





ORIGINAL ARTICLE

Self-expandable metal stents have longer patency and less cholangitis than inside stents in malignant perihilar biliary obstruction

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Key words

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Abstract

Background and Aim: Outcomes of an inside stent (IS, a plastic stent placed above the sphincter of Oddi) *versus* a self-expandable metal stent (SEMS) for the drainage of malignant perihilar biliary obstruction has not been fully studied. The drainage strategy for perihilar biliary obstruction is difficult and should be clarified.

Methods: Clinical data of patients who underwent biliary drainage for malignant perihilar biliary obstruction with IS or SEMS between April 2016 and September 2021 at our institution were retrospectively examined. Outcomes, including the time to recurrent biliary obstruction (TRBO), survival, and incidence of recurrent biliary obstruction with concomitant cholangitis (RBOC), were retrospectively evaluated.

Results: Median TRBO was 280 (95% confidence interval [CI], 110–not available) days in the SEMS group ($n = 24$) and 113 (95% CI, 74–192) days in the IS group ($n = 25$) ($P = 0.043$). Among the patients with perihilar cholangiocarcinoma, the median survival of the two groups was comparable, namely 330 days in the SEMS group and 359 days in the IS group ($P = 0.46$). The incidence of RBOC at re-intervention was significantly higher in patients with ISs (83.9%) than in those with SEMSs (0%) ($P = 0.00004$).

Conclusions: TRBO was significantly longer in the SEMS group. Regardless of whether SEMSs or ISs were placed during the first intervention, patient survival was similar. Using easily removable ISs first might be a reasonable option because TRBO with SEMSs was shorter than patient survival. Cholangitis is a problem associated with the placement of IS.

Introduction

Malignant perihilar biliary obstruction is a condition associated with biliary tract cancer (e.g. extrahepatic cholangiocarcinoma and gallbladder cancer), primary liver tumors (e.g. hepatocellular carcinoma and intrahepatic cholangiocarcinoma), metastatic liver tumors, pancreatic cancer, and lymph node metastasis. Proper management of obstructive jaundice, a major symptom of malignant perihilar biliary obstruction, is directly linked to patient survival. There are several endoscopic drainage methods available for obstructive jaundice secondary to malignant perihilar biliary obstruction, including endoscopic nasobiliary drainage (ENBD), self-expandable metal stent (SEMS) placement, plastic stent (PS) placement, and inside stent (IS) placement. Although ENBD has advantages with respect to the ability to directly monitor the drained bile juice and a relatively low risk of ascending bacterial infection, the ENBD tube might cause discomfort and decrease the patient's ability to perform activities of daily living. Therefore, ENBD is not suitable for long-term drainage. Several

reports comparing SEMS (which is placed into the bile duct) with PS (which is placed across the papilla) to treat malignant perihilar biliary obstruction have shown that SEMS has longer patency.^{1–4} PS patency is short because of food impaction and cholangitis secondary to ascending bacterial infection from the duodenum.^{5,6} Problems sometimes occur within 30 days after placement.^{1,2} However, one disadvantage of SEMS is that re-intervention is difficult because of its permanence after placement. IS is a type of PS that can theoretically resolve such problems.⁷ Because IS is placed in the bile duct above the sphincter of Oddi, there is little concern about food impaction and ascending infection from the duodenum. Moreover, IS removal is easy, by pulling on a thread attached to the distal end of the stent that extends into the duodenum. Thus, re-intervention can be easily performed in patients after IS placement.^{7–9} There have been few studies comparing the duration of patency of IS *versus* SEMS in patients with malignant perihilar biliary obstruction. One study showed that there was no difference in stent patency between

them, but another study showed that IS had significantly longer patency than SEMs.^{7,10} In this study, we retrospectively compared the patency of IS *versus* SEMs for malignant perihilar biliary obstruction. Based on the results from this study, we discuss the treatment strategy with regard to stent selection.

