

Predictive Factors for Endoscopic Stenting Patency and Patient Survival in Unresectable Malignant Biliary Obstruction: A Cohort Study at a Tertiary Institution

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ABSTRACT

AIM: Factors associated with the biliary stent dysfunction and long-term survival are not clearly established. To analyze factors associated with stent patency in palliative biliary drainage (BD) and to evaluate the factors associated with patient survival.

MATERIAL AND METHODS: Observational retrospective study with consecutive inclusion of patients with unresectable biliopancreatic tumours who underwent BD by ERCP between January-2015 and December-2016. To analyze the factors associated with patient survival, the hazard ratio obtained through a Cox model was used. The follow-up review period was limited up to January 2018 (from at least one year after the endoscopic procedure) or the patient's death.

RESULTS: Forty-four patients were included during the study period. The clinical success rate of overall biliary stents was 93.2% and total AE rate was 18.2%. The basal biliary stent was functional in 79.5%; in the remaining cases, endoscopic reinterventions were necessary. The median time until the loss of stent patency was 131 days (Q1-Q3; 85-387days). None of the parameters analyzed were associated with stent dysfunction. The patients who required endoscopic reinterventions had a longer survival time (median of 422days [Q1-Q3; 281-520] vs 162days [Q1-Q3; 37-264], $p = 0.001$). Oncological treatment, partially covered self-expandable metal stent, and high albumin were statistically associated with a longer survival.

CONCLUSIONS: The majority of biliary stents were functional, without the need to repeat the ERCP sessions. The need for stent repermeabilization did not negatively influence patient survival.

Keywords: Biliary drainage; Endoscopic retrograde cholangiopancreatography; Pancreatic cancer; Biliopancreatic diseases; Self-expandable metal stents

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INTRODUCTION

Stent placement by endoscopic retrograde cholangiopancreatography (ERCP) is the procedure of choice for palliative biliary drainage (BD) in patients with malignant tumors of the biliopancreatic region^[1-3]. Two types of stents, plastic stents (PS) and self-expandable metal stents (SEMS), have been compared in various meta-analyses; SEMSs are associated with a significantly lower stent dysfunction, less need for reintervention, and longer patient survival^[4,5]. Although the initial placement of PSs has a lower cost in comparison with SEMSs, a meta-analysis and a more recent randomized clinical trial did not show significant differences between the two strategies^[4,6]. Even, in patients with short survival times (≤ 3 months) or those with metastatic disease, the total cost per patient did not differ between PS and SEMS^[6]. In accordance, the recently updated ESGE guideline recommends SEMS insertion for palliative BD of malignant extrahepatic biliary obstruction^[1].

A comparative meta-analysis of covered and uncovered SEMS did not show differences in patient survival or global adverse events (AEs), although there was controversy regarding stent dysfunction^[1,7-13]. Furthermore, the results of a prospective multicenter study showed that fully covered (FC) SEMSs were comparable to partially covered (PC) SEMSs in terms of patency, without a significant increase in stent migration rate^[14].

Based on the variability of the published data, we can affirm that the optimal stent for palliative BD and the factors associated with stent failure or the patient's survival have not been clearly established. Additionally, we must bear in mind that improvements in oncological treatment in recent years demand greater performance and functionality from the endoscopic stenting.

The main aim here was to analyze predictive factors associated with the loss of the stent patency, or recurrent biliary obstruction, in patients with unresectable malignant biliopancreatic disease. The secondary aim was to evaluate the factors associated with patient survival.

METHODS

This was an observational retrospective specific-cohort study, in a single tertiary-care referral center. All patients with unresectable or inoperable malignant tumours of the biliopancreatic region who underwent endoscopy BD were consecutively recruited in a specific ERCP database. The inclusion period was from January 2015 to December 2016.

The criteria for tumour unresectability were based on the imaging test findings, consistent with the presence of metastatic disease or the involvement of artery or vein invasion. In the pancreatic cancer cases, the consensus of the National Comprehensive Cancer Network was followed^[15]. The patients were labelled as palliative after an individualized assessment of each case by the hepato-biliary-pancreatic tumours committee of the center, according to the general clinical condition of the patient, the baseline pathologies, and the performance status.

Exclusion criteria were benign pathology, a previous transpapillary

BD, the failure of or inability to perform transpapillary stent placement, EUS-guided or percutaneous BD cases, resectable borderline cancer, severe coagulopathy (protombin time >1.5), or severe thrombocytopenia (platelet count $< 50 \times 10^9/L$).

