with advanced chronic pancreatitis. Some teams recommend systematic concomitant biliary stenting to guarantee adequate bile outflow before

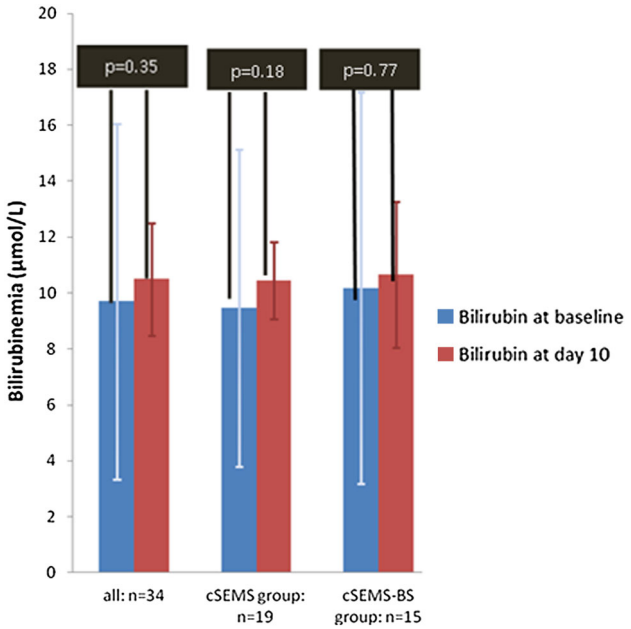

Fig. 3 Evolution of bilirubinemia before and after SEMS placement is subjects matched for age gender and bilirubinemia

duodenal cSEMS placement whenever papilla occlusion is expected [9–14]. However, this recommendation appears to be based on a theoretical risk of mechanical occlusion of the papilla that could lead to jaundice or cholangitis: Indeed, data come from small case-series and observational retrospective studies with various types of covered stents. None of those studies were designed to focus on this specific issue. Furthermore, cases of obstructive jaundice despite biliary stenting have been reported [11], and some teams report lower rates of biliary adverse events after cSEMS placement [23, 24].

Another point supporting concomitant biliary stenting is the presumed inaccessibility of the common bile duct after cSEMS placement [11]. However, covered stents are removable, even at 3 months after initial placement. Thus, after covered stent removal, secondary access to the papilla can be achieved in cases of initially impassable duodenal stricture. We found no cases of stent fracture or incarceration or difficulties during covered stent retrieval.

On the other hand, concomitant or previous common bile duct drainage can lead to specific and sometimes life-threatening adverse events such as post-ERCP pancreatitis or bleeding. A second antegrade or retrograde biliary stent is costly and time-consuming to place compared to single duodenal stent. Cases of advanced pancreatic cancer or chronic pancreatitis can make fail retrograde biliary stenting due to periampullary tumor infiltration or altered ampulla position, respectively, and may require antegrade EUS-guided or percutaneous biliary drainage, which bring their own specific morbidities, particularly risk of bile leak [25]. There was one case of bile leak with peritonitis in the cSEMS + BS group due to a concomitant EUS-guided biliary drainage. The issue of concomitant or previous biliary stenting before duodenal cSEMS placement thus remains crucial and as yet unresolved.

To our knowledge, this study reports the largest series in the literature to date on covered duodenal stents (Table 5). We report no case of jaundice in 53 patients with covered duodenal stents bridging the ampulla of Vater nor in a control group with duodenal covered stents associated with concomitant or previously efficient biliary stenting during a 3-month follow-up period. Patients receiving duodenal stents without biliary drainage showed no significant change in bilirubin levels after stent placement. This was confirmed by comparison of two patient groups re-matched on age, gender and bilirubin level at baseline, which found no between-group differences in terms of bilirubinemia patterns. The presence of a control group with associated biliary stenting is an important feature of this study design as it strengthens the evidence that duodenal cSEMS does not cause biliary obstruction. The follow-up period of 90 days after stent placement corresponds to the deadline beyond which cSEMS were retrieved in benign indications. Furthermore, previous studies reported cases of jaundice occurring from 2 to 73 days post-procedure (median = 10 days) [15, 23, 24]. We assume that this 90-day follow-up window associated with bilirubin measurement on day 10 was adequate to detect mechanical occlusion of the bile duct due to duodenal stent covering. Our results are consistent with Kim et al. [15], which is the only other study designed to assess this specific issue, despite a different study design and different endpoints. Kim et al. [15] studied duodenal cSEMS placed under fluoroscopic guidance by radiologists and reported only one case of stent-caused jaundice among nine patients receiving covered stent bridging the ampulla of Vater with no associated biliary stenting. Here, the primary endpoint was the occurrence of jaundice after stent placement and is associated with the secondary endpoint, i.e., bilirubinemia at baseline versus at day 10 after stent placement. The rationale for choosing these clinical and biological criteria was that patients with advanced malignancies or complicated benign diseases such as chronic pancreatitis may present increased bile duct diameter without cholestasis or jaundice. All patients in Kim's study presented with malignant disease, and CT scans were mandatory to distinguish malignant bile duct obstruction from obstruction due to the stent itself. This is contrast to our study, where 55 % of cSEMS group patients had benign disease. Thus, jaundice or cholestasis appears more suitable criteria than radiological criteria. To explain the absence of jaundice or cholestasis, we presume that despite mechanical contact between the impermeable silicon membrane of covered stents and the ampulla of Vater, bile flow is not interrupted: Indeed,