Methods

Study design and patients. This retrospective, single-center, case–control study included all patients who underwent transpapillary biliary drainage for malignant perihilar biliary obstruction with IS or SEMs placement above the sphincter of Oddi via endoscopic retrograde cholangiopancreatography (ERCP) between April 2016 and September 2021. Exclusion criteria were (i) history of bile duct, pancreas, or stomach surgery, except for subtotal gastrectomy with Billroth I method of reconstruction; (ii) biliary drainage with stents placed across the papilla; and (iii) biliary drainage with multiple stent types. During this period, 54 patients underwent transpapillary biliary drainage for malignant perihilar biliary obstruction, of which five were excluded. Four patients were excluded for biliary drainage with stent placed across the papilla, and one patient was excluded for biliary drainage with multiple stent types. Of the remaining 49 patients, 24 patients were in the SEMs group and 25 patients were in the IS group (Fig. 1).

Endoscopic procedures. ERCP was performed with a duodenoscope (TJF-260V, JF-260V, or TJF-Q290V) (Olympus Marketing). All patients received diclofenac 50 mg via rectal suppository 30 min before ERCP. One of the following was used as the cannula: Star Tip V Short Taper (Olympus Marketing, Tokyo, Japan), Star Tip 2 V (Olympus Marketing), or Tandem XL (Boston Scientific Corporation, Marlborough, MA, USA). One of the following guidewires was used: EndoSelector (Boston Scientific), Pathcourse (Boston Scientific), VisiGlide 2 (Olympus Marketing), RevoWave SeekMaster (Piolax Medical Devices, Kanagawa, Japan), or Hydra Jagwire (Boston Scientific). Biliary cannulation was typically performed with wire-guided techniques. In cases of difficult cannulation, pancreatic guidewire

cannulation or precut sphincterotomy was performed. The endoscopist determined the type of stent to be used. During the study period, a total of five endoscopists, from trainees to specialists, were involved. The ISs used in this study included the ThroughPass IS (Gadelius Medical K.K., Tokyo, Japan) or Advanix J IS (Boston Scientific). Before 2018, ThroughPass IS was used, and after then, Advanix J IS was used. Both stents have the same caliber, shape, and length. The IS diameter was 7Fr. The length was 9 or 12 cm. Depending on the degree of bile duct flexion, a light-angle or a deep-angle IS could be selected. In general, a light-angle IS was used for the right anterior segmental duct, a deep-angle IS was used for the right posterior segmental duct, and either a light- or deep-angle IS was used for the left hepatic duct. The SEMs used were the Zeo Stent V (Zeon Medical, Tokyo, Japan) or Niti-S Large Cell D-type Stent (Taewoong Medical, Gyeonggi, South Korea). Before 2018, Niti-S Large Cell D-type stent was used, and after then, Zeo Stent V was used. There was no difference in variation in the choice of stent among endoscopists. In patients with multiple stents in the SEMs group, all stents were placed using a partial stent-in-stent method. ISs or SEMs were placed in ducts that were expected to achieve the most effective drainage based on computed tomography images. In general, multiple stents were placed. Biliary drainage by ENBD before stent placement was not performed based on the patient's burden even if there was concomitant cholangitis, except in life-threatening cases. The endoscopist decided whether to perform endoscopic sphincterotomy (EST) or endoscopic papillary balloon dilation (EPBD). In general, EST was not performed in patients taking antithrombotic or anticoagulant medications. EST was performed in patients who required transpapillary bile duct biopsy. Recently, a small diameter SEMs delivery system was used, making it unnecessary to perform EST before SEMs placement. On the other hand, we have come across one case in which severe post-ERCP pancreatitis (PEP) developed after IS drainage without EST. After this case, we performed EST before IS placement. Re-intervention was performed when there was clinical suspicion of biliary obstruction or cholangitis.

Definitions. Recurrent biliary obstruction (RBO) was defined as recurrent liver dysfunction with proximal bile duct dilatation with or without inflammation that occurred as a result of stent migration or stent occlusion due to tumor ingrowth, overgrowth, sludge, or hemobilia.¹¹ Technical success was defined as successful stent deployment in the intended location with sufficient coverage of the stricture. Functional success was defined as a 50% decrease in or normalization of bilirubin levels within 14 days of stent placement.¹¹ The severity of procedure-related adverse events such as PEP, cholecystitis, hemorrhage, or perforation was based on the definitions by Cotton *et al.*¹² We also investigated the incidence of RBO with cholangitis (RBOC), which was defined as RBO with high-grade fever ($\geq 38.0^{\circ}\text{C}$) and increasing C-reactive protein level or white blood cell count. The incidence of RBOC was investigated for all interventions, including first interventions and re-interventions.

