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Suspended over length biliary stents versus conventional plastic biliary stents for the treatment of biliary stricture

A retrospective single-center study

Xiue Yan, MD, Yonghui Huang, MD*, Hong Chang, MM, Yaopeng Zhang, MM, Wei Yao, MD, Ke Li, MD

Abstract

To compare patency between suspended over length biliary stents (SOBSs; made from nasobiliary tube) and conventional plastic biliary stents (CPBSs).

We retrospectively analyzed 61 patients with extrahepatic biliary stricture who underwent SOBS placement (intrahepatic bile duct) and 74 patients who underwent CPBS placement. Stent patency and complications were compared.

The SOBS group was slightly older and contained more females than the CPBS group but other baseline characteristics were similar. Malignant biliary obstruction accounted for 57.4% (SOBS group) and 45.9% (CPBS group) of cases. Technical success rate, hospital stay and post-procedure complications were similar between groups. Median patency in the CPBS and SOBS group was 116 (2–360) days and 175 (3–480) days, respectively ($P < .001$). The SOBS group had lower stent occlusion rates than the CPBS group at 3 months (9.8% vs 36.5%), 4 months (22.0% vs 55.4%), 5 months (35.6% vs 67.6%), and 6 months (39.3% vs 77.0%) (all $P < .01$). In Cox regression analysis, stent type (SOBS vs CPBS) was the only factor associated with patency (hazard ratio [HR]: 3.449; 95% CI: 1.973-6.028; $P < .001$).

SOBS may have better medium-term patency than CPBS for benign/malignant biliary stricture.

Abbreviations: CPBSs = conventional plastic biliary stents, ERCP = endoscopic retrograde cholangiopancreatography, HRs = hazard ratios, SEMSs = self-expandable metal stents, SOBSs = suspended overlength biliary stents.

Keywords: biliary stasis, biliary tract diseases, extrahepatic, stents, stricture

1. Introduction

Metal and plastic biliary stents are used to relieve jaundice in patients with benign or malignant biliary obstruction.[1] Plastic stents are recommended for benign common bile duct stricture and malignant stricture if the expected survival is <4 months. The main limitation of plastic stents is occlusion,[2] as the median patency is only 77 to 126 days.[3–5] Self-expandable metal stents (SEMSs) have lower rates of occlusion and less need for reintervention than plastic stents[6–8] and are considered cost-effective when life expectancy is >4 months. Nonetheless, occlusion and migration are still issues encountered with SEMSs.[9]

The mechanisms underlying stent occlusion include biliary sludge caused by bacterial accumulation and duodenobiliary reflux.[10,11] Despite efforts to prolong plastic stent patency, sludge due to duodenobiliary reflux remains an unresolved issue. The irregular inner surface of Teflon stents (seen on scanning electron microscopy) may contribute to bacterial accumulation.[12] Previous attempts to prevent duodenobiliary reflux and sludge formation have not been particularly successful.

We hypothesized that a new strategy, utilizing a suspended overlength biliary stent (SOBS) formed from nasobiliary drainage tube, would have advantages over a conventional plastic biliary stent (CPBS) with regard to duodenobiliary reflux and patency. Therefore, this study aimed to compare efficacy and medium-term patency between a SOBS and a CPBS.

2. Methods

2.1. Patients and grouping

This retrospective analysis included consecutive patients with extrahepatic bile duct stricture treated at the Gastroenterology and Hepatology Department, Peking University Third Hospital (Beijing, China) either by SOBS placement or CPBS placement. The study was carried out in accordance with the Helsinki Declaration principles and approved by the Institutional Review Board of Peking University Third Hospital (no. 201721802). Informed consent was waived due to the retrospective design.

The inclusion criteria were:

1) male/female patients of any age with extrahepatic bile duct stricture due to malignant causes (cholangiocarcinoma, extrahepatic bile duct infiltration by pancreatic cancer or

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Department of Gastroenterology and Hepatology, Peking University Third Hospital, Haidian District, Beijing, China.

