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Impact of a shorter replacement interval of plastic stents on premature stent exchange rate in benign and malignant biliary strictures

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[Correction added on 15 June 2022, after first online publication: Alica Kubesch has been added as one of the corresponding author]

Abstract

Background and Aim: The main disadvantage of plastic stents is the high rate of stent occlusion. The usual replacement interval of biliary plastic stents is 3 months. This study aimed to investigate if a shorter interval of 6–8 weeks impacts the median premature exchange rate (mPER) in benign and malignant biliary strictures.
Methods: All cases with endoscopic retrograde cholangiopancreatography (ERCP) and plastic stent placement were retrospectively analyzed since establishing an elective replacement interval of every 6–8 weeks at our institution and mPER was determined.
Results: A total of 3979 ERCPs (1199 patients) were analyzed, including 1262 (31.7%) malignant and 2717 (68.3%) benign cases, respectively. The median stent patency (mSP) was 41 days (range 14–120) for scheduled stent exchanges, whereas it was 17 days (1–75) for prematurely exchanged stents. The mPER was significantly higher for malignant (28.1%, 35–50%) compared with benign strictures (15.2%, 10–28%), $P < 0.0001$, respectively. mSP was significantly shorter in cases with only one stent (34 days [1–87] *vs* 41 days [1–120]) and in cases with only a 7-Fr stent (28 days [2–79]) compared with a larger stent (34 days [1–87], $P = 0.001$). Correspondingly, mPER was significantly higher in cases with only one stent (23% *vs* 16.2%, $P < 0.0001$) and only a 7-Fr stent (31.3% *vs* 22.4%, $P = 0.03$).
Conclusion: A shorter replacement interval does not seem to lead to a clinically meaningful reduction of mPER in benign and malignant strictures. Large stents and multiple stenting should be favored as possible.

Introduction

Endoscopic retrograde biliary drainage with plastic stents was introduced in the 1980 s.[1] Later on, self-expandable metal stents (SEMSs) were adapted to improve stent patency in specific patient subgroups.[2,3] In many benign strictures, the temporary placement of multiple plastic stents is the treatment of choice. Especially in postsurgical strictures, it provides the advantage of a stepwise dilatation of the strictures.[4] In malignant strictures, SEMSs are recommended in the current practice guidelines whenever possible to be placed in distal and hilar malignant strictures.[4] However, there are still various situations in which plastic stents are also used in malignant strictures, for example, in initial biliary drainage when the origin of the stenosis is unknown or complex hilar strictures with multiple stenoses. Moreover, in some regions, availability of SEMSs is limited because of economic reasons.[5]

The main disadvantage of plastic stents is shorter patency due to stent dysfunction, most frequently caused by stent occlusion. This is highly important because patients can experience acute cholangitis and potential life-threatening sepsis if stent occlusion happens before scheduled stent replacement. On the other hand, if stent replacement is performed too frequently, it increases medical costs and reduces patient's quality of life. Various types of plastic stents have been investigated to increase stent patency, but none of these subtypes have shown convincing benefits so far over conventional stents, and usually straight or double-pigtail plastic stents are used.[6–9] Straight plastic stents are thought to have longer patency, while less stent migration occurs in pigtail stents, but subtype-specific data are minimal.[10] Most commonly, a 3-month exchange period is recommended, but there is a lack of data on whether a shorter interval might decrease the rate of premature stent exchange depending on the underlying etiology.[4]

This highlights the need of further investigation for predictors of early stent occlusion to individualize stent exchange intervals and to include these recommendations in the current practice guidelines. In this context, the current study aimed to analyze the impact of a short replacement interval of 6–8 weeks of double-pigtail stents in malignant and benign biliary strictures.

