A new 12-French plastic stent for unresectable distal malignant biliary obstruction

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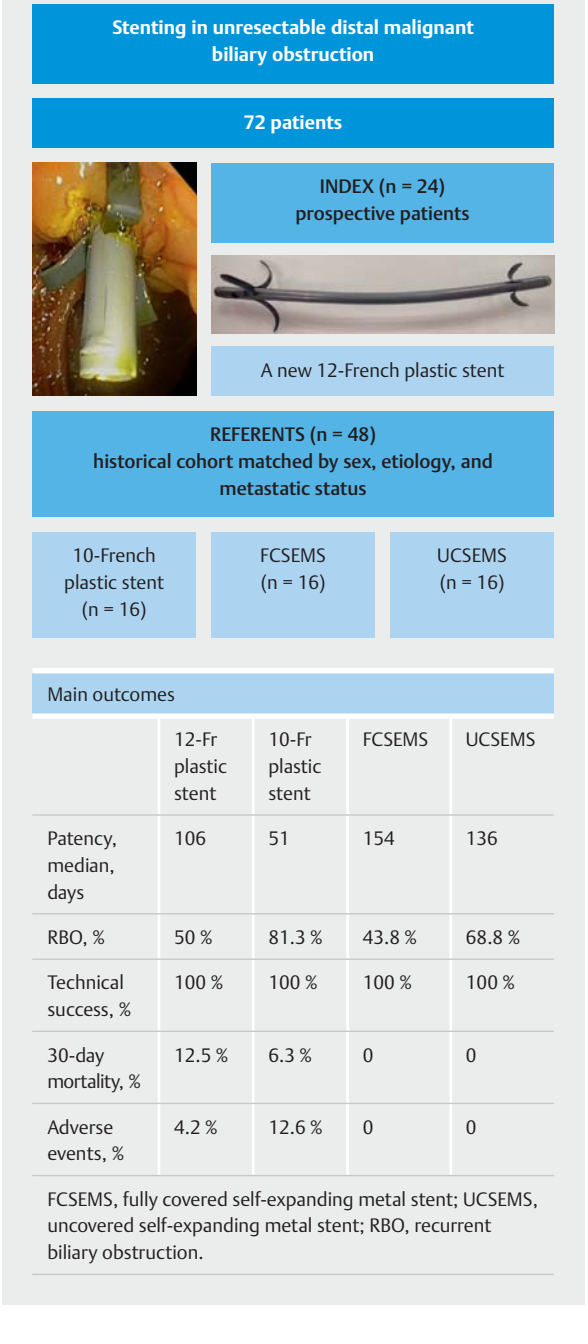
ABSTRACT

Background Self-expanding metal stents (SEMSs) are recommended in unresectable distal malignant biliary obstruction. However, problems with dysfunction and migration of these stents are not negligible. We aimed to investigate the effectiveness and safety of a new 12-Fr plastic stent.

Methods In an observational, prospective study, all consecutive patients who underwent biliary stenting with the 12-Fr stent were considered (index group). Referent groups were a historical cohort, matched by sex, etiology, and metastatic status, including patients with 10-Fr plastic stents and with fully covered and uncovered SEMSs (FCSEMSs and UCSEMSs). Outcomes were stent patency, recurrent biliary obstruction (RBO), technical success, 30-day mortality and adverse events. A post-procedure examination of removed stents was done.

GRAPHICAL ABSTRACT



Main outcomes

	12-Fr plastic stent	10-Fr plastic stent	FCSEMS	UCSEMS
Patency, median, days	106	51	154	136
RBO, %	50 %	81.3 %	43.8 %	68.8 %
Technical success, %	100 %	100 %	100 %	100 %
30-day mortality, %	12.5 %	6.3 %	0	0
Adverse events, %	4.2 %	12.6 %	0	0

FCSEMS, fully covered self-expanding metal stent; UCSEMS, uncovered self-expanding metal stent; RBO, recurrent biliary obstruction.

Results 72 patients (median age 66, range 32 – 94 years, 50 % men) were included (24 index, 48 referents). There were no differences in median stent patency time (P = 0.684). RBO was significantly lower with the 12-Fr compared with the 10-Fr profile stent (50 % vs. 81.3 %, P = 0.04), but no difference was found compared with the FCSEMSs (50 % vs. 43.8 %, P = 0.698). Technical success was 100 %, with no differences in 30-day mortality P = 0.105). The adverse events rate was 4.2 % for both groups (index n = 1, referents n = 2). Of 11 removed 12-Fr plastic stents suspected to be dysfunctional, 7 (64 %) were still patent.

Conclusions This new 12-Fr plastic stent could be an effective and cheaper alternative to SEMSs in distal malignant biliary obstruction.

Introduction

Endoscopic biliary stenting is a widely accepted palliative procedure for the management of unresectable malignant biliary obstruction [1]. Distal malignant biliary obstruction often presents at an advanced, unresectable stage. The use of plastic and self-expandable metal stents (SEMSs) has been described in this setting [2 – 4].

Regarding plastic stents, stent clogging occurs more rapidly in those with small diameter because of protein adsorption into their inner surface, with subsequent bacterial colonization due to duodenobiliary reflux [5]. A larger stent diameter may decrease the incidence of stent occlusion by sludge but increasing the size from 10 to 11.5 Fr has not been found to affect patency [6].