The institutional review board approved the study. All patients provided written informed consent for the interventional endoscopy procedure.

Procedures

Two expert interventional endoscopists performed the procedures using duodenoscope. Prophylactic doses of intravenous antibiotics were administered before all procedures, which were carried out with an anesthesiologist providing deep sedation.

The stent choice was uncontrolled and based on the endoscopist's decision, extension or location of the biliary strictures, and the baseline status of the patients. Biliary SEMSs (10×60 -mm, 10×80 -mm or 8×80 -mm; Wallflex, Boston Scientific, MA, USA) were used in distal biliary obstruction cases. PS (7, 8.5 or 10 Fr $\times 12$ or 15-cm; Advanix, Boston Scientific, MA, USA) were indicated only in proximal biliary stenosis.

Definitions

Clinical success was defined as a reduction in bilirubin by 50% at 2-4 weeks after the stent placement. To assess the procedure-related AEs, safety was considered within the first 2 weeks. AEs were graded according to the ASGE lexicon's severity grading system^[16]. Procedure time was defined as the time elapsed from the insertion of the duodenoscope until its removal. Recurrent biliary obstruction was defined as a composite endpoint of either occlusion or stent migration. Time to recurrent biliary obstruction was defined as the time from stent placement until the point to symptoms associated with occlusion or migration were observed.

Patient follow-up

On discharge, patients were followed up in outpatient clinics, with an analytical evaluation being made between 2 and 4 weeks after the procedure. Subsequently, patients received oncological treatment or palliative care according to the criteria of our oncological center. The follow-up review period was limited up to January 2018 (from at least one year after the endoscopic procedure) or the patient's death.

The indications for a second ERCP due to the loss of stent patency, or recurrent biliary obstruction, were the presence of clinical and analytical symptoms of biliary obstruction: cholangitis, biliary bacteremia, obstructive jaundice.

Statistical analysis

Categorical variables were described by number of cases and the percentage with respect to the total by category. Continuous variables were described by the mean and the standard deviation or the median and the interquartile range (IQR).

Continuous variables were compared using Student's t-test or Mann-Whitney U test where appropriate. Fisher's exact test or Pearson's χ^2 test were applied to assess the relationship between categorical variables.

To analyse the factors associated with the time elapsed until the stent dysfunction or the patient's survival, the hazard ratio for each factor was obtained through a Cox model.

Confidence intervals at 95% were estimated and the proportionality of risks was validated in Cox models. The statistical package R version 3.4.0 or higher for Windows was used to process the data and perform the analysis.

RESULTS

Patient characteristics

During the study period, a total of 52 patients with unresectable or inoperable malignant biliary strictures were referred to our endoscopy unit for palliative BD. Among these, it was possible to place a transpapillary biliary stent by ERCP in 44 patients, making up our cohort. In the remaining cases an EUS-guided BD was performed. Table 1 summarizes the demographic data and the baseline and tumour-related characteristics of the patients included in the study.

Procedure details and outcomes

Table 2 summarizes the endoscopic procedure details, the outcomes, and the AEs of the first transpapillary BD. SEMs were the most frequently employed stents in our cohort (90.9% of cases). The remaining cases corresponded to proximal cholangiocarcinomas in which PSs were used. The overall clinical success rate of transpapillary biliary stents was 93.2%. The global AE rate was 18.2%, with most of these cases being mild or moderate. Pancreatitis was the most frequently reported AE, appearing in 11.4% of cases of our cohort, with the majority of these being mild (80%). There was a fatal AE (a post-ERCP pancreatitis) with unsatisfactory response to normal measures that died one week after the procedure. The median survival of the patients was 203 days.

Table 1 Demographic data, baseline information, and tumour-related characteristics of the cases.