Patients and methods

All patients treated with endoscopic retrograde cholangiopancreatography (ERCP) and biliary disease at Frankfurt University Hospital were retrospectively analyzed between December 2007 and December 2019. Inclusion criteria were the insertion, exchange or extraction of plastic stents, and age over 18 years. Patients might have undergone previous treatment with plastic stents. Exclusion criteria were previous or concurrent treatment with a SEMS, unknown date of stent extraction, only stenting of the ductus wirsungianus, or stent placement via percutaneous access. Because straight plastic stents are rarely used at our institution for bile duct stenosis, only double-pigtail stents were included to have a homogeneous patient cohort. The medical records noted demographic data, etiology of the stricture, size and length of the stents, and indwell time. If the stent was exchanged prematurely, the reason was documented: A cholangitis was filed as documented in the electronic records including fever at admission or evident pus during the procedure. Stent migration was defined as the complete disappearance of the stent from the bile duct. Cholestasis was recorded if there were signs of cholestasis in the medical history such as icterus, discolored stool, brown urine, and elevated laboratory values of cholestasis (bilirubin, γ-glutamyltransferase, and alkaline phosphatase). To differentiate between stent occlusion and other potential reasons for cholestasis or cholangitis, such as progression of the underlying disease, was not always possible. Thus, the cholangitis group and the cholestasis group include cases of stent occlusion.

The primary outcome of interest was to determine the premature exchange rate. Standard protocol at our institution is to schedule ERCP at 6 to 8 weeks following placement of a stent, unless warranted sooner for reintervention if there is clinical suspicion for a high risk of recurrent cholangitis. The shorter stent exchange interval was introduced at our center due to various reasons. For patients with benign stenosis, for example, posttransplant strictures, chronic pancreatitis, and postoperative strictures, the intention was to accelerate the dilatation process. In the case of biliary stones, we chose the interval of 4–6 weeks between stone extractions or simply stent removal after cholecystectomy if there was no reason for a longer patency. For patients with malignant stenosis, the shorter interval was chosen to prevent cholangitis as we frequently experienced cholangitis episodes in these patients.

Additional outcomes of interest were identifying risk factors for premature stent exchange rate according to the number and size of stents and underlying etiology.

All patients provided written informed consent before endoscopic interventions. We used duodenoscopes TJF-160VR or TJF-Q180V (both Olympus, Tokyo, Japan) with an outer diameter of 11.3 mm and a working channel of 4.2 mm. Double-pigtail stents between 5 and 10 Fr were used (optimed, Ettlingen, Germany) with lengths ranging from 4 to 15 cm. The institutional review board of the Johann Wolfgang Goethe University Hospital approved this retrospective study (study ID: 74/19).

Statistical analysis. Statistical analyses were conducted using IBM SPSS STATISTICS version 22.0 (International Business Machine Corporation, Endicott, NY, USA) and R version 4.0.4 (R Foundation for Statistical Computing, Vienna, Austria). *P*-values ≤ 0.05 were considered to be statistically significant. All tests are two-sided. Associations of outcomes with dichotomic variables were assessed in mixed logistic regression models. After univariate analyses, multivariate analyses were performed for significant associations. Using a *P*-value > 0.1 for removal from the model, multivariate models were obtained by backward selection. The Kaplan–Meier method was applied to determine stent patency over the study period. Analyses were performed concerning to premature stent exchange/extraction (i.e. patients with premature stent exchange).

