Gut and Liver
https://doi.org/10.5009/gnl220012
pISSN 1976-2283 eISSN 2005-1212

Original Article

Comparison of Bilateral and Trisegment Drainage in Patients with High-Grade Hilar Malignant Biliary Obstruction: A Multicenter Retrospective Study

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Article Info

Received January 14, 2022
Revised April 1, 2022
Accepted April 14, 2022
Published online July 19, 2022

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Background/Aims: Bilateral endoscopic drainage with self-expanding metallic stent (SEMS) can be used to effectively manage hilar malignant biliary obstruction. However, the benefits of using a trisegment drainage method remain unknown.

Methods: This study retrospectively reviewed the data of 125 patients with Bismuth type IIIa or IV unresectable malignant strictures who underwent bilateral endoscopic drainage using SEMSs at four tertiary centers. The patients were divided into the bilateral and trisegment drainage groups for comparison. The primary endpoint was stent patency and the secondary endpoints were technical success, technical and clinical success of reintervention, and overall survival.

Results: The technical success rates of the bilateral and trisegment drainage groups were 95% (34/36) and 90% (80/89) (p=0.41), respectively, with median stent patency durations of 226 and 170 days (p=0.26), respectively. Although the technical success of reintervention was not significantly different between the two groups (p=0.51), the clinical success rate of reintrvention was significantly higher in the trisegment drainage group (73% [11/15] vs 96% [47/49], p=0.009). The median survival times were 324 and 323 days in the bilateral and trisegment drainage groups, respectively (p=0.72). Multivariate Cox hazards model revealed no stent patency-associated factor; however, chemotherapy was associated with longer survival.

Conclusions: Although no significant difference was noted with respect to stent patency, significantly higher clinical success rates were achieved with reintervention using the trisegment drainage method than using the bilateral drainage method alone. **(Gut Liver 2023;17:170-178)**

Key Words: Bile duct obstruction; Neoplasms; Endoscopic biliary drainage; Bilateral drainage; Self-expandable metallic stents

INTRODUCTION

Endoscopic management of high-grade hilar malignant biliary obstruction (HMBO) is technically challenging even for well experienced endoscopists.[1-9] Despite the technical advantages of the percutaneous approach over the transpapillary approach, expert endoscopists naturally encourage themselves to optimize the short- and long-term outcomes of endoscopic treatment for these patients.[10,11] To manage high-grade HMBO, multiple stent deployment has been considered ideal.[12-14] Although a self-expanding metallic stent (SEMS) has a superior patency time compared with a plastic stent (PS), some technical difficulties associated with the use of multiple metallic stent deployment for HMBO management should be addressed.[15-17]

Biliary drainage for patients with HMBO is basically performed based on the total liver volume. Vienne *et al.*[18] reported that the drainage of ≥50% of the total liver volume was associated with the achievement of effective drainage and improvement of prognosis. Theoretically,

bilateral or unilateral drainage should be selected to obtain ≥50% drainage. Occasionally, however, liver function in the drainage area does not coincide with the calculated liver volume. This is because some patients with high-grade HMBO have portal vein infiltrations and/or highly divided bile duct branches at the drainage area due to the presence of tumors. Thus, in certain patients, sufficient drainage cannot be obtained with the use of unilateral drainage alone.

A recent randomized study on unilateral and bilateral drainage performed using SEMS in patients with advanced HMBO showed that bilateral drainage had superior stent patency, lower reintervention rates, and similar adverse event rates compared with unilateral drainage.[5] Accordingly, the results of the aforementioned study predicted that a smaller nondrainage area was associated with fewer obstruction events, such as cholangitis and longer patency. However, it remains unclear whether the use of bilateral drainage involving the left and right lobes (anterior and posterior) would promote better outcomes for patients with high-grade HMBO. Few studies have examined the efficacy of trisegment drainage method in patients with high-grade HMBO.[12-14] Moreover, the trisegment drainage method is indeed technically difficult compared with bilateral drainage and its benefits and complications remain unclear.

Therefore, this large multicenter cohort study sought to investigate and compare the clinical outcomes of bilateral and trisegment drainage methods using SEMSs in patients with high-grade HMBO.