Outcomes. The primary outcome measure was the time to RBO (TRBO) of the first intervention. Technical success, functional success, procedure-related adverse events, re-intervention

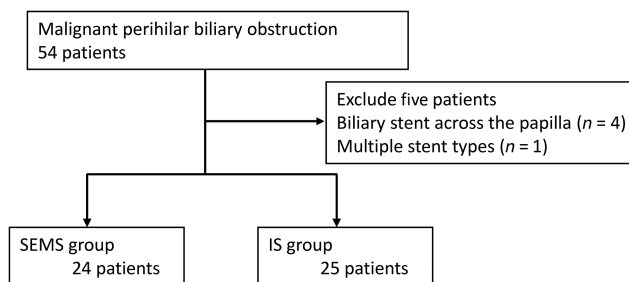


Figure 1 Study flow chart.

Between April 2016 and September 2021, 54 patients underwent transpapillary drainage for malignant perihilar biliary obstruction, of which five patients were excluded (four patients with a biliary stent across the papilla and one patient with multiple stent types). There were 24 patients in the self-expandable metal stent (SEMs) group and 25 patients in the inside stent (IS) group.

TRBO, patient survival, and incidence of RBOC were analyzed as secondary outcomes.

Statistical analysis. Cumulative TRBO and survival were estimated using the Kaplan–Meier technique, and the log-rank test was used to compare groups. The unpaired *t*-test was used for comparison of continuous variables. Fisher's exact test was used to compare categorical variables. All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of the R commander designed to add statistical functions frequently used in biostatistics.

Results

Patient characteristics. Fifty-four patients with malignant perihilar biliary obstruction underwent endoscopic drainage during the study period. There were 24 patients who underwent SEMS placement (SEMS group) and 25 patients who underwent IS placement (IS group) (Fig. 1). Two preoperative patients were included in the IS group. Patient characteristics of the two groups were mostly similar. However, patients in the IS group were older, on average, and underwent EST or EPBD more frequently than patients in the SEMS group. The proportion of patients who underwent chemotherapy after stent placement was similar between the two groups. In the SEMS group, two or more stents were placed 83.4% of patients, compared with 76% in the IS group ($P = 0.86$) (Table 1).

Table 1 Characteristics of patients in the self-expandable metal stent (SEMS) and inside stent (IS) groups

	SEMS ($n = 24$)	IS ($n = 25$)	<i>P</i> -value
Sex, male: female	14:10	12:13	0.57
Age, mean \pm SD, years	72.8 \pm 10.3	80.2 \pm 8.7	0.009
Cause of biliary obstruction			0.088
Perihilar cholangiocarcinoma	10 (41.7%)	17 (68.0%)	
Gallbladder cancer	0 (0%)	3 (12.0%)	
Primary hepatic cancer	3 (12.5%)	3 (12.0%)	
Pancreatic cancer	5 (20.8%)	1 (4.0%)	
Metastatic lymph node	6 (25.0%)	1 (4.0%)	
Parapapillary duodenal diverticulum	5 (20.8%)	3 (12.0%)	0.46
Antithrombotic medication	3 (12.5%)	6 (24.0%)	0.46
EST/EPBD	9 (37.5%)	17 (68.0%)	0.046
Bismuth type			0.61
I	1 (4.2%)	3 (15.0%)	
II	5 (20.1%)	2 (8.0%)	
IIIa or IIIb	2 (8.3%)	4 (16.0%)	
IV	16 (66.7%)	14 (56.0%)	
Unclassifiable	0 (0%)	2 (8%)	
Number of stents			0.86
1	4 (16.6%)	6 (24.0%)	
2	19 (79.2%)	18 (72.0%)	
3	1 (4.2%)	1 (4.0%)	
Chemotherapy after intervention	9 (37.5%)	9 (36.0%)	1.00

EPBD, endoscopic papillary balloon dilation; EST, endoscopic sphincterotomy.