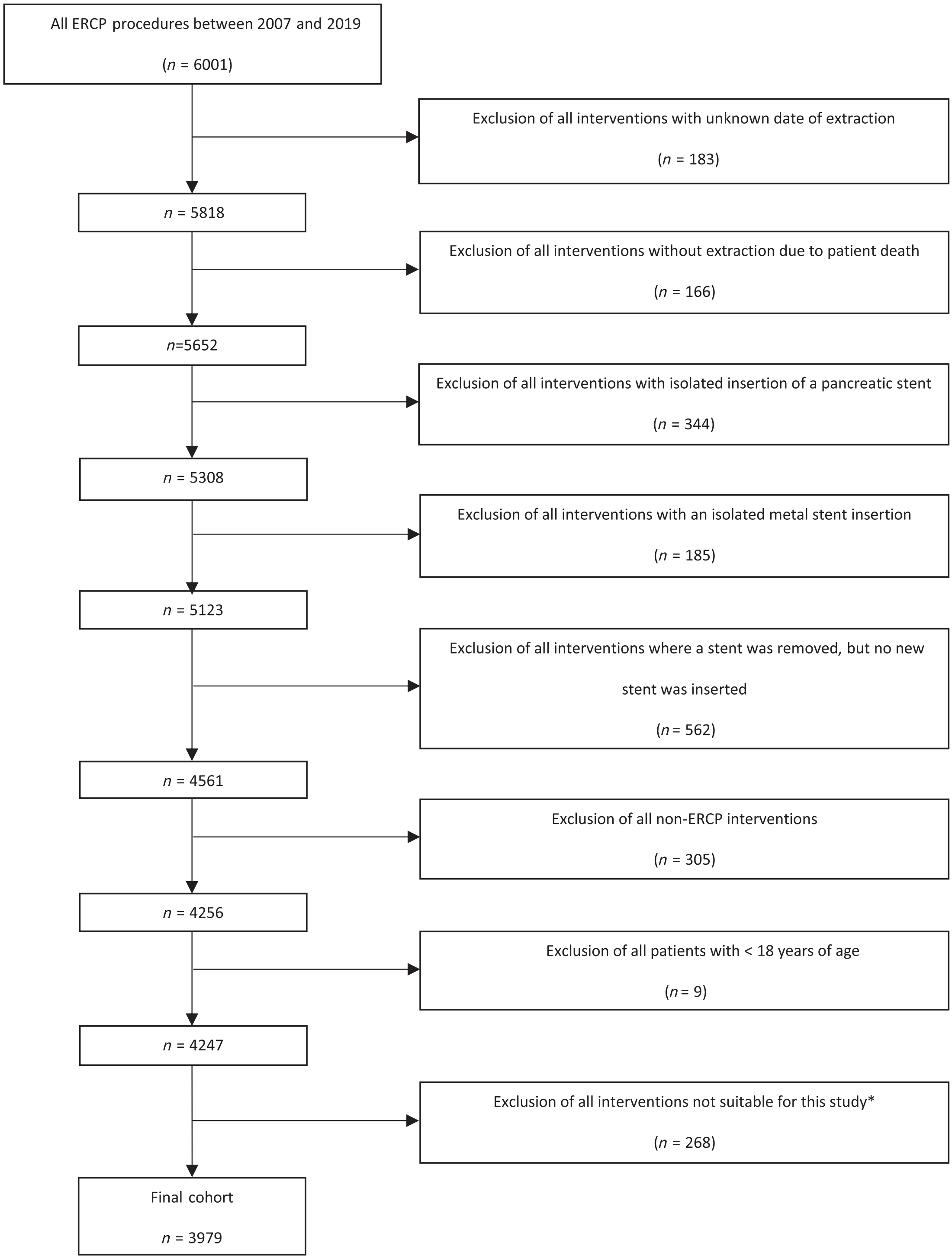
Results

Patients and procedural characteristics. A total of 3979 ERCPs of 1199 patients were included in this study (Fig. 1). In 1199 cases (30.1%), it was the first stent insertion. In 2660 cases (66.9%), it was a repeated stent insertion, and lastly, in 120 cases (3%), it was a resumed stent insertion after a preceding pause. In most cases (n = 1777, 44.7%), one stent was inserted during the procedure, followed by two stents (n = 1485, 37.3%). The most frequently used stent size was 10 Fr (3377, 84.2). The majority of patients had a benign disease as a reason for the stent insertion (n = 817, 68.1%). The number of female patients were comparable for benign (n = 353, 43.2%) and malignant strictures (n = 154, 40.3%). Clinical characteristics of the study cohort are shown in Table 1. Data on stent characteristics are provided in Table S1.

