



# Percutaneous Transhepatic Treatment of Benign Bile Duct Strictures Using Retrievable Covered Stents: Long-Term Outcomes in 148 Patients

Byung Soo Im, Dong Il Gwon, Hee Ho Chu, Jin Hyung Kim, Gi-Young Ko, Hyun-Ki Yoon

All authors: Department of Radiology and Research Institute of Radiology, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea

**Objective:** To investigate the long-term outcomes of percutaneous treatment of benign biliary strictures using temporary placement of a retrievable expanded polytetrafluoroethylene (PTFE) covered stent.

**Materials and Methods:** We retrospectively analyzed the outcomes of 148 patients (84 male and 64 female; age range, 11–92 years) who underwent percutaneous transhepatic placement and removal of a retrievable PTFE-covered stent for the treatment of benign biliary strictures between March 2007 and August 2019 through long-term follow-up. Ninety-two patients had treatment-naïve strictures and 56 had recurrent/refractory strictures.

**Results:** Stent placement was technically successful in all 148 patients. The mean indwelling period of the stent was 2.4 months (median period, 2.3 months; range, 0.2–7.7 months). Stent migration, either early or late, occurred in 28 (18.9%) patients. Clinical success, defined as resolution of stricture after completing stent placement and removal, was achieved in 94.2% (131 of 139 patients). The overall complication rate was 15.5% (23 of 148 patients). During the mean follow-up of 60.2 months (median period, 52.7 months; range, 1.6–146.1 months), 37 patients had a recurrence of clinically significant strictures at 0.5–124.5 months after removal of biliary stent and catheter (median, 16.1 months). The primary patency rates at 1, 3, 5, 7, and 10 years after removal of biliary stent and catheter were 88.2%, 70.0%, 66.2%, 60.5%, and 54.5%, respectively. In the multivariable Cox proportional hazard regression analysis, sex, age, underlying disease, relation to surgery, stricture type, biliary stones, history of previous treatment, and stricture site were not significantly associated with the primary patency.

**Conclusion:** Long-term outcomes suggest that percutaneous treatment of benign biliary strictures using temporary placement of retrievable PTFE-covered stents may be a clinically effective method.

**Keywords:** *Benign biliary stricture; Percutaneous transhepatic treatment; Retrievable covered stent; Long-term outcomes*

## INTRODUCTION

Benign biliary strictures represent a major issue for patients and physicians, as the recurrence rate after

standard treatment is quite high, with relevant problems for patients such as recurrent cholangitis and the need for multiple readmissions to the hospital [1]. Surgical revision of a benign biliary stricture is still considered the optimal treatment, with a primary success rate of up to 90% [2]. However, if biliary strictures recur after surgery, they are difficult to manage, and the success rate of surgical restoration decreases with each successive surgical intervention [3].

Endoscopic treatment is the first-line management option for most patients with benign biliary strictures; however, it is almost impossible to perform in patients who have already undergone bilioenterostomy [4,5]. Therefore, percutaneous transhepatic approaches can be effective

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**Corresponding author:** Dong Il Gwon, MD, PhD, Department of Radiology and Research Institute of Radiology, University of Ulsan College of Medicine, Asan Medical Center, 88 Olympic-ro 43-gil, Songpa-gu, Seoul 05505, Korea.

• E-mail: radgwon@amc.seoul.kr

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alternative treatment options [5-9].

Percutaneous balloon dilatation and large-bore catheter placement are the most widely used alternatives to endoscopic treatment [5-11]. However, the treatment requires multiple procedures and the prolonged use of indwelling percutaneous catheters, which are often associated with catheter-related complications and decreased quality of life. Limited data exist regarding the long-term outcomes of percutaneous treatment, but previous studies have reported 10-year patency rates between 49% and 72% [9-11].

Over the past two decades, several investigators have reported that percutaneous transhepatic placement of a temporary covered stent is feasible for the treatment of benign biliary strictures [12-18]. The use of a temporary covered stent has been postulated to have a higher expansion force and a larger diameter than indwelling catheters, leading to a sustained dilatation effect. Compared to percutaneous balloon dilatation and large-bore catheters, stents may increase the possibility of stricture resolution and shorten the duration of treatment [17-19].