	ERCP transpapillary drainage (n = 44)
Age, mean (SD), years	69.9 (10.8)
Sex male, n (%)	22 (50)
ASA, n (%)	
I	2 (4.55)
II	19 (43.2)
III	21 (47.7)
IV	2 (4.55)
Bilirubin, median [Q1; Q3] mg/dl	12.3 [3.39; 21.4]
Albumin, median [Q1; Q3] g/dl	3.3 [2.65; 3.78]
Clinical manifestation, n (%)	
Obstructive jaundice	32 (72.7)
Acute cholangitis	4 (9.09)
Cholestasis	5 (11.4)
Constitutional syndrome	2 (4.55)
Abdominal pain	1 (2.27)
Tumours, n (%)	
Pancreas	34 (77.3)
Cholangiocarcinoma	7 (15.9)
Others †	3 (6.8)
Pancreas tumour locations, n (%)	
Head	27 (79.4)
Head-body	4 (11.8)
Body	2 (5.88)
Body-tail	1 (2.94)
Metastatic disease, n (%)	20 (45.5)
Unresectable tumours, n (%)	40 (90.9)
Inoperable patients, n (%)	4 (9.1)
Chemotherapy treatment, n (%)	24 (54.5)
Radiotherapy treatment, n (%)	6 (13.6)

ASA: American Society of Anesthesiologists physical status classification. † Other tumours include ampullary neoplasm and biliopancreatic involvement due to colorectal cancer or osteosarcoma.

Factors associated with stent patency

In 79.5% of the cases included in our cohort, the basal biliary stent was functional until the patient's death or the end of follow-up period. In the remaining patients endoscopic reinterventions to permeabilize the BD were necessary; these cases summarized in Table 3. A simple second session was enough in 55.6%, while the rest needed between 2 and 4 reinterventions. The median time elapsed in these patients until the loss of stent patency, was 131 days (Q1-Q3 85-387 days). The most frequent findings were stent occlusion due to detritus or biliary content (77.8%), resolved by cleaning the SEMS with saline serum and an extractor balloon, and in some cases (28.6%) additionally inserting a coaxial plastic or metallic stent.

None of the cholangiocarcinomas drained with PS required endoscopic reintervention.

Table 4 is a comparison of different variables between the groups of patients who presented loss of stent patency, and those who did not. The HR obtained through a Cox model showed that none of the parameters evaluated was significantly associated with the time elapsed until the need for endoscopic reintervention.

Factors associated with patient survival

The influence of stent permeability dysfunction on patient survival was evaluated. It was observed that patients who required reintervention with additional ERCP had a longer survival.

A flow chart, showing the different scenarios of all cases included in the cohort study until the study ending vs death, is detailed in figure 1.

Table 2 Endoscopic procedure observations, outcomes, and adverse events.

	ERCP transpapillary drainage (n = 44)
Biliary cannulation, n (%)	
Sphincterotome and guidewire	22 (50)
Needle-knife precut	16 (36.4)
Transpancreatic sphincterotomy	6 (13.6)
Stent type, n (%)	
FCSEMS	7 (15.9)
PCSEMS	32 (72.7)
UCSEMS	1 (2.3)
PS	4 (9.1)
Clinical success, n (%)	41 (93.2)
Procedure time, median [Q1 ; Q3], minutes	38 [35; 45]
Adverse events ‡, n (%)	8 (18.2)
Pancreatitis	5 (11.4)
Bleeding	2 (4.6)
Infection	1 (2.3)
Severity of adverse events ‡, n (%)	
Mild	4 (9.1)
Moderate	3 (6.8)
Fatal	1 (2.3)
Number of drainage interventions required, median [Q1; Q3] eguridad Stenting patency 18.05.18.doc	1 [1; 3]
Basal stent functional until death / end of follow-up, n (%)	35 (79.5)
Basal stent patency, median [Q1 ; Q3], days †	146 [41; 285]
Survival, median [Q1; Q3] days	203 [46; 410]

FCSEMS: fully-covered self-expandable metal stent; PCSEMS: partially-covered: self-expandable metal stent; UCSEMS: uncovered self-expandable metal stent; PS: plastic stent. ‡ Adverse events within first 2 weeks. † Survival until death or until first endoscopic intervention depending of each case.

Table 3 Cases with need for endoscopic reinterventions to repermeabilize the biliary stent patency.