Reason for premature stent exchange and impact of etiology. In 766 cases (19.3%), the stent was extracted prematurely, whereas in 3213 cases (80.7%), the stent was extracted during a scheduled procedure. The main reason for a premature stent exchange or extraction was cholangitis in 556 cases (72.6%, Table 2).

The overall median stent patency for prematurely exchanged/extracted stents was 17 days (range 1–75), whereas the stent patency in the planned exchanged/extracted group was 41 days (14–120). In 1262 cases (31.7), the indication for stent insertion was an underlying malignant indication, whereas in 2717 cases (68.3%), the underlying condition was benign. Of interest, the rate of premature stent exchange was significantly higher for malignant (28.1% [n = 354]) indications compared with benign strictures (15.2% [n = 414], $P < 0.0001$, Fig. 2a). The most frequent underlying etiology was stenosis after orthotopic liver transplant with 21% of all cases (n = 835) followed by ischemic-type biliary lesion with 12.7% (504). The most frequent malignant diagnosis was cholangiocarcinoma (13.2%, 527). The range of premature exchange rates within the groups was comparably homogeneous, with 10–28% in benign and 34–50% in malignant strictures, respectively (Table 3).

In the mixed multivariate regression analysis, the parameters placement of one stent only (multivariate $P < 0.0001$, odds ratio [OR]= 1.95, 95% confidence interval [CI] = 1.53–2.51), a malignant indication (multivariate P = 0.001, OR = 2.1, 95% CI =1.34–3.16, associated with a premature stent exchange. The parameter biliary stones (multivariate $P < 0.0001$, OR = 0.49, 95% CI = 0.33–0.73) as an underlying condition were inversely associated with a premature stent exchange (Table 4).



* All ERCPs without placement or extraction of a plastic stent were excluded. Likewise, patients who did not show up for scheduled stent extraction appointments were excluded as well as patients presenting intermittently at other hospitals than our center.

Figure 1 Flow diagram of patient inclusion.

Impact of the number of stents. To examine whether the number of stents might influence the premature stent exchange rate, we compared stent patency between cases in which only one stent was placed (n = 1777, 44.7%) with cases where multiple stents were placed (n = 2202, 55.3%). The median stent patency in the one-stent group was 34 days (range 1–87), whereas it was

Table 1 Study population and stent characteristics

	Entire cohort	Benign	Malignant	*P*-value
Age, median (years), range	63 (18–97)	59 (18–97)	69 (22–95)	< 0.0001
Male, *n* (%)	692 (57.7)	464 (56.8)	228 (59.7)	0.415
Single-stent insertion, *n* (%)	618 (51.5)	432 (52.9)	186 (48.7)	0.193
Indication, *n* (%)				
OLT stenosis		110 (9.2)		
ITBL post-OLT		37 (3.1)		
Postoperative		152 (12.7)		
Chronic pancreatitis		38 (3.2)		
Biliary stones		319 (26.6)		
PSC		42 (3.5)		
Acute pancreatitis		27 (2.3)		
Unknown stenosis		30 (2.5)		
Other benign		62 (5.2)		
CCA			127 (10.6)	
HCC			36 (3.0)	
Pancreatic cancer			75 (6.3)	
Colorectal cancer			46 (3.8)	
Gallbladder cancer			19 (1.6)	
Other malignant			79 (6.6)	

Other benign: secondary sclerosing cholangitis; other malignant: breast cancer and papillary cancer.

CCA, cholangiocarcinoma; HCC, hepatocellular carcinoma; ITBL, ischemic-type biliary lesion; OLT, orthotopic liver transplantation; PSC, primary sclerosing cholangitis.