* Correspondence: Yonghui Huang, Department of Gastroenterology and Hepatology, Peking University Third Hospital, 49 Huayuan North Road, Haidian District, Beijing 100191, China (e-mail: 15611908652@163.com).

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duodenal papilla carcinoma) or benign causes (chronic pancreatitis, autoimmune pancreatitis, postoperative anastomotic stenosis or inflammatory stenosis of the extrahepatic bile duct);
2) cholangitis, worsening liver function tests and/or abnormal CT/MRCP findings indicating cholestasis or acute biliary pancreatitis were considered due to bile duct occlusion; and either
3) a SOBS was surgically placed in the intrahepatic bile duct between January 1, 2016 and 31 December 2016 and the patient was followed up for ≥3 months; or
4) a CPBS was surgically placed in the intrahepatic bile duct between January 1, 2007 and 31 December 2016 and complete medical and endoscopic retrograde cholangiopancreatography (ERCP) records were available; patients who received a CPBS due to occlusion of a previous plastic stent were also included. Although plastic stents are usually recommended for patients with an expected survival <4 months, some of the included patients had a longer expected survival but either refused metal stents (due to the higher costs or risks of complications such as obstruction and migration) or declined surgery in favor of conservative treatment.

The exclusion criteria were:

1) previous biliary stenting (with plastic and/or metal stents in those who received a SOBS; with metal stents in those who received a CPBS);
2) resectable biliary occlusion;
3) guidewire could not be passed through the stricture;
4) expected survival <3 months; and
5) endoscopy in those presenting with duodenal obstruction could not reach the papillary region.

The patients were divided into 2 groups (SOBS or CPBS) according to the type of stent implanted.

2.2. SOBS placement

The SOBS was placed in the biliary duct at the end of ERCP. The same experienced endoscopist (Professor YH Huang) performed all procedures. The SOBS was constructed from nasobiliary tube (8.5Fr) with multiple side-holes (Boston Scientific Corporation, Spencer, IN) made from polyvinyl chloride. A 30-cm section from the top was cut with a scalpel on a sterile operating table (Fig. 1). The 30-cm length ensured that the end of the SOBS reached the horizontal part of the duodenum.

After deep cannulation of the main bile duct with a guidewire, contrast agent was introduced to elucidate the stricture margins. The guidewire was passed through the stricture to the proximal biliary tree, and intrahepatic filling was obtained if necessary. A minor biliary sphincterotomy was performed, and the SOBS was placed in the left or right intrahepatic biliary duct using a stent delivery catheter under fluoroscopic guidance. The placement procedure (Fig. 2) was similar to that for a nasobiliary tube. Briefly, when the stent tip had been positioned in the appropriate intrahepatic biliary duct, fluoroscopic scanning was adjusted to ensure the entire stent was under X-ray surveillance. Under endoscopic and fluoroscopic guidance, the stent was loosened from the delivery catheter with a small twist and advanced, with the guidewire maintained in the SOBS. Once the stent end had been placed in the duodenal cavity in an unhindered condition, the guidewire was retrieved slowly while ensuring that the stent tail did not curl over.

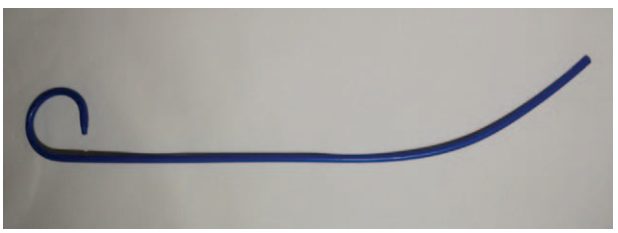

Figure 1. Suspended overlength biliary stent formed from a 30-cm section of nasobiliary drainage tube (8.5Fr). The nasobiliary tube had multiple side-holes and was made from polyvinyl chloride.

2.3. CPBS placement

A plastic stent (8.5Fr; straight rather than pigtailed) was inserted into the bile duct using a standard technique. The stent length was selected to ensure that the side-holes rested upstream of the stricture. The distal end was deployed in the duodenal lumen. Only 1 stent was placed in all cases of hepatic hilar stenosis.