Case	Basal stent	Basal stent patency(days)	Indication	Findings	Management	Re-interventions (number)
1	PCSEMS	107	Cholangitis	Stent obstruction detritus or biliary contents	Stent cleaning	4
2	PCSEMS	387	Cholangitis	Stent obstruction detritus or biliary contents	Stent cleaning	1
3	PCSEMS	567	Cholangitis	Stent obstruction detritus or biliary contents	Stent cleaning, coaxial PS insertion	3
4	PCSEMS	170	Obstructive jaundice	Stent migration	PCSEMS insertion	1
5	PCSEMS	131	Biliary bacteremia	Stent obstruction detritus or biliary contents	Stent cleaning	1
6	PCSEMS	42	Cholangitis	Stent obstruction detritus or biliary contents	Stent cleaning	3
7	PCSEMS	85	Cholangitis	Stent obstruction detritus or biliary contents	Stent cleaning	2
8	PCSEMS	409	Cholangitis	Stent obstruction detritus or biliary contents	Stent cleaning, PCSEMS insertion	1
9	UCSEMS	34	Obstructive jaundice	Stent obstruction tumor growth	Coaxial PS insertion	1

PCSEMS: partially covered self-expandable metal stent; PS: plastic stent; UCMS: uncovered self-expandable metal stent.

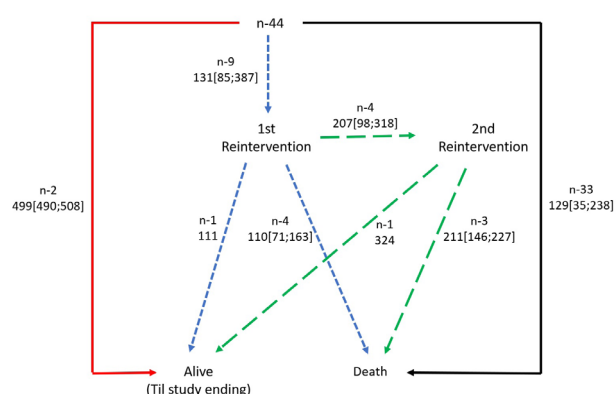


Figure 1 Flow chart showing the scenarios of all cases included in the cohort study. Median [Q1; Q3] days.

Figure 2 represents a graph, with the Kaplan-Meier estimator, which compares the survival curves of both groups.

Table 5 summarizes the evaluation of factors associated with patient survival. As we can see, elevated levels of albumin were statistically associated with a longer survival of the patients included in our cohort. Regarding the type of stent, patients with PCSEMSs (the most frequently used) had significantly longer survival compared with PSs or FCSEMSs. The administration of QMT and RDT was also associated with longer survival. Finally, ASA category stretched to the limit of significance (p-value 0.058), with categories 3-4 presenting an HR - 1.91--almost twice the risk of dying as categories 1-2.

There were no statistically significant differences between the survival of patients drained with SEMS and patients with cholangiocarcinomas drained with PS, with a median of 212 days [Q1-Q3; 46.8-421] vs. 97 days [Q1-Q3; 31.2-181], $p = 0.159$.

Descriptive analysis of the subgroups with extreme results

Some 27.3% of the patients included in the study had a survival of at least 12 months. Of these, 50%, mostly women, survived with the basal stent, with lower ASA levels and lower bilirubin values compared to those who needed a second drainage session (or with the total patients of our cohort). No differences were observed regarding the tumour characteristics or the BD procedural details.

Some 6.8% of the patients of our cohort required a precocious (before 3 months) second drainage intervention. This group was made up of a greater proportion of men, younger, with higher albumin levels and receiving chemotherapy treatment, in comparison with the total patients of the cohort. In all these patients the tumour was located in the pancreatic head and 66% required a needle knife precut for biliary cannulation. Two cases from this subgroup presented pancreatitis as AE.

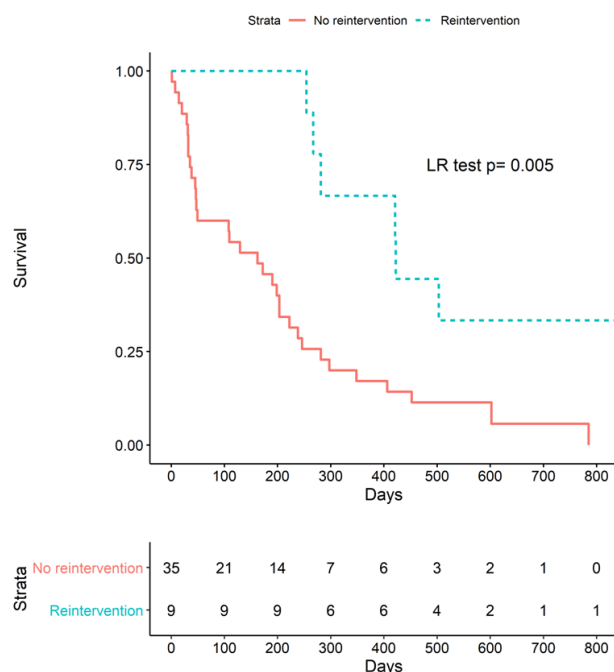


Figure 2 Kaplan-Meier survival curves for reintervention vs no reintervention. LR test=Log-rank test.

