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Retrospective Comparison of Initial vs. Subsequent Simultaneous Side-by-Side Stenting with Uncovered Metal Stents during Endoscopic Retrograde Cholangiopancreatography for Unresectable Malignant Hilar Biliary Obstructions

Koji Takahashi[1, 2], Hiroshi Ohyama[1], Motoyasu Kan[1], Mayu Ouchi[1], Hiroki Nagashima[1], Kohichiroh Okitsu[1], Izumi Ohno[1,2], Naoya Kato[1]

1) Department of Gastroenterology, Graduate School of Medicine, Chiba University, Chiba;
2) Department of Medical Oncology, Graduate School of Medicine, Chiba University, Chiba, Japan

Address for correspondence:
Koji Takahashi, M.D.
Department of Gastroenterology, Graduate School of Medicine, Chiba University, Chiba, Japan
1-8-1 Inohana, Chuo-ku, Chiba 260-8670, Japan
takahashi.koji@chiba-u.jp

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ABSTRACT

Background & Aims: This study aimed to evaluate the efficacy and safety of transpapillary simultaneous side-by-side (SBS) stenting using uncovered self-expandable metal stents (UCSEMSs) at the initial endoscopic retrograde cholangiopancreatography (ERCP) for unresectable malignant hilar biliary obstruction (UMHBO).
Methods: A total of 67 patients with UMHBO who underwent simultaneous SBS stenting at our institution were retrospectively divided into two groups: the SBS stenting at the initial ERCP group (n=13) and the SBS stenting at the subsequent ERCP group (n=54). Clinical outcomes were compared between the groups.
Results: There were no significant differences between the SBS stenting at the initial ERCP group and the SBS stenting at the subsequent ERCP group in procedural time (median: 50 vs. 40 minutes, p=0.31), functional success rate (69.2% vs. 83.3%, p=0.25), adverse event rate (30.8% vs. 14.8%, p=0.18), recurrent biliary obstruction (RBO) rate (23.1% vs. 38.9%, p=0.29), technical success rate of re-intervention (100% vs. 90.5%, p=0.58), cumulative time to RBO (not reached vs. 252 days, p=0.80), or median overall survival (73 vs. 212 days, p=0.12).
Conclusions: Simultaneous SBS stenting using UCSEMSs at the initial ERCP is a safe and effective strategy for managing UMHBO, with outcomes comparable to those of SBS stenting performed at the subsequent ERCP.

Key words: cholangiopancreatography – drainage – endoscopic retrograde cholangiopancreatography – self-expandable metallic stents – bile ducts.

Abbreviations: CT: computed tomography; ERCP: endoscopic retrograde cholangiopancreatography; IHD: intrahepatic bile duct; RBO: recurrent biliary obstruction; SBS: side-by-side; SIS: stent-in-stent; TRBO: time to recurrent biliary obstruction; UCSEMS: uncovered self-expandable metal stent; UMHBO: unresectable malignant hilar biliary obstruction.

INTRODUCTION

Malignant biliary obstruction can cause obstructive jaundice and other complications, severely affecting the quality of life [1]. It may trigger systemic inflammatory response syndrome, potentially resulting in multiple organ dysfunction [2]. Common complications include hemodynamic instability, acute renal failure, cardiovascular suppression, immune compromise, coagulation disorders, and impaired wound healing [2, 3]. Treatment options for obstructive jaundice include surgical bypass, percutaneous drainage, and endoscopic stenting [4]. Of these, endoscopic transpapillary biliary stenting during endoscopic retrograde cholangiopancreatography (ERCP) is the preferred method for managing malignant biliary obstruction [5]. Moreover, metal stents are considered superior to plastic stents for malignant hilar biliary obstruction, with multiple studies demonstrating better patency period and fewer re-interventions [6, 7].