2.4. Follow-up

All patients in the SOBS group were followed up as outpatients approximately every 3 months until April 30, 2017 or death, whichever occurred first. For the CPBS group, follow-up information was extracted from medical records. Follow-up included the assessment of indicators of stent occlusion, such as abdominal pain, fever, jaundice, and elevated levels of serum total bilirubin (TBIL), alkaline phosphatase (ALP), and white blood cell count (WBC). Patients with cholangitis symptoms and worsening liver function suggestive of cholestasis were considered as premature stent occlusion[13] and admitted to our hospital for stent replacement. The biliary stricture was reevaluated, and (in the CPBS group) choledocholithiasis was treated with an extraction balloon and/or basket if necessary during stent exchange. Stents were not changed prophylactically but replaced when a patient developed signs or symptoms of occlusion.

2.5. Data collection

The following data were extracted from medical records: baseline demographic/clinical characteristics (age, gender, cause of stricture, chief presenting symptoms/signs, stricture length, stricture location, and presence/absence of cholangitis or acute pancreatitis), procedural characteristics (technical success rate, duration of hospital stay and post-ERCP complications), and occurrence/timing of stent obstruction.

2.6. Statistical analysis

The analysis was carried out using SPSS 24.0 (IBM Corp., Armonk, NY). Normally-distributed continuous data are shown as the mean ± standard deviation (SD) and were compared between groups using Student *t* test. Non-normally-distributed continuous data are presented as median (range) and were compared between groups using the Mann–Whitney *U* test. Enumeration data are shown as *n*(%) and were compared between groups using the chi-squared test or Fisher exact test. Occlusion-free survival was compared between groups using Kaplan–Meier analysis and the log-rank test. Multivariate Cox regression analysis (enter method) was performed to identify factors associated with stent patency. The independent variables