DISCUSSION

The current guidelines recommend that palliative decompression of malignant extrahepatic biliary obstruction be performed via ERCP rather than by EUS-guided techniques, surgery, or percutaneously^[1]. Various types of stents with different specificities have been developed to perform transpapillary BD, with the fundamental aim of prolonging patient survival and stent patency. This is important because each time a stent becomes dysfunctional implying a recurrent biliary obstruction, patient hospital admission for endoscopic reintervention is required, with the consequent cessation of oncological treatment, carrying associated comorbidities and a significant reduction in the quality of life, which is extremely detrimental in palliative oncological patients whose life expectancy is very limited. So, the continuous improvement of oncological therapies demands an improvement in stent biliary patency, and the factors associated with longer survival or the loss of stent functionality, are not clearly established.

Almost a quarter of patients from our study required at least a second endoscopy session to repermeabilize the BD. The mean time for stent dysfunction and need for endoscopic reintervention in our

cohort was 215 days, similar to the results reported in meta-analyses (mean time 250 days)^[4]. Despite the inconveniences related to additional endoscopic procedures, according to our results patients with reinterventions survived longer compared to those who did not undergo reintervention. However, we must take into account the presence of bias in analyzing this comparison. The need for endoscopic repermeabilization has a competing risk (patient death) which prevents us from observing it; therefore, patients with additional ERCP sessions enjoyed longer survival because they lived long enough to require them. For this reason, regardless of this biased result, our choice would be the stent that offered the longer patency, assuming that prolonged survivals are associated with an increased risk of stent dysfunction. In the same line as our results, Buxbaum *et al.* reported that the risk of developing cholangitis was 11.5% in patients surviving one year or less compared to 46.5% for those who survived more than one year, representing a five-fold increase in the odds of developing cholangitis (odds ratio: 4.92; $p = 0.017$)^[17].

None of the parameters analyzed (age, sex, ASA, bilirubin, metastasis, tumour characteristics or stent type) as a possible association with a loss of stent patency were encountered.

In a multicenter study, no significant differences in patency rates according to age, bilirubin levels, tumour type, or length and morphologic type of stricture were found^[18]. However, the authors reported that the degree of narrowing (assessed by cannula or guidewire passage) and the time to adequate expansion of the stent were independent factors associated with stent patency^[18]. In another report, among the multiple variables evaluated, only the presence of a hilar biliary stricture, metastatic cancer, and length of stent were predictors of occlusion^[19]. It should be noted that stents used in those studies were uncovered. In another multicenter study, from among the multiple variables evaluated only PS, a tight stricture requiring preceding dilation, and a high initial bilirubin level were independently associated with an increased risk of stent occlusion^[20]. Based on these variable results, we may conclude that no common concordant factors were

Table 4 Predictive factors associated with need of endoscopic reintervention.

