Observational Study

Medicine®

OPEN

# Endoscopic reintervention for stent malfunction after stent-in-stent deployment for malignant hilar obstruction

Joung Boom Hong, MD, Dae Hwan Kang, PhD, MD*, Hyeong Seok Nam, MD*, Cheol Woong Choi, PhD, MD, Hyung Wook Kim, PhD, MD, Su Bum Park, PhD, MD, Su Jin Kim, MD, Woo Hyeok Choi, MD

**Abstract**

Endoscopic bilateral stenting has been increasingly performed for advanced hilar obstruction. As disease progresses, stent malfunction eventually occurs. However, endoscopic reintervention is difficult in these patients. We aimed to evaluate a suitable reintervention procedure for stent malfunction after stent-in-stent (SIS) deployment for malignant hilar obstruction.

Among 52 patients with bilateral stenting performed using the SIS method between September 2009 and June 2016, 20 patients with stent malfunction were enrolled in this study. Reintervention was performed endoscopically or percutaneously. Technical and functional success rates were evaluated retrospectively.

Technical and functional success rates of endoscopic reintervention were 83% (10/12) and 80% (8/10), respectively. Endoscopic bilateral and unilateral reintervention success rates were 75% (6/8) and 100% (4/4), respectively. For bilateral reintervention, either plastic or plastic and metal stents were used.

Endoscopic reintervention could be considered for in-stent malfunction if patients are in fair condition after SIS placement for malignant hilar obstruction. Decisions regarding whether to use bilateral or unilateral drainage and the type of stent to use should depend on the conditions of the disease and the patient.

**Abbreviations:** CCC = cholangiocarcinoma, ERCP = endoscopic retrograde cholangiopancreatography, GB = gallbladder, MS = metal stent, PS = plastic stent, PTBD = percutaneous transhepatic biliary drainage, SIS = stent-in-stent.

**Keywords:** ERCP, malfunction, malignant bile duct obstruction, self expandable metallic stents

## 1. Introduction

Endoscopic biliary decompression is widely used to improve the survival and quality of life of patients with advanced hilar cholangiocarcinoma. However, a consensus has not been reached regarding whether bilateral drainage or unilateral drainage is the better method. Bilateral stenting is required for adequate drainage of >50% of the liver volume[1] and has become more feasible with more experienced endoscopists and the development of new devices. The stent-in-stent (SIS) method or stent-by-stent method can be used for bilateral stenting. The SIS method has been widely used since the introduction of various types of recently developed open-cell stents.[2–4] However, stent dysfunction develops in 3% to 45% because of tumor ingrowth, overgrowth, or debris as disease progresses.[5] Endoscopic reintervention is difficult and complex with worsening bile duct strictures and the previously placed overlapped wire mesh. The present study aimed to evaluate a suitable reintervention procedure for stent malfunction after SIS deployment for malignant hilar obstruction.

## 2. Materials and methods

### 2.1. Patients

From September 2009 to June 2016, a total of 52 patients who underwent endoscopic bilateral stenting at Pusan National University Yangsan Hospital were enrolled in this study. All patients were treated with endoscopic SIS deployment for Bismuth type II or higher malignant hilar obstruction. Among them, 20 patients who underwent reintervention due to stent malfunction were analyzed retrospectively. Stent malfunction was defined as cholangitis and/or jaundice, elevated liver enzyme levels, and bile duct dilation compared with previous computed tomography (CT) images. The reintervention methods used for patients with stent malfunction were decided on according to their condition. Endoscopic reintervention was performed for patients with stent malfunction who were in stable condition. Percutaneous transhepatic biliary drainage (PTBD) was considered in patients in poor condition who could not tolerate

Editor: Yan Li.

Written informed consent was obtained from all patients before the procedure. The study was approved by the Ethics Committee of the Institutional Review Board (Institutional Review Board no. 05–2017–029).

This study was supported by a research grant from Pusan National University Yangsan Hospital. (IRB No.03-2014-011).

All the authors have no conflict of interest or financial ties to declare.