Different types of temporary covered stents have been used to treat benign biliary strictures for varying durations, achieving successful stricture resolution in 80%–90.6% of the patients [12-18]. However, data on the percutaneous use of temporary covered stents during the treatment of benign biliary strictures are limited, and the reported series dealt with relatively small groups of patients [16-19]. Most patients with benign biliary strictures have a life expectancy greater than 5 years; to our knowledge, no long-term patency data (> 5 years) exist for radiologic management. Therefore, this study aimed to investigate the long-term outcomes of the percutaneous treatment of benign biliary strictures using temporary placement of a retrievable polytetrafluoroethylene (PTFE)-covered stent.

## MATERIALS AND METHODS

### Patient Population

This study was approved by the Institutional Review Board of Asan Medical Center, which waived the need for written informed consent because of the retrospective nature of this study (IRB No. S2019-1844-0005). This study enrolled 148 patients (84 male and 64 female; median age, 59.5 years; age range, 11–92 years) who underwent percutaneous transhepatic placement and removal of a retrievable covered stent between March 2007 and August

2019 for the treatment of benign biliary strictures. The baseline characteristics of the 148 patients with benign biliary strictures are presented in Table 1. In a prior study, we reported 68 patients included in the present study. A prior report evaluated mid-term outcomes [16]. The present study expands on this by including a larger number of patients and a longer follow-up period.

The initial diagnosis of a biliary stricture was based on the clinical symptoms or biochemical data of the patients and the results of imaging with various modalities, including ultrasonography, computed tomography (CT), magnetic resonance cholangiopancreatography, and percutaneous transhepatic cholangiography. Patients with benign biliary strictures were selected for inclusion in this study using the following inclusion criteria: 1) initially documented benign biliary strictures, 2) previous bilioenterostomy, and 3) failed endoscopic cannulation of the intrahepatic or common bile duct. Among 148 patients with benign biliary strictures, 98 (66.2%) patients received a retrievable covered stent placement as the initial treatment for previously untreated strictures (i.e., treatment-naïve) and 50 (33.8%) patients underwent the procedure for recurrent/refractory benign biliary strictures after previous repeated balloon dilatation

**Table 1. Demographics and Characteristics of Study Patients**

Characteristics	Total (n = 148)	Clinical Success (n = 131)
Median age (range), year	59.5 (11–92)	60 (11–84)
Sex, male:female	84:64	72:59
Underlying disease		
Benign	96 (64.9)	84 (64.1)
Malignant	52 (35.1)	47 (35.9)
Cause		
Anastomotic stricture	114 (77.0)	103 (78.6)
Bilioenterostomy	112 (75.7)	101 (77.1)
Duct-to-duct anastomosis	2 (1.4)	2 (1.5)
Non-anastomotic stricture	34 (23.0)	28 (21.4)
Inflammation	28 (19.0)	23 (17.6)
Trauma	1 (0.7)	0 (0)
Sclerosing cholangitis	2 (1.4)	2 (1.5)
Iatrogenic	3 (2.0)	3 (2.3)
Previous treatment		
Treatment-naïve	98 (66.2)	87 (66.4)
Recurrent/refractory	50 (33.8)	44 (33.6)
Type of stricture		
Single	127 (85.8)	110 (84.0)
Multiple	21 (14.2)	21 (16.0)

Data are number of patients with the percentage in parentheses, unless specified otherwise.

and prolonged catheter placement.

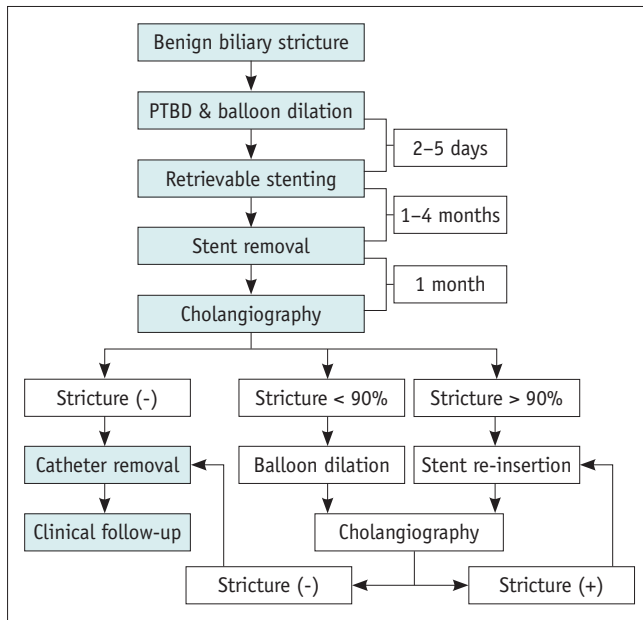
**Technique**

The treatment protocol is summarized in Figure 1. All procedures, including percutaneous transhepatic biliary drainage (PTBD) and placement and removal of retrievable stents, were performed following a previously described methodology [16]. Two experienced

