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Original Article

A Comparison of the Efficacy of Plastic Stent Placement Above and Across the Sphincter of Oddi for Benign Biliary Hilar Stricture

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We investigated the efficacy and safety of endoscopic plastic stent (PS) placement for hilar benign biliary strictures (BBSs) and compared cases with PS placement above (inside stent, IS) and across (usual stent, US) the sphincter of Oddi. Patients who underwent initial endoscopic PS placement for hilar BBSs between August 2012 and December 2021 were retrospectively analyzed. Hilar BBSs in 88 patients were investigated. Clinical success was achieved in 81 of these cases (92.0%), including 38 patients in the IS group and 43 patients in the US group. Unexpected stent exchange (uSE) before the first scheduled PS exchange occurred in 18 cases (22.2%). The median time from first stent placement to uSE was 35 days. There was no significant difference in the rate and median time to uSE between the two groups. The rates of adverse events such as pancreatitis or cholangitis in the two groups did not significantly differ. However, the rate of difficult stent removal in the IS group (15.8%) was significantly higher than that in the US group (0%) ($p=0.0019$). US placement is preferable to IS placement for scheduled stent exchange, as it offers the same effectiveness and risk of adverse events with easier stent removal.

Key words: benign biliary stricture, inside stent, plastic stent

Benign biliary strictures (BBSs) developing after surgeries such as liver transplantation and hepatectomy or radiofrequency ablation procedures for hepatocellular carcinoma are associated with several clinical problems [1]. Endoscopic biliary stenting is commonly performed in the management of BBSs, and plastic stents (PS) have classically been used. Although the procedures for placement and re-intervention are relatively easy, the patency period of a PS is short, such that PSs should be exchanged by an endoscopic procedure every three to four months [2-5].

Recently, several articles have shown the efficacy of temporary placement of covered self-expandable metallic stents (CSEMSs) for benign biliary stricture [6-8]. However, in the case of BBSs of the hepatic hilum, placement of CSEMSs is often difficult due to the presence of multiple strictures, a smaller bile duct above the stricture, and the deep angle of the proximal bile duct.

Placement across the sphincter of Oddi is the usual technique for PS placement. In most cases, endoscopic sphincterotomy (EST) is performed to prevent post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis, particularly when multiple PSs are placed across the papilla. At the same time, EST and PS placement across the sphincter of Oddi cause dysfunc-

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tion of the biliary sphincter and are associated with duodeno-biliary reflux, which results in bile infection, the formation of biliary sludge and stones, and stent occlusion [9-11].

Several papers have described the efficacy of endoscopic PS placement above the intact sphincter of Oddi ("inside stent", IS), especially for biliary stricture of the hepatic hilum [12-14]. This may prevent both duodeno-biliary reflux and stent occlusion and provide long-term patency. However, in these studies, the indication of IS placement was a malignant stricture; the usefulness of such placement for BBSs of the perihilum remains unclear.

In the current study, we retrospectively evaluated the efficacy and safety of endoscopic therapy using PS placement for hilar BBSs and compared the efficacy between IS placement and usual PS placement across the sphincter of Oddi (US) in patients with hilar BBSs. We then evaluated the factors associated with unexpected stent exchange (uSE) after clinically successful PS placement for these patients.

Patients and Methods

This retrospective study was based on Okayama University Hospital's databases. Data of patients who underwent initial endoscopic PS placement for hilar BBSs from August 2012 to December 2021 were extracted. Among these patients, those who underwent IS placement were classified as the IS group and those who underwent PS placement with the distal end located outside the papilla of Vater were classified as the usual stent group (US group).

The study was approved by the review board of our institution, and informed consent was obtained via an opt-out option on the website.