The side-by-side (SBS) stenting technique involves deploying two uncovered self-expandable metal stents (UCSEMSs) in parallel and is widely used to treat unresectable malignant hilar biliary obstruction (UMHBO). This approach is technically simpler than the stent-in-stent (SIS) method, particularly during its initial placement and re-intervention [8]. Traditionally, SBS stenting has followed a sequential process, with one stent deployed after the other. With the development of thinner 6 Fr delivery systems, simultaneous SBS stent placement has become more common. In recent

years, even smaller delivery systems, measuring less than 6Fr, have also been introduced [9-12]. There is still no consensus on the optimal timing for SBS stenting in cases of UMHBO, and whether SBS stenting is more effective when performed during the initial ERCP or a subsequent ERCP remains insufficiently investigated. To evaluate the efficacy and safety of simultaneous SBS stenting at the initial ERCP for UMHBO patients, we conducted a retrospective comparison between patients who underwent simultaneous SBS stenting at the initial ERCP and those who underwent simultaneous SBS stenting at the subsequent ERCP.

METHODS

Study Design

This single-center retrospective study analyzed data from 67 patients with UMHBO who underwent endoscopic transpapillary UCSEMS placement using the simultaneous SBS technique at Chiba University Hospital between May 2013 and December 2023. The study excluded cases of Bismuth type I, those involving biliary or intestinal reconstruction other than distal gastrectomy with Billroth I anastomosis, cases where UCSEMSs were placed in three or more intrahepatic bile ducts (IHDs) during a single ERCP session, and cases with incomplete or unclear data.

Patients were categorized into two groups: those who underwent simultaneous SBS stenting at the initial ERCP (SBS at the initial ERCP group) and those who initially received plastic stent placement followed by simultaneous SBS stenting at the subsequent ERCP (SBS at the subsequent ERCP group). Baseline characteristics and clinical outcomes were compared between the two groups. Baseline characteristics included age, gender, pre-ERCP serum total bilirubin levels, pre-ERCP serum albumin levels, type of Bismuth classification, etiology of biliary obstruction, rates of above the papilla stent placement, and chemotherapy administration after UCSEMS placement. Clinical outcomes included procedural time, rate of functional success, incidence of adverse events, rate of recurrent biliary obstruction (RBO), cumulative time to RBO (TRBO) in cases with effective drainage, re-intervention rates, technical success rates of the first re-intervention, and overall survival. Written informed consent for the procedure was obtained from all patients, and participation consent was collected using an opt-out methodology.

Definitions

Functional success was determined based on the Tokyo Criteria 2014 [13]. It was defined as a reduction in serum bilirubin to less than 50% of its initial level or below 2.0 mg/dL within 14 days after stenting, without requiring additional biliary drainage. Procedural time was measured from the insertion of the endoscope to its removal. The technical success of re-intervention was defined as either the successful placement of an additional stent at the targeted site, as identified by pre-procedure computed tomography (CT), or the removal of stones or biliary sludge obstructing the UCSEMSs using a balloon catheter. Adverse events associated with the endoscopic procedures were classified according to the severity grading system outlined in the lexicon recommended by the American Society for Gastrointestinal Endoscopy [14]. The analysis of TRBO was conducted exclusively on cases where clinical success was achieved following SBS stenting.

Techniques

Uncovered self-expandable metal stents were placed transpapillary during ERCP. Prophylactic antibiotics were administered intravenously before the procedure. Endoscopic retrograde cholangiopancreatography was performed using oblique-viewing endoscopes (TJF-260V and TJF-Q290V; Olympus, Tokyo, Japan) with carbon dioxide insufflation. Patients underwent conscious sedation, and sodium meglumine amidotrizoate was used as the contrast medium for cholangiography. After cholangiography and identification of biliary stenosis, guidewires (VisiGlide 2, Olympus, Tokyo, Japan; M-Through, ASAHI INTECC, Aichi, Japan; EndoSelector, Boston Scientific, Marlborough, Massachusetts, USA) were advanced into the IHDs. Two UCSEMS delivery systems (Niti-S Large Cell D-type Stent, Taewoong Medical, Gimpo, Republic of Korea; Zeo Stent V, Zeon Medical, Tokyo, Japan; BileRush Selective, Piolax, Yokohama, Japan; Zilver 635 Biliary Stent, Cook Medical, Bloomington, Indiana, USA; YABUSAME, Kaneka Medix, Osaka, Japan) were then inserted over the guidewires and positioned. The UCSEMSs were deployed simultaneously at the desired locations (Fig. 1).