Table 2 Outcomes in the self-expandable metal stent (SEMS) and inside stent (IS) groups

Outcomes	SEMS ($n = 24$)	IS ($n = 25$)	<i>P</i> -value
TRBO, median (95% CI), days	280 (110–NA)	113 (74–192)	0.043
Follow up period, mean \pm SD, days	145 \pm 131	374 \pm 366	0.006
Technical success	24 (100%)	25 (100%)	—
Functional success	21 (87.5%)	25 (100%)	0.11
Adverse events			1.00
PEP (mild)	1	2	
PEP (severe)	0	1	
Acute cholangitis	0	0	
Hemorrhage	0	0	
Perforation	1	0	

CI, confidence interval; NA, not available; PEP, post-endoscopic retrograde cholangiopancreatography pancreatitis; TRBO, time to recurrent biliary obstruction.

Clinical outcomes

TRBO of the first intervention, SEMS versus IS. TRBO, follow-up duration, adverse events, and technical and functional success rates are summarized in Table 2. Median TRBO of the

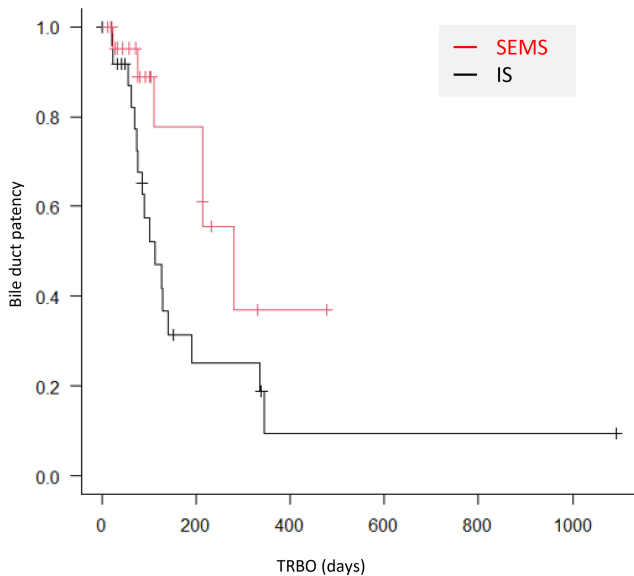


Figure 2 Kaplan–Meier curves of cumulative time to recurrent biliary obstruction (TRBO). Median TRBO was 280 (95% confidence interval [CI], 110–not available) days in the self-expandable metal stent (SEMS) group and 113 (95% CI, 74–192) days in the inside stent (IS) group ($P = 0.0425$).

SEMS group (280 days; 95% confidence interval [CI]; 110–not available [NA] days) was significantly longer than that of the IS group (113 days, 95% CI, 74–192 days) ($P = 0.042$) (Fig. 2). The cause of early RBO (≤ 30 days) was sludge in one case in the SEMS group and non-occlusion cholangitis in one case in the IS group. The cause of late RBO (>30 days) was tumor ingrowth (100%) in the SEMS group and sludge (73.3%) and non-occlusion cholangitis (26.7%) in the IS group. TRBO in single or multiple stent placement was compared in both the SEMS and IS groups, but no significant differences were found. The technical success rate was 100% in both groups. The functional success rate was 87.5% (21/24) in the SEMS group and 100% (25/25) in the IS group ($P = 0.11$). There were no significant differences in the incidence of adverse events between the two groups. Severe PEP developed in one patient with a small major papilla in the IS group who did not undergo EST during the endoscopic procedure.

Survival period. There are several causes of malignant perihilar biliary obstruction other than perihilar cholangiocarcinoma (Table 1). Differences in survival were investigated based on the cause of the obstruction. Expected survival was an important factor in stent selection because re-intervention should be considered if expected survival would be longer than the predicted TRBO. In general, perihilar cholangiocarcinoma can cause biliary obstruction at an earlier stage than cancers from other sites. To investigate survival, we divided patients into two groups according to the cause of biliary obstruction: perihilar cholangiocarcinoma ($n = 27$) or other cancer ($n = 22$). The other causes consisted of gallbladder cancer ($n = 3$), primary hepatic cancer ($n = 6$), pancreatic cancer ($n = 6$), and metastatic lymph