A recent ESGE Guideline recommends the use of self-expanding metal stents (SEMSs) in unresectable malignant disease [7]. SEMSs have shown less stent dysfunction, lower re-intervention rates, better survival, and higher patency time in recent meta-analyses [8, 9]. In addition, fully covered SEMSs (FCSEMs) may have a longer patency compared to uncovered SEMSs (UCSEMSs) at the expense of higher risks of migration [10] and tumor overgrowth [11]. Although SEMSs are more expensive than plastic stents, overall costs can be comparable because of the higher hospitalization costs in patients with plastic stents [7]. Finally, the use of stents with a partially covered metallic design has also been reported, with conflicting results [12, 13].

The purpose of this study was to address the effectiveness and safety of a new larger 12-Fr flexible single-use biliary plastic stent in distal malignant biliary obstruction. This large-bore biliary plastic stent is expected to increase patency to the level of that of a metal stent, with the advantage of much lower cost and lower migration rate.

Methods

Patients and design

This is a hospital-based, observational, prospective study, approved by the local Ethics Committee (reference 2014/20MAI/269).

All consecutive patients aged ≥ 18 years who underwent a therapeutic endoscopic retrograde cholangiopancreatography (ERCP) between March 2015 and June 2017 for a histologically proven distal malignant biliary obstruction were invited to participate in the study. Only those presenting with an unresectable or inoperable disease were considered. The definition of unresectability included locally advanced or metastatic disease. Inoperability was defined by the institutional multidisciplinary oncological consultation based on the patient's co-morbidities and age. Written informed consent was provided prior to enrollment in all cases.

Exclusion criteria were as follows:

- History of biliary surgery (except cholecystectomy)
- Life expectancy < 4 months (Karnovski score < 70)
- Participation in a clinical trial < 90 days prior to inclusion.
- Previous biliary drainage with a SEMS
- Altered anatomy precluding access to the ampulla, or making performance of conventional ERCP impossible
- Duodenal obstruction with previous metal stenting or need for stenting
- Ampullary tumor
- Hemobilia
- Refusal of or inability to obtain informed consent.

Age, sex and demographic variables were noted. The underlying diagnosis of distal malignant biliary obstruction, the reasons for inoperability, and current treatment (chemotherapy) were also recorded.

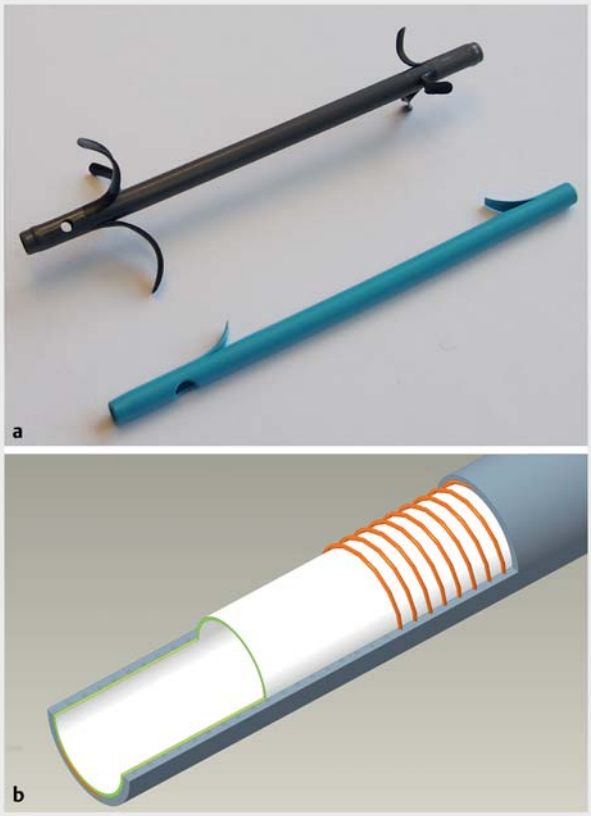
ERCP procedure

ERCP was performed with fluoroscopy and with patients under general anesthesia, by novice (< 3000 ERCPs; E.P.C.R.) and expert (P.D., T.M., T.A., H.P.) endoscopists, using a therapeutic duodenoscope (TJF-Q180V; Olympus Europe, Berchem, Belgium) with a 4.2-mm working channel. Antibiotics (ciprofloxacin 400 mg, intravenously) and rectal indomethacin were given before the procedure. Biliary endoscopic sphincterotomy was performed to ease access to the common bile duct.

A single 12-Fr plastic stent (PBD-Y0011) was used. The length of the stent between the side flaps (5, 7, or 9 cm) was chosen on the basis of the characteristics of the stenosis and bile duct. This new plastic stent has three layers, a proximal X-ray mark, three flaps at each end, and protective sleeves to keep the proximal and distal flaps straight. The inner layer is fluorine-coated, the intermediate layer is a metal coil metal and the outer layer is made of a special resin (▶ **Fig. 1**). The stent was inserted, without using the elevator function, by means of push-and-pull endoscope movements and up – down movement of the outer control knob.

The maximum diameter of the bile duct, the length of the stenosis and the length of the stent were noted. Previous ERCP data were collected if that had been performed.