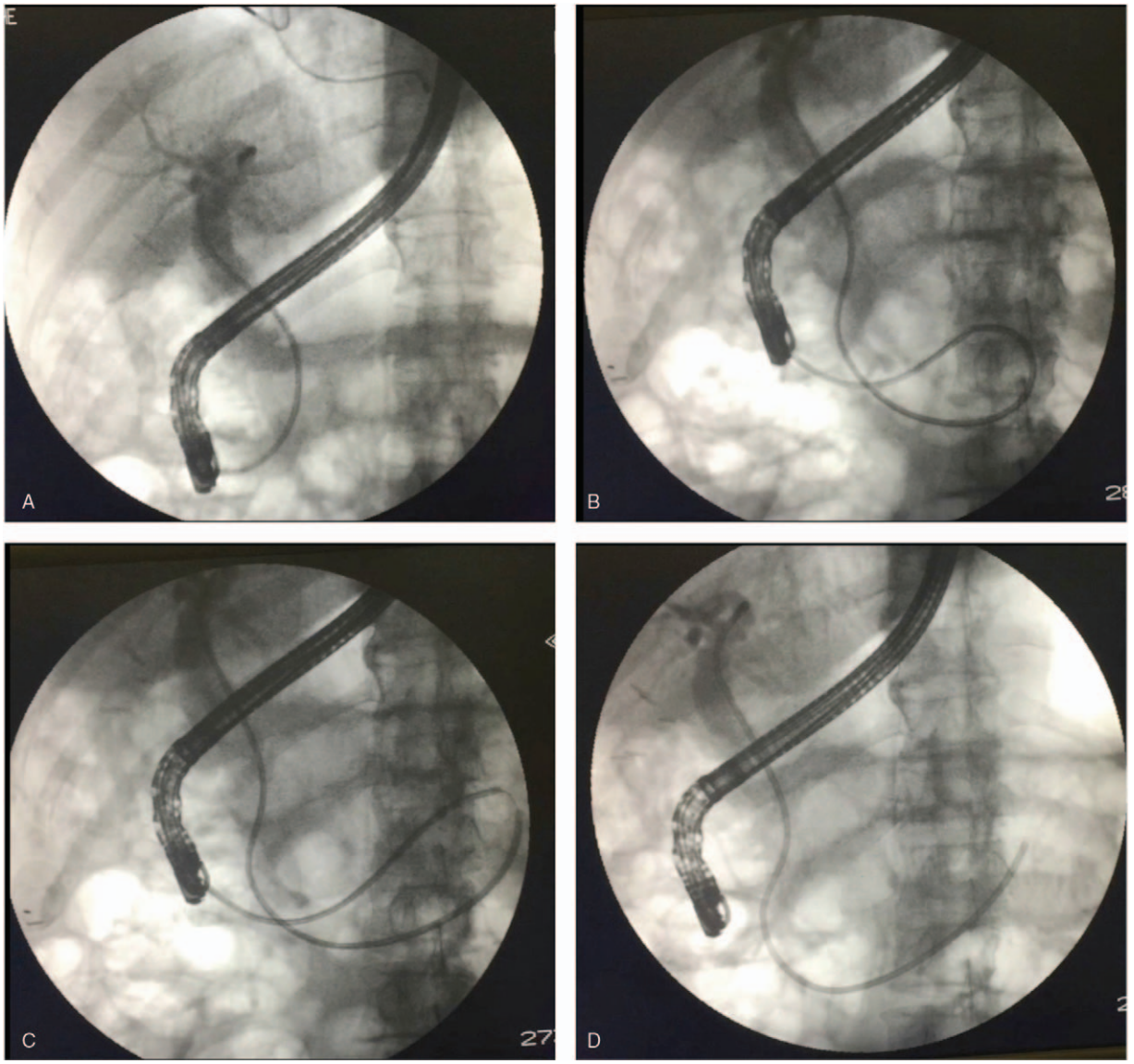

Figure 2. Representative fluoroscopic images illustrating the placement of a SOBS. A. At the end of endoscopic retrograde cholangiopancreatography, a SOBS was placed in the descending branch of the intrahepatic bile duct under fluoroscopic guidance. B. When the tip of the stent had been positioned in the biliary duct, fluoroscopic scanning was adjusted to ensure that the entire stent was visible. C. Under fluoroscopic guidance, the stent was loosened from the delivery catheter with a small twist and advanced, with the guidewire maintained in the SOBS. Once the end of the stent had been placed in the distal duodenal cavity in an unhindered position, the guidewire was retrieved slowly. D. Successful stent placement ensured that the tail of the stent had not curled over. SOBS = suspended overlength biliary stent.

were gender (male or female), age (continuous), cause of stricture (malignant or benign), stricture location (common bile duct, hilar, bilioenteric anastomosis, common hepatic duct, or multiple stricture of the extrahepatic duct), and stent type used (SOBS or CPBS). Hazard ratios (HRs) and 95% confidence intervals (95% CIs) were calculated. $P<.05$ was taken as statistically significant.

3. Results

3.1. Baseline characteristics

The final analysis included 61 patients in the SOBS group and 74 patients in the CPBS group. The baseline demographic/clinical characteristics are summarized in Table 1. Compared with the CPBS group, the SOBS group had higher mean patient age (68.8 ± 15.8 years vs 60.4 ± 14.7 years; $P=.002$) and contained proportionally more females (41.0% vs 21.6%; $P=.015$). However, the 2 groups exhibited no significant differences with regard to the cause of the biliary stricture, chief presenting symptoms/signs, incidence of concomitant cholangitis/pancreatitis before the first ERCP, stricture location or stricture length (Table 1). Furthermore, the distributions of the benign (Fig. 3) and malignant (Fig. 4) causes of biliary stricture did not differ significantly between groups (Fig. 5).

3.2. Procedural characteristics

There were no significant differences between the SOBS and CPBS groups in technical success rate, length of hospital stay, and post-ERCP complications (Table 1).

Table 1

Demographic, clinical, and procedural characteristics of the study participants.