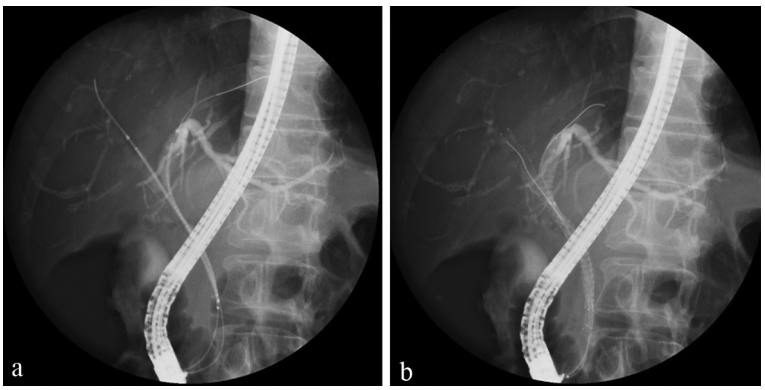

Fig.1. Simultaneous side-by-side stent placement. a) The tips of two metal stent delivery systems are positioned in the left and right intrahepatic bile ducts, respectively. b) Both metal stents are deployed simultaneously.

For all cases of SBS stenting, UCSEMSs with a diameter of 8 mm were used.

Statistical Analysis

Data are presented as medians with interquartile ranges or as numbers with percentages. Continuous variables were compared using the Mann–Whitney U test, while categorical variables were analyzed with Pearson's χ^2 test. Cumulative TRBO and overall survival were estimated using Kaplan–Meier analysis, with comparisons performed using the log-rank test. For cases where the median cumulative TRBO or overall survival could not be determined due to insufficient events during the observation period, the result was described as "not reached." Statistical significance was defined as $p<0.05$. All analyses were conducted using BellCurve for Excel (Social Survey Research Information Co., Ltd., Tokyo, Japan).

Ethical Statement

This study was approved by the Institutional Review Board of Chiba University Hospital (protocol code: HK202403-13; date of approval: March 29, 2024) and conducted in accordance with the latest revision of the Declaration of Helsinki.

RESULTS

The median age of the participants was 71 years (range: 36–90). Among the 67 patients, 13 underwent SBS stenting at the initial ERCP, while 54 underwent SBS stenting at the subsequent ERCP. Table I summarizes the patient characteristics for both groups. In the SBS at the initial ERCP group, all patients underwent endoscopic sphincterotomy at the time of SBS stenting. Conversely, in the SBS at the subsequent ERCP group, endoscopic sphincterotomy was performed during the prior ERCP session. No significant differences were observed between the groups in terms of gender, pre-ERCP serum bilirubin levels, or Bismuth type. However, patients in the SBS at the initial ERCP group were significantly younger and had higher pre-ERCP serum albumin levels. This group also exhibited significantly fewer cases of perihilar cholangiocarcinoma but a greater number of metastatic liver tumors compared to the SBS at the subsequent ERCP group.

Clinical outcomes for the two groups are shown in Table II. The median procedural time was 50 minutes for the SBS at the initial ERCP group and 40 minutes for the SBS at the subsequent group, with no statistically significant difference ($p=0.31$). Functional success rates were 69.2% and 83.3% in the SBS at the initial ERCP group and the SBS at the subsequent ERCP group, respectively, without a significant difference ($p=0.25$). Adverse events occurred in 30.8% of patients in the SBS at the initial ERCP group and in 14.8% of those in the SBS at the subsequent ERCP group, with no significant difference ($p=0.18$). These events included cholangitis, pancreatitis, liver abscess, pneumonia, and heart failure, but their incidence did not significantly differ between the groups. The rates of RBO were 23.1% in the SBS at the initial ERCP group and 38.9% in the SBS at the subsequent ERCP group, with no significant difference ($p=0.29$).