Endoscopic procedures. Endoscopic procedures were performed under conscious sedation with intravenous diazepam (5-10 mg) and pethidine hydrochloride (35-140 mg). A TJF260V or JF260V duodenoscope (Olympus Optical Co., Ltd., Tokyo, Japan) was used for the procedure. After selective bile duct cannulation and confirmation of biliary strictures by the injection of contrast material, a 0.025-inch guidewire (VisiGlide2 guidewire; Olympus or Radifocus guidewire; Terumo Co., Tokyo, Japan) was advanced into the intrahepatic bile duct (IHBD) through the stricture, and the stricture was dilated with a balloon catheter of 6-8 mm in diameter. When concomitant biliary stones or debris were encountered, they were removed after dilation. In the US group, a 7-Fr PS with both ends of the pigtail type (Zimmon Biliary Stent; COOK Medical, Tokyo, Japan) or both straight ends (Flexima Biliary Stent System; Boston Scientific Corporation, Tokyo, Japan) was placed through the stricture, and the distal end was exposed in the duodenal lumen through the duodenal papilla. In the IS group, a 7-Fr straight-type PS (Through & Pass IS; Gadelius Medical K.K., Tokyo, Japan) was placed; its distal end was located in the common bile duct. After placement of the IS, strings attached to the distal end were exposed in the duodenum lumen. We were able to remove the IS by grasping the string using forceps (Fig. 1). Endoscopic nasobiliary drainage was not employed before PS placement. The selection of IS or US was performed at the doctor's discretion according to the patient's condition and/or endoscopic findings.

In cases with insufficient dilation of the IHBD, a 6- or 5-Fr stent, available only in the US group, was placed to avoid wedging the tip of the 7-Fr stent into a small biliary branch. The stent length was decided depending on the anatomic location of the stricture. EST was routinely performed in the US group. In the IS group, we avoided EST if possible in order to preserve the function of the sphincter of Oddi. However, EST tended to be performed in cases involving bile leakage and difficult cannulation.

If successful PS placement was not achieved, percutaneous transhepatic biliary drainage (PTBD) was employed. At approximately 10 days after PTBD, transpapillary PS placement was attempted using the rendezvous technique [15, 16]. The endoscopic procedure was performed again for patients with no improvement in clinical symptoms or biochemical tests despite successful stent placement.

Management after clinical success. After successful stent placement and the improvement of clinical symptoms and biochemical tests, patients were evaluated every month. Scheduled PS exchange was performed approximately every three months until the stricture improved, even if there were no findings of stent dysfunction such as occlusion with debris or migration. Scheduled PS exchange was performed to avoid liver damage due to cholangitis or obstructive jaundice, especially in patients who had undergone liver resection or liver transplantation. Stent dysfunc-

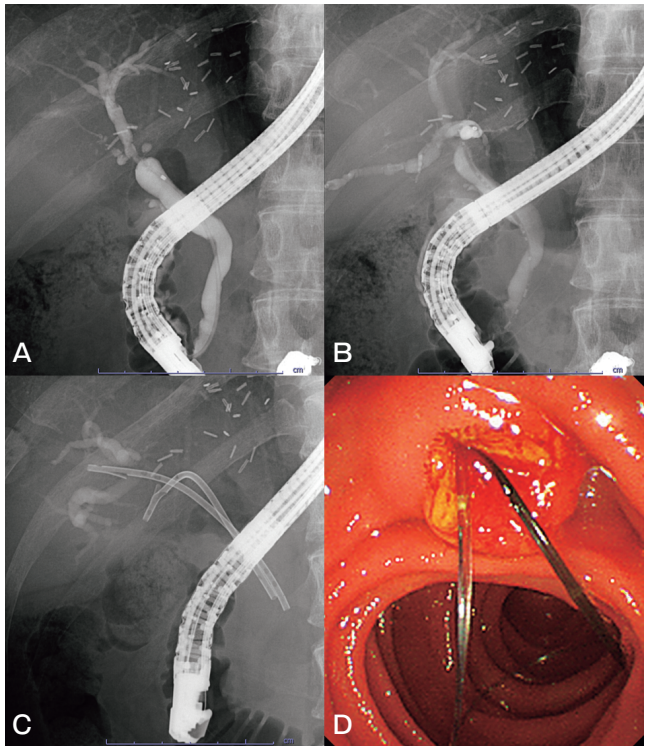

Fig. 1 Placement of the IS for benign hilar biliary strictures after living donor liver transplantation. **A**, Stricture of the anterior branch of the right hepatic duct; **B**, Stricture of the posterior branch of the right hepatic duct; **C**, Placement of an IS into each hepatic duct; **D**, Strings of the ISs that were exposed to the duodenal lumen.

tion was suspected when a patient had a fever and/or jaundice with abnormal laboratory parameters that indicated cholangitis. In such cases, patients immediately underwent PS exchange, *i.e.*, before the scheduled stent exchange.