	SOBS ($N=61$)	CPBS ($N=74$)	P value
Age (years)	68.8 ± 15.8	60.4 ± 14.7	.002
Gender (male:female)	36:25	58:16	.015
Cause of biliary stricture			
Malignant	35 (57.4%)	34 (45.9%)	.186
Benign	26 (42.6%)	40 (54.1%)	
Chief presenting symptom/sign			
Abdominal pain	12 (19.7%)	9 (12.2%)	.323
Jaundice	17 (27.8%)	20 (27.0%)	
Abdominal pain and jaundice	21 (34.4%)	14 (18.9%)	
Fever	1 (1.6%)	0 (0.0%)	
Abdominal pain and fever	1 (1.6%)	5 (6.7%)	
Jaundice and fever	15 (24.6%)	10 (13.5%)	
Cholangiectasis with no symptoms	5 (8.2%)	1 (1.4%)	
Elevated r-GT with no symptoms	2 (3.3%)	2 (2.7%)	
Concomitant disease			
Cholangitis during initial episodes	14 (22.9%)	8 (10.8%)	.149
Acute pancreatitis during initial episodes	1 (1.6%)	4 (5.4%)	.377
Location of bile duct stricture			
Middle and/or lower	39 (63.9%)	43 (58.1%)	.313
Hilar	11 (18.0%)	15 (20.3%)	
Duct-jejunum anastomosis	5 (8.2%)	11 (14.9%)	
Multiple	0 (0.0%)	2 (2.7%)	
Common hepatic duct	0 (0.0%)	3 (4.1%)	
Choledocholithiasis (difficult to extract)	6 (9.8%)	0 (0.0%)	
Stricture length (cm)	2.0 (0.4–5.0)	2 (0.5–4.0)	.909
Technical success	61 (100%)	74 (100%)	1.000
Hospital stay (days)	9 (5.5–11.0)	10 (8–16)	.079
Post-ERCP complications			
Mild pancreatitis	6 (9.8%)	10 (13.5%)	.764
Moderate/severe pancreatitis	1 (1.6%)	0 (0.0%)	
Biliary infection	2 (3.3%)	3 (4.1%)	
None	52 (85.2%)	61 (82.4%)	

The data are presented as mean ± standard deviation, *n*(%) or median (minimum–maximum). CPBS = conventional plastic biliary stent, ERCP = endoscopic retrograde cholangiopancreatography, SOBS = suspended overlength biliary stent.

3.3. Duration of stent patency

All patients in the CPBS group experienced a minimum of 2 ERCPs before replacement of their plastic stents. Occlusion-free survival was significantly longer in the SOBS group than in the CPBS group ($P<.001$, log-rank test). Median duration of stent patency was 116 (2–360) days in the CPBS group after the first ERCP, significantly shorter than the value of 175 (3–480) days in the SOBS group ($P<.001$). Furthermore, subgroup analysis showed that median duration of stent patency was significantly shorter in the CPBS group than in the SOBS group for both malignant causes of biliary stricture [90 (3–360) days vs 150 (3–450) days; $P=.041$] and benign causes [119 (2–360) days vs 186 (90–480) days; $P=.002$] (Fig. 5).

3.4. Stent occlusion rate

The stent occlusion rates were significantly lower in the SOBS group than in the CPBS group at 3 months (9.8% vs 36.5%, $P<.001$), 4 months (22.0% vs 55.4%, $P<.001$), 5 months (35.6% vs 67.6%, $P<.001$), and 6 months (39.3% vs 77.0%, $P=.001$) after the first ERCP.

3.5. Factors associated with stent patency

Multivariate regression analysis revealed that stent type (SOBS vs CPBS) was the only factor independently associated with stent patency (HR: 3.449; 95% CI: 1.973–6.028; $P<.001$). Gender, age, stricture location, and stricture cause (malignant or benign) were not significantly related to stent patency (Table 2).

