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# Long-term outcomes of EUS–guided antegrade intervention with transmural and transanastomotic plastic stenting for benign bilioenteric anastomotic strictures (with video)

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## Abstract

**Background and Objectives:** Recurrence of benign bilioenteric anastomotic strictures (BAS) is common after enteroscopy-assisted endoscopic retrograde cholangiopancreatography (ERCP), percutaneous intervention, or EUS-guided antegrade intervention (EUS-AI). This study evaluated the long-term outcomes of EUS-AI with transmural and transanastomotic stenting (TAS) following EUS-guided hepaticogastrostomy (HGS) in BAS.

**Methods:** Consecutive patients with BAS undergoing EUS-AI with or without TAS after failed deep enteroscopy between January 2016 and June 2023 were retrospectively analyzed. The primary outcome was BAS recurrence rate after TAS removal; secondary outcomes included technical success of AI, on demand endoscopic procedure (DP) rate, the time to DP, and adverse events.

**Results:** Among 38 patients who underwent EUS-HGS, EUS-AI succeeded in 34 (89.5%), and 28 (73.7%) proceeded to TAS. The median follow-up duration for 28 patients with TAS was 53.4 months (IQR, 22.8–85.2). During TAS placement without regular stent change, DP occurred in 43% (12/28) at a median time of 23 months. The 1-year procedure-free rate was 81.2%. After TAS removal ($n$ = 12), with a median stent duration of 21.6 months, there was no BAS recurrence (0%).

**Conclusion:** EUS-AI with indwelling TAS, without regular stent change, may offer promising long-term outcomes for BAS by reducing recurrence.

**Keywords:** Bilioenteric anastomotic strictures (BAS); EUS–guided antegrade intervention (EUS-AI); Transanastomotic stenting (TAS); Hepaticogastrostomy (HGS); Recurrence prevention

## INTRODUCTION

The management of benign bilioenteric anastomotic strictures (BAS) remains challenging despite advancements in endoscopic and percutaneous interventions.[1,2] Balloon enteroscopy-assisted endoscopic retrograde cholangiopancreatography (ERCP) is an effective treatment option for BAS but is often technically demanding and time-consuming.[3,4] Recurrence rates after ERCP or percutaneous interventions are reported as high as 26.9%–56% after stent removal, highlighting the difficulty in achieving long-term patency.[4–8]

EUS–guided antegrade intervention (EUS-AI) for BAS has emerged as a viable alternative for patients unsuitable for conventional methods, with favorable long-term outcomes and a manageable safety profile.[9–15] However, the need for regular stent changes and timely removal, which require frequent endoscopic sessions, remains a major limitation of existing EUS-AI protocols. Furthermore, the recurrence rates were reported approximately 33% over a median follow-up of 56.7 months.[16] This underscores the need for improved strategies to enhance long-term patency and reduce recurrence.[6]

Long-term indwelling of endoscopic transmural and transanastomotic plastic stents (TAS) without regular stent changes, guided by EUS-AI after EUS-guided hepaticogastrostomy (EUS-HGS), is hypothesized to improve patient outcomes by prolonging stricture dilation, reducing the procedural frequency, and minimizing complication risks.[17] However, the absence of standardized protocols for EUS-AI has hindered its widespread adoption and optimization, leaving critical gaps in the long-term management of BAS.

This study aimed to evaluate the feasibility and long-term outcomes of a EUS-AI approach with prolonged indwelling stent and no regular stent changes in preventing BAS recurrence.