Table 2 Overview of reasons for premature stent exchange or extraction

Reason	*n* (%)	Benign	Malignant	*P*-value
Cholangitis	556 (72.6)	284 (68.9)	272 (76.8)	< 0.0001
Stent migration	41 (5.4)	27 (6.6)	14 (4)	0.002
Cholestasis	106 (13.8)	49 (11.9)	57 (16.1)	< 0.0001
Leakage	29 (3.8)	27 (6.6)	2 (0.6)	0.51
Bleeding	11 (1.4)	5 (1.2)	6 (1.7)	0.36
Other[†]	23 (3.0)	20 (4.9)	3 (0.8)	0.29

[†]Other (necrosis, abscess, pancreatitis, pain, liver failure, and choledocholithiasis [suspected recurrence]).

41 days (range 1–120) in the multiple-stent group. The rate of prematurely exchanged stents was significantly higher in the one-stent group (409 cases, 23%) compared with the > 1-stent group in 357 cases (16.2%, $P < 0.0001$, Fig. 2b). This significant difference could also be observed in benign indications (20% [$n = 259$] *vs* 10.7% [153]; $P < 0.0001$), but not for malignant strictures (31% [150] *vs* 26.2% [204 days]; $P = 0.071$).

Impact of the size of the stent. To investigate a potential higher risk of occlusion of a single 7-Fr stent, we compared stent patency of cases with a 7-Fr stent (n = 128, 7.2%) *versus* cases with bigger single stents (n = 1469, 92.18%). The median stent patency in the 7-Fr stent group was 28 days (range 2–79) compared with 34 days (range 1–87) in the other than 7-Fr group (P = 0.001, Fig. 2c). The rate of prematurely exchanged/extracted stents was significantly higher (P = 0.03) for the 7-Fr group (n = 40, 31.3%) compared with the non-7-Fr group (369, 22.4%). This significant difference could also be observed when only benign indications were investigated (34.8% [31] *versus* 18.9% [228], P = 0.001), but again not in malignant strictures (23.1% [9] *vs* 31.8% [141], P = 0.285).

Discussion

Plastic stents are widely used in the endoscopic treatment of benign and malignant biliary strictures. A 3-month exchange interval is often scheduled, but intervals may vary locally depending on the etiology and expertise of the endoscopist.[4] At our institution, a protocol with an exchange interval of usually 6–8 weeks and use of double-pigtail stents was established. The current study aimed to investigate whether this might influence the rate of premature stent exchanges in benign and malignant strictures.

Data on premature stent exchange rate of plastic stents in benign strictures are highly heterogeneous, and the subtype of the plastic stent and the underlying etiology needs to be considered. In our cohort, the premature exchange rate in the benign group varied between 12% in posttransplant stenosis and 28% in other postoperative strictures. These data are comparable with premature exchange rates described in the literature, such as 18% for postoperative strictures in a study by Costamagna *et al.*[11] For posttransplant stenosis, a prospective trial from 2018 reported stent-related adverse events in the multiple-stent group with a 3-month exchange interval only in 9/141 cases (4.2%). Notably, at least two stents were placed at the initial ERCP.[12] On the other hand, in a smaller prospective trial, 4/10 patients (40%) experienced cholangitis in the multiple-stent group.[13] In biliary stones, a retrospective trial from 2010 observed a low premature exchange rate of 5% for multiple stents and removal/exchange after more than 6 months.[14] In the present study, we observed a low rate of premature stent exchanges of 13%. Of interest, most mentioned studies used straight plastic stents, while a few did not specify the subtype of their device. Although comparing of these studies with our data is only possible to a limited extent, the results suggest that our protocol most likely does not lead to a remarkable reduction of the premature exchange rate in benign biliary strictures using double-pigtail stents. The inverse association of biliary stones in the multivariate analysis suggests that in these cases, a longer stent duration can be recommended if clinically justified. The comparably high premature extraction rate of 28% in postoperative strictures warrants further investigation in this heterogeneous group of patients.