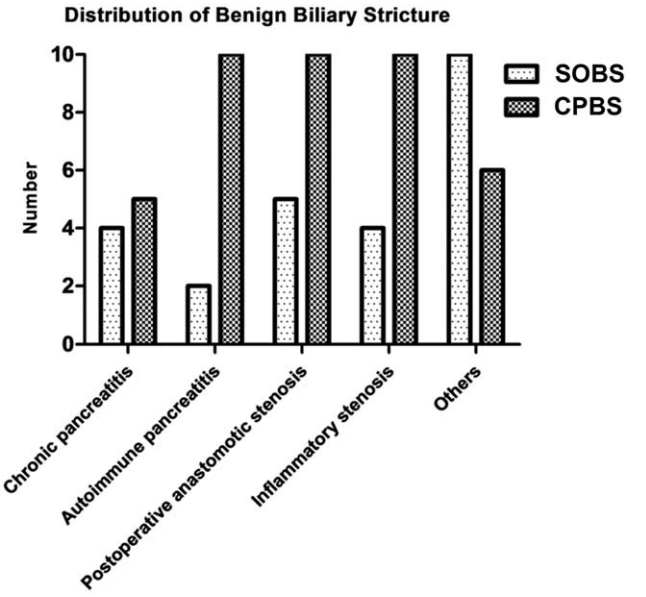

Figure 3. Distribution of the causes of benign biliary stricture. The distribution of the causes of benign biliary stricture did not differ significantly between groups. CPBS = conventional plastic biliary stent, Others = large calculi of the common bile duct in patients more than 80 years old, SOBS = suspended overlength biliary stent.

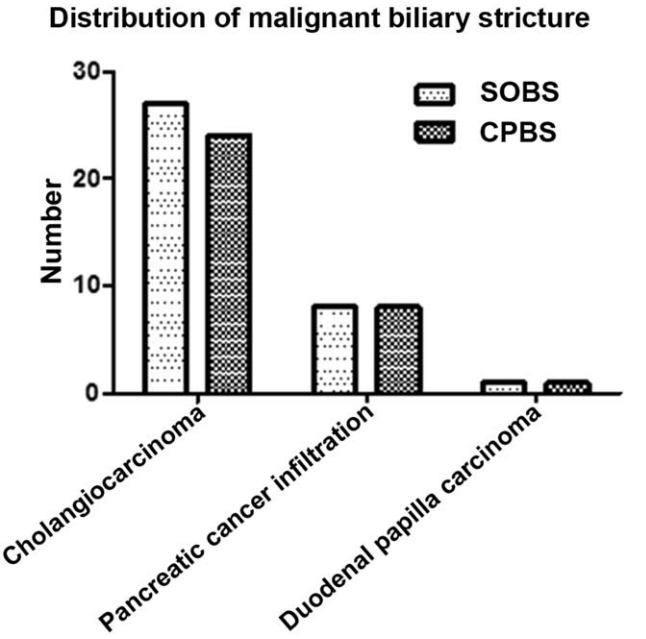

Figure 4. Distribution of the causes of malignant biliary stricture. The distribution of the causes of malignant biliary stricture did not differ significantly between groups. CPBS = conventional plastic biliary stent, SOBS = suspended overlength biliary stent.

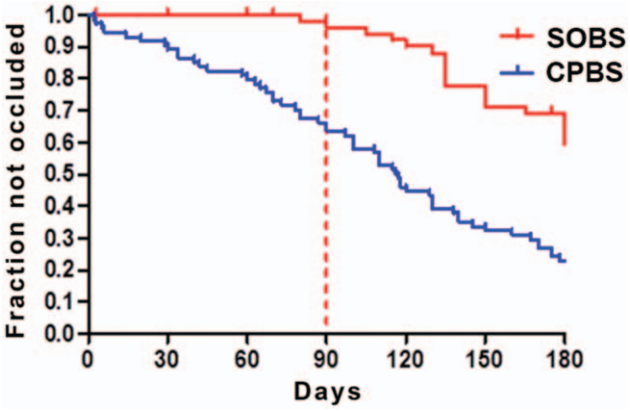

Figure 5. Kaplan–Meier analysis of occlusion-free survival. Occlusion free survival was 116 (2–360) days in the CPBS group after the first ERCP and 175 (3–480) days in the SOBS group (hazard ratio: 2.047; 95% confidence interval: 1.339–3.131; $P < .001$). CPBS = conventional plastic biliary stent, ERCP = endoscopic retrograde cholangiopancreatography, SOBS = suspended overlength biliary stent.