Patients were discharged depending on their clinical course and need for further work-up or treatments.



▶ **Fig. 1** **a** A 12-Fr plastic stent (upper) and a standard 10-Fr plastic stent (lower). **b** Structure of the 12-Fr stent; the three layers include an intermediate metal coil layer. Source Olympus.

Outcomes and definitions

The following outcomes were assessed: stent patency, the recurrent biliary obstruction (RBO) rate, technical success, 30-day mortality, and adverse events.

The stent patency period was calculated as the interval between stent insertion and its dysfunction or patient death with a patent stent. RBO was recorded when a dysfunction (with or without cholangitis) or a symptomatic migration was observed. The time to RBO from stent insertion was calculated. Stent dysfunction was defined as a dilated bile duct with either biliary pain, presence of cholestasis (greater than twofold normal values), or presence of jaundice (total bilirubin > 3 mg/dL) with or without fever at least 48 h after the procedure. Stent occlusion in removed stents was further analyzed as described below.

Technical success was defined as correct positioning of the stent across the malignant stricture with appropriate radiographic positioning (at least 1 cm above and below the stricture with the distal end in the duodenum). The 30-day mortality was defined as death from any cause within 30 days of stent placement.

Adverse events were defined as previously reported [14] and classified as early or late depending on whether they happened < 30 days or ≥ 30 days, respectively. They included post-ERCP pancreatitis, cholecystitis, perforation, and bleeding.

Monitoring and follow-up

Blood biochemical values, including bilirubin, were monitored, before stent insertion, 1 day after insertion, and at 1 week, 1 month, and then every 3 months. Clinical signs and symptoms were monitored on an outpatient basis at monthly intervals. Overall patient survival was noted.

Stent occlusion analysis after removal

When 12-Fr plastic stents were removed endoscopically, the causes of obstruction or dysfunction were investigated by examining the removed stents.

First, an irrigation test was carried out. Removed stents were connected to an irrigation pump at different water pressures as shown in ▶ **Fig. 2**, to ascertain the degree of obstruction. Occlusion was defined as requirement of water pressure of ≥ 350 mmH_2O for flow through the stent [15].

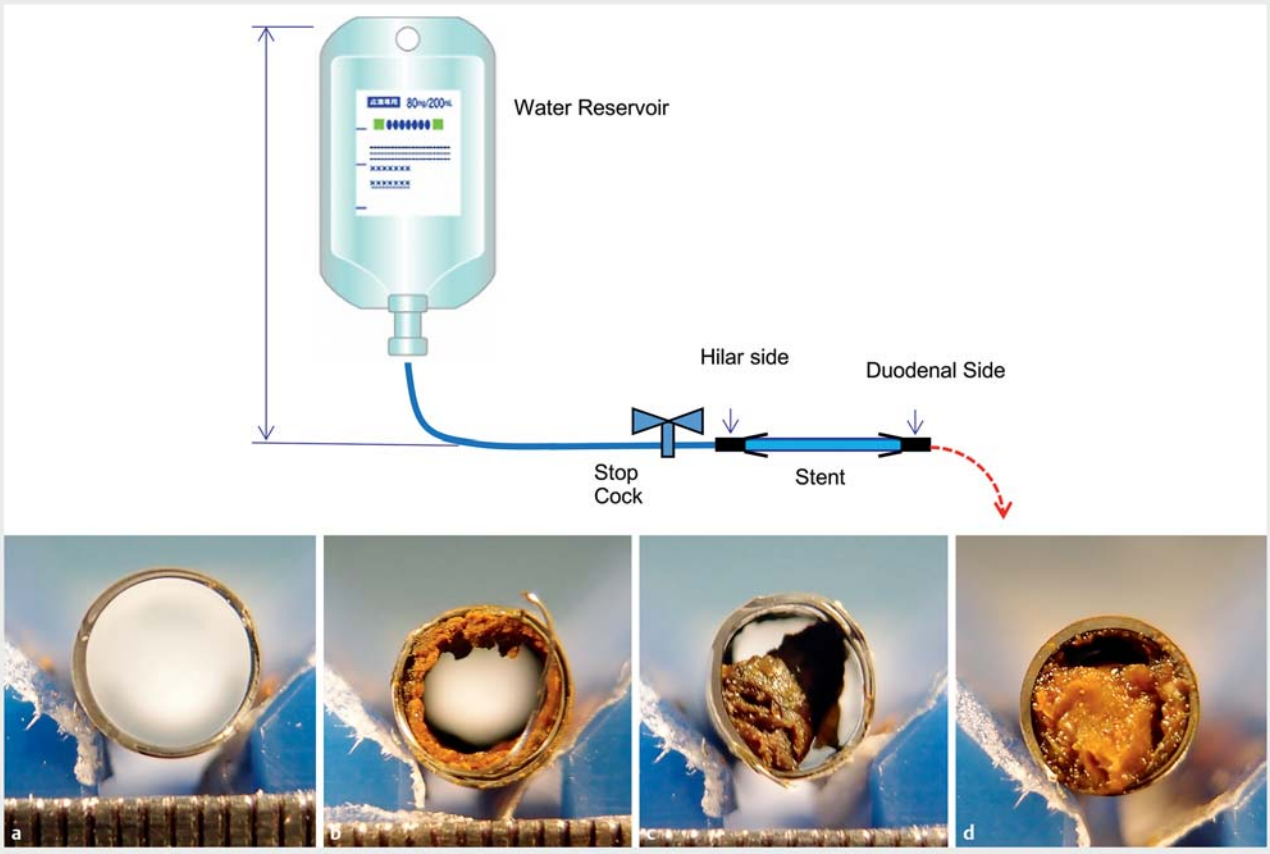
Second, all the retrieved stents were dissected and visually evaluated. They were cut transversely by a custom-made device into 1-cm cross-sections and assessed in detail with regard to the location and degree of occlusion. This was classified as follows: no occlusion, nonsignificant occlusion, significant occlusion, and complete occlusion. Nonsignificant occlusion was defined as an unimpeded view through > 50 % of the lumen through all stent segments. Significant or complete occlusion were recorded when ≥ 50 % or all, respectively, of the lumen was seen to be obstructed in at least one segment.