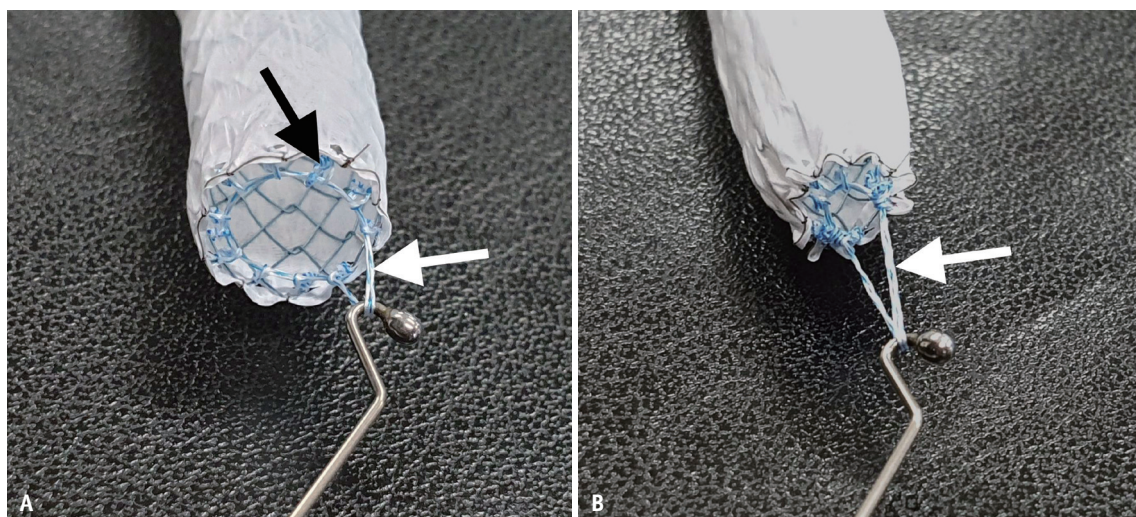
radiologists with at least 20 years of experience performed all procedures. All procedures were performed under conscious sedation using intravenous pethidine hydrochloride (Demerol; Keukdong Pharmaceuticals) and local anesthesia using intramuscular lidocaine (Jeil Pharmaceuticals). Broad-spectrum antibiotics were administered intravenously 2 hours before the procedures and for at least 48 hours afterward.

PTBD was performed under fluoroscopic or ultrasonographic guidance. A right or left approach was determined based on stricture location. Before inserting the drainage catheter, dilation of the stricture was performed using a balloon catheter 6–8 mm in diameter (Synergy; Boston Scientific). An internal-external 8.5-F drainage catheter (Cook) was then placed across the stricture.

A retrievable expanded PTFE (e-PTFE)-covered stent (Song retrievable stent; TaeWoong Medical) with two drawstrings attached to the upper margin of the stent was used (Fig. 2A). Balloon dilation was performed using a balloon catheter with a diameter of 8–10 mm (Boston Scientific) immediately before and after stent placement. A stent diameter of 8–12 mm was chosen depending on the diameter of the bile duct and bilioenterostomy site. Two stents were deployed in a single session in patients with complex biliary strictures. To prevent distal migration of the stent after deployment, a 10–14-F multi-side-holes, pigtail-shaped drainage catheter was placed across the stent, and the catheter tip was placed beneath the distal margin of the



**Fig. 1. Schematic diagram of our treatment protocol.** PTBD = percutaneous transhepatic biliary drainage



**Fig. 2. Retrievable covered stent and retrieval hook wire used in the procedures.**

**A.** “End on” view of the proximal end of the retrievable covered stent. A 2-mm-diameter nylon loop (black arrow) is hooked inside each bend of the proximal end of the stent and attached to the upper inner margin of the stent. Two drawstrings (white arrow) are caught by the retrieval hook wire. **B.** Traction on the drawstrings (arrow) causes the end of the stent to be pulled together.

stent. After placement, an internal drainage catheter was inserted. The duration of stent indwelling was determined according to the severity and nature of the biliary stricture. If the patients had treatment-naïve benign biliary strictures, the indwelling period was one or two months; in contrast, if the patients had recurrent/refractory strictures despite previous treatment, the indwelling period was three or four months. To evaluate stent migration, patients returned for cholangiography via the drainage catheter within 1 month of stent placement. If the stent had migrated, repositioning of the stent was performed using a retrieval hook wire or balloon catheter. If repositioning of the stent failed, another stent was inserted.