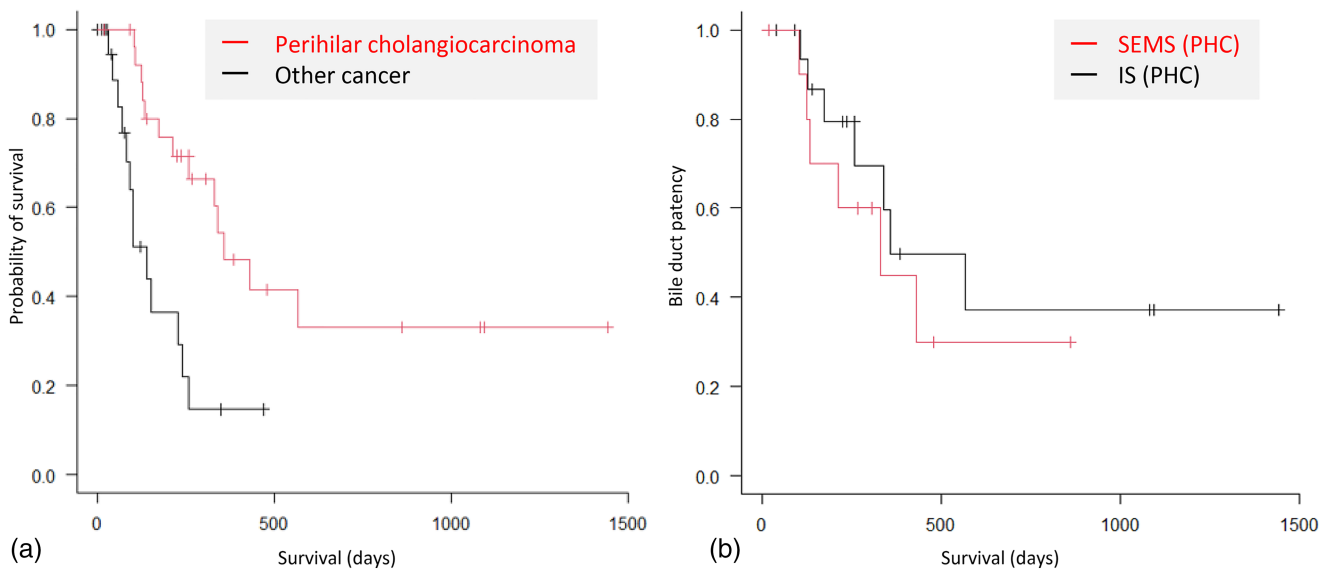


Figure 3 (a) Kaplan–Meier curves of cumulative survival by cause of biliary obstruction. Median survival was 359 (95% confidence interval [CI], 214–not available [NA]) days in patients with perihilar cholangiocarcinoma and 140 (95% CI, 72–241) days in patients with other cancers ($P = 0.0011$). (b) Kaplan–Meier curves of cumulative survival in patients with perihilar cholangiocarcinoma (PHC). Median survival was 330 (95% CI, 105–NA) days in the self-expandable metal stent (SEMS) (PHC) group and 359 (95% CI, 174–NA) days in the inside stent (IS) (PHC) group ($P = 0.46$).

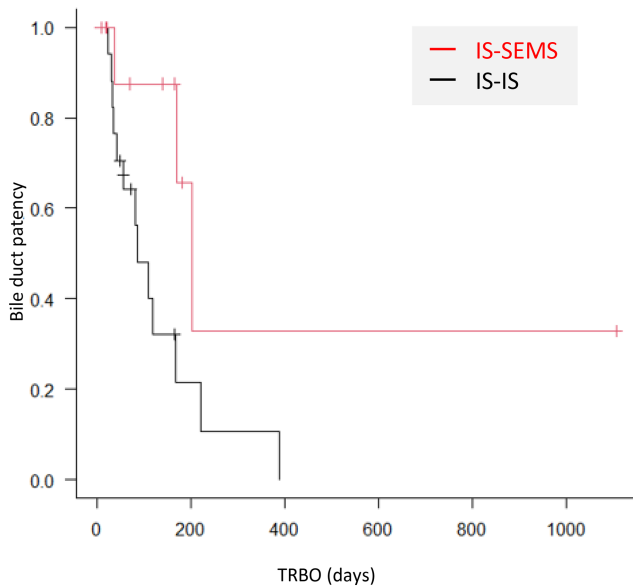


Figure 4 Kaplan–Meier curves of cumulative time to recurrent biliary obstruction (TRBO) for patients in the inside stent (IS) group who underwent re-intervention. Median TRBO was 203 (95% confidence interval [CI], 38–not available) days in the IS-self-expandable metal stent (SEMS) group and 87 (95% CI, 35–169) days in the IS-IS group ($P = 0.040$). The IS-SEMS group underwent IS placement initially and SEMS replacement at re-intervention. The IS-IS group underwent IS placement initially and IS replacement at re-intervention.