Resolution of the stricture was evaluated by the injection of contrast material after removal of the PS. In cases suspected of having a stone or sludge, stone or sludge removal was performed using a balloon or basket catheter, whether or not the stricture was resolved. If resolution of the stricture was not achieved, balloon dilatation and PS placement were performed again.

Definitions. "Technical success" was defined as the achievement of technically successful PS placement at the first procedure. "Clinical success" was defined as the achievement of clinical and biological improvement of jaundice and/or cholangitis after technical success. Clinical success sometimes was not achieved irrespective of technical success after the first procedure. Stent exchange and/or repeated PTBD was employed in such cases, and some of them finally achieved clinical success. These cases were included in the "clinical success" group.

As previously mentioned, scheduled stent exchange was conducted in this study to avoid liver damage with cholangitis or jaundice. However, stent dysfunction sometimes occurred before the first scheduled stent exchange, and the stent exchange employed in all such cases was defined as "unexpected stent exchange (uSE)". Of all uSE, stent exchange within 4 weeks was defined as "early uSE". The "number of obstructed branches" was defined as the number of dilated branches caused by the stricture.

Complications associated with procedures were defined and their severity was graded according to the classifications of the ASGE Standards of Practice Committee [17]. Pancreatitis was defined as severe abdominal pain that required an analgesic with a serum amylase level elevated to more than three times the upper limit of normal. In cases with stent or string migration into the bile duct, stent removal sometimes took more than 10 min; this was defined as difficult

stent removal.

The study period for each patient with hilar BBSs enrolled in this study was from the first endoscopic attempt to the first stent exchange after clinical success. Observation period was defined as period from the first endoscopic attempt to the end of April 2022. During observation period, outcomes after clinical success such as stent removal and recurrent biliary stricture were evaluated.

Statistical analyses. The JMP software program (Version 14.0.0; SAS Institute Inc., Cary, NC, USA) was used to conduct the statistical analyses. Continuous and categorical variables were expressed as medians (range) and numbers of patients (%), and the Mann-Whitney *U*-test or chi-squared test was used to compare the parameters between patients in the US and IS groups. The cumulative stent patency period was estimated by a Kaplan–Meier analysis. *P* values of < 0.05 were considered to indicate statistical significance.

Results

The overall outcomes of the patients are summarized in Fig. 2. We investigated 88 patients with hepatic hilar BBS, and technical successful was achieved in 79 cases (89.8%). In nine cases, the stent could not be advanced through the stricture, and PTBD was required. Successful stent placement by the Rendezvous technique was finally achieved in 7 of these 9 cases.

Among the 86 cases with ultimately successful stent placement, ISs were placed in 41 cases (IS group), and a PS was placed across the papilla in 45 cases (US group). Among the 12 cases from the two groups in which clinical success was not achieved, stents were exchanged in nine cases; in the remaining three cases, the stents were not exchanged due to suspected liver failure. Among the nine cases with stent exchange, clinical success was achieved in seven cases. In the two cases in which clinical success was not achieved, PTBD was performed in one case. In the remaining case, clinical success was ruled out by the presence of liver failure. The ultimate clinical success rate was 92.0% (81/88) in an intention-to-treat analysis. The clinical success rates of the two groups were 92.7% (38/41) in the IS group and 95.6% (43/45) in the US group ($p = 0.57$).