Re-intervention was performed in all cases of RBO. The technical success rates for the first re-intervention were 100% in the SBS at the initial ERCP group and 90.5% in the SBS at the subsequent ERCP group, without a significant difference ($p=0.58$). The median cumulative TRBO was 252 days in the SBS at the subsequent ERCP group, whereas it was reported as "not reached" for the SBS at the initial ERCP group using the Kaplan–Meier method. No significant difference in cumulative

Table I. Patient characteristics of the two groups

	SBS stenting at the initial ERCP group (n = 13)	SBS stenting at the subsequent ERCP group (n = 54)	P-value
Age, year, median (IQR)	65 (60–68)	74 (67–80)	0.0094
Gender, male, n (%)	6 (46.2)	36 (66.7)	0.17
Pre-ERCP serum total bilirubin level, mg/dL, median (IQR)	6.4 (2.3–11.3)	4.7 (1.3–7.5)	0.093
Pre-ERCP serum albumin level, mg/dL→g/dL, median (IQR)	3.2 (2.9–3.4)	2.7 (2.2–3.3)	0.040
Bismuth type, n (%)			
Type I	3 (23.1)	8 (14.8)	0.47
Type II a	1 (7.7)	12 (22.2)	0.23
Type III b	3 (23.1)	6 (11.1)	0.26
Type IV	6 (46.2)	28 (51.9)	0.71
Etiology of biliary obstruction, n (%)			
Perihilar cholangiocarcinoma	1 (7.7)	29 (53.7)	0.0027
Gallbladder cancer	4 (30.8)	10 (18.5)	0.33
Intrahepatic cholangiocarcinoma	1 (7.7)	4 (7.4)	0.97
Hepatocellular carcinoma	1 (7.7)	5 (9.3)	0.86
Metastatic liver tumor	5 (38.5)	3 (5.6)	0.0010
Hilar lymph node metastasis	1 (7.7)	3 (5.6)	0.77
Above the papilla stent placement, n (%)	13 (100)	50 (92.6)	0.31
Chemotherapy after UCSEMS placement, n (%)	2 (15.4)	21 (38.9)	0.11

SBS: side-by-side; IQR: interquartile range; UCSEMS: uncovered self-expandable metal stent; ERCP: endoscopic retrograde cholangiopancreatography.

Table II. Clinical outcomes of the two groups

	SBS stenting at the initial ERCP group (n = 13)	SBS stenting at the subsequent ERCP group (n = 54)	P-value
Procedure time, min, median (IQR)	50 (30–54)	40 (27–52)	0.31
Functional success, n (%)	9 (69.2)	45 (83.3)	0.25
Adverse events, n (%)	4 (30.8)	8 (14.8)	0.18
Cholangitis	2 (15.4)	3 (5.6)	0.23
Pancreatitis	1 (7.7)	2 (3.7)	0.53
Liver abscess	1 (7.7)	1 (1.9)	0.27
Pneumonia	0	1 (1.9)	0.62
Heart failure	0	1 (1.9)	0.62
RBO, n (%)	3 (23.1)	21 (38.9)	0.29
Cumulative TRBO in effective drainage cases, days, median (95% CI)	NR	252 (73–431)	0.80
Re-intervention, n (%)	3 (23.1)	21 (38.9)	0.29
Technical success rates of the first re-intervention, n (%)	3 (100)	19 (90.5)	0.58
Overall survival, days, median (95% CI)	73 (52–94)	212 (109–315)	0.12

NR: not reached. For the rest of abbreviations see Table I.

TRBO was observed between the groups (p=0.80) (Fig. 2). The median overall survival was 73 days in the SBS at the initial ERCP group and 212 days in the SBS at the subsequent ERCP group, although this difference was not statistically significant (p=0.12) (Fig. 3).

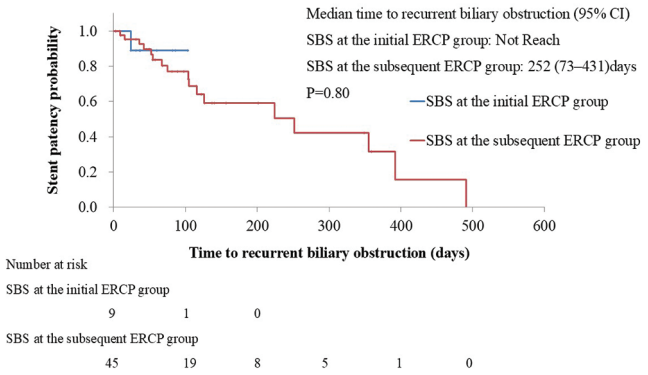

Fig. 2. Kaplan–Meier curves illustrating the time to recurrent biliary obstruction in cases with effective drainage following SBS stenting. CI, confidence interval; SBS, side-by-side stenting; ERCP, endoscopic retrograde cholangiopancreatography.