nodes from various cancers ($n = 7$). Median survival was 359 (95% CI, 214–NA) days in patients with perihilar cholangiocarcinoma and 140 (95% CI, 72–241) days in patients with other cancers ($P = 0.0011$) (Fig. 3a).

Next, we investigated whether there was a difference in survival by stent type. In this study, patients with perihilar cholangiocarcinoma were divided into the SEMS (PHC) group ($n = 10$) and the IS (PHC) group ($n = 17$). Median survival was 330 (95% CI, 105–NA) days in the SEMS (PHC) group and 359 (95% CI, 174–NA) days in the IS (PHC) group ($P = 0.46$) (Fig. 3b).

Re-intervention TRBO in the IS group. The most remarkable advantage of using ISs for biliary obstruction is their easy removability. The IS can be replaced or an additional IS can be placed in a different biliary branch to obtain better drainage, depending on the situation. We focused on re-interventions performed after the removal of dysfunctional ISs to investigate TRBO of the newly placed SEMSs or ISs. In some cases, up to six re-interventions were performed in a patient. Each re-intervention was analyzed separately. Patients in the IS group who underwent re-intervention were further divided into the IS-SEMS group and the IS-IS group depending on the stent used in the re-intervention. Patients who underwent re-intervention using stents other than SEMS or IS were excluded. In the IS group, 28 re-interventions were performed in 15 patients, of which 11 involved SEMSs and 17 involved ISs. Median TRBO was

Table 3 Inside stent (IS) placement is associated with a high frequency of developing recurrent biliary obstruction with cholangitis (RBOC)

Stent	RBOC (+)	RBOC (–)	<i>P</i> -value
IS	26	5	0.00004
SEMS	0	9	

SEMS, self-expandable metal stent.

203 (95% CI, 38–NA) days in the IS-SEMS group and 87 (95% CI, 35–169) days in IS-IS group ($P = 0.040$) (Fig. 4).

Incidence of RBOC. Cholangitis was a major indication for re-intervention in patients with malignant biliary obstruction. To compare the frequency of RBOC between patients by stent type, all re-interventions ($n = 40$) were analyzed. The incidence of RBOC in all re-interventions was 65.0% (26/40). The incidence of RBOC in re-interventions for patients who received ISs was 83.9% (26/31). The incidence for patients who received SEMSs was 0% (0/9). A higher proportion of patients who received ISs experienced RBOC ($P = 0.00004$) (Table 3).

Discussion

Our study showed that TRBO was significantly longer in the SEMS group (280 days) than in the IS group (113 days) in patients with perihilar malignant biliary obstruction. Two previous case–control studies had compared SEMS with IS in this setting.^{7,10} Inatomi *et al.* found that IS and SEMS had comparable patency duration (142 days vs 150 days; $P = 0.83$).⁷ However, Kanno *et al.* reported that TRBO after IS placement was significantly longer than TRBO after SEMS placement (561 days vs 209 days; $P = 0.008$).¹⁰ Previous studies had found that IS patency in malignant biliary obstruction ranged from 85.2 to 190 days.^{7–10,13,14} In addition, a multicenter prospective study showed that TRBO for malignant biliary stricture was 4.7 months.¹⁵ Thus, our results regarding TRBO in the IS group were comparable with those of most previous studies. However, the reason why the median TRBO with ISs (113 days, or 3.7 months) in this study was slightly shorter than the results of a previous prospective study (4.7 months) might be explained by aggressive IS exchange when cholangitis occurred, even in patients who had non-occlusion cholangitis without obvious jaundice (total bilirubin < 2.0 mg/dl).¹⁶ Possible causes of RBO include migration of the stent, dislocation of the stent, sludge, tumor ingrowth/overgrowth, and non-occlusion cholangitis. Early RBO (≤ 30 days) occurred in only one case in each group, and there was no difference in incidence. The cause of RBO in the SEMS group was mainly tumor ingrowth whereas those in IS group was sludge and non-occlusive cholangitis. Non-occlusion cholangitis accounted for more than 30% of the causes of RBO in the IS group.