Statistical analysis

Categorical variables were compared using the chi-squared test. Normally distributed continuous variables were analyzed using Student's *t* test, and non-normally distributed variables were analyzed using the Mann–Whitney *U* or Kruskal–Wallis tests. The data were presented as the mean (standard deviation [SD]) or median (range). There was no sample size calculation as this is a pilot study and the estimated occlusion rate of this new stent was unknown. However, a 24-month inclusion period was chosen.

In addition, frequency-matching by systematic random sampling was designed to compare the outcomes. The index patients were defined as prospective patients who underwent a 12-Fr plastic stenting. The eligibility criteria for the historical cohort included patients with a distal malignant biliary obstruction who underwent an ERCP with a 10-Fr plastic stent, FCSEMS, or uncovered SEMS (UCSEMS) placement. All referents were identified, using the same inclusion criteria, from a medical records database of 2654 patients who had undergone an ERCP at our unit between January 2012 and February 2015. Then, the referents were randomly selected by frequency-matching for sex, metastatic disease, and pancreatic cancer etiology (yes/no), with a 1: 2 ratio and a similar proportion of different types of stents. When a patient had undergone several ERCPs with stent placements, only the first was considered in the analysis. The choice of stent in the historical cohort had been at the discretion of the endoscopist.

Cumulative stent patency and time to RBO were analyzed using the Kaplan–Meier method and log-rank test. *P* values <



▶ **Fig. 2** Stent occlusion analysis following removal of 12-Fr plastic stents. Upper panel: Irrigation test using three water pressures (110, 350, and 550 mmH_2O) for a 3-minute duration, and observation of whether water flowed out (patent stent) or not (occluded stent). For each water pressure, a score of "open", "partially occluded", or "completely occluded" was recorded. Lower panel: Dissection analysis and visual assessment of the stent luminal cross-sections. Degree of clogging was classified as follows: **a** no occlusion; **b** nonsignificant occlusion; **c** significant occlusion; and **d** complete occlusion. Source: Olympus.

0.05 were considered statistically significant. SPSS v.24 software was used (IBM, SPSS Inc., Illinois, USA).

Results

Patients

A total of 72 patients (median age 66 years, range 32 – 94; 50 % male) were included in our study. The baseline characteristics of the whole population including the index group (n = 24, 33.3 %) and referent groups (n = 48, 66.7 %) are presented in ▶ **Table 1**. There were no statistically significant differences in sex, pancreatic cancer etiology and metastatic disease status, as these features had been previously matched.

In the index group, 24 patients underwent placement of a 12-Fr plastic stent (median length 7 cm, range 5 – 9) (▶ **Fig. 3**). The metastatic status was lower in pancreatic cancer (n = 12, 70.6 %) compared to other etiologies (n = 6, 85.7 %), but this difference was not significant ($P = 0.629$). Other reasons for nonresection were locally advanced disease (n = 4, 16.7 %), advanced age (n = 1, 4.2 %), and concomitant diseases (n = 1, 4.2 %). Five patients (20.8 %) had previously undergone ERCP with 10-Fr stent placement. After 12-Fr stenting, the median decreases in bilirubinemia at 24 h and 1 week were 1.8 mg/dL (range 0.6 – 8.7) and 3 mg/dL (range 0.6 – 14.3), respectively.

Regarding the referent group, 48 patients, with 10-Fr plastic stents (n = 16), FCSEMSs (n = 16), and UCCEMSs (n = 16) were matched and randomly allocated to the referent group. The most frequent etiology after pancreatic cancer was distal cholangiocarcinoma (n = 6, 12.5 %). There were no statistically significant differences in prior bilirubin level ($P = 0.984$), bile duct diameter ($P = 0.166$) and length of the stenosis ($P = 0.053$) according to the type of stent within the patients in the referent group.