MATERIALS AND METHODS

1. Patients

Between April 2003 and December 2020, 227 consecutive patients with unresectable HMBO who underwent endoscopic drainage using SEMS at four tertiary referral centers were evaluated. Among them, a total of 125 patients with Bismuth type IIIa or IV HMBO who underwent endoscopic bilateral SEMS drainage, including some patients who were included in our previous study, were included in the current study (Fig. 1).[13,19] All patients were histologically confirmed to have malignancy. Stricture patterns were classified into different Bismuth types according to magnetic resonance cholangiopancreatography and/or endoscopic retrograde cholangiography. The clinical parameters of all patients were retrieved from a prospectively maintained database. Written informed consent was obtained from all patients before any procedure was performed. This study was approved by the review board for human research in Okayama University Hospital (IRB number: 2108-001) and conducted following the guidelines of the Declaration of Helsinki.

2. Stent deployment techniques

All patients underwent endoscopic retrograde cholangiopancreatography using a standard duodenal scope (TJF-260, TJF-240, JF-260 or JF-260V; Olympus Optical Co., Ltd., Tokyo, Japan). The procedure was performed for patients who underwent overnight fasting; the patient was asked to maintain the prone position and was under conscious sedation. Prophylactic antibiotics were used before,

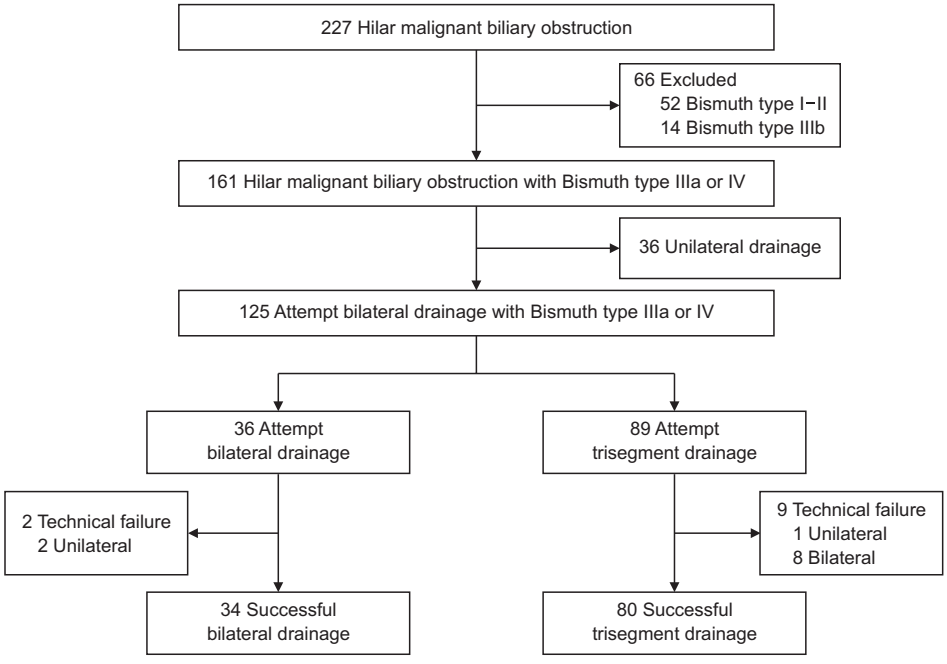

Fig. 1. Study flowchart.

during, and 2 to 3 days after endoscopic retrograde cholangiopancreatography. Before undergoing SEMS deployment, most of the patients underwent endoscopic biliary drainage with PS or a nasobiliary catheter for estimation of the effectiveness of biliary drainage in the target branch into which we planned to place the SEMS. When the drainage effect was sufficient after biliary decompression, SEMS was deployed within 3 weeks after the initial drainage.