Department of Internal Medicine, Pusan National University School of Medicine and Research Institute for Convergence of Biomedical Science and Technology, Pusan National University Yangsan Hospital, Yangsan, Korea.

* Correspondence: Dae Hwan Kang and Hyeong Seok Nam, Department of Internal Medicine, Medical Research Institute, Pusan National University School of Medicine and Research Institute for Convergence of Biomedical Science and Technology, Pusan National University Yangsan Hospital, Geumo-ro, Mulgeum-eup, Yangsan-si, Gyeongsangnam-do 50612, Korea
(e-mails: sulsulpul@naver.com; skyace27@hanmail.net).

Copyright © 2017 the Author(s). Published by Wolters Kluwer Health, Inc. This is an open access article distributed under the Creative Commons Attribution-NoDerivatives License 4.0, which allows for redistribution, commercial and non-commercial, as long as it is passed along unchanged and in whole, with credit to the author.

Medicine (2017) 96:48(e8867)

Received: 19 October 2017 / Received in final form: 31 October 2017 / Accepted: 3 November 2017

http://dx.doi.org/10.1097/MD.0000000000008867

endoscopic retrograde cholangiopancreatography (ERCP). PTBD was also considered without hesitation in cases of endoscopic reintervention failure. Written informed consent was obtained from all patients and the institutional review board of Pusan National University Yangsan Hospital approved this study (IRB no. 05–2017–029).

### 2.2. Endoscopic technique

To manage hilar obstruction, endoscopic bilateral stenting was performed using the SIS deployment method. The Y-type stent (Hanarostent Biliary Hilar Uncovered; M.I. Tech Inc., Seoul, South Korea) and Zilver stent (Cook Endoscopy, Bloomington) were used as the first and second metal stents, respectively. The Y stent has a wide, openable, central mesh portion and a regular mesh structure on the proximal and distal portions. The Zilver stent is made by laser-cutting and has an open cell design.

During the follow-up period, stent malfunctions were considered reasons for reintervention. Initially, the choice of drainage route (endoscopic or percutaneous approach) was determined according to the conditions of the patients. Endoscopic intervention was considered the first choice for stent malfunction in those with stable vital signs. If endoscopic intervention failed or if the patient was in poor condition, then PTBD was performed.

Experienced endoscopists performed endoscopic interventions under conscious sedation using midazolam and pethidine. Broad-spectrum antibiotics were used before ERCP and thereafter until infection was controlled. Endoscopic reintervention was performed by inserting a guidewire into the intended bile duct and then placing a plastic stent or metal stent through the preexisting bilateral stents. The drainage area was determined on the basis of the CT findings. Choices regarding the use of plastic stents (7-Fr and both pigtails) or Zilver stents (6-Fr delivery system and 10 mm diameter) depended on the difficulty passing the ERCP catheter through the preexisting metal mesh during reintervention.

## 3. Results

A total of 52 patients were included in this study. Endoscopic bilateral stenting was accomplished in patients with malignant hilar obstruction corrected by the SIS method. Hilar cholangiocarcinoma, gallbladder cancer, and other complications were found in 44, 6, and 2 patients, respectively (Table 1). Bismuth classifications were type II for 8 patients (15%), type III for 33 patients (64%), and type IV for 11 patients (21%).

Stent malfunction occurred during follow-up in 20 (38%) of the 52 patients with placement performed using the SIS method (Table 2). The median age was 69 years (range, 47–84 years). Cholangiocarcinoma, gallbladder cancer, and other complications were found in 17, 2, and 1 patient, respectively. Bismuth classifications were type II in 2 (10%) patients, type III in 10 (50%) patients, and type IV in 8 (40%) patients. The median time to stent malfunction after placement using the SIS method was 143 days. Endoscopic reintervention was attempted in 12 patients (Table 3). Technical success was achieved in 10 patients (10/12; 83%). Bilateral stenting was attempted in 8 patients. Bilateral plastic stents were placed in 4 patients and bilateral plastic and metal stents were placed in 2 patients (Figs. 1 and 2). However, bilateral stenting failed in 2 patients due to very tight strictures (1 selective insertion of the guidewire failure and 1 Soehendra dilation failure despite guidewire insertion). Single stenting was attempted in 4 patients and achieved in all of them (1 lobe of the liver was replaced by a massive tumor mass and there was no significant dilation of its bile duct). Functional success was observed in 8 of 10 patients (80%) who achieved technical success. PTBD was performed in 8 patients because of duodenal stenosis (2 patients) and poor conditions.