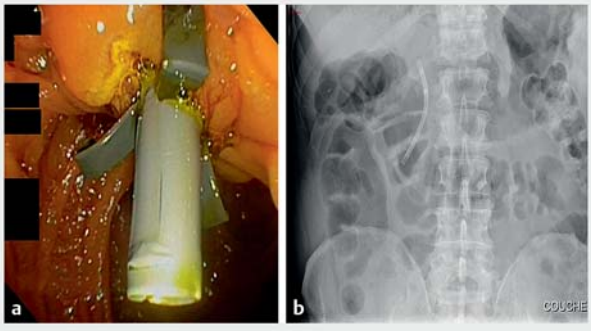
Outcomes

The technical success was 100 % in all subgroups. The 30-day mortalities in the index and referent groups were 12.5 % and 2.1 %, respectively ($P = 0.105$). The overall mortality rate in the whole population during a median follow-up of 110 days (range 2 – 835) was 73.6 % (n = 53). Mean overall survival was 240.4 days (SD 202). Taking into account that patients were not followed-up after the first RBO or death, the median follow-up in those with a patent stent was 127 days (range 32 – 356). The adverse events rate was 4.2 % in both groups.

▶ **Table 1** Baseline characteristics of index patients (12-Fr plastic stent) and referent patient groups (10-Fr plastic stent, FCSEMS, UCSEMS) who underwent biliary stenting because of a distal malignant biliary obstruction.

	Study population	Index patients	Referent groups			
			Total	10-Fr plastic	FCSEMS	UCSEMS
n (%)	72	24 (33.3)	48 (66.7)	16 (22.2)	16 (22.2)	16 (22.2)
Age, median (range), years		69 (32 – 94)	65 (41 – 83)	65 (41 – 71)	66 (49 – 83)	64 (46 – 70)
Sex, male, n (%)*	36 (50)	12 (50)	24 (50)	8 (50)	8 (50)	8 (50)
Etiology, n (%)*						
▪ Pancreatic cancer	50 (69.4)	17 (70.8)	33 (68.8)	11 (68.8)	11 (68.8)	11 (68.8)
▪ Cholangiocarcinoma	8	2	6	3	1	2
▪ Gallbladder cancer	2	2	0	0	0	0
▪ Colon cancer	4	0	4	1	2	1
▪ Other	8	3	5	1	2	2
Metastatic disease, n (%)*	54 (75)	18 (75)	36 (75)	12 (75)	12 (75)	12 (75)
Previous ERCP, n (%)	13 (18.1)	5 (20.8)	8 (16.7)	3 (18.8)	2 (12.5)	3 (18.8)
Prior bilirubin, median (range), mg/dL	7.8 (4 – 31.9)	5.6 (0.4 – 26.2)	9.1 (3 – 31.9)	9.1 (3.6 – 14.2)	8.8 (3 – 17.6)	8.7 (3 – 31.9)
Bile duct diameter, median (range), mm	15 (10 – 30)	15 (10 – 30)	15 (10 – 30)	15 (10 – 25)	15 (10 – 30)	20 (10 – 20)
Stenosis length, median, (range), mm	20 (10 – 60)	20 (10 – 60)	20 (10 – 55)	28 (15 – 30)	18 (10 – 55)	18 (10 – 40)
Treatment, n (%)						
▪ Chemotherapy	61 (84.7)	19 (79.2)	42 (87.5)	13 (81.3)	14 (87.5)	15 (93.8)
▪ Best supportive care	11 (15.3)	5 (20.8)	6 (12.5)	3 (18.8)	2 (12.5)	1 (6.3)

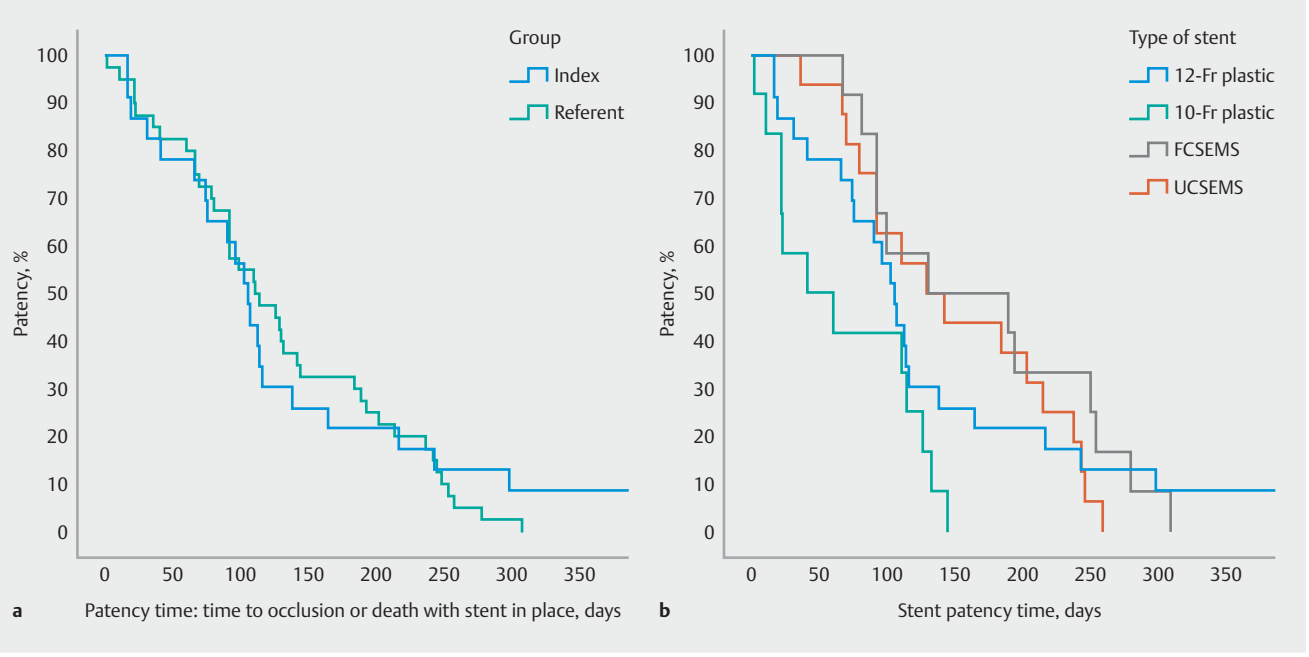
ERCP, Endoscopic retrograde cholangiopancreatography; FCSEMS, fully covered self-expanding metal stent; UCSEMS, uncovered self-expanding metal stent.
* Frequency matched for index and referent groups.