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## METHODS

### Patients

We retrospectively reviewed prospectively collected data on endoscopic treatments for BAS performed by a single expert (D.H.P.) at Asan Medical Center between January 2016 and June 2023. The study included consecutive patients with failed deep enteroscopy including a cap-assisted pediatric colonoscope who subsequently underwent EUS-AI for BAS treatment, with follow-up period of more than 6 months. The clinical diagnosis of BAS was based on CT scans, MRCP, and endoscopic findings, with or without an endoscopic biopsy.[13] Patients undergoing 1-stage EUS-AI without EUS-HGS and those with malignant anastomotic strictures were excluded. This study was approved by our institutional review board (no. 2024-1212)

### Standardized protocol

Under a standardized 2-stage protocol, EUS-HGS with transmural metal stenting was followed by stent removal and AI 4 weeks later to allow fistula tract maturation and facilitate access using a side-viewing duodenoscope (TJF 260; Olympus, Tokyo, Japan).

For EUS-HGS, the left intrahepatic bile duct was punctured with a 19-gauge EUS needle. After contrast injection, a 0.025-inch guidewire (VisiGlide2 [Olympus Medical Systems, Tokyo, Japan]) was advanced into the bile duct. A fully covered metal stent with anchoring flaps (6 mm in diameter and 10 cm in length; MI Tech, Seoul, Korea) was placed after fistula dilation with a 4-mm dilating balloon (Hurricane balloon [Boston Scientific, Marlborough, MA] or 4-mm REN balloon [Kaneka Medix Corp, Osaka, Japan]) or 7Fr cystotome (Taewoong Medical, Seoul, Korea).

In the second session, 4 weeks after EUS-HGS, the transmural stent was removed. Depending on the degree of stricture and presence of bile duct stones at the BAS, balloon dilation or a Soehendra stent retriever (Cook Medical, Bloomington, IN) was used. Bile duct stones were removed with or without peroral cholangioscopy using a digital cholangioscope (SpyGlass DS Direct Visualization System; Boston Scientific Corp, Marlborough, MA). TAS, through the HGS tract and BAS (Supplementary Video 1), or transmural metal stenting alone was performed. For patients with concomitant stones, TAS was considered only after complete stone clearance, whereas transmural metal stenting was performed for incomplete removal. TAS involved placing 1 or 2 double pigtail 7Fr plastic stents (Cook Medical, Bloomington, IN) with the intent of long-term indwelling for refractory or recurrent BAS or for on-demand endoscopic procedures (DP) [Figure 1], [Fig. S1, http://links.lww.com/ENUS/A367].

TAS removal was performed based on the following criteria: normal liver function panel, no sign of bile duct stone, or bile duct dilatation on CT scan, and at least 1 year of stent indwelling time. For patients with a history of recurrent or refractory BAS, long-term indwelling (over 1 year) of TAS was considered [Fig. S1, http://links.lww.com/ENUS/A367]. TAS removal was done using a duodenoscope without fluoroscopy in an outpatient setting.

### Outcome measurements and definitions

The primary outcome was the recurrence rate of BAS after TAS removal. Recurrence of BAS was defined as elevated liver enzymes or cholangitis requiring reintervention with cholangiography showing bile duct dilatation. Secondary outcomes included the technical success of the AI, the rate of DP, the time to DP, and adverse events (AEs).

Technical success of the AI was defined as successful balloon dilation of BAS, with or without antegrade stone removal. A severe stricture was defined as cases in which the guidewire could only pass through the stricture using peroral cholangioscopy or where a standard dilation balloon could not pass, requiring specialized tools such as the Soehendra stent retriever during the second session of EUS-AI.[13] DP was defined as any unanticipated endoscopic procedure including stent revision for cholangitis or cholestasis, and removal of recurrent stone removal.