**Table 1**

**Baseline characteristics of patients undergoing endoscopic bilateral stenting using SIS deployment for malignant hilar obstruction.**

| Characteristics | Number |
|---|---|
| Patients | 52 |
| Sex, n (male/female) | 28/24 |
| Median age, y (range) | 74 (49–93) |
| Etiology, n (%) | |
| CCC | 44 (85%) |
| GB cancer | 6 (12%) |
| Other | 2 (3%) |
| Bismuth classification, n (%) | |
| II | 8 (15%) |
| III | 33 (64%) |
| IV | 11 (21%) |
| SIS | |
| Left to right | 44 (85%) |
| Right to left | 8 (3) |

CCC = cholangiocarcinoma, GB = GB cancer, SIS = stent-in-stent.

**Table 2**

**Characteristics of patients with stent malfunction.**

| Characteristics | Number | Endoscopic | Percutaneous |
|---|---|---|---|
| Patients | 20 | 12 | 8 |
| Sex, n (male/female) | 12/8 | 6/6 | 6/2 |
| Median age, y (range) | 69 (47–84) | 67 | 73 |
| Etiology, n (%) | | | |
| CCC | 17 (85%) | 11 | 6 |
| GB cancer | 2 (10%) | | 2 |
| Other | 1 (5%) | 1 | |
| Bismuth classification, n (%) | | | |
| II | 2 (10%) | 1 | 1 |
| III | 10 (50%) | 6 | 4 |
| IV | 8 (40%) | 5 | 3 |
| Median time of occlusion from SIS placement, d | 143 | 174 | 96 |

CCC = cholangiocarcinoma, GB = GB cancer, SIS = stent-in-stent.

**Table 3**

**Reintervention for stent malfunction in stent-in-stent placement.**

| Characteristics | Number |
|---|---|
| Stent malfunction | 20/52 (38%) |
| Endoscopic technical success | 10/12 (83%) |
| Reintervention methods | |
| Unilateral PS | 1 (1 unilateral dilation) |
| Unilateral MS | 3 (3 unilateral dilation) |
| Bilateral PS | 4/6 (2 patients with additional PTBD) |
| Bilateral PS+MS | 2 |
| Functional success | 8/10 (80%) |
| PTBD | 8/20 (40%) |
| Duodenal stenosis | 2 |
| Poor patient conditions | 6 |

MS = metal stent, PS = plastic stent.

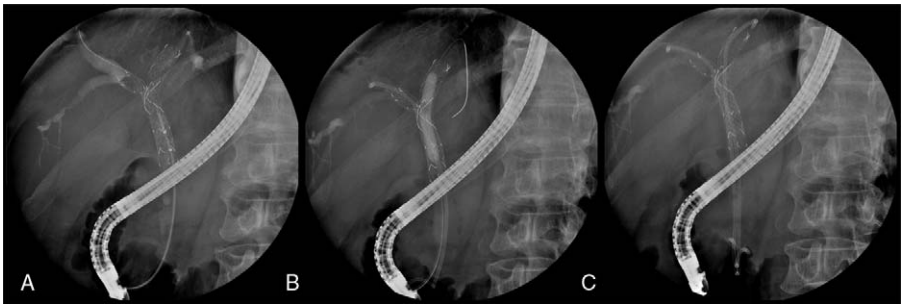


**Figure 1.** (A) Fluoroscopic image of the guidewire advanced to the RASD with a balloon catheter through previously placed bilateral metal stents. (B) Fluoroscopic image of plastic stent placement in the RASD and balloon dilatation in the LHD. (C) Fluoroscopic image new bilateral plastic stents. LHD = left hepatic duct, RASD = right anterior sectoral duct.