▶ **Fig. 3a** A 9-cm 12 Fr plastic stent with distal flaps was placed in a patient presenting with a distal malignant biliary obstruction and metastatic pancreatic cancer. **b** Fluoroscopy shows the correctly positioned stent in the bile duct.

A comparative analysis of the outcomes is shown in ▶ **Table 2**. There was no statistically significant difference in the median stent patency time between the index and referent patients ($P = 0.684$). In addition, no difference was observed in the survival analysis ($P = 0.781$), as shown in ▶ **Fig. 4**. However, a significant difference was found between the different referent subgroups, as the patency time of 10-Fr plastic stents (median 51 days, range 2 – 144) was lower compared with that of FCSEMS and UCSEMS ($P = 0.01$). The difference in median patency time between 12-Fr and 10-Fr plastic stents was 55 days, but this did not reach statistical significance ($P = 0.131$). A total of 25 patients (34.7 %) died with a patent stent, as follows: 12-Fr plastic stent (n = 11), 10-Fr plastic stent (n = 3), FCSEMS (n = 6) and UCSEMS (n = 5).

The RBO rate for the 12-Fr stent was lower (50 %) than that of the 10-Fr stent (81.3 %), and the difference was significant ($P = 0.046$). Conversely, there was no statistically significant difference between 12-Fr plastic stents and FCSEMSs in RBO (50 % vs. 43.8 %, $P = 0.698$) or stent dysfunction rates (50 % vs. 37.5 %, $P = 0.436$). Previous ERCP was not associated with RBO ($P = 0.271$). RBO in the index group was due to stent dysfunction in all cases, and in most cases in the referent group (n = 26, 83.9 %),



▶ **Fig. 4** Kaplan–Meier analyses of stent patency times. **a** The index group patients had a 12-Fr biliary plastic stent in place, while the referent group patients had other stents. No difference was observed between the index group and the referent group, $P = 0.781$ (log-rank test). **b** The 10-Fr plastic stent was associated with a lower patency duration compared with 12-Fr stents and with metallic stents, $P = 0.023$ (log-rank test). FCSEMS, fully covered metal stent; UCSEMS, uncovered metal stent.

mostly because of sludge (91.7 %) rather than tumor overgrowth (8.3 %). No kinking or tumor ingrowth was suspected. There was no migration in the index group and all migrations in the referent group were distal and mainly associated with a 10-Fr plastic stent (n = 4, 80 %).

Time to RBO was not statistically different between the index and referent group, by either quantitative ($P = 0.786$) or survival analysis ($P = 0.553$). However the median time to RBO was lower in the 10-Fr plastic stent subgroup (23 days, range 2 – 127) and this finding was significant, compared with the index group (105 days, range 42 – 217 days; $P = 0.008$) and with the SEMS group (87 days, range 92 – 308; $P < 0.001$). The Kaplan–Meier curves confirmed that there were different cumulative incidences of RBO according to the type of stent ($P < 0.001$) (▶ **Fig. 5**). Notably, there was a difference in the survival analysis when comparing both types of plastic stents ($P = 0.014$).

Post-operative analysis of removed stents

A total of 11 12-Fr plastic stents (45.8 %) were removed and analyzed from patients with suspected stent dysfunction. Of these, 4 stents (36 %) were found to be occluded either completely (n = 2) or partially (n = 2) in the irrigation test; the remaining 7 of the 11 stents (64 %) removed because of stent dysfunction were patent at the irrigation test. On visual analysis after dissection of the stents, partial clogging was observed in the patent stents, either in the distal (n = 4) or proximal ends (n = 3).

Discussion

In the setting of unresectable distal malignant biliary obstruction, a new 12-Fr plastic stent showed better patency time and lower recurrent biliary obstruction rates compared with 10-Fr stents. In this prospective study on 72 patients who underwent ERCP for palliative biliary drainage, these large-bore stents showed comparable RBO and mortality rates compared with SEMSs. They achieved a technical success of 100 % with a safe profile, and stent migration was not observed. In addition, 64 % of 12-Fr stents removed in patients with RBO were patent at the irrigation and dissection tests.