AEs were defined as those occurring after initial EUS-HGS.[18] Hepatic fibrosis progression was assessed using the Fibrosis-4 (FIB-4 = Age (years) × AST (U/L)/[platelets (109/L) × $ALT^{1/2}$ (U/L)]) index. A FIB-4 index of <1.30 was classified as grade 1, 1.30 to 2.67 as grade 2, and >2.67 as grade 3.[19] The FIB-4 score slope between TAS and control group (without TAS) was compared because an increase in the ΔFIB-4 index/year was reported to be strongly associated with the progression to cirrhosis.[20]

### Statistical analyses

Data were presented as whole numbers with percentages for categorical variables and median with interquartile range (IQR) for continuous variables. Estimates of the time to DP were calculated using the Kaplan-Meir method. Cox proportional hazard regression analysis was conducted to identify risk factors associated with on demand endoscopic procedure (DP). Person-years were calculated as the sum of the duration of follow-up duration from baseline to either the progression of fibrosis or until the last available visit. Incidence rates were calculated as the number of incident cases divided by person-years of follow-up.

A longitudinal mixed-effects model was applied to evaluate the differences in FIB4 changes over time between the treatment group (TAS) and the control (no stent) groups.[21–23] This approach was chosen to account for the repeated measurements of FIB4 at different time points for each patient, which is characteristic of longitudinal data analysis. The model included a fixed effect for time, group (treatment *vs*. control), and the group-by-time interaction. The log transformation was applied to normalize the distribution of FIB4 differences (%FIB4 = 100 × FIB4post/FIB4pre) and address potential skewness in the data. Random intercepts were included in the model to account for within-subject variability over time. *P* values of <0.05 were considered to indicate statistical significance. All statistical analyses were performed using the R software, version 4.2.1 (R Foundation for Statistical Computing, Vienna, Austria [http://www.R-project.org]) or SPSS (IBM SPSS Statistics 29.0, IBM Corp., Armonk, NY).

## RESULTS

### Baseline characteristics

A total of 38 consecutive patients underwent EUS-HGS with transmural stenting with the intent of EUS-AI. The baseline characteristics of the patients are summarized in Table 1. Biliary stones were complicated in 30 patients (78.9%). Fourteen patients (36.8%) had recurrent or refractory stricture after previous percutaneous or endoscopic treatment.

**Table 1**

**Baseline characteristics.**

| Variable | Total ($n$ = 38) |
|---|---|
| Age, yr | 65 (58–71) |
| Sex, male | 16 (42.1%) |
| Primary disease | |
| Benign | 21 (55.3%) |
| IPMN/bile duct injury after cholecystectomy/choledochal cyst/PNET/SPN | 6/5/5/4/1 |
| Malignancy | 17 (44.7%) |
| EHCCC/PDAC/AoV cancer/gallbladder cancer | 9/4/3/1 |
| Operation | |
| Whipple/PPPD | 28 (73.7%) |
| Bile duct resection with Roux-en-Y | 10 (26.3%) |
| Time from operation to clinically meaningful BAS*, mo | 51.2 (24.0, 66.6) |
| Time from operation to EUS-guided biliary drainage, mo | 70.5 (41.1, 108.5) |
| Recurrent or refractory BAS | 14 (36.8%) |
| Complicated by the stone | 30 (78.9%) |
| Fib-4 index grade | |
| 1/2/3 | 12/17/9 |

Data are presented as no. (%) or median (interquartile range).

*BAS associated with liver function test abnormality or cholangitis.

IPMN, intraductal papillary mucinous neoplasm; PNET, pancreatic neuroendocrine tumor; SPN, solid pseudopapillary neoplasm; EHCCC, extrahepatic cholangiocarcinoma; PDAC, pancreatic ductal adenocarcinoma; AoV, ampulla of Vater; PPPD, pyloric preserving pancreaticoduodenectomy; BAS, bilioenteric anastomotic stricture; mo, month.

### *Creation of the HGS tract with EUS-HGS with transmural metal stent*

Procedural details are summarized in Table 2. AEs associated with EUS-HGS occurred in 15.8% (6 of 38 patients), with 2 events being mild and 4 being moderate: cholangitis ($n$ = 4), bleeding ($n$ = 1), and partial proximal stent migration ($n$ = 1). No bile peritonitis was observed in all patients. All were managed successfully with uneventful recovery.