In contrast to benign strictures, malignant strictures had a significantly higher premature exchange rate in the present study. The rate varied between 34% for cholangiocarcinoma and 50% for gallbladder cancer. For pancreatic cancer, we observed a rate of 46%. High rates in this setting are known; for example, a recent trial reported a rate of 34.3% in patients with pancreatic adenocarcinoma and a scheduled period of stent exchange of 3 months leading the authors to suggest a shorter interval of stent exchange.[15] In the same setting, rates of 55% (49 patients) up to even 75% (79 patients) were described.[16,17] Moreover, a meta-analysis including five studies (247 patients) comparing

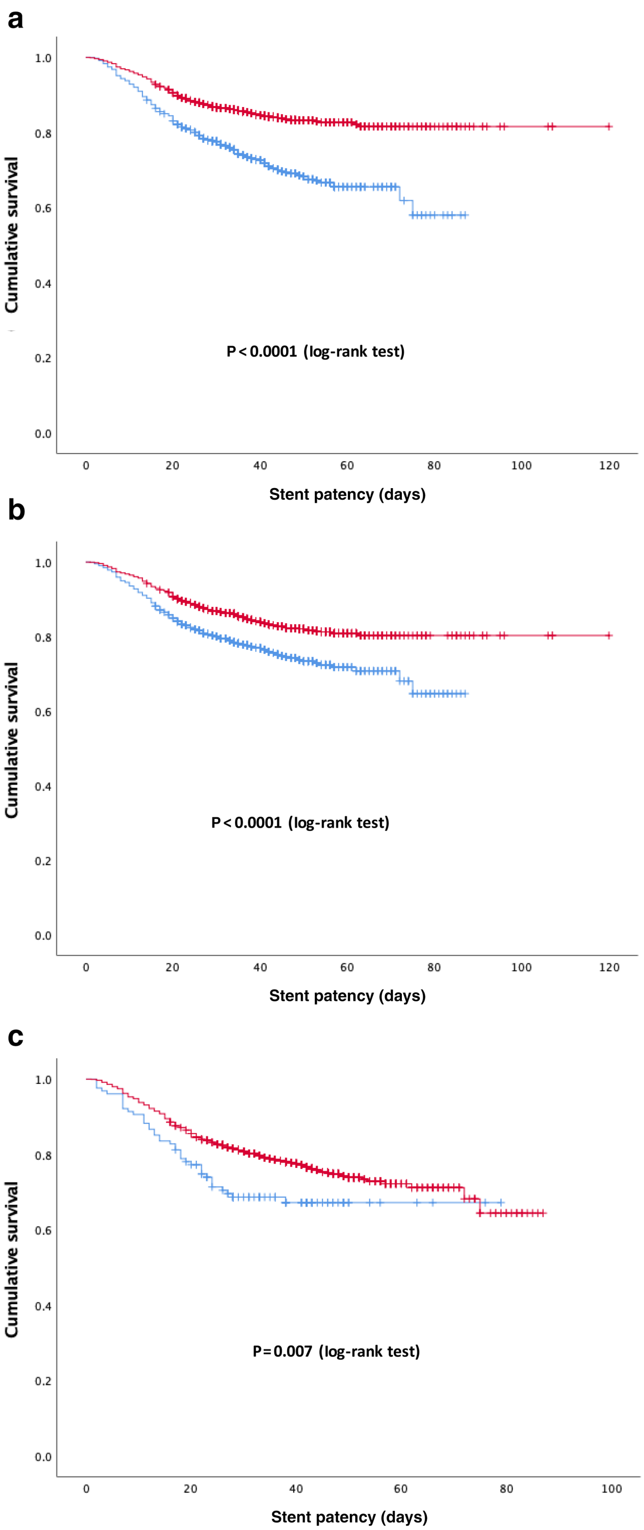


Figure 2 (a) Kaplan–Meier curve for the probability of premature stent exchange up to 120 days for benign and malignant indications. ▪▪▪, malignant indication: n = 1260; ▪▪▪, benign indication: n = 2719; ▪▪▪, malignant censored; ▪▪▪, benign censored. (b) Kaplan–Meier curve for the probability of premature stent exchange up to 120 days for 1 *versus* > 1 stent placed. ▪▪▪, 1 stent: n = 1777; ▪▪▪, > 1 stent: n = 2202; ▪▪▪, 1 stent censored; ▪▪▪, > 1 stent censored. (c) Kaplan–Meier curve for the probability of premature stent exchange up to 120 days for one 7-Fr *versus* one stent placed other than a 7-Fr size. ▪▪▪, one 7-Fr stent: n = 128; ▪▪▪, 1 stent (other than 7 Fr): n = 1649; ▪▪▪, one 7 Fr censored; ▪▪▪, one other Fr censored.

plastic stents with SEMSs in distal malignant stricture observed a rate of recurrent biliary obstruction of 39.7%.[18] In hilar malignant strictures, insertion of plastic stents is recommended if the patient is an operative candidate or life expectancy is expected to be less than 4 months.[4] We observed high rates ranging from 34% for CCA to 50% for gallbladder cancer in this setting. This is comparable with the results of a small prospective study including 28 patients, where adverse events occurred in 39% after 30 days treated with plastic stents.[19] Another small trial, including 54 patients, observed median patency of 35 days for plastic stents in complex hilar stenosis due to early (41%) and late complications (> 30 days, 33%).[20] Mukai *et al*. observed an occlusion rate of