	No endoscopic reintervention (N=35)	Endoscopic reintervention (N=9)	Hazard ratio (95% CI)	p value
Baseline patient's profile				
Age, mean (SD), years	70.0 (11.4)	69.6 (8.5)	1.02 (0.95;1.10)	0.615
Sex male, n (%)	16 (45.7)	6 (66.7)	3.60 (0.72;18.16)	0.12
ASA, n (%)				
I-II	16 (45.7)	5 (55.6)	Ref	-
III-IV	19 (54.3)	4 (44.4)	1.40 (0.33;6.01)	0.651
Bilirubin, mean (SD), mg/dl	13.1 (10.4)	14.0 (6.78) [10.9;17.7]	1.05 (0.98;1.13)	0.169
Albumin, mean (SD), g/dl	3.05 (1.08)	3.59 (0.50) [2.98;3.37]	0.83 (0.29;2.38)	0.736
Clinical manifestation, n (%)				
Obstructive jaundice	26 (74.3)	6 (66.7)	Ref	-
Acute cholangitis	3 (8.57)	1 (11.1)	1.80 (0.21;15.7)	0.595
Cholestasis	3 (8.57)	2 (22.2)	0.68 (0.13;3.61)	0.653
Constitutional syndrome	2 (5.71)	0 (0)	NA	0.998
Abdominal pain	1 (2.86)	0 (0)	NA	1
Tumours, n (%)				
Pancreas	27 (77.1)	7 (77.8)	Ref	-
Others‡	8 (22.9)	2 (22.2)	1.57 (0.32;7.86)	0.58
Pancreatic tumours location, n (%)				
Head	24 (88.9)	7 (100)	Ref	-
No head	3 (11.1)	0 (0)	NA	0.999
Metastatic disease, n (%)	17 (48.6)	3 (33.3)	0.70 (0.17;2.86)	0.615
Procedures				
Biliary cannulation, n (%)				
Sphincterotome and guidewire	19 (54.3)	3 (33.3)	Ref	-
Transpancreatic sphincterotomy	5 (14.3)	1 (11.1)	1.10 (0.11;10.7)	0.933
Needle-knife precut	11 (31.4)	5 (55.6)	1.73 (0.40;7.50)	0.461
Stent type, n (%)				
PCSEMS	24 (68.6)	8 (88.9)	Ref	-
No PCSEMS	11 (31.4)	1 (11.1)	0.71 (0.08;5.96)	0.752
Procedure time, mean (SD), minutes	43.3 (14.9)	35.2 (3.77)	0.98 (0.90;1.06)	0.569
Results and oncological treatment				
No clinical success, n (%)	3 (8.57)	0 (0)	NA	-
Adverse events †, n (%)	5 (14.3)	3 (33.3)	3.51 (0.84;14.8)	0.067
Chemotherapy, n (%)	17 (48.6)	7 (77.8)	1.56 (0.32;7.55)	0.578
Radiotherapy, n (%)	3 (8.57)	3 (33.3)	1.87 (0.46;7.59)	0.374

ASA: American Society of Anesthesiologists physical status classification; PCSEMS: fully-covered self-expandable metal stent; PCSEMS: partially-covered self-expandable metal stent; UCSEMS: uncovered self-expandable metal stent; PS: plastic stent. NA: not applicable. ‡Other tumours include cholangiocarcinoma, ampullary neoplasm and biliopancreatic involvement due to colorectal cancer or osteosarcoma. † Adverse events within first 2 weeks.

associated with the loss of stent patency in the different reports.

In our cohort, higher albumin levels and, as expected, oncological therapies were also associated with longer survival. In addition, we also observed that patients with PCSEMSs had longer survival compared to FCSEMSs and PSs, but these results are biased as the PCSEMS was the most-used stent in this cohort. The recently updated ESGE guidelines recommend employing SEMs for palliative endoscopic BD, without specifying a specific type^[1]. PCSEMSs have emerged as a very promising alternative since they combine the advantages of a lower theoretical migration due to the presence of bilateral uncovered ends with a theoretically lower occlusion rate due to the presence of a mesh coating in their central region. However, a prospective and comparative multicenter study comparing FCSEMSs and PCSEMSs did not show significant differences between them in terms of patency, migration rates, or survival^[14].

With respect to the predictive factors of survival in patients with palliative transpapillary BD, there are also very limited data available. Prat *et al.* reported that age, sex, bilirubinaemia, type of primary tumour, the presence of metastases, and the percentage of weight loss were not associated with survival; tumour size was the only independent prognostic factor, and it distinguished two survival profiles: the median survival of patients with a tumour greater than 30 mm was 3.2 months, whereas it was 6.6 months for patients with a tumour less than 30 mm ($p < 0.001$)^[21]. In another study, elevated albumin levels and post-stenting chemotherapy were independent predictors of improved survival, whereas bilirubin, alanine aminotransferase and alkaline phosphatase levels, type of stent, and the cause of obstruction were not found to have a statistically significant effect on overall survival^[22]. In light of this, the results of our study should be treated with caution; more quality evidence is needed to clarify the

Table 5 Predictive factors associated with patient survival.