This study used the following SEMSs: JOSTENT SelfX units (Abbott Vascular Devices, Redwood City, CA, USA), Zilver stent (Cook Medical, Winston-Salem, NC, USA), Zeo stent/Zeo stent V (Zeon Medical Inc., Tokyo, Japan), Niti-S biliary stent (Taewoong Medical Co., Gimpo, Korea), and BileRush selective (Piolax, Kanagawa, Japan). Bilateral (left hepatic duct and the anterior branch of the right hepatic duct or posterior branch of the right hepatic duct) or bilateral with trisegment (left hepatic duct, anterior branch of the right hepatic duct, and posterior branch of the right hepatic duct) drainage were performed depending on the physician's discretion. Most of the patients underwent multiple SEMS deployment using the partial stent-in-stent (PSIS) method described by Kawamoto *et al.* (Fig. 2A and B).[12] Hybrid and side-by-side methods were also performed based on previous reports.[3,20] The PSIS method was performed typically using 10-mm diameter SEMSs. For the side-by-side and hybrid methods, the diameter of the SEMS used depended on the diameter of the common bile duct. Typically, 8-mm diameter SEMSs were used for a common bile duct with a diameter of <10 mm. The lengths of SEMSs were 6, 8, and 10 cm depending on the length of the stricture. Endoscopic sphincterotomy was performed to account for endoscopic reintervention at the stent obstruction, and all SEMSs were placed above the papilla.

For reintervention, after confirming tissue ingrowth/overgrowth, sludge, or hemorrhage as the cause of SEMS obstruction, 6-F or 7-F PSs (TTM stent, Gadelius Medical, Tokyo, Japan; Flexima stent, Boston Scientific, Marlborough, MA, USA; Zimmon-type stent, Cook Endoscopy, Winston-Salem, NC, USA) were inserted into each lumen of the previously deployed SEMS (Fig. 2C and D).

After discharge, patients receiving chemotherapy were followed up every 1 to 2 weeks, whereas those who did not receive chemotherapy were followed up every 2 to 3 months. In addition, patients with symptoms such as fever and abdominal pain were treated as appropriate.

3. Chemotherapy

Chemotherapy was administered after the patient's jaundice and cholangitis were controlled. A total bilirubin level of <3.0 mg/dL and a transaminase level within five times the normal value were used as laboratory test indices. The chemotherapy regimen consisted of gemcitabine and cisplatin for 38 patients; gemcitabine monotherapy for 21 patients; S1 for 16 patients; and other drugs for six patients. After the induction of chemotherapy, tumor size was evaluated every 3 to 4 months using computed tomography or magnetic resonance imaging. The antitumor response was assessed using the Response Evaluation Criteria in Solid Tumors criteria (version 1.1).

4. Outcome measures

The following endpoints were compared between the bilateral and trisegment drainage groups. The primary endpoint was stent patency, whereas secondary endpoints included technical success, procedure time, procedure-related adverse events, technical and clinical success of reintervention, and overall survival (OS). Stent patency was defined as the period between initial SEMS deployment and stent obstruction. Data regarding patient death

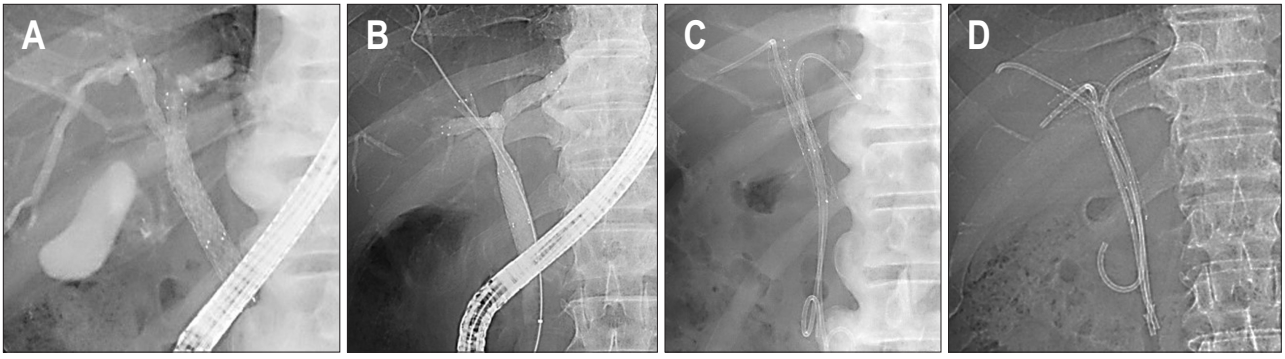

Fig. 2. Bilateral or trisegment drainage using metallic stents and each reintervention using plastic stents for stent obstruction. (A) Bilateral drainage using two self-expandable metallic stents (SEMSs) via the stent-in-stent method (left and right anterior brunches). (B) Trisegment drainage using three SEMSs via the stent-in-stent method (left, right posterior, and right anterior brunches). (C) Endoscopic reintervention for stent obstruction after the stent-in-stent method. Two plastic stents were successfully inserted into each SEMS. (D) Three plastic stents were successfully inserted into each SEMS.