A large number of systematic reviews and meta-analyses assess the performance of different stents in distal malignant biliary obstruction. However, in clinical practice or individual cases it may be difficult interpret the outcomes of RBO or stent dysfunction (often equivalent terms) [8] and stent patency. Indeed, the longer the patient survives, the higher the probability of RBO or re-intervention. On the other hand, a short duration of stent patency without dysfunction will be observed in patients with a short survival. The balance for assessing both outcomes has been driven by randomized controlled trials in patients with similar baseline conditions and follow-up [16, 17]; however, most of the recent articles have addressed SEMS results [18, 19]. Similarly, metastatic disease status and tumor etiology have been shown to be factors related to the short-term and overall mortality, so they can bias results [20]. For these reasons we have designed an observational study that matches these factors according to the type of stent, and obtaining comparable populations.

▶ **Table 2** Outcomes of patients with a malignant biliary obstruction treated by different types of stents.

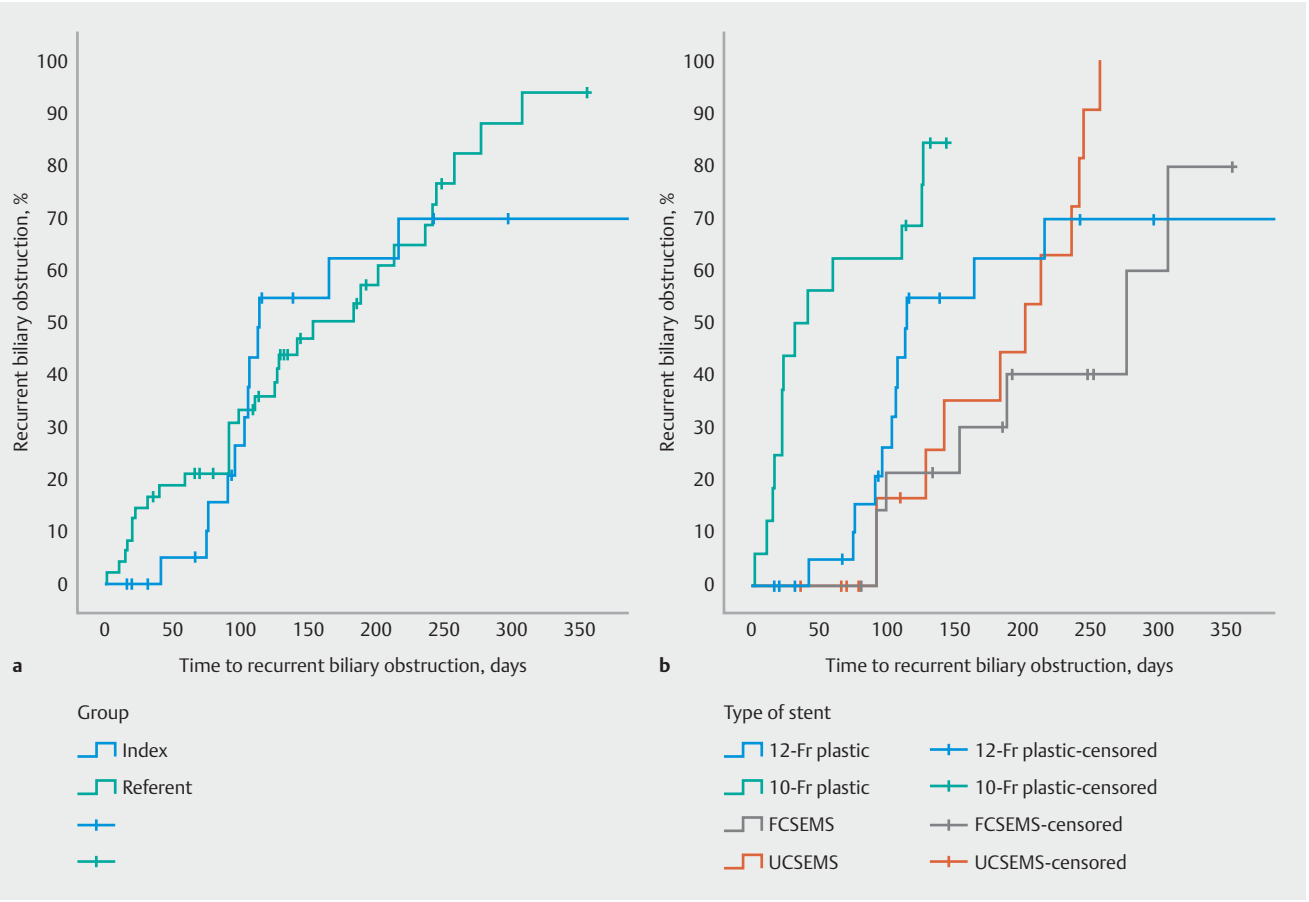
	Index patients (12-Fr plastic)	Referent groups				*P* value*
		Total	10-Fr plastic	FCSEMS	UCSEMS	
n (%)	24 (33.3)	48 (66.7)	16 (22.2)	16 (22.2)	16 (22.2)	–
Stent patency, median (range), days	106 (17 – 835)	114 (2 – 308)	51 (2 – 144)	154 (67 – 308)	136 (36 – 258)	0.684
Recurrent biliary obstruction (RBO)						
▪ Total, n (%)	12 (50)	31 (64.6)	13 (81.3)	7 (43.8)	11 (68.8)	0.234
▪ Stent occlusion, n (%)	12 (50)	26 (54.2)	9 (56.3)	6 (37.5)	11 (68.8)	0.738
▪ Migration	0	5 (10.4)	4 (25)	1 (6.3)	0	–
▪ Time to RBO, median, (range), days	105 (42 – 217)	111 (2 – 308)	23 (2 – 127)	154 (92 – 308)	202 (92 – 258)	0.786
Technical success, n (%)	24 (100)	48 (100)	16 (100)	16 (100)	16 (100)	1
30-day mortality, n (%)	3 (12.5)	1 (2.1)	1 (6.3)	0	0	0.105
Overall survival, mean (SD), days	202.7 (168.9)	258.3 (216)	220.6 (213.8)	268 (209.9)	289.5 (238.2)	0.315
Adverse events, n (%)						
▪ Total	1 (4.2)	2 (4.2)	2 (12.6)	0	0	1
▪ Post-ERCP pancreatitis	0	1 (2.1)	1 (6.3)	0	0	1
▪ Cholecystitis	1	1 (2.1)	1 (6.3)	0	0	
▪ Bleeding	0	0	0	0	0	
▪ Perforation	0	0	0	0	0	
▪ Early (< 30 days)	0	1 (2.1)	1 (6.3)	0	0	
▪ Late (≥ 30 days)	1 (4.2)	1 (2.1)	1 (6.3)	0	0	