### *Outcomes of AI*

A total of 38 patients underwent scheduled AI using a duodenoscope and were followed up for a median of 36.5 months (range, 6.2–101.0). No adverse events related to HGS metal stent removal or AI were observed. AI was successful in 34 patients (89.5%) [Table 2]. In the remaining 4 patients, cannulation of tight BAS was not achieved despite the use of the peroral cholangioscopy.

Among 34 patients with successful AI, 6 patients with mild BAS underwent HGS transmural metal stenting but without TAS, based on the endoscopist's discretion. Consequently, TAS was performed in 28 out of 38 patients with either one ($n$ = 22) or 2 ($n$ = 6) double-pigtail 7Fr plastic stents [Fig. S2, http://links.lww.com/ENUS/A367].

### *Follow-up of patients without TAS (n = 10)*

For 4 patients in whom AI failed due to tight stricture of BAS, a transmural metal stent was placed and managed with DP. Two of these patients received DP because of suspected stent dysfunction at 3.5 and 6.8 months. The remaining 2 patients exhibited no recurrent biliary obstruction for 32.0 and 59.3 months, respectively. Among 6 patients with successful AI and mild BAS, a transmural metal stent was placed with the intent of either (1) stent removal at the next scheduled session ($n$ = 4) or (2) follow-up with DP ($n$ = 2). Four patients had their stents removed at the next scheduled session after confirming resolution of the stricture; 2 remained free from recurrent biliary obstruction over a follow-up period of 14.8 and 27.9 months, respectively, whereas the other 2 underwent additional EUS-HGS at 4.5 and 21.9 months, respectively, due to recurrent BAS. Two patients with HGS stent *in situ* remained free from recurrent biliary obstruction during the follow-up periods of 9.3 and 17.1 months, respectively Figure 1.

### *Follow-up of patients with TAS in situ (n = 28)*

The median follow-up duration for 28 patients who received TAS was 53.4 months (IQR, 22.8–85.2). The rate of DP was 43% ($n$ = 12/28). The median time to DP after TAS was 23 months (95% CI, 18.8–NA) with a median follow-up duration of 28.5 months

**Table 2**

**Procedural details.**

| Variables | Total ($n$ = 38) |
|---|---|
| First stage: EUS-HGS with 6 mm fully covered SEMS | |
| Biliary access site | |
| B2 | 11 (28.9%) |
| B3 | 27 (71.1%) |
| Median diameter of intrahepatic bile duct (IQR), mm | 3.7 (3.0, 4.7) |
| Median procedure time (IQR), min | 15 (10–22) |
| Second stage: antegrade intervention | |
| Antegrade intervention | 34 (89.5%) |
| Balloon dilation alone | 4 (10.5%) |
| Balloon dilation and stone removal | 30 (79.0%) |
| Peroral cholangioscopy through HGS tract | 6 (15.8%) |
| Transmural metal stenting with or without EUS-AI (without TAS) | 10 (26.3%) |
| Transmural transanastomotic stenting (TAS) | 28 (73.7%) |
| Number of TAS | |
| 1/2 | 23/5 |
| Length of TAS, cm | |
| 7/9/10/12/13 | 1/6/7/12/7 |
| Median procedure time (IQR), min | 15 (9–22) |

Data are presented as no. (%) or median (IQR) unless otherwise specified.

B, bile duct segment; SEMS, self-expandable metal stent; IQR, interquartile range; AI, antegrade intervention; HGS, hepataticogastrostomy.