## 4. Discussion

Recently, endoscopic bilateral drainage has been widely used for advanced hilar biliary obstruction, although there is still controversy regarding the drainage area (bilateral or unilateral). Bilateral drainage seems to be useful for effective drainage of volumes >50% and is associated with benefits such as prolonged survival.[6,7] The SIS method using an open-cell stent and a laser-cut stent was introduced a few years ago.[2,3] Since then, the SIS method has been used more frequently than the stent-by-stent method to accomplish bilateral stenting because devices and endoscopic techniques have been improved. However, SIS placement is still difficult and complex. As disease progresses, stent malfunction inevitably develops due to tumor ingrowth, overgrowth, and biliary sludge. Revision of SIS deployment is very difficult and complex because of tight strictures aggravated by tumor progression and anatomic complexity associated with acute angles. In addition, overlapped metal mesh previously placed using SIS deployment impedes insertion of the guidewire, reintervention stent, and other devices during revision (Fig. 3). Accordingly, reintervention after the SIS method is the most technically challenging procedure; it is sometimes impossible, especially on the first stenting side compared with the second stenting side. Various reintervention methods have been reported after SIS placement, but a suitable reintervention method, including an appropriate approach route, drainage area, and type of revision stent has not yet been established.[5,8–10]

In our study, stent malfunction developed in 38% (20/52), which is comparable with the results of other reports using the SIS technique (6–58%).[2–4,8,11–13] Complications after stenting for malignant hilar obstruction are inevitable as the tumor progresses through the self-expanding metal stent. Its incidence is expected to increase with the prolonged survival achieved by anticancer therapy and better supportive care.

Endoscopic reintervention is considered the method of choice because of its advantages such as minimal invasiveness, less mortality, short hospital stay, and availability of expertise and various types of drainage devices. Of 20 patients with stent malfunction, endoscopic reintervention was attempted in 12 patients and PTBD was performed in 8 patients because of very poor general conditions (6 patients) and duodenal stenosis (2 patients). Endoscopic reintervention was successful in 10 patients (83%): 6 with bilateral stenting and 4 with unilateral stenting. Principally, bilateral reintervention was attempted in patients with duct dilation and unilateral reintervention was attempted for unilateral duct dilation. In 8 patients for whom bilateral revision was attempted, bilateral restenting was successful in 6 (75%). For bilateral stenting, 2 plastic stents and combined plastic and metal stents were used in 4 and 2 patients, respectively. Bilateral revision failed in 2 patients and only unilateral drainage was achieved (failure of the guidewire to insert into the target bile duct in 1 patient and failure to insert the Soehendra stent retrieval dilator even after successful guidewire