FCSEMS, fully-covered self-expanding metal stent; UCSEMS, uncovered self-expanding metal stent.
* Comparative analysis between index and referent groups.

An increasing amount of evidence suggests that the 10-Fr plastic stent should not be the first choice in most cases of unresectable distal malignant biliary obstruction [8]. A meta-analysis of 13 studies comparing SEMSs and plastic stents confirmed that SEMSs are associated with longer patency time, less stent dysfunction, lower re-intervention rates, and better survival [9]. Similarly, Sawas et al. [21], in a meta-analysis of 1989 patients, reported a lower risk of occlusion of SEMSs (18 % – 33 %) with a comparable 30-day mortality rate. A 36 % reduction in recurrent obstruction has also been reported [22]. In our study, the overall dysfunction rates for FCSEMSs and UCSEMSs were higher (37.5 % and 68.8 % respectively). These results could be explained by the long-term survival and follow-up of the historical cohort. However, the overall survival rates were not different between the 12-Fr plastic stent group and the referent group, with comparable rates of dysfunction and adverse events. Notably, the 12-Fr stent achieved good survival times without RBO in patients with previous plastic stenting.

The impact of the diameter of the plastic stent is a crucial point to consider. Sizes lower than 10 Fr result in higher dysfunction rates and should be discouraged, while little is known about large-bore plastic stents. In the present series, the 12-Fr plastic stent achieved more than double the patency time compared to the 10-Fr profile (106 vs. 51 days), with much lower migration risk (0 vs. 25 %) and RBO rate (50 % vs. 81.3 %). In addition, the stent was still patent in almost half of the patients (n = 11, 45.8 %) who died with a 12-Fr stent; therefore the patency time has probably been underestimated in this subgroup. Wagh et al. [23], in a multicenter randomized controlled trial, compared 11.5-Fr versus 10-Fr plastic stents for malignant biliary obstruction, reporting no significant differences in median patency times (258 vs. 149 days, $P = 0.16$). Previous similar studies have shown conflicting results, reporting longer patency times (190 vs. 150 days) favoring large-diameter plastic stents [24] or comparable dysfunction rates (55 % vs. 46 %) [6], but most of these series are old with heterogeneous populations. Moreover, as well as the diameter, also the stent design is important, including number and characteristics of layers, flaps, and the shape of the stent ends [25]. In our series, no 12-Fr stent showed migration, probably because of the three-flaps design, the increased flexibility of the three-layer structure, and the large diameter.

Interestingly stent dysfunction (fever with cholestasis) was overestimated for the 12-Fr plastic stents, as clogging was not confirmed by irrigation and dissection analyses in 64 % of cases. Although we have not evaluated this outcome in other stents, these findings suggest that other factors (e. g. intrahepatic cholangitis, progression of liver metastasis, or cholecystitis)



▶ **Fig. 5a** Cumulative recurrent biliary obstruction in patients with 12-Fr plastic stents (index cases) or other stents (referents) during a period of 1 year, $P = 0.553$ (log-rank test). **b** Median times to recurrent biliary obstruction were different according to the type of stent, $P < 0.001$ (log-rank test). FCSEMS, fully covered metal stent; UCSEMS, uncovered metal stent.

can lead to an incorrect assumption of stent occlusion, with consequent stent removal.

The present study has a number of limitations in addition to its nonrandomized design and small sample size. Although the matching ensured the same frequencies of potential confounders in different subgroups, the survival analysis has probably underestimated the real times to the outcomes, as this can be particularly biased when there are isolated patients with very short or very long survival times. In addition, the different chemotherapy protocols, stent lengths, and patient co-morbidities can also have influenced the results.

In conclusion, our study shows that this new 12-Fr plastic stent could be an effective and cheaper alternative to SEMS in distal biliary malignant obstruction. However, all types of stents had high RBO and dysfunction rates, suggesting that more efforts should be made regarding the development of new models with longer patency times. Finally, stent dysfunction is probably overestimated in these patients.

Competing interests

This study was supported by Olympus (Berchem, Belgium).

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