without stent obstruction was censored. Stent obstruction was diagnosed based on the biochemical evidence of cholestasis, i.e., elevated liver enzyme levels relative to baseline values in addition to findings of biliary dilation on computed tomography or endoscopy.[21] The causes of stent obstruction were categorized as follows: tumor ingrowth, tumor overgrowth, sludge, and hemobilia. Tumor ingrowth diagnosis was based on radiological findings of a persistent biliary stricture inside the SEMS after bile duct cleaning. Tumor overgrowth diagnosis was based on the presence of a persistent stricture outside the SEMS. Sludge and hemobilia were diagnosed based on the presence of a large amount of sludge and clot residue, respectively, in an occluded SEMS revealed during reintervention. Technical success was defined as successful stent placement in each planned drainage area. The length of the procedure was determined starting from the moment the endoscope reached the papilla of Vater to endoscope removal. Procedure-related adverse events were defined as the events that occurred within 30 days after the procedure. For reintervention, technical success was defined as successful PS deployment in all the SEMSs that were placed during initial drainage. The 2014 Tokyo criteria was used to evaluate clinical success, which was defined as a 50% decrease in or normalization of the patient's bilirubin level within 14 days of stent deployment.[21] Clinical success of initial SEMS placement could not be evaluated because most patients underwent endoscopic biliary drainage using PS before SEMS deployment; thus, clinical success was evaluated for reintervention only. OS was measured from the day the SEMSs were deployed for the HMBO to the date of death or loss to follow-up.

5. Statistical analysis

Intention-to-treat and per-protocol methods were used for analysis. Intention-to-treat analysis was based on the original cohort of patients enrolled, whereas per-protocol analysis was based on the subset of patients in whom SEMSs deployment for bilateral or trisegment drainage was successful. The technical success of SEMSs placement and procedure-related adverse events were evaluated using intention-to-treat analysis. The rate of stent patency, reintervention, and survival were evaluated using per-protocol analysis.

Continuous variables were expressed as medians and interquartile ranges (IQRs). The Mann-Whitney U and the Fisher exact tests were used to compare continuous and categorical variables, respectively. Stent patency and OS were calculated using the Kaplan-Meier analysis and compared using the log-rank test. Univariate and multivariate analyses were conducted using the Cox proportional hazards model. Statistical analysis was performed using JMP Pro version 15 (SAS Institute Inc., Cary, NC, USA). Probability values <0.05 indicated statistical significance.

RESULTS

1. Patient characteristics

The clinical characteristics are summarized in Table 1. No significant differences in age, sex, Bismuth type, and chemotherapy was observed between the two groups. The trisegment drainage group consisted of more patients with cholangiocarcinoma compared with the bilateral drainage group (p=0.027).

2. Technical outcomes

Regarding stent deployment methods, 120 patients underwent stent deployment via the PSIS method, two via the side-by-side method, and three via the hybrid method. The technical success rate was 95% (34/36) and 90% (80/89) for the bilateral and trisegment drainage groups, respectively (p=0.41). In the trisegment drainage group, three stents placed in 69 patients and four stents in 11 patients. All patients who experienced technical failures underwent stent deployment via the PSIS method. The trisegment drainage group had a significantly longer median procedure time compared with the bilateral drainage group (78 minutes vs

Table 1. Clinical Characteristics of the Patients Who Underwent Bilateral and Trisegment Drainage (n=125)

Parameter	Bilateral drainage group (n=36)	Trisegment drainage group (n=89)	p-value
Age, median (interquartile range), yr	76 (70–81)	75 (64–83)	0.48
Sex (male/female)	16/20	51/38	0.19
Primary disease			0.027
Cholangiocarcinoma	20	66	
Gallbladder cancer	15	17	
Others	1	6	
Bismuth type			0.12
IIIa	20	36	
IV	16	53	
Chemotherapy	25	56	0.49

54 minutes, respectively, p=0.002). Procedure-related adverse events occurred in eight (22%) and 13 patients (15%) in the bilateral and trisegment drainage groups, respectively (p=0.3). Among the seven patients with cholangitis, one required additional percutaneous biliary drainage, whereas the remaining six were treated with antibiotics. Among the four patients with cholecystitis, two underwent percutaneous gallbladder drainage, one underwent endoscopic ultrasound-guided gallbladder drainage, and one treated with antibiotics. All patients with pancreatitis received conservative therapy. Patients who experienced bleeding after endoscopic sphincterotomy were treated with SEMS deployment (Table 2).