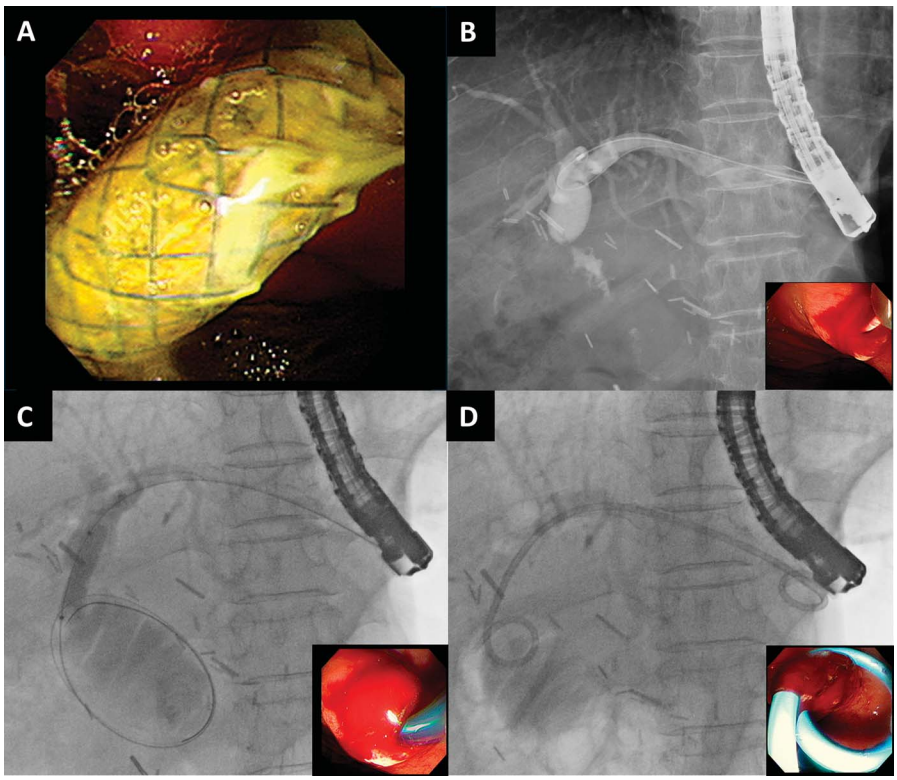


**Figure 1.** EUS-AI with TAS. A, The previously inserted transmural metal stent was observed upon advancing a side-viewing duodenoscope into the stomach. B, Following stent removal, the cholangiogram via the HGS fistula tract revealed a stricture at the choledochojejunostomy site. C, The anastomotic stricture was dilated using a balloon catheter (8 mm in diameter). D, TAS was performed using a 7Fr double pigtail plastic stent (inset) for long-term indwelling, aiming to manage refractory or recurrent bilioenteric anastomotic stricture and facilitate on-demand endoscopic procedures. EUS-AI, endoscopic ultrasound–guided antegrade intervention; TAS, transmural transanastomotic stenting.

(95% CI, 19.3–NA) [Fig. 2]. Twelve- and 36-month DP-free rates by Kaplan-Meier estimates were 81.2% and 47.7%, respectively.

The indications for DP included recurrence of biliary stones ($n$ = 6) identified on scheduled imaging, elevated liver enzyme without signs of cholangitis ($n$ = 2), and elevated liver enzyme with signs of cholangitis ($n$ = 4). This DP was successful in 83.3% of cases, whereas percutaneous intervention was required in 16.7% owing to the concomitant bile duct stones in the right intrahepatic duct. According to the Cox proportional hazard regression analysis, severe stricture was the only factor associated with shorter time to DP (HR, 3.816; 95% CI, 1.157–12.591; $P$ = 0.028) [Suppl. Table 1, http://links.lww.com/ENUS/A367].

### *Outcomes after TAS removal (n = 12)*

TAS removal was performed in 12 patients (42.9%) after a median stent maintenance time of 21.6 months, with no BAS recurrence (0%) requiring any DP during a median follow-up period of 14.0 months [Suppl. Table 2, http://links.lww.com/ENUS/A367]. Median number of endoscopic sessions before TAS removal (including the initial TAS and the last TAS removal session) was 2 (IQR, 2–2).