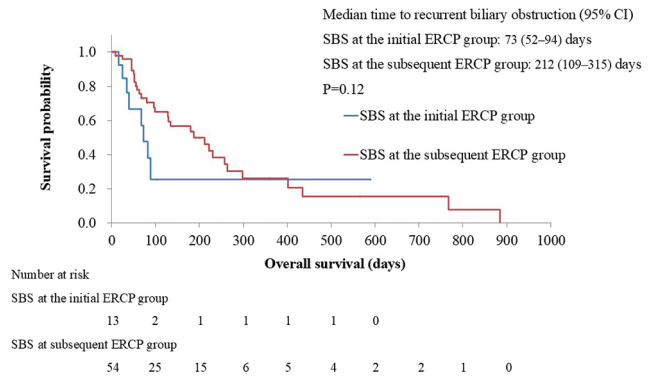

Fig. 3. Kaplan–Meier curves depicting overall survival. CI, confidence interval; SBS, side-by-side stenting; ERCP, endoscopic retrograde cholangiopancreatography.

DISCUSSION

This study evaluated the efficacy and safety of simultaneous SBS stenting with UCSEMSs at the initial ERCP for UMHBO by comparing outcomes with SBS stenting performed at the subsequent ERCP. The findings revealed no significant differences between the groups in terms of procedural time, functional success rate, or adverse event rate. Although the median cumulative TRBO in the SBS at the initial ERCP group could not be calculated, the log-rank test indicated no significant difference compared to the SBS at the subsequent ERCP group.

Various studies have been conducted on biliary drainage for UMHBO. In the past, unilateral stenting was the mainstream approach, as it could achieve effective drainage in most cases by selectively targeting drainage using MRCP and/or CT. Additionally, unilateral stenting offered high technical success rates, making it a widely adopted method [15-17]. However, in recent years, studies have reported that draining ≥50% of the liver volume in patients with malignant hilar biliary obstruction is associated with better clinical outcomes, including higher success rates and longer survival [18, 19]. In 2023, a study reported that draining more than 80% of the liver volume may improve survival in patients undergoing chemotherapy [20]. Thus, many studies have shown that stenting to drain a larger liver volume is associated with longer survival. Consequently, bilateral drainage is now widely practiced.

Simultaneous SBS stenting has become feasible with the development of smaller delivery systems. The simultaneous SBS stenting was associated with shorter procedural times and higher technical success rates compared to sequential SBS stenting [12, 21]. Recent advancements in stent technology, such as the development of thin delivery systems, along with improvements in endoscopes themselves, have made SBS stent placement feasible even for patients with surgically altered anatomy or duodenal strictures [22, 23].

Another approach for placing UCSEMSs in two IHDs is the SIS technique. Studies comparing the SBS and SIS

techniques for UMHBO have reported mixed results. Some research has found no significant differences in technical success, clinical outcomes, or overall survival between the two methods [24, 25]. However, a meta-analysis indicated that SIS offers superior stent patency [26]. While SBS is technically simpler for both initial placement and reintervention, it may increase the risk of portal vein thrombosis due to common bile duct overexpansion [8]. Consequently, there is currently no consensus on whether SBS or SIS is the preferred method [12], and the choice often depends on patient-specific factors and the physician's expertise.

Recently, a new stenting technique combining SBS and SIS methods has been reported. This approach involves initially placing UCSEMSs using the SBS technique, followed by threading a new stent delivery system through the mesh gap and deploying the stent using the SIS technique, all during a single ERCP session [27]. While promising, this method can be technically challenging.