3. Outcomes after stent deployment

The median stent patency was 226 days (IQR, 96 to 586 days) and 170 days (IQR, 76 to 415 days) (p=0.26, log-rank test). After initial SEMS placement, stent obstruction occurred in 15 (44%) and 49 (61%) patients in the bilateral and trisegment drainage groups, respectively. The technical success rate of reintervention was 80% (12/15) and 71% (35/49) (p=0.51) in the bilateral and trisegment drainage groups, respectively. Although no difference was observed between the two groups in terms of the success rate of reintervention, the trisegment drainage group had significantly higher clinical success rate compared with the bilateral drainage group (96% [47/49] vs 73% [11/15], p=0.009). The three patients in the bilateral drainage group who experienced technical failure for reintervention underwent PS deployment into the unilateral SEMS and did not achieve clinical success. In one patient, two PSs were successfully deployed through bilateral SEMSs; however, the patient developed cholangitis in the nondrainage area. The causes of stent obstruction with clinical failure were tumor ingrowth in three patients and hemobilia in one patient. All three patients with ingrowth could be treated with additional endoscopic PS deployment into the failed branch or the nondrainage area during the first reintervention, while the patient with hemobilia required interventional radiology for the development of pseudoaneurysm at the right hepatic artery. Conversely, among the 14 patients in the trisegment drainage group who experienced technical failure for reintervention, 11 underwent successful deployment of two PSs through the bilateral SEMSs

Table 2. Technical Outcomes of the Patients Who Underwent Bilateral and Trisegment Drainage (n=125)

Outcomes	Bilateral drainage group (n=36)	Trisegment drainage group (n=89)	p-value
Technical success rate, No. (%)	34 (95)	80 (90)	0.41
Stent deployment methods, No. (technical failure case)			
PSIS	35 (2)	85 (9)	
SBS	1 (0)	1 (0)	
Hybrid	-	3 (0)	
Procedure time, median (IQR), min	54 (47–82)	78 (58–95)	0.002
Procedure-related adverse event, No. (%)	8 (22)	13 (15)	0.3
Cholangitis	1	6	
Cholecystitis	1	3	
Pancreatitis	5	4	
Bleeding post-endoscopic sphincterotomy	1	0	

PSIS, partial stent-in-stent; SBS, side-by-side; IQR, interquartile range.

Table 3. Outcomes after Stent Deployment in Patients Who Underwent Bilateral and Trisegment Drainage (n=114)

Outcomes	Bilateral drainage group (n=34)	Trisegment drainage group (n=80)	p-value
Stent patency time, median (IQR), day	226 (96–586)	170 (76–415)	0.34
Stent obstruction, No. (%)	15 (44)	49 (61)	
Ingrowth	11	36	
Overgrowth	1	2	
Sludge	1	8	
Hemobilia	2	3	
Technical success rate of reintervention, % (No./No.)	80 (12/15)	71 (35/49)	0.51
Unilateral PS placement	3	3	
Bilateral two PSs placement	12	11	
Bilateral three PSs placement	-	35	
Clinical success rate of reintervention, % (No./No.)	73 (11/15)	96 (47/49)	0.009
Survival time, median (IQR), day	324 (152–843)	323 (154–686)	0.72

IQR, interquartile range; PS, plastic stent.

and 10 patients achieved clinical success. Among the three patients who underwent PS deployment into the unilateral SEMS, two patients achieved clinical success. The causes of stent obstruction resulting in clinical failure were tumor ingrowth in one patient and hemobilia in another patient. The patient with ingrowth could be treated with additional endoscopic PS deployment into the failed branch at the first reintervention, whereas the patient with hemobilia was treated with percutaneous biliary drainage. The median survival time was 324 days (IQR, 152 to 843 days) and 323 days (IQR, 154 to 686 days) in the bilateral and trisegment drainage groups, respectively (p=0.72, log-rank test) (Table 3).