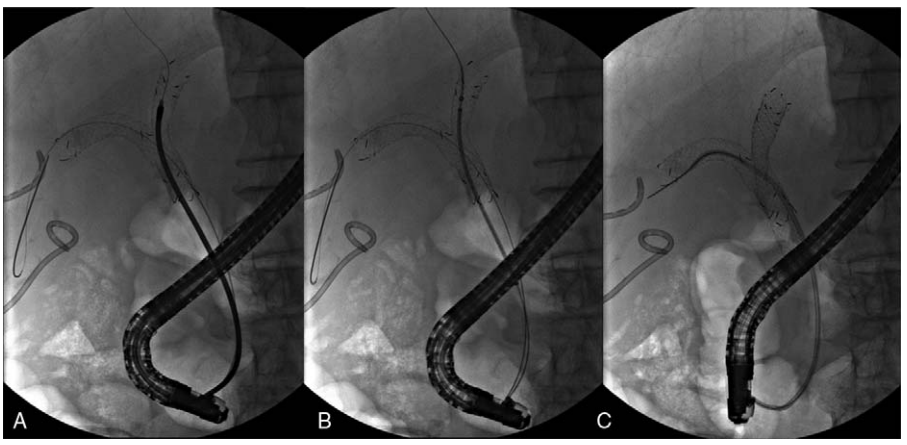


**Figure 2.** (A) Fluoroscopic image of guidewires advanced into both IHD followed by expansion of the stricture area with a Soehendra stent retriever. (B) Fluoroscopic image of the Zilver stent advanced using a 6-Fr delivery system. (C) Fluoroscopic image of bilateral plastic and metal stents through previously placed bilateral metal stents. IHD = intrahepatic duct.

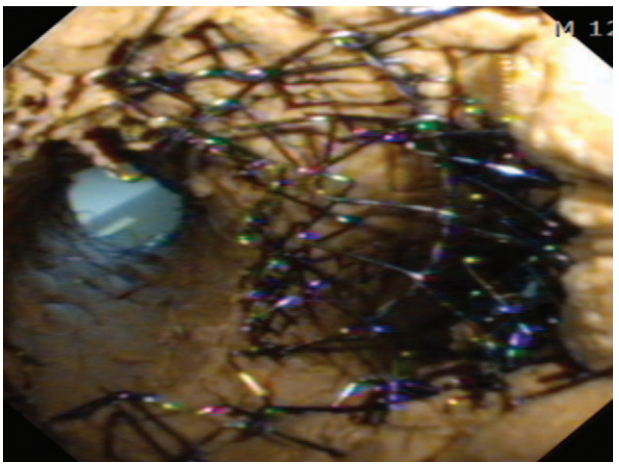

**Figure 3.** Schematic diagram showing too many metal mesh pieces on the first stenting side compared with the second stenting side with a gaping hole.

passing in 1 patient). In 4 patients who had planned to undergo unilateral drainage because only the unilateral bile duct was dilated by tumor replacement on the other side of the liver, unilateral stenting was successful. Our technical success rate of endoscopic reintervention is comparable to that of others (83–100%).[8,9,14] Open-cell and large-cell stents were usually used for both bilateral stenting and bilateral revisions. Those studies reported the performance of endoscopic reintervention exclusively for the purpose of reintervention; however, we frequently performed PTBD based on patient conditions because endoscopic intervention can worsen the clinical course (possibly leading to cholangitis) and result in sepsis or even death in patients with poor general conditions.

A consensus regarding the stenting area (unilateral or bilateral) is not yet established for revision. However, bilateral reintervention should be considered in cases of stent malfunction with bilateral duct dilation. It should especially be considered when both ducts are opacified during endoscopic reintervention. PTBD was immediately performed to relieve stent malfunction and prevent cholangitis in cases of failure. We think a single stent is enough for patients with unilateral bile duct dilation.

The optimal types of stents for endoscopic reintervention have not yet been decided. Generally, a plastic stent is used because it is easily removed and of low cost. Inoue et al[9] reported that metal stents have longer patency than plastic stents (131 vs 47 days). Therefore, using self-expanding metal stents for reintervention is more advantageous for reducing the number of reintervention procedures and the overall treatment cost. However, there are so many mesh pieces in the hilar portion that it is difficult or impossible to perform endoscopic re-reinterventions for future stent malfunctions. Further studies are needed to confirm the advantages and disadvantages of plastic and metal stents for reintervention.

Using metal and plastic stents simultaneously for revision in our patients seemed to have merits such as the longer patency of metal stents and the possibility of future re-reintervention. When stent malfunction develops, the metal stenting site has enough lumen and re-restenting is easily performed using a plastic or metal stent. At a plastic stenting site, re-reintervention can be attempted as mentioned by Hookey et al.[15] The preexisting plastic stent is positioned temporarily in the subhilar portion by pulling it back so that it can provide room for passage of the guidewire and the third or fourth stent. The temporary plastic stent is then removed after re-reintervention.