Patients and endoscopic findings. Among the 81 cases in which clinical success was achieved, 38 patients were in the IS group, and 43 were in the US group (Fig. 2). The baseline characteristics of patients in cases in which clinical success was achieved are shown in Table 1. The most common cause of BBS was post-liver transplantation (79.0%), and the most common reason for ERCP was elevation of aminotransferase (54.3%). The causes of hepatectomy were hepatocellular carcinoma (HCC) (n = 4), cholangiocarcinoma (n = 1), metastatic liver tumor (n = 1) and multiple liver cysts (n = 1). Other reasons for BBS included suspected chronic inflammation of the bile duct (n = 3), cholecystectomy (n = 2), and IgG4-related sclerosing cholangitis (n = 2). No significant differences were recognized in the baseline characteristics of the IS and US groups

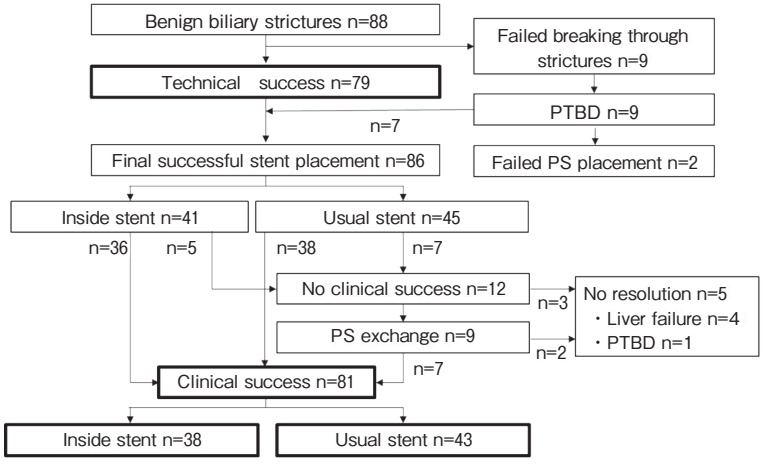

Fig. 2 The clinical outcomes of 88 patients who underwent PS placement for benign biliary strictures of the hepatic hilum.

except age.

The endoscopic findings are shown in Table 2. The number of obstructed branches was significantly larger in the IS group ($p=0.005$). The number of cases with bile leakage and in which EST was performed in the US group was significantly larger than that in the IS group ($p=0.0002$, $p<0.0001$ respectively). The minimum stent diameter was significantly smaller in the US group than in the IS group, which is natural because of the lack of small-diameter IS. Although there was no significant difference, the procedure time tended to be longer in IS group than in US group. The other endoscopic findings of the two groups did not significantly differ.

Unexpected stent exchange. An unexpected stent exchange (uSE) was required before the first scheduled PS exchange in 18 cases (22.2%) (Table 3), with no significant difference in incidence between the two groups. The median time from the first stent placement that achieved clinical success to stent-dysfunction uSE was

Table 1 Patient characteristics

	All n=81	Inside stent n=38	Usual stent n=43	*P*-value
Age, y	58 (8–84)	61 (8–84)	55 (33–84)	0.04
Sex male, no (%)	51 (63.0)	22 (57.9)	29 (67.4)	0.37
Cause of benign biliary strictures Liver transplantation: Hepatectomy: RFA: Other	64 : 7 : 3 : 7	28 : 3 : 2 : 5	36 : 4 : 1 : 2	0.47
Reason for ERCP Elevation of aminotransferase: Jaundice: Cholangitis: Bile leakage	44 : 13 : 11 : 13	20 : 8 : 7 : 3	24 : 5 : 4 : 10	0.14

RFA, radiofrequency ablation; ERCP, endocopic retrograde cholangiopancreatography.

Table 2 Endoscopic findings

	All n=81	Inside stent n=38	Usual stent n=43	*P*-value
Length of the stricture, median (range) (mm)	2 (1–25)	2.5 (1–15)	2 (1–25)	0.09
Maximum diameter of proximal branches (range)	6 (3–15)	6 (4–10)	6 (3–15)	0.08
Number of obstructed branches (range)	1 (1–4)	2 (1–4)	1 (1–2)	0.005
Bile leakage, no (%)	24 (29.6)	4 (10.5)	13 (46.5)	0.0002
Bile duct stone, no (%)	11 (13.6)	8 (21.1)	3 (7.0)	0.06
EST, no (%)	46 (56.8)	11 (28.9)	35 (81.4)	<0.0001
Number of stents	1 (1–3)	2 (1–2)	1 (1–3)	0.39
Minimum diameter of stents, 5 : 6 : 7 : 8.5 Fr	5 : 8 : 66 : 2	0 : 0 : 37 : 1	5 : 8 : 29 : 1	0.0003
Procedure time, median (range)	40 (8–120)	55.5 (9–88)	37 (8–120)	0.06
Concurrent PTBD, no (%)	8 (9.9)	2 (5.3)	6 (14.0)	0.18

EST, endoscopic sphincterotomy; PTBD, percutaneous transhepatic biliary drainage.