4. Predictors of stent patency and survival

The Cox proportional hazards model revealed no significant factor associated with stent patency. Females tended to have longer median stent patency than males (hazard ratio [HR], 0.64; p=0.10; median 310 days vs 160 days). Stent patency did not differ significantly according to Bismuth type (HR, 0.71; p=0.21; median for Bismuth type IIIa 170 days vs median for Bismuth type IV 196 days) and trisegment drainage (HR, 1.37; p=0.29) (Fig. 3A and B).

Survival analysis showed that cholangiocarcinoma (HR, 0.38; 95% confidence interval, 0.22 to 0.64; p<0.001; median 372 days vs median 181 days) and chemotherapy (HR, 0.28; 95% confidence interval, 0.16 to 0.49; p<0.001; median 408 days vs 160 days) were associated with long survival. OS did not differ significantly according to Bismuth type (HR, 1.29; p=0.28; median for Bismuth type IIIa 226 days vs median for Bismuth type IV 346 days) and triseg-

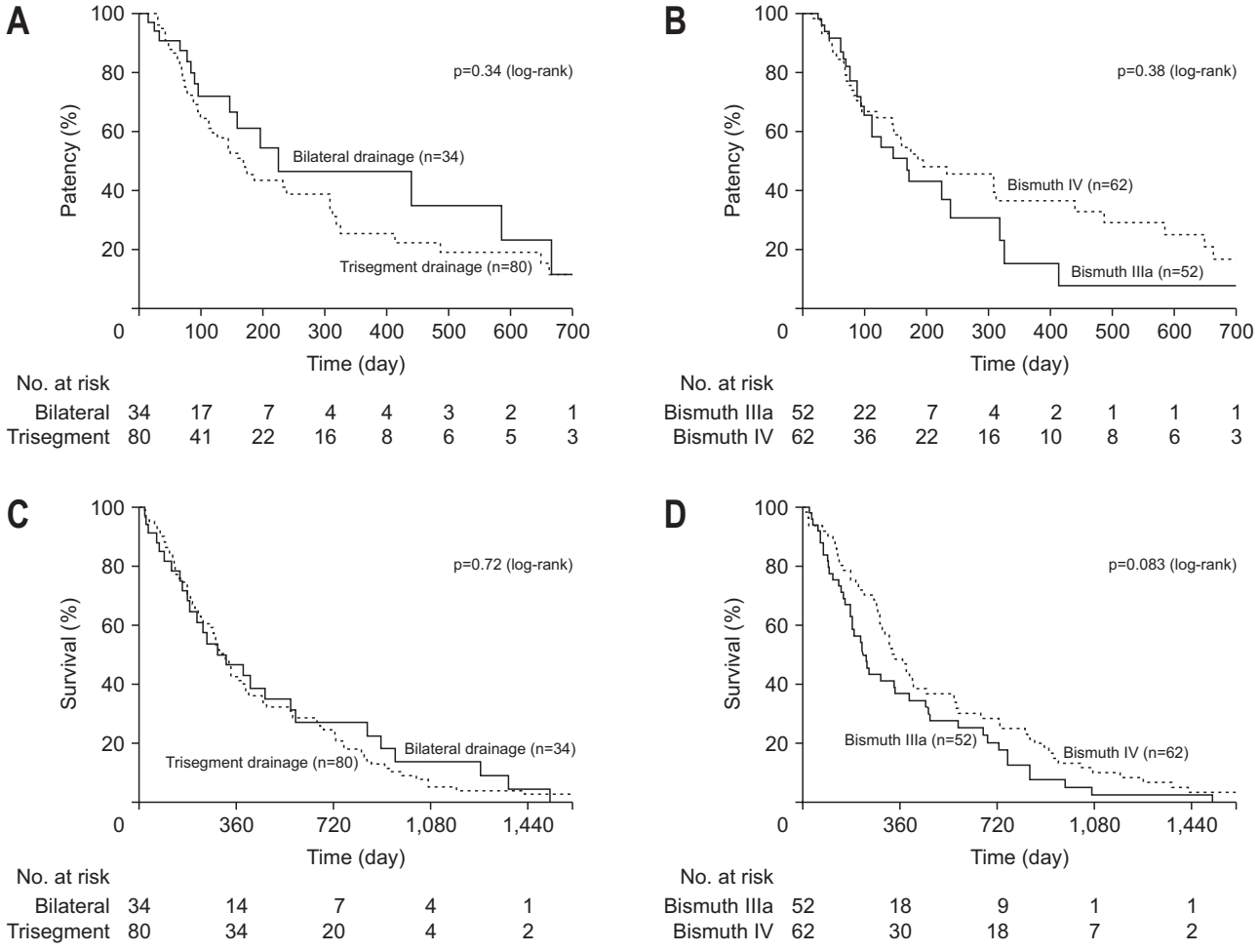

Fig. 3. Cumulative stent patency and survival time curves plotted using the Kaplan-Meier method. (A) The median stent patency duration was 226 days (interquartile range [IQR], 96–586 days) and 170 days (IQR, 76–415 days) following bilateral and trisegment drainage, respectively (p=0.34, log-rank test). (B) The median stent patency duration was 170 days (IQR, 90–320 days) and 196 days (IQR, 81–650 days) for patients with Bismuth type IIIa and IV hilar malignant biliary obstruction (HMBO), respectively (p=0.38, log-rank test). (C) The median survival time was 324 days (IQR, 152–843 days) and 323 days (IQR, 154–686 days) following bilateral and trisegment drainage, respectively (p=0.72, log-rank test). (D) The median survival time was 226 days (IQR, 136–670 days) and 346 days (IQR, 200–825 days) in patient with Bismuth type IIIa and IV HMBO, respectively (p=0.083, log-rank test).

Table 4. Univariate and Multivariate Cox Proportional Hazard Models for Stent Patency and Survival

Risk factor	No.	Univariate analysis		Multivariate analysis	
		HR (95% CI)	p-value	HR (95% CI)	p-value
Stent patency					
Age ≥75 yr	62	0.95 (0.58–1.57)	0.84		
Female sex	53	0.69 (0.42–1.15)	0.16	0.64 (0.38–1.08)	0.10
Cholangiocarcinoma	80	1.24 (0.64–2.40)	0.52		
Bismuth type IV	62	0.79 (0.47–1.33)	0.38	0.71 (0.42–1.21)	0.21
Trisegment drainage	80	1.32 (0.74–2.36)	0.34	1.37 (0.76–2.45)	0.29
Procedure time >70 min	58	1.02 (0.62–1.68)	0.92		