Table 5 Comparison of biliary adverse events reported after cSEMS placement in the second duodenal area

Author	Year	Journal	Design	Control group	Numbers	Associated BS	cSEMS without BS	Jaundice	Delay	Comments
JUNG [12]	2000	Radiology	Retrospective	NO	3	66.7 %	1	1	J1	–
SONG [23]	2004	JVIR	Retrospective	NO	24	91.7 %	2	2	J1, J73	1 case of jaundice despite BS
YOON [24]	2006	JVIR	Retrospective	NO	43	65.0 %	15	3	J7	cSEMS imputability not proven
KIM [15]	2008	JVIR	Retrospective	cSEMS versus SEMS	27	66.7 %	9	7	11	1 case of jaundice due to cSEMS itself—6 malignant biliary obstruction
DIDDEN [11]	2013	GIE	Prospective	NO	7	100.0 %	0	1	J 148	1 case of jaundice despite BS
WAIDMANN [5]	2013	WJG	Retrospective	cSEMS versus SEMS	16	50.0 %	8	0	–	
Current study	2014	–	Retrospective	cSEMS versus cSEMS + BD	106	50.0 %	53	0	–	

duodenal angulation and intense peristalsis probably help keep a gap between the stent and the duodenal wall, even when the stent is completely expanded, thus enabled continued bile outflow.

In conclusion, this study suggests that previous biliary stenting is not required before endoscopic covered duodenal stent placement in patients with no associated biliary obstruction. Further prospective randomized studies are needed to confirm these results.

Conflict of interest All authors have no conflict of interest to declare.

Disclosures L. Poincloux, F. Goutorbe, O. Rouquette, A. Mulliez, M. Goutte, G. Bommelaer, and A. Abergel have no conflicts of interest or financial ties to disclose.

References

1. Maire F, Hammel P, Ponsot P, Aubert A, O'Toole D, Hentic O, Levy P, Ruszniewski P (2006) Long-term outcome of biliary and duodenal stents in palliative treatment of patients with unresectable adenocarcinoma of the head of pancreas. Am J Gastroenterol 101(4):735–742
2. Del Piano M, Ballaré M, Montino F, Todesco A, Orsello M, Magnani C, Garello E (2005) Endoscopy or surgery for malignant GI outlet obstruction? Gastrointest Endosc 61(3):421–426
3. Chandrasegaram MD, Eslick GD, Mansfield CO, Liem H, Richardson M, Ahmed S, Cox MR (2012) Endoscopic stenting versus operative gastrojejunostomy for malignant gastric outlet obstruction. Surg Endosc 26(2):323–329
4. Costamagna G, Tringali A, Spicak J, Mutignani M, Shaw J, Roy A, Johnsson E, De Moura EG, Cheng S, Ponchon T, Bittinger M, Messmann H, Neuhaus H, Schumacher B, Laugier R, Saarnio J, Ariqueta FI (2012) Treatment of malignant gastroduodenal obstruction with a nitinol self-expanding metal stent: an international prospective multicentre registry. Dig Liver Dis 44(1):37–43
5. Lee SM, Kang DH, Kim GH, Park WI, Kim HW, Park JH (2007) Self-expanding metallic stents for gastric outlet obstruction resulting from stomach cancer: a preliminary study with a newly designed double-layered pyloric stent. Gastrointest Endosc 66(6):1206–1210
6. Waidmann O, Trojan J, Friedrich-Rust M, Sarrazin C, Bechstein WO, Ulrich F, Zeuzem S, Albert JG (2013) SEMS vs cSEMS in duodenal and small bowel obstruction: high risk of migration in the covered stent group. World J Gastroenterol 19(37):6199–6206
7. ASGE Standards of Practice Committee, Fukami N, Anderson MA, Khan K, Harrison ME, Appalaneni V, Ben-Menachem T, Decker GA, Fanelli RD, Fisher L, Ikenberry SO, Jain R, Jue TL, Krinsky ML, Maple JT, Sharaf RN, Dominitz JA (2011) The role of endoscopy in gastroduodenal obstruction and gastroparesis. Gastrointest Endosc 74(1):13–21
8. Choi HJ, Lee BI, Kim JJ, Kim JH, Song JY, Ji JS, Kim BW, Choi H, Choi KY (2013) The temporary placement of covered self-expandable metal stents to seal various gastrointestinal leaks after surgery. Gut Liver 7(1):112–115
9. Adler DG, Baron TH (2002) Endoscopic palliation of malignant gastric outlet obstruction using self-expanding metal stents: experience in 36 patients. Am J Gastroenterol 97(1):72–78
10. Baron TH, Schöfl R, Puespoek A, Sakai Y (2001) Expandable metal stent placement for gastric outlet obstruction. Endoscopy 33(7):623–628