The stent was removed electively from each patient. A safety wire was placed in the small bowel or common bile duct to gain access. Then, a 9-F sheath with a dilator was passed over the guidewire into the proximal lumen of the stent. After the dilator was removed from the sheath, a retrieval hook wire was introduced into the sheath to remove the stent, and the hook was pulled out of the stent so that the hook caught the extraction strings. Traction on any one drawstring caused the end of the stent to pull together and collapse into a funnel configuration (Fig. 2B). When this occurred, the retrieval hook wire was withdrawn through the sheath in order to collapse the stent. The stent and retrieval hook wire were pulled out of the biliary duct through the sheath.

Cholangiography was performed immediately after stent removal via the sheath to evaluate the stricture. If the absence of a significant stricture was noted on cholangiography obtained immediately after stent removal, a 10–14-F external drainage catheter was placed in the intrahepatic bile duct with its tip clamped until 1 month follow-up cholangiography. If there was a persistent stricture, depending on the severity of the stricture, a retrievable covered stent was reinserted across the stricture site for an additional 1–3 months in patients with severe strictures of more than 90% on the follow-up angiography, while one or two sessions of balloon dilatation with a 1 month interval were performed in less severe cases. If the absence of a significant stricture was noted on completion cholangiography, without recurrence of the patient's symptoms or changes in biochemical data, the drainage catheter was removed (Fig. 3).

### Follow-Up

All patients were evaluated routinely at 1, 3, 6, and

12 months after drainage catheter removal to check for recurrence of biliary strictures at the interventional radiology outpatient clinic and when there were unexpected symptoms suggestive of recurrence. Liver enzyme analysis was also performed during this follow-up period, and imaging studies, including CT, were performed 6–8 months after drainage catheter removal. After that, the patients were followed at 1-year intervals for 3 years. Telephone interviews were performed from 5 years after drainage catheter removal, and patients were advised to visit our clinic if symptoms were present. Patients were followed-up until August 31, 2019, unless they developed recurrence of biliary stricture or were censored at earlier time points.

### Study Endpoints, Definitions, and Statistical Analysis

The primary endpoint was the primary patency rate without clinically significant stricture recurrence after achieving clinical success. Clinical success was defined as the disappearance of the patient's symptoms, normalized biochemical data in the clamp test period, and the ultimate removal of the biliary stent and drainage catheter. Clinically significant recurrence after achieving clinical success was determined based on clinical manifestations, serum biochemical data, and imaging findings that required subsequent intervention. The secondary endpoints were technical and clinical success and procedure-related complications. Technical success was defined as immediate successful technical performance of the required procedures (such as deployment across the stricture with confirmation of patency using cholangiography and stent removal without bile duct injury). Complications were classified as major or minor according to the guidelines of the Society of Interventional Radiology Standards of Practice Committee [20]. Based on the time frame, early migration was defined as stent migration within 1 month of stent placement, whereas late migration was detected 1 month after stent placement.

Primary patency rates were calculated using the Kaplan-Meier method. The association between recurrence of biliary stricture after clinical success and the following variables was analyzed using multivariable Cox proportional hazard regression: sex, age, underlying disease (benign versus malignant), relation to surgery (non-postsurgical versus surgical), stricture type (single versus multiple), combined biliary stones, history of previous treatment (treatment-naïve versus recurrent/refractory), and stricture site (anastomotic versus non-anastomotic). Variables with  $p$  values < 0.2 by

univariable analysis were considered candidate variables for multivariable analysis. R software version 4.1.3 (The R Foundation for Statistical Computing) and SPSS Statistics version 23.0 (IBM Corp.) were used for the statistical analyses. A two-sided  $p$  value less than 0.05 was considered statistically significant.