Chemotherapy	74	0.87 (0.48–1.57)	0.64		
Survival					
Age ≥75 yr	62	1.50 (1.01–2.23)	0.041	0.92 (0.57–1.50)	0.76
Female sex	53	1.04 (0.70–1.53)	0.83		
Cholangiocarcinoma	80	0.56 (0.37–0.87)	0.01	0.38 (0.22–0.64)	<0.001
Bismuth type IV	62	0.70 (0.47–1.04)	0.085	1.29 (0.80–2.07)	0.28
Trisegment drainage	80	1.08 (0.69–1.68)	0.72		
Procedure-related adverse events	17	1.10 (0.63–1.91)	0.72		
Chemotherapy	74	0.36 (0.23–0.56)	<0.001	0.28 (0.16–0.49)	<0.001

HR, hazard ratio; CI, confidence interval.

ment drainage (Table 4, Fig. 3C and D).

DISCUSSION

This is the first report to compare stent patency achieved using bilateral and trisegment drainage in patients with high-grade HMBO. Although more than three stents were considered necessary for achieving sufficient drainage in patients with Bismuth type IIIa or IV HMBO, no significant difference in stent patency was noted between two groups. However, the trisegment drainage group showed significantly better clinical success rates of reintervention. Moreover, our findings showed that chemotherapy was associated with longer survival.

Recent literature has reported a technical success rate of approximately 90% to 100% for bilateral drainage using SEMS in patients with HMBO.[5-8] Owing to advances in devices, such as SEMSs or guidewires and stent deployment methods, the technical success rates of bilateral drainage have continued to improve. Moreover, the same studies reported a stent patency of 4.2 to 16.3 months for bilateral drainage with SEMS.[5-8] Notably, two previous studies on trisegment drainage using three SEMSs reported a technical success rate and stent patency of 100% and 7.1 months, respectively, with the PSIS method and 82% and 6.3 months, respectively, with the hybrid method.[12,14] The technical success rate and stent patency reported in the current study are in agreement with those reported in previous studies. Despite insufficient data regarding trisegment drainage, similar technical success and stent patency had been reported for bilateral and trisegment drainage. The main cause of stent obstruction was tumor ingrowth in both groups; however, sludge accumulation appeared to be more common in the trisegment drainage group. The overlap between the three SEMSs has been considered to create a more complex and dense bile duct lumen, which reduces bile juice clearance. Moreover, placing the SEMS in a noninfected area may increase the risk of biliary infection.