The present study has limitations. This was a retrospective, small study. The number of patients with preexisting bilateral stents was small, and endoscopic reintervention is indicated for small numbers of patients with stent malfunction and good general conditions. In addition, it was difficult to provide uniform therapy because of the heterogeneity of the patients and conditions. Therefore, prospective, multicenter studies including a large number of patients should be considered.

In conclusion, endoscopic reintervention could be considered in the case of stent malfunction and fair patient conditions after SIS placement for malignant hilar obstruction. Decisions regarding bilateral or unilateral drainage and types of stents should depend on the conditions of the disease and the patient.

## References


[1] Rerknimit R, Angsuwatcharakon P, Ratanachu-ek T, et al. Asia-Pacific consensus recommendations for endoscopic and interventional management of hilar cholangiocarcinoma. J Gastroenterol Hepatol 2013;28:593–607.

[2] Lee JH, Kang DH, Kim JY, et al. Endoscopic bilateral metal stent placement for advanced hilar cholangiocarcinoma: a pilot study of a newly designed Y stent. Gastrointest Endosc 2007;66:364–9.

[3] Kim JY, Kang DH, Kim HW, et al. Usefulness of slimmer and open-cell-design stents for endoscopic bilateral stenting and endoscopic revision in patients with hilar cholangiocarcinoma (with video). Gastrointest Endosc 2009;70:1109–15.

[4] Park DH, Lee SS, Moon JH, et al. Newly designed stent for endoscopic bilateral stent-in-stent placement of metallic stents in patients with malignant hilar biliary strictures: multicenter prospective feasibility study (with video). Gastrointest Endosc 2009;69:1357–60.

[5] Lee TH, Moon JH, Park SH. Bilateral metallic stenting in malignant hilar obstruction. Clin Endosc 2014;47:440–6.

[6] Kato H, Tsutsumi K, Harada R, et al. Endoscopic bilateral deployment of multiple metallic stents for malignant hilar biliary strictures. Dig Endosc 2013;25(Suppl 2):75–80.

[7] Vienne A, Hobeika E, Gouya H, et al. Prediction of drainage effectiveness during endoscopic stenting of malignant hilar strictures: the role of liver volume assessment. Gastrointest Endosc 2010;72:728–35.

[8] Lee TH, Moon JH, Kim JH, et al. Primary and revision efficacy of cross-wired metallic stents for endoscopic bilateral stent-in-stent placement in malignant hilar biliary strictures. Endoscopy 2013;45:106–13.

[9] Inoue T, Naitoh I, Okumura F, et al. Reintervention for stent occlusion after bilateral self-expandable metallic stent placement for malignant hilar biliary obstruction. Dig Endosc 2016;28:731–7.

[10] Naitoh I, Nakazawa T, Ban T, et al. 8-mm versus 10-mm diameter self-expandable metallic stent in bilateral endoscopic stent-in-stent deployment for malignant hilar biliary obstruction. J Hepatobiliary Pancreat Sci 2015;22:396–401.

[11] Kawamoto H, Tsutsumi K, Fujii M, et al. Endoscopic 3-branched partial stent-in-stent deployment of metallic stents in high-grade malignant hilar biliary stricture (with videos). Gastrointest Endosc 2007;66:1030–7.

[12] Hwang JC, Kim JZ, Lim SG, et al. Y-shaped endoscopic bilateral metal stent placement for malignant hilar biliary obstruction: prospective long-term study. Scand J Gastroenterol 2011;46:326–32.

[13] Kogure H, Isayama H, Nakai Y, et al. Newly designed large cell Niti-S stent for malignant hilar biliary obstruction: a pilot study. Surg Endosc 2011;25:463–7.

[14] Chahal P, Baron TH. Expandable metal stents for endoscopic bilateral stent-within-stent placement for malignant hilar biliary obstruction. Gastrointest Endosc 2010;71:195–9.

[15] Hookey LC, Le Moine O, Deviere J. Use of a temporary plastic stent to facilitate the placement of multiple self-expanding metal stents in malignant biliary hilar stricture. Gastrointest Endosc 2005;62:605–9.