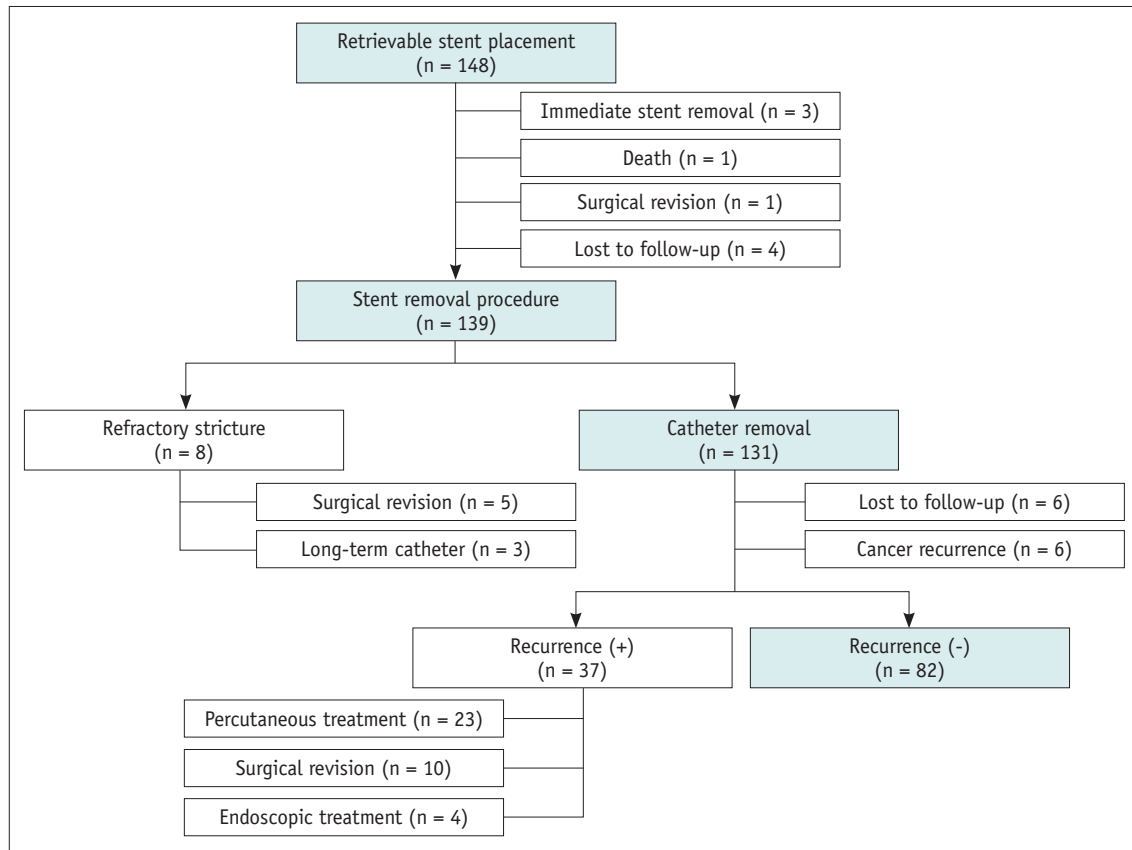
## RESULTS

### Placement of Retrievable Stent

Stent deployment was technically successful in all 148 patients (Fig. 4). Ten patients required the placement of two stents because of two separated bilioenterostomy



**Fig. 3. A 60-year-old male with choledochojejunostomy stricture following pylorus-preserving pancreatoduodenectomy.** **A.** Cholangiography shows severe stricture at the choledochojejunostomy anastomosis. **B.** A 10-mm-diameter and 80-mm-long retrievable covered stent (white arrows) was inserted across the stricture, and a 10-F pigtail catheter was inserted across the stent for follow-up cholangiography and stent removal. To prevent stent migration, the pigtail-shaped drainage catheter tip (black arrow) was placed just beneath the distal stent margin. **C.** A fluoroscopic image obtained 2 months after stent insertion shows a good stent position without migration. A retrieval hook (white arrow) for stent removal was inserted through a 9-F sheath (black arrow). The stent was successfully removed through the 9-F sheath. **D.** A cholangiography obtained immediately after the stent removal shows the anastomosis is patent. **E.** A follow-up cholangiography obtained 1 month after stent removal shows the anastomosis to be patent without recurrence. The drainage catheter was removed immediately after the follow-up cholangiography. **F.** Contrast-enhanced coronal CT image obtained 74 months after the drainage catheter removal shows patent anastomosis (arrow). The patient remained healthy and without a recurrence for 103 months after the drainage catheter removal.