Stent patency did not differ significantly according to Bismuth type (median stent patency; Bismuth type IIIa 170 days vs Bismuth type IV 196 days). Among patients with Bismuth type IIIa HMBO, 18 and 34 patients underwent bilateral and trisegment drainage, respectively. The median stent patency was 226 and 128 days following bilateral and trisegment drainage, respectively; no difference was observed between the two groups (p=0.71, log-rank test). Of the patients with Bismuth type IV HMBO, 16 and 46 patients underwent bilateral and trisegment drainage, respectively. The median stent patency was 441 and 176 days following bilateral and trisegment drainage, respectively, and no difference was observed between the two groups (p=0.41, log-rank test). Patients with a highly divided bile duct due to high-grade HMBO were not allowed an extension of the patency period even when one additional drainage area was obtained. In the present study, patients with Bismuth type IIIb malignant strictures were excluded because in them the volume of the left liver lobe is usually lesser than that of the right liver lobe. Thus, complete drainage of the right liver lobe is important to achieve effective drainage.

Previous studies have reported 49% to 85% and 72% to 100% technical and clinical success rates of reintervention

for bilateral stent deployment, respectively.[5,22-25] Reintervention in patients with stent occlusion does not always necessarily require stent placement into each SEMS for clinical improvement. Notably, our findings showed that trisegment drainage promoted significant clinical success rates after reintervention compared with bilateral drainage (96% [47/49] vs 73% [11/15], p<0.05). Among the 14 patients in the trisegment drainage group who experienced technical failure for reintervention, 11 underwent successful deployment of two PSs through the bilateral SEMSs, among them, 10 achieved clinical success. The three patients in the bilateral drainage group who experienced technical failure for reintervention underwent PS deployment into the unilateral SEMS and did not achieve clinical success. The clinical success rates of bilateral and unilateral PS deployment were 91% (21/23) and 33% (2/6), respectively. The aforementioned results suggest that drainage with bilateral PS deployment can be effective for the clinical improvement of patients with stent obstructions. Given that the trisegment drainage group patients had more drainage routes for PS deployment through the SEMSs compared with the bilateral drainage group patient, the latter will certainly have better clinical reintervention success rates compared with the former. In the present study, the high clinical success rate of reintervention was the only advantage of using trisegment drainage, which should be considered as an important aspect in daily clinical management given the prolonged OS caused by the introduction of newly developed drugs, such as immune checkpoint inhibitors.

The present study has several limitations. First, this was a retrospective study that included a small number of patients in the bilateral drainage group. Therefore, the underpowered comparison did not reveal meaningful differences. Second, the decision to perform bilateral or trisegment drainage was left to the discretion of each physician. Third, the clinical success rate of initial drainage could not be evaluated because almost all patients underwent drainage using PS or nasobiliary catheter. Additionally, the study included only patients who achieved clinical success after PS placement; therefore, it did not represent all patients with HMBO. Fourth, although most cases underwent drainage using the PSIS method, three drainage methods had been utilized. Finally, various devices, SEMSs, and PSs were used.

In conclusion, the current study showed no significant differences between bilateral and trisegment drainage in terms of stent patency in patients with high-grade HMBO. However, the latter exhibited a significantly higher clinical success rate of reintervention compared with the former. Nonetheless, further prospective randomized studies using the same procedures, method, and devices will be needed to evaluate the effectiveness of trisegment drainage.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

AUTHOR CONTRIBUTIONS

Study concept and design: K. Matsumoto, H. Kato. Data acquisition, analysis, and interpretation: K. Matsumoto, H. Kato, K. Morimoto, K. Miyamoto, Y.S. Drafting of the manuscript: K. Matsumoto, H. Kato. Critical revision of the manuscript for important intellectual content: H. Kawamoto. Administrative, technical, or material support; study supervision: H.O. Approval of final manuscript: all authors.

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