Table 3 Impact of etiologies in premature stent exchange

Indication	*n* (%)	Overall stent patency, days (median, range)	Regular stenting, days (*n*; median, range)	Premature stenting, days (*n*; median, range)	Premature/regular (rate of premature stent exchange)
Benign	2719 (68.3)	37 (1–120)	2307 (84.8%)	412 (15.2%)	18%
OLT stenosis	835 (21)	38 (2–107)	746; 41 (17–107)	89; 17 (2–54)	12%
ITBL post-OLT	504 (12.7)	39.5 (1–92)	421; 42 (20–92)	83; 20 (1–46)	20%
Postoperative	436 (11)	35 (1–120)	340; 40 (16–120)	96; 17 (1–63)	28%
Chronic pancreatitis	137 (3.4)	42 (7–107)	123; 42 (26–107)	14; 22.5 (7–37)	11%
Biliary stone	436 (11)	37.5 (3–86)	385; 40 (19–86)	51; 15 (3–53)	13%
PSC	113 (2.8)	30 (2–67)	89; 35 (19–67)	24; 16 (2–36)	27%
Acute pancreatitis	43 (1.1)	42 (20–84)	39; 42 (23–84)	4; 26 (20–44)	10%
Unknown stenosis	64 (1.6)	41.5 (4–77)	52; 43 (22–77)	12; 17.5 (4–43)	23%
Other benign[†]	151 (3.6)	34.5 (6–78)	112; 41 (16–78)	39; 17 (6–49)	34%
Malignant	1260 (31.7)	35 (2–87)	906 (72)	354 (28)	39%
CCA	527 (13.2)	38 (2–87)	393; 42 (14–87)	134; 17 (2–75)	34%
HCC	148 (3.7)	33 (5–68)	106; 37 (17–68)	42; 16.5 (5–53)	40%
Pancreatic cancer	136 (3.4)	33 (5–68)	93; 41 (18–82)	43, 22 (3–57)	46%
Colorectal cancer	185 (4.6)	34 (3–84)	130; 42 (20–84)	55; 14 (3–57)	42%
Gallbladder cancer	102 (2.6)	31 (6–84)	68; 37 (21–84)	34; 24.5 (6–54)	50%
Other malignant[†]	162 (4.1)	33 (2–86)	116; 39 (21–86)	46; 14 (2–42)	40%

Other benign: secondary sclerosing cholangitis; other malignant: breast cancer and papillary cancer.
[†]Diagnoses with less than 1% were included under other benign or malignant conditions.
CCA, cholangiocarcinoma; HCC, hepatocellular carcinoma; ITBL, ischemic-type biliary lesion; OLT, orthotopic liver transplantation; PSC, primary sclerosing cholangitis.