We found that there were no significant differences in survival between patients with perihilar cholangiocarcinoma who received primary SEMSs (330 days) versus primary ISs (359 days). These results showed that IS placement at least did not affect survival even though TRBO was short. We also found that there were significant differences in survival

between patients with perihilar cholangiocarcinoma (359 days) *versus* other causes of malignant perihilar biliary obstruction (140 days). Taken together, these results suggest that IS placement can be an option for some types of malignant perihilar biliary obstruction, in addition to SEMs placement. Malignant perihilar biliary obstruction secondary to causes other than perihilar cholangiocarcinoma can be treated by SEMs placement at the first intervention because re-intervention can be avoided in most patients due to TRBO (280 days), which is much longer to patient survival (140 days). However, the treatment strategy for malignant biliary obstruction due to perihilar cholangiocarcinoma can be different because survival (359 days) is longer than TRBO with SEMs (280 days). In fact, 50% of patients in this study with primary SEMs placement required re-intervention. Because it is often difficult to place additional stents into a target bile duct owing to the permanence of preexisting SEMs, we can choose IS for the first intervention, which is easy to remove, should re-intervention be needed. Based on our data, TRBO with SEMs was sufficiently long (203 days) even if SEMs replaced IS. Therefore, in patients with perihilar cholangiocarcinoma, we propose a treatment strategy of initial IS placement and exchange if necessary, followed by SEMs placement if subsequent re-intervention was predicted to be difficult due to tumor progression or clinical status. The usefulness of this strategy, such as survival and cost benefit, needs to be validated in future research.

We pointed out the problem of cholangitis occurring in a high proportion of patient after IS placement. Theoretically, since SEMs and IS placement are both completely inside the biliary tract above the papilla, the frequency of cholangitis should be similar. However, in this study, we found that the frequency of RBOC was significantly higher in patients who received IS *versus* SEMs. EST is associated with a risk of retrograde cholangitis.^{17,18} Inatomi *et al.*⁷ reported no differences in the duration of stent patency by EST status in all patients who received ISs. In this study, there were no significant differences in the frequency of RBOC in patients after IS placement between those who underwent EST (frequency, 83%) and those who did not (frequency, 83%) undergo EST before stent placement. One possible reason why cholangitis frequently developed in patients after IS placement might be related to the IS structure. It has a thread tied to the lower end, and the thread exits across the papilla into the duodenum. By pulling on the thread, the stent can be easily removed. Despite this important function, the thread is constantly exposed to bacteria in the duodenum, which might cause retrograde infection into the bile duct. Although frequent cholangitis in patients with ISs did not cause shortened survival, further studies are needed to resolve this problem.

Limitations of this study include its retrospective, single-center design and relatively small sample size. Therefore, treatment selection might be biased. In other words, indications for re-intervention might be inconsistent. For patients with ISs, because stent exchange was easy, it was possible that stent exchange was more aggressively performed than for patients with SEMs, which might have affected the results of this study. A randomized controlled trial should be planned to validate our findings. In addition, we placed SEMs using a partial stent-in-stent method in all patients with multiple stents in the SEMs

group. As the next step, it is necessary to verify the superiority of TRBO between the partial stent-in-stent method and the side-by-side method in the SEMs group.

In conclusion, TRBO was longer for SEMs than ISs used to drain malignant perihilar biliary obstructions. However, in perihilar cholangiocarcinoma, patients often had survival that was longer than TRBO with SEMs. Instead of SEMs placement, after which re-intervention is difficult, using removable ISs during the first intervention might be an acceptable strategy.