11. Didden P, Spander MC, de Ridder R, Berk L, van Tilburg AJ, Leeuwenburgh I, Kuipers EJ, Bruno MJ (2013) Efficacy and safety of a partially covered stent in malignant gastric outlet obstruction: a prospective Western series. Gastrointest Endosc 77(4):664–668
12. Jung GS, Song HY, Kang SG, Huh JD, Park SJ, Koo JY, Cho YD (2000) Malignant gastroduodenal obstructions: treatment by means of a covered expandable metallic stent-initial experience. Radiology 216(3):758–763
13. Yates MR 3rd, Morgan DE, Baron TH (1998) Palliation of malignant gastric and small intestinal strictures with self-expandable metal stents. Endoscopy 30(3):266–272
14. Jeurnink SM, van Eijck CH, Steyerberg EW, Kuipers EJ, Siersema PD (2007) Stent versus gastrojejunostomy for the palliation of gastric outlet obstruction: a systematic review. BMC Gastroenterol 8(7):18
15. Kim SY, Song HY, Kim JH, Kim KR, Shin JH, Lee SS, Park SW (2008) Bridging across the ampulla of Vater with covered self-expanding metallic stents: is it contraindicated when treating malignant gastroduodenal obstruction? J Vasc Interv Radiol 19(11):1607–1613
16. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG (2009) Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 42(2):377–381
17. Choi WJ, Park JJ, Park J, Lim EH, Joo MK, Yun JW, Noh H, Kim SH, Choi WS, Lee BJ, Kim JH, Yeon JE, Kim JS, Byun KS, Bak YT (2013) Effects of the temporary placement of a self-expandable metallic stent in benign pyloric stenosis. Gut Liver 7(4):417–422
18. Binkert CA, Jost R, Steiner A, Zollikofer CL (1996) Benign and malignant stenoses of the stomach and duodenum: treatment with self-expanding metallic endoprostheses. Radiology 199(2):335–338
19. Dormann AJ, Deppe H, Wigginghaus B (2001) Self-expanding metallic stents for continuous dilatation of benign stenoses in gastrointestinal tract - first results of long-term follow-up in interim stent application in pyloric and colonic obstructions. Z Gastroenterol 39(11):957–960
20. ASGE Standards of Practice Committee, Banerjee S, Cash BD, Dominitz JA, Baron TH, Anderson MA, Ben-Menachem T, Fisher L, Fukami N, Harrison ME, Ikenberry SO, Khan K, Krinsky ML, Maple J, Fanelli RD, Strohmeyer L (2010) The role of endoscopy in the management of patients with peptic ulcer disease. Gastrointes. Endosc. 71(4):663–668
21. Huguet F, Andre T, Hammel P, Artru P, Balosso J, Selle F, Deniaud-Alexandre E, Ruszniewski P, Touboul E, Labianca R, de Gramont A, Louvet C (2007) Impact of chemoradiotherapy after disease control with chemotherapy in locally advanced pancreatic adenocarcinoma in GERCOR phase II and III studies. J Clin Oncol 25(3):326–331
22. Dormann A, Meisner S, Verin N, Wenk Lang A (2004) Self-expanding metal stents for gastroduodenal malignancies: systematic review of their clinical effectiveness. Endoscopy 36(6):543–550
23. Song HY, Shin JH, Yoon CJ, Lee GH, Kim TW, Lee SK, Yook JH, Kim BS (2004) A dual expandable nitinol stent: experience in 102 patients with malignant gastroduodenal strictures. J Vasc Interv Radiol 15(12):1443–1449
24. Yoon CJ, Song HY, Shin JH, Bae JI, Jung GS, Kichikawa K, Lopera JE, Castaneda-Zuniga W (2006) Malignant duodenal obstructions: palliative treatment using self-expandable nitinol stents. J Vasc Interv Radiol 17(2Pt1):319–326
25. Park DH, Jang JW, Lee SS, Seo DW, Lee SK, Kim MH (2011) EUS-guided biliary drainage with transluminal stenting after failed ERCP: predictors of adverse events and long-term results. Gastrointest Endosc 74(6):1276–1284