Table 4 Logistic regression analysis for factors associated with premature stent extraction/exchange

	Univariate analysis		Multivariate analysis	
	P-value	OR (95% CI)	*P*-value	OR (95% CI)
OLT stenosis	< 0.0001	0.27 (0.24–0.39)		
ITBL post-OLT	0.957	0.31 (0.53–1.22)		
Postoperative	0.213	1.21 (0.89–1.64)		
Chronic pancreatitis	0.052	0.47 (0.22–1.01)		
Biliary stone	< 0.0001	0.52 (0.38–0.72)	< 0.0001	0.49 (0.33–0.73)
PSC	0.70	1.1 (0.59–2.19)		
Acute pancreatitis	0148	0.48 (0.14–1.35)		
CCA	< 0.0001	0.269 (0.24–0.35)		
HCC	0.068	1.7 (0.96–3.01)		
Pancreatic cancer	0.002	1.99 (1.29–3.1)		
Colorectal cancer	0.004	1.84 (1.21–2.79)		
Gallbladder cancer	0.003	2.15 (1.3–3.57)		
Malignant indication	< 0.0001	2.18 (1.73–2.74)	0.001	2.1 (1.34–3.16)
1 stent placed	< 0.0001	1.54 (1.26–188)	< 0.0001	1.95 (1.53–2.51)

Other benign: secondary sclerosing cholangitis; other malignant: breast cancer and papillary cancer.
CCA, cholangiocarcinoma; CI, confidence interval; HCC, hepatocellular carcinoma; ITBL, ischemic-type biliary lesion; OLT, orthotopic liver transplantation; OR, odds ratio; PSC, primary sclerosing cholangitis.

70% in plastic stents in a study with 30 patients.[21] Conclusively, the present study's high observed premature exchange rates underline the recommendation to place a SEMS whenever possible in malignant strictures.[4] Moreover, in malignant strictures with the initial placement of a plastic stent and planned exchange to a SEMS, a short interval of 3–4 weeks should be discussed.

Of interest, we observed a significantly higher rate of premature stent exchanges for cases with only a 7-Fr stent and only one *versus* multiple stents. These observations could be made not only in malignant but also in benign strictures. The longer stent indwelling times suggest a lower risk of stent occlusion in larger stents and when multiple stents are placed. This should be kept in mind, especially in patients with a potentially high risk of recurrent cholangitis. However, there are only limited data in the literature, and systematic studies addressing this question are warranted.

The main limitation of our study is the retrospective single-center design. Still, to the best of our knowledge, this is the first study analyzing a short exchange interval for biliary plastic stents. Another limitation is that in some cases, a scheduled exchange interval even shorter than 6 weeks was chosen as an individual treatment decision based on the examiner's experience and patient record. However, median stent patency in the regular exchange group was homogeneous across all etiologies ranging from 35 to 43 days. Lastly, as we had no control group in our study, comparisons concerning the reduction of median premature exchange rate can only be drawn in relation to historical data from other studies.

In summary, the present study provides the first comprehensive data of patients treated with plastic stents and a shorter than the usual replacement interval. Our findings suggest that a shorter interval than 3 months does not lead to a clinically meaningful decrease of premature stent exchange in benign biliary strictures. In malignant strictures, plastic stents have a shorter than the expected duration of patency. If an exchange to a SEMS is planned in this situation, a short interval such as 3–4 weeks should be discussed. When no SEMSs can be placed, multiple stenting and large stents should be favored as possible.

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