	No death (N=4)	Death (N=40)	Hazard ratio (95% CI)	p value
Baseline patient's profile				
Age, mean (SD), years	67.8 (7.37)	70.1 (11.1)	1.03 (0.99;1.06)	0.142
Sex male, n (%)	3 (75.0)	19 (47.5)	1.02 (0.54;1.93)	0.956
ASA, n (%)				
I-II	3 (75.0)	18 (45.0)	Ref	-
III-IV	1 (25.0)	22 (55.0)	1.91 (0.98;3.72)	0.058
Bilirubin, mean (SD), mg/dl	11.3 (7.15)	13.5 (9.97) [10.9;17.7]	1.02 (0.99;1.06)	0.176
Albumin, mean (SD), g/dl	3.83 (0.35)	3.09 (1.03) [2.98;3.37]	0.44 (0.30;0.63)	<0.001
Clinical manifestation, n (%)				
Obstructive jaundice	3 (75.0)	29 (72.5)	Ref	-
Acute cholangitis	0 (0)	4 (10.0)	1.08 (0.38;3.11)	0.88
Cholestasis	1 (2)	4 (10.0)	0.41 (0.14;1.20)	0.104
Constitutional syndrome	0 (0)	2 (5.0)	0.79 (0.18;3.42)	0.754
Abdominal pain	0 (0)	1 (2.5)	3.48 (0.44;27.3)	0.236
Tumours, n (%)				
Pancreas	3 (75.0)	31 (77.5)	Ref	-
Others‡	1 (25.0)	9 (22.5)	1.48 (0.69;3.15)	0.313
Pancreatic tumours location, n (%)				
Head	3 (100)	28 (90.2)	Ref	-
No head	0 (0)	3 (9.68)	1.78 (0.53;5.99)	0.351
Metastatic disease, n (%)	0 (0)	20 (50.0)	1.64 (0.87;3.08)	1.125
Procedures				
Biliary cannulation, n (%)				
Sphincterotome and guidewire	2 (50.0)	20 (50.0)	Ref	-
Transpancreatic sphincterotomy	1 (25.0)	5 (12.5)	0.76 (0.28;2.04)	0.586
Needle-knife precut	1 (25.0)	15 (37.5)	0.62 (0.31;1.26)	0.189
Stent type, n (%)				
PCSEMS	4 (100)	28 (70.0)	Ref	-
FCSEMS	0 (0)	7 (17.5)	2.66 (1.10;6.40)	0.029
UCSEMS	0 (0)	1 (2.5)	1.16 (0.16;8.70)	0.884
PS	0 (0)	4 (10)	3.36 (1.11;10.1)	0.032
Procedure time, mean (SD), minutes	35 (.)	40.9 (13.0)	1.06 (1.00;1.13)	0.067
Results and oncological treatment				
No clinical success, n (%)	0 (0)	3 (7.5)	43.4 (6.97;270)	<0.001
Adverse events †, n (%)	1 (25.0)	7 (17.5)	0.97 (0.43;2.21)	0.943
Chemotherapy, n (%)	3 (75.0)	21 (52.2)	0.42 (0.22;0.80)	0.008
Radiotherapy, n (%)	2 (50.0)	4 (10.0)	0.23 (0.07;0.76)	0.016

ASA: American Society of Anesthesiologists physical status classification; FCSEMS: fully-covered self-expandable metal stent; PCSEMS: partially-covered self-expandable metal stent; UCSEMS: uncovered self-expandable metal stent; PS: plastic stent; NA: not applicable. ‡ Other tumours include cholangiocarcinoma, ampullary neoplasm and biliopancreatic involvement due to colorectal cancer or osteosarcoma. † Adverse events within first 2 weeks.

factors associated with greater stent patency and survival of patients with palliative BD.

The current study has some strengths and limitations that require further comment. It should be noted that this is a retrospective analysis of a limited number of patients, in whom different types of stents were placed, with the choice uncontrolled and at the discretion of the endoscopist. However, other strengths should be pointed out, such as the homogeneity of our cohort with rigorous inclusion and exclusion criteria, the consecutive inclusion of patients during a period of 2 calendar years, and the fact that all procedures were carried out by the same experienced interventional endoscopy team, which means that the procedures and patient management were highly standardized.

In conclusion, the majority of biliary stents were functional, without need for repeating the ERCP sessions. Secondly, the need for stent repermeabilization did not negatively influence patient survival. And lastly, a high albumin levels seems to be associated with longer survival, in patients with unresectable biliopancreatic tumours. However, it is important to highlight the lack of studies of great statistical power that provide clear evidence for the identification of factors associated with the loss of stent patency and the longer survival of these patients.

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