Table 3 Analysis of stent exchange

	All n=81	Inside stent n=38	Usual stent n=43	*P*-value
Unexpected stent exchange before the scheduled stent exchange (n (%))	18 (22.2)	8 (21.1)	10 (23.3)	0.81
Time to the unexpected stent exchange with stent dysfunction, median (days (IQR))	35 (27–61)	35 (27–73.5)	41 (26–57)	0.69

IQR, interquartile range.

35 days (interquartile range [IQR] 27-61) and did not significantly differ between the two groups. The time from the first stent placement to the scheduled stent change without uSE was 91 days in all patients, 96 days in the IS group and 87.5 days in the US group.

The patency rates (IS group vs. US group) were 94.7% vs. 90.7% ($p=0.48$) at 1 month and 86.8% vs. 79% ($p=0.35$) at 2 months, respectively, and showed no significant differences between groups. Likewise, stent patency in patients with uSE did not differ between the two groups in Kaplan-Meier analysis (Fig. 3).

Analysis of the factors contributing to uSE before the first scheduled exchange is shown in Table 4. Stricture after liver transplantation was negatively associated with uSE ($p=0.009$). The median period until the scheduled exchange was 92 days (IQR: 85.8-105) in patients with

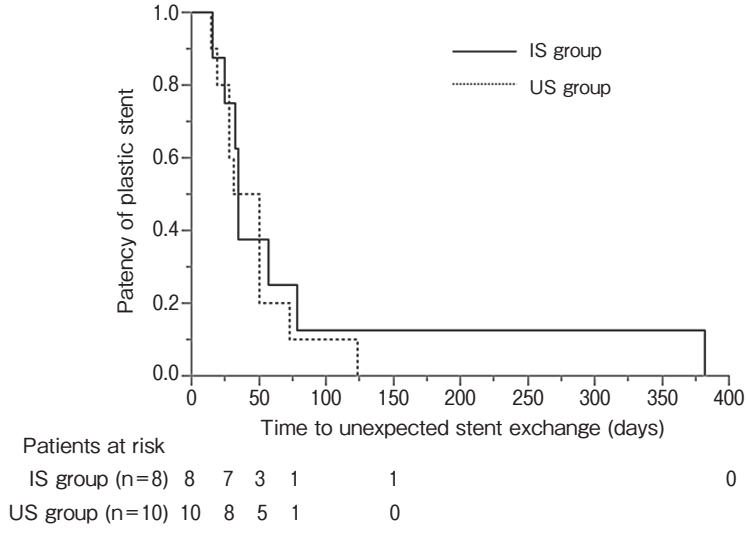

Fig. 3 Comparison of patency period in patients with unexpected stent exchange between the IS and US groups.

Table 4 Risk factors of uSE

	uSE n=18	Non-uSE n=63	*P*-value
Age, y (range)	58 (46–84)	58 (8–84)	0.38
Sex male (%)	11 (61.1)	40 (63.5)	0.85
Cause of benign biliary stricture Liver transplantation: Non-liver transplantation (hepatectomy, RFA and others)	10 : 8	54 : 9	0.009
Cholangitis before PS placement (%)	3 (16.7)	7 (11.1)	0.54
Length of the stricture (range)	2 (1–9)	2 (1–25)	0.82
Maximum diameter of proximal branches (range)	6 (3–10)	6 (3–15)	0.92
Number of obstructed branches (range)	1 (1–4)	2 (1–2)	0.86
Bile leakage (%)	6 (33.3)	18 (28.6)	0.45
Bile duct stone (%)	3 (16.7)	8 (12.7)	0.67
EST (%)	12 (66.7)	34 (54.0)	0.33
Number of stents (range)	2 (1–2)	1 (1–3)	0.3
Minimum diameter of stents, 5 : 6 : 7 : 8.5 Fr	1 : 0 : 17 : 0	4 : 8 : 49 : 2	0.14
PTBD (%)	2 (11.1)	6 (9.5)	0.84
PS exchange within 1 week (%)	2 (11.1)	5 (7.9)	0.68
Inside stent (%)	8 (44.4)	30 (47.6)	0.81

uSE, unexpected stent exchange; RFA, radiofrequency ablation; PS, plactic stent; EST, endoscopic sphincterotomy; PTBD, percutaneous transhepatic biliary drainage.