### *The progression and comparison of hepatic fibrosis between patients with TAS and without TAS*

The incidence rate of hepatic fibrosis progression was 116 per 1000 person-years (14 incidents/121 person-years): specifically, 6 patients progressed from grades 1 to 2, 2 patients from grades 1 to 3, and 6 patients from grades 2 to 3. The median time to hepatic fibrosis progression was 85.0 months (95% CI, 57–NA). The mixed-effects model revealed significant differences in the slope of log-transformed FIB4 changes over time between the TAS and control (without TAS, including patients with HGS metal stenting with or without EUS-AI) groups ($P$ < 0.001 for group, $P$ = 0.023 for time, $P$ = 0.015 for interaction) [Fig. S3, http://links.lww.com/ENUS/A367].

## DISCUSSION

In the present study, EUS-AI with TAS approach without regular stent change showed a median 23-month endoscopy-free time, reducing the need for endoscopic procedures. In 12 patients with TAS removal after median stent maintenance time of 21.6 months, there was no BAS recurrence requiring any DP during a median follow-up period of 14 months.

In a recent study,[16] EUS-AI with regular stent change demonstrated a 33% rate of BAS recurrence (6/18 patients) during a median of 31.2 months of (range, 9.1–55.6) from stent removal to recurrence [Suppl. Table 2, http://links.lww.com/ENUS/A367]. Furthermore, when BAS recurs, an endoscopic revision for patients with an indwelling TAS placed in the stomach may be easier than performing deep enteroscopy or a percutaneous approach for those with BAS recurrence without an indwelling TAS. In a

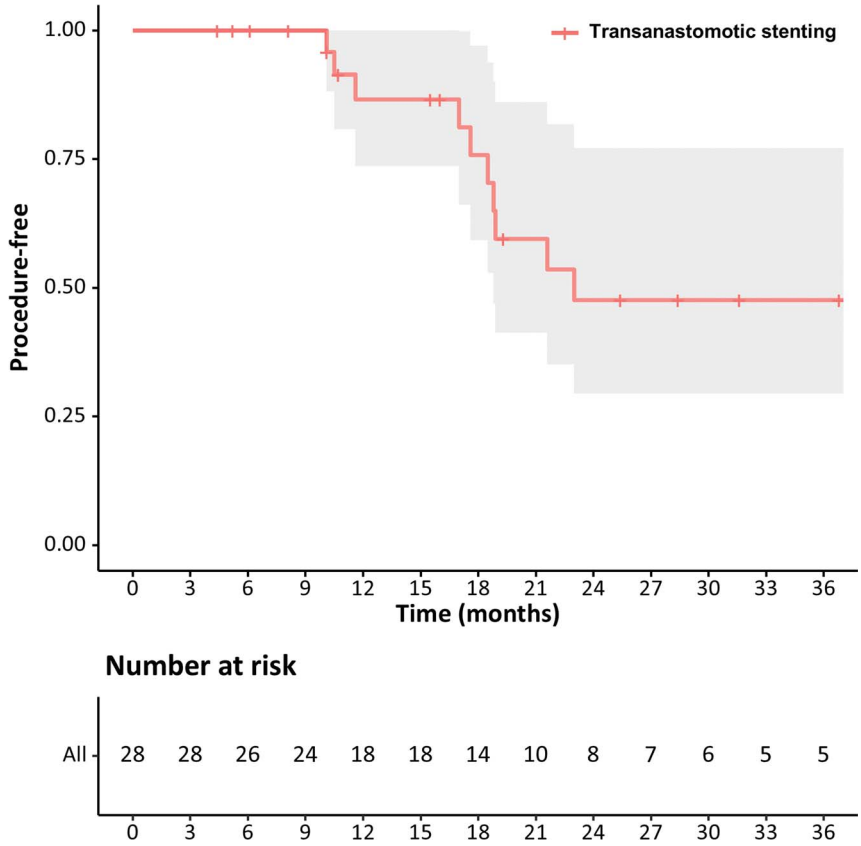


**Figure 2.** Kaplan-Meier curve for the time to on-demand endoscopic procedure (DP) after transanastomotic stenting (TAS). The median time to DP was 23 months (95% CI, 564–NA).

previous study,[3] not utilizing a biliary stent in patients with BAS significantly increased the risk of recurrence with a hazard ratio of 0.15 (95% CI, 0.06–0.40). Therefore, our protocol with prolonged indwelling TAS may prevent the BAS recurrence by maintaining patency, reducing inflammation, and promoting enhanced tissue remodeling although further validation may be required.