4. Discussion

The main findings of this study were that median patency was significantly longer for the SOBS than for the CPBS. Furthermore, occlusion rates at 3 to 6 months (the period when most plastic stents fail) were significantly lower for the SOBS than for the CPBS. Complications were similar between stent types. These novel data indicate that our innovative stent may show better patency than a CPBS when used in the management of extrahepatic biliary obstruction due to benign or malignant causes.

Plastic biliary stents are most commonly straight, slightly curved or pigtailed.[14] Although biliary stents can relieve symptoms of biliary stricture, sludge-induced occlusion of plastic stents remains a concern. The present study found that median patency was 116 (2–360) days in the CPBS group after the first ERCP. These data are consistent with previous studies reporting median patency as 142 days,[4] 128 days,[15] 126 days,[3] 105 days,[5] 90 days,[16] and 89 days.[17] Furthermore, in this study, 77% of the CPBSs were occluded at 6 months, in agreement with a previously reported value for plastic stents of 80%.[18] Plastic stents with larger diameter and side-holes have been used to improve bile flow and postpone the clogging; nevertheless, stents with a diameter >12Fr (the maximum inner diameter of the therapeutic channel of current duodenoscopes) are not acceptable. However, a recent study found that the theoretical advantages of a larger stent (11.5Fr vs 10Fr) did not translate into prolonged patency, better clinical response or longer patient survival.[19] Thus, simply increasing the diameter of a plastic stent may not necessarily prolong its patency.

Table 2

Cox regression analysis of factors associated with stent patency.

	B	SE	*P* value	95% CI
Gender	0.297	0.388	.444	0.629–2.876
Age			.639	
Cause of the stricture	0.451	0.357	.206	0.780–3.162
Stent type (SOBS vs. CPBS)	2.215	0.465	<.001	3.684–22.785
Location of stricture	−0.480	0.365	.189	0.302–1.266

95% CI = 95% confidence interval, B = unstandardized beta value, CPBS = conventional plastic biliary stent, SE = standard error of the unstandardized beta value, SOBS = suspended overlength biliary stent.

Biliary sludge contains bacteria/fungi, microbial byproducts, proteins, dietary fibers, crystals of fatty acid calcium salts and amorphous calcium bilirubinate.[20–22] Oddi's sphincter prevents the reflux of duodenal contents into the bile duct and/or pancreatic duct under physiological conditions,[23] but this anti-reflux action disappears after the insertion of a biliary plastic stent.[24] Here, we used a 30-cm section of nasobiliary tube as a modified plastic stent. The proximal part of the SOBS was positioned in the intrahepatic duct to ensure its suspension and prevent its dislocation, and the distal part was positioned in the duodenal cavity at the ligament of Treitz. The advantages of this method are that duodenobiliary reflux is decreased (due to the extended length of the reflux path) and stent dislocation is minimized (by suspension in the intrahepatic duct). Indeed, we observed no stent shifting in the SOBS group (abdominal radiography or fluoroscopy). By contrast, dislocation is a known complication of an endoscopic nasobiliary drainage tube, which is also placed in the intrahepatic bile duct. However, human factors not relevant to a SOBS may contribute to the risk of dislocation of an endoscopic nasobiliary drainage tube (e.g., traction on the drainage catheter by a disoriented patient). Other possible reasons why we observed no cases of SOBS dislocation include SOBS placement in the descending branch of the intrahepatic bile duct (which reduces the dislocation rate) and small sample size (too small to detect a low incidence of dislocation). An additional advantage of the SOBS is that the presence of multiple side-holes in an extended stent improves bile outflow. The key to this technique was positioning the side-holes of the SOBS upstream of the biliary stricture and maintaining a SOBS configuration that matched the duodenal lumen curvature.