BBS after liver transplantation and 91 days (IQR; 76-101.5) in patients with BBS for other reasons. Analysis of the factors contributing to early uSE is shown Table 5. The rates of early uSE in the two groups did not significantly differ.

Adverse events. Several complications related to the ERCP procedure and stent placement occurred, including post-ERCP pancreatitis (n=8; 9.1%) and cholangitis (n=11; 12.5%). In the IS group, difficult stent removal occurred in 6 cases (15.8%) while there was no case in the US group in which the PS was difficult to exchange. The frequency of difficult stent removal was significantly higher in the IS group than in the US group (15.8% vs. 0%; $p=0.0019$). All complications were managed conservatively, and there were no deaths associated with endoscopic intervention.

Outcomes after clinical success. Of the 81 patients with clinical success, removal of the PS could be achieved in 65 patients within a median of 66.4 months (range: 2.7-118.6) of observation period. The median period of stent placement was 12.1 months (range: 2.6-89.8). Of the 65 patients with removal of the PS, biliary stricture recurred in 10, and eight of these 10 patients underwent stent placement again. The remaining two patients underwent choledochojejunostomy or PTBD. Five of the eight patients undergoing this second round of stent placement achieved removal of the PS within the observation period. Conclusively, clinical success and removal of the PS was achieved in 60 of 88 patients (68.2%).

Discussion

BBS, which causes severe cholangitis and is associated with mortality, is a severe complication after pancreato-biliary surgery, including radiofrequency ablation for hepatocellular carcinoma. Although PTBD or surgery is employed for the treatment of postoperative biliary stricture, endoscopic therapy has become the first-line therapy.

Metallic stents are reported to be superior to PSs in terms of the rate of improvement of stricture and stent patency. Covered metallic stents (CSEMSs) are usually used for BBSs. However, if a CSEMS is placed in the hilar portion, the cover of the CSEMS can sometimes obstruct the lateral branches diverging from the bile duct into which the CSEMS is placed. Thus, the use of CSEMSs for hilar biliary stricture is controversial [6-8], and in this situation PSs are often used instead.

Recently, several articles have reported the efficacy of ISs in the treatment of malignant hilar biliary obstruction, with the median patency period of ISs

Table 5 Risk factors of early uSE before the first scheduled exchange

	Within 4 weeks		
	uSE n=6	Non-uSE n=75	*P*-value
Age, y (range)	60.5 (46–84)	58 (8–84)	0.44
Sex male (%)	5 (83.3)	46 (61.3)	0.26
Cause of benign biliary stricture			
Liver transplantation: Non-liver transplantation (hepatectomy, RFA and others)	3 : 3	61 : 14	0.1
Cholangitis before PS placement (%)	1 (16.7)	9 (12.0)	0.75
Length of the stricture (range)	2 (1–4)	2 (1–25)	0.85
Maximum diameter of proximal branches (range)	6 (4–10)	6 (3–15)	0.92
Number of obstructed branches (range)	1 (1–4)	1 (1–2)	0.84
Bile leakage (%)	3 (50.0)	21 (28.0)	0.28
Bile duct stone (%)	1 (16.7)	10 (13.3)	0.82
EST (%)	3 (50.0)	43 (57.3)	0.73
Number of stents (range)	1 (1–2)	2 (1–3)	0.41
Minimum diameter of stents, 5 : 6 : 7 : 8.5 Fr	0 : 0 : 6 : 0	5 : 8 : 60 : 2	0.46
PTBD (%)	0 (0)	8 (10.7)	0.25
PS exchange within 1 week (%)	1 (16.7)	6 (8.0)	0.51
Inside stent (%)	2 (33.3)	36 (48.0)	0.48

uSE, unexpected stent exchange; RFA, radiofrequency ablation; PS, plactic stent; EST, endoscopic sphincterotomy; PTBD, percutaneous transhepatic biliary drainage.