In patients with UMHBO, a plastic stent is often placed initially, followed by metal stenting at the subsequent ERCP. However, plastic stents frequently require re-intervention, which is sometimes unplanned. The benefit of placing a plastic stent at the initial ERCP is that it allows clinicians to evaluate the effectiveness of drainage before proceeding with the placement of UCSEMSs. In contrast to plastic stents, which are easy to remove, uncovered metal stents become difficult to remove once placed. If adequate liver drainage is not achieved after metal stent placement, an additional stent may be required, necessitating another ERCP. The primary advantage of placing a metal stent during the initial ERCP is the reduction in the number of endoscopic procedures needed. This is particularly important for the small subset of UMHBO patients with compromised respiratory function or poor physical condition, for whom repeated procedures pose significant risks. Furthermore, ERCP carries a risk of adverse events such as pancreatitis, which, although rare, can be severe and potentially life-threatening. Therefore, minimizing the number of procedures is preferable. Nevertheless, under certain conditions, the patency periods of metal and plastic stents may be comparable.

A recent randomized trial on biliary stent placement for UMHBO patients found no statistically significant difference in stent patency between suprapapillary plastic stents and UCSEMSs. The study concluded that suprapapillary plastic stents could serve as a viable alternative to UCSEMSs [28]. Further reports with similar findings may lead to a reconsideration of the assumption that metal stents offer a longer patency period.

In our study, the number of cases in the SBS at the subsequent ERCP group was approximately four times greater than in the SBS at the initial ERCP group. While longer procedural times were anticipated for the SBS at the initial ERCP group due to the need for biliary cannulation and endoscopic sphincterotomy, no significant difference was observed. This may be because more time was dedicated to carefully inserting the guidewire into the targeted bile duct branch, positioning the stent delivery system, and deploying the stent, rather than performing biliary cannulation and sphincterotomy. Although adverse event rates did not show a statistically significant difference between the two groups, 30.8% of patients in the SBS at the initial ERCP group experienced adverse events, with half of these being cases of cholangitis. In the SBS at the subsequent ERCP group, cholangiography had already been completed during the previous procedure. Conversely, in the SBS at the initial ERCP group, comprehensive cholangiography was required to visualize the branches of the bile duct prior to UCSEMS placement. Initial ERCP with SBS stenting is particularly beneficial in cases where repeated endoscopic procedures pose a risk, such as in patients with unstable respiratory conditions or high sedation risks.

This study has several limitations. First, the small sample size, particularly in the SBS at the initial ERCP (13 cases), may limit the statistical power to detect significant differences between groups. This limitation could also have impacted the ability to calculate cumulative TRBO for effective drainage cases in the SBS at the initial ERCP. Second, the retrospective design of this study inherently introduces the potential for selection bias, as the assignment of patients to the SBS at the initial ERCP group or the SBS at the subsequent ERCP group was not randomized. Third, differences in patient backgrounds between the two groups, such as age, serum albumin levels, and disease etiology, could have influenced the results. Fourth, the inclusion of various diseases causing biliary obstruction may have introduced heterogeneity that could affect the generalizability of our findings. These limitations highlight the need for future multicenter, prospective, randomized studies with larger sample sizes to validate our findings and provide a more comprehensive understanding of the optimal timing for simultaneous SBS stenting in patients with UMHBO. Furthermore, subgroup analyses stratified by disease etiology and patient condition may help clarify the specific populations that would benefit most from initial ERCP with simultaneous SBS stenting.

CONCLUSIONS

No significant differences were observed between the SBS at the initial ERCP group and the SBS at the subsequent ERCP group in terms of procedural time, functional success rates, adverse event rates, RBO rates, or cumulative TRBO. Simultaneous SBS stenting with UCSEMSs at the initial ERCP is a safe and effective treatment option for patients with UMHBO.

Conflicts of interest: None to declare.

Authors' contribution: K.T. drafted the manuscript; K.T., H.O., M.K., M.O., H.N., K.O. and I.O. collected the data; K.T., H.O., M.K., M.O. and H.N. performed the endoscopic procedures; K.T., H.O., M.K., M.O., H.N., K.O. and I.O. managed the patients; H.O. and N.K. critically revised the paper. All the authors approved the final version of the manuscript.

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