In our study, the mean patency of the SOBS (175 days after the first ERCP) was longer than that of the CPBS. The occlusion rate at 6 months was only 39% for the SOBS, similar to the value of 37% reported for a fully covered SEMS.[25] We speculate that the side-holes of the SOBS allowed increased bile flow while the extended length reduced duodenobiliary reflux, which together postponed the onset of sludge-induced clogging. The SOBS was made from the same material as a CPBS and thus should be safe to use for an extended duration. Furthermore, the risks of SOBS placement are ERCP-related complications; in our study, safety outcomes were comparable between the SOBS and CPBS. Importantly, prolongation of stent patency will decrease the frequency of stent replacement and thus reduce ERCP-related risks and costs. Although SEMSs can lessen the need for frequent ERCP to change stents, they are expensive and stent occlusion is still inevitable. Furthermore, a recent analysis concluded that repeated plastic stent insertions were more effective than a SEMS in patients with malignant biliary strictures.[17] We suggest that SOBSs are a safe and cost-effective alternative to CPBSs that prolong patency and reduce the need for repeated ERCP.

Biliary sludge accumulation is a multifactorial process involving microbial growth, slime production, and biofilm formation.[26] Dietary fibers and crystals of fatty acid calcium salts arising from duodenal reflux may contribute to stent clogging.[27] Although anti-reflux plastic stents have been developed with a mean patency 31 days longer than CPBSs,[28] their occlusion is inevitable. In fact, 1 study suggested that anti-reflux stents had a shorter median patency of only 34 (8–49) days

compared to a conventional stent patency of 167 (38–214) days.[29] The search for materials that inhibit microbial colonization, which likely contributes to stent obstruction, is ongoing, and experimental stents have been developed.[30,31] However, these innovative stents cannot yet be considered as definitive substitutes for conventional stents.

This study has several limitations. This was a retrospective study, so selection bias and/or information bias cannot be excluded. This was a single-center study with a small sample size, so the generalizability of the results is unknown. Although increasing stent size above 10Fr appears not to prolong patency,[19] stent survival may be longer for 10Fr stents than for 8Fr stents;[32] however, our study only compared SOBSs and CPBSs that were 8.5Fr in size, so it remains unknown whether the advantages of SOBS are maintained if larger stents are used (e.g. 10Fr). Malignant and benign strictures were involved in both groups, but stricture location was not standardized between groups. Follow-up varied between groups. Other unknown confounding factors may have influenced the results. Evidence of an effect on duodenobiliary reflux (e.g., using radionuclide examination) was not established. Although the SOBS was made by cutting a nasobiliary tube under sterile conditions, failure to ensure sterility would increase the risk of postoperative biliary infection. It cannot be excluded that the cut end of the SOBS might cause some intestinal damage (a pigtail stent would theoretically cause less duodenal damage than the cut end of a SOBS, but no pigtail stents of sufficient length are available, and the shape of a pigtail stent may not be conducive to release in the horizontal part of the duodenum). The possibility of stent-induced damage to the intestinal wall long-term was not investigated.

In conclusion, the SOBS may have a longer patency than the CPBS, thereby reducing the need for repeat ERCP and stent replacement in patients with extrahepatic biliary obstruction. Placement of a SOBS may be a useful therapeutic option for patients in whom a plastic stent is preferred over a SEMS, such as patients with benign stricture of the common bile duct or malignant stricture and an expected survival <4 months. In addition, a SOBS may be a good alternative to a SEMS in patients who consider the cost of a metal stent to be prohibitive.

Author contributions

Conceptualization: Xiue Yan, Yonghui Huang.
Data curation: Xiue Yan, Hong Chang, Yaopeng Zhang, Wei Yao, Ke Li.
Formal analysis: Xiue Yan, Yonghui Huang, Hong Chang, Yaopeng Zhang, Wei Yao, Ke Li.
Funding acquisition: Yonghui Huang.
Project administration: Yonghui Huang.
Writing – original draft: Xiue Yan.
Writing – review & editing: Yonghui Huang, Hong Chang, Yaopeng Zhang, Wei Yao, Ke Li.

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