reported to be 136-190 days [18-20]. Inatomi *et al.* compared ISs and conventional PSs in patients with malignant hilar biliary stricture, and the median duration of IS patency was significantly longer than that of conventional PS patency (142 vs. 32 days; $p=0.04$) [20]. In BBSs, Kurita *et al.* reported that ISs were successfully placed across the stricture in 94 (80%) of 118 patients with biliary stricture after living donor liver transplantation (LDLT), and the median patency period was 189 days [21]. Tsujino *et al.* reported that, in 63 patients who had undergone LDLT, the median interval of IS exchange was 161 days, and the cumulative incidence of uSE was 7.8% at 3 months, 12.3% at 6 months, and 18. 1% at 12 months [22]. Although these studies suggested that IS placement is effective for treating benign biliary hilar obstruction, they did not compare the results of IS and US placement. The present report is therefore the first to evaluate the results of endoscopic treatment using a PS for hepatic hilar BBSs that compares the efficacy of IS and US placement.

The short patency of approximately three months is a major problem associated with PSs, and longer patency is thought to be an advantage of IS placement. However, evidence to support a longer patency with IS placement is not sufficient. In addition, cholangitis due to stent occlusion is sometimes associated with mortality, especially in patients after liver transplantation due to immunosuppression. Therefore, stent exchange was scheduled every three months in both the US and IS groups in this study. Contrary to expectations based on previous reports, the rate of uSE within approximately three months did not differ markedly between the US and IS groups, and the placement of an IS was not effective for preventing uSE within three months. IS placement has a technical disadvantage in that it can be difficult to remove when the string breaks. Therefore, stent exchange with US placement is thought to be easier than that with IS placement. Given the present findings, US placement seems preferable to IS placement in cases for which PS exchange is scheduled within approximately three months.

However, one crucial advantage of an IS is its avoidance of EST. EST is associated with loss of the sphincter of Oddi function, which is thought to cause repeated reflux cholangitis and bile duct stone disease [9-11]. In addition, some papers have suggested that reflux of duodenal juice is associated with bile duct cancer [23, 24]. Therefore, IS placement is appropriate and reasonable for patients who require preservation of sphincter of Oddi function, such as those who have undergone liver transplantation or young patients, because of the similar effectiveness and risk of adverse events with US.

Liver transplantation was a protective factor against uSE. It is difficult to explain the reason for this result accurately. Among the 18 patients with uSE before scheduled stent exchange, 10 underwent PS placement after liver transplantation. In six of the remaining eight patients, the baseline diseases were HCC in four patients, multiple liver cysts in one patient, and suspected chronic inflammation in one patient. These five patients were thought to have chronic liver dysfunction, which might have been associated with early uSE. However, patients after liver transplantation have no liver dysfunction due to the transplantation of a healthy liver, which might be associated with their reduced incidence of early uSE.

Several limitations associated with the present study warrant mention. First, the study was retrospective and included a relatively small number of patients. Second, the observation period was short. We investigated the period from the first stent placement to the first stent exchange because the endoscopists might have decided to switch to a different type of stent at the second stent placement. Thus, a prospective study with a larger sample size is needed to confirm our results. Third, there is a strong bias in the selection of stents. As previously mentioned, IS placement without EST may be preferable to avoid the long-term effects of duodenal fluid. However, in many cases with biliary stricture complicated by bile leakage, US with EST was selected in order to decompress the internal pressure of the bile duct. In addition, multiple stent placement is thought to broaden biliary fistulae; therefore, single US placement is thought to be adequate in such cases. Also, a 6- or 5-Fr stent was available only for US placement; hence, IS could not be used in cases with insufficient dilation of the IHBD.

In conclusion, endoscopic therapy using a PS for hilar BBSs can be employed effectively and safely. US placement is preferable to IS placement for scheduled stent exchange, as it offers the same effectiveness while facilitating easier stent exchange. However, reflux of duodenal fluid into the bile duct following EST may be associated with long-term unfavorable results such as bile duct stones or bile duct cancer, and long-term

observation and consideration is warranted.

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