References

- 1 Wagner HJ, Knyrim K, Vakil N, Klose KJ. Plastic endoprotheses versus metal stents in the palliative treatment of malignant hilar biliary obstruction. A prospective and randomized trial. *Endoscopy*. 1993; **25**: 213–8.
- 2 Sangchan A, Kongkasame W, Pugkhem A, Jenwitheesuk K, Mairiang P. Efficacy of metal and plastic stents in unresectable complex hilar cholangiocarcinoma: a randomized controlled trial. *Gastrointest. Endosc.* 2012; **76**: 93–9.
- 3 Mukai T, Yasuda I, Nakashima M *et al.* Metallic stents are more efficacious than plastic stents in unresectable malignant hilar biliary strictures: a randomized controlled trial. *J. Hepatobiliary Pancreat. Sci.* 2013; **20**: 214–22.
- 4 Dumonceau JM, Tringali A, Papanikolaou I *et al.* Endoscopic biliary stenting: indications, choice of stents, and results: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline - updated October 2017. *Endoscopy*. 2018; **50**: 910–30.
- 5 Weickert U, Venzke T, König J, Janssen J, Remberger K, Greiner L. Why do bilioduodenal plastic stents become occluded? A clinical and pathological investigation on 100 consecutive patients. *Endoscopy*. 2001; **33**: 786–90.
- 6 Perdue DG, Freeman ML, DiSario JA *et al.* Plastic versus self-expanding metallic stents for malignant hilar biliary obstruction: a prospective multicenter observational cohort study. *J. Clin. Gastroenterol.* 2008; **42**: 1040–6.
- 7 Inatomi O, Bamba S, Shioya M *et al.* Threaded biliary inside stents are a safe and effective therapeutic option in cases of malignant hilar obstruction. *BMC Gastroenterol.* 2013; **13**: 31.
- 8 Ishiwatari H, Hayashi T, Ono M, Sato T, Kato J. Newly designed plastic stent for endoscopic placement above the sphincter of Oddi in patients with malignant hilar biliary obstruction. *Dig. Endosc.* 2013; **25**(Suppl. 2): 94–9.
- 9 Kaneko T, Sugimori K, Shimizu Y *et al.* Efficacy of plastic stent placement inside bile ducts for the treatment of unresectable malignant hilar obstruction (with videos). *J. Hepatobiliary Pancreat. Sci.* 2014; **21**: 349–55.
- 10 Kanno Y, Koshita S, Ogawa T *et al.* Inside plastic stents versus metal stents for treating unresectable malignant perihilar biliary obstructions: a retrospective comparative study. *Clin. Endosc.* 2020; **53**: 735–42.
- 11 Isayama H, Hamada T, Yasuda I *et al.* TOKYO criteria 2014 for transpapillary biliary stenting. *Dig. Endosc.* 2015; **27**: 259–64.
- 12 Cotton PB, Eisen GM, Aabakken L *et al.* A lexicon for endoscopic adverse events: report of an ASGE workshop. *Gastrointest. Endosc.* 2010; **71**: 446–54.
- 13 Pedersen FM, Lassen AT, Schaffalitzky de Muckadell OB. Randomized trial of stent placed above and across the sphincter of Oddi in malignant bile duct obstruction. *Gastrointest. Endosc.* 1998; **48**: 574–9.
- 14 Kobayashi N, Watanabe S, Hosono K *et al.* Endoscopic inside stent placement is suitable as a bridging treatment for preoperative biliary tract cancer. *BMC Gastroenterol.* 2015; **15**: 8.

- 15 Kogure H, Kato H, Kawakubo *et al.* A prospective multicenter study of “Inside Stents” for biliary stricture: multicenter evolving inside stent registry (MEISter). *J. Clin. Med.*2021; **10**: 2936.
- 16 Hamada T, Isayama H, Nakai *et al.* Duodenal invasion is a risk factor for the early dysfunction of biliary metal stents in unresectable pancreatic cancer. *Gastrointest. Endosc.*2011; **74**: 548–666.
- 17 Sugiyama M, Atomi Y. Does endoscopic sphincterotomy cause prolonged pancreatobiliary reflux?*Am. J. Gastroenterol.*1999; **94**: 795–8.
- 18 Sand J, Airo I, Hiltunen KM, Mattila J, Nordback I. Changes in biliary bacteria after endoscopic cholangiography and sphincterotomy. *Am. Surg.*1992; **58**: 324–8.