In terms of the progression of hepatic fibrosis, a significant interaction between TAS placement and the rate of fibrosis progression was observed; the slope of FIB4 change differed between the treatment (TAS) and control (without TAS) groups. Specifically, although both groups showed an increase in FIB4 over time, the TAS group exhibited a slower rate of FIB4 increase compared to the control (without TAS, HGS metal stent with or without AI) group, as indicated by the lower slope ($P < 0.001$), which suggests that TAS for BAS may have a meaningful impact on the progression of liver fibrosis. Further larger studies may be required to validate our results because this study had a relatively small size of enrolled patients with TAS or without TAS.

This study has several limitations. First, the retrospective design inherently carries a risk of selection bias and limits the ability to establish causality, although enrolling consecutive patients may have mitigated the bias. Second, the study was conducted at a single center, which may affect the generalizability of the findings to other clinical settings with different patient populations or varying levels of expertise in performing EUS-HGS and EUS-AI. Finally, the median follow-up period may not be sufficient to capture long-term complications or late recurrences of BAS. Despite these limitations, the study lays the groundwork for larger, prospective, multicenter studies. The promising results provide a basis for further investigation into optimizing EUS-HGS and AI protocols and establishing standardized treatment guidelines for BAS.

In conclusion, EUS-AI with indwelling TAS in patients with BAS may reduce unnecessary regular stent change and yield promising long-term clinical outcomes for BAS patients in terms of stricture recurrence. This approach may be particularly valuable where experts in EUS-AI are available, and device-assisted enteroscopy is not feasible.

## Video Legend 1

Endoscopic antegrade intervention with transmural and transanastomotic plastic stenting after 4 weeks of EUS-HGS. A previously placed metal stent was removed, and antegrade intervention was performed through the hepaticogastric fistula. The guidewire successfully passed through the hepaticojejunal stricture using endoscopic antegrade intervention. Following this, balloon dilation was performed for the hepaticojejunal (HJ) stricture. After gaining access to the right posterior intrahepatic duct, balloon dilation was performed for the stricture in this duct. Due to the rapid runoff of contrast injected into the right posterior intrahepatic duct, a 7Fr double pigtail stent was placed across the HJ stricture using the transmural and transanastomotic stenting (TAS) technique.

Videos are only available at the official website of the journal (www.eusjournal.com).

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## Ethical Approval

The study protocol was approved by the Institutional Review Board of Asan Medical Center (IRB No. 2024-1212).

## Informed consent

Not applicable.

## Conflict of Interest

V.J.J. is a consultant for SterisMedical and Olympus, Inc., and received the research grant from Olympus, Inc. All other authors declare no disclosures relevant to this publication.

## Author Contributions

Gunn Huh and Do Hyun Park contributed to the study conceptualization and design. Analysis and interpretation of the data were performed by Gunn Huh, Taehyung Lee, Jinhee Kwon, Ce Hwan Park, and Do Hyun Park. The first draft of the article was written by Gunn Huh and Do Hyun Park.Critical revision of the article for important intellectual content was performed by Gunn Huh, Taehyung Lee, JinheeKwon, CeHwan Park, John J. Vargo, Steven A. Edmundowicz, Sunguk Jang, and Do Hyun Park. All authors gave their final approval of the article.

## Data Availability Statement

Data described in the manuscript, code book, and analytic code will be made available upon request pending.

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