**Fig. 4. Flow chart of the study patients.** n = number of patients

strictures (n = 6) and complex-type strictures (n = 4). A single stent was sufficient to treat the biliary strictures in the remaining 138 patients.

Cholangiography immediately after stent placement showed ipsilateral or opposite intrahepatic bile duct occlusion by the stents in 35 of the 148 patients. In 32 patients, stents were placed in situ because their liver enzyme levels were within the normal range. In the remaining three patients, stents were removed 1–3 days after stent placement because of markedly elevated liver enzymes; the strictures were then managed using repeated balloon dilatation. Among the 145 patients, six patients were excluded before the 1-month follow-up cholangiography, four patients were lost to follow-up, one underwent a revisional operation, and one died. Therefore, 1-month follow-up cholangiography was performed in 139 patients. One-month follow-up cholangiography after stent placement showed early stent migration in 14 patients. Among these 14 patients, 12 experienced total downward stent migration into the jejunum; therefore, an additional stent placement was performed. The other two patients showed upward stent migration; in those cases, the stents

were successfully repositioned using a balloon catheter.

#### Removal of Retrievable Stent and Biliary Catheter

A total of 139 patients were eligible for stent removal (Fig. 4). The mean indwelling period of the stent was 2.4 months (median period, 2.3 months; range, 0.2–7.7 months). The mean indwelling period was 2.6 months (median period, 2.3 months; range, 1.0–5.4 months) in patients with treatment-naïve benign biliary stricture, whereas it was 2.2 months (median period, 2.1 months; range, 0.2–7.7 months) in the patients with recurrent/refractory benign biliary stricture. In seven patients, the indwelling period of the stent was > 5 months.

Cholangiography performed at the time of stent removal revealed late stent migration in 14 of 139 patients. In 11 patients, the stent migrated distally and was evacuated through the bowel. In three patients, the stent migrated proximally and was successfully removed via the percutaneous route. Among the 14 patients with late stent migration, 12 had improved strictures, whereas two required additional treatment due to persistent strictures. The overall stent migration (early migration [n = 14], late

migration [n = 14]) rate was 18.9% (28 of 148 patients).

Percutaneous stent removal was performed in 128 patients, excluding 11 patients with distal stent migration. In 125 patients, after removal of the stents, the e-PTFE material was seen to be intact and the lumen of the stent was also visualized to be sure it was clear. In the remaining three patients with bilioenterostomy strictures, partial tearing of the e-PTFE membrane with partial luminal narrowing (n = 2; indwelling period, 5.5 months and 6 months, respectively) or complete occlusion (n = 1; indwelling period, 7 months) due to sludge being seen. During the stent removal procedure in one patient, the drawstring became untied with the stent remaining in the peripheral intrahepatic bile duct, and the stent could not be removed under fluoroscopic guidance. The stent was then surgically removed. Therefore, the technical success rate of the percutaneous stent removal procedure (excluding 11 patients who did not need the procedure because of late distal stent migration) was 99.2% (127 of 128 patients). Cholangiography immediately after stent removal revealed a widened stricture with free passage of contrast media in 98 patients. However, the remaining 30 patients had persistent strictures. Of these 30 patients, 11 patients required a second session of stent placement (n = 9) or a third session of stent placement (n = 2), and 19 patients needed 1–5 sessions (mean, 2 sessions) of balloon dilatation.

Completion cholangiography obtained 1–3 months after the aforementioned stent removal session (with additional balloon dilatation in some patients) revealed patency with free passage of contrast media in the previous stricture site in 131 patients. The biliary drainage catheters were then removed. However, the remaining eight patients showed persistent refractory strictures. These eight patients underwent surgical revision (n = 5) or long-term large-bore (14-F) biliary catheter placement (n = 3). Considering the 139 patients who went through all stages of stent placement and removal, clinical success was achieved in 94.2% (131 of 139 patients).

### Complications

Major complications included markedly elevated liver enzymes after stent placement in three patients, stent migration requiring a second stent placement in 14 patients, and failure of percutaneous stent removal in one patient. Minor procedure-related complications occurred in five patients. In these five patients, self-limiting hemobilia was noted after balloon dilatation, which was completely resolved 1–2 days later. Therefore, the overall complication rate was 15.5% (23 of 148 patients).

### Follow-Up after Clinical Success and Primary Patency

Among 131 patients with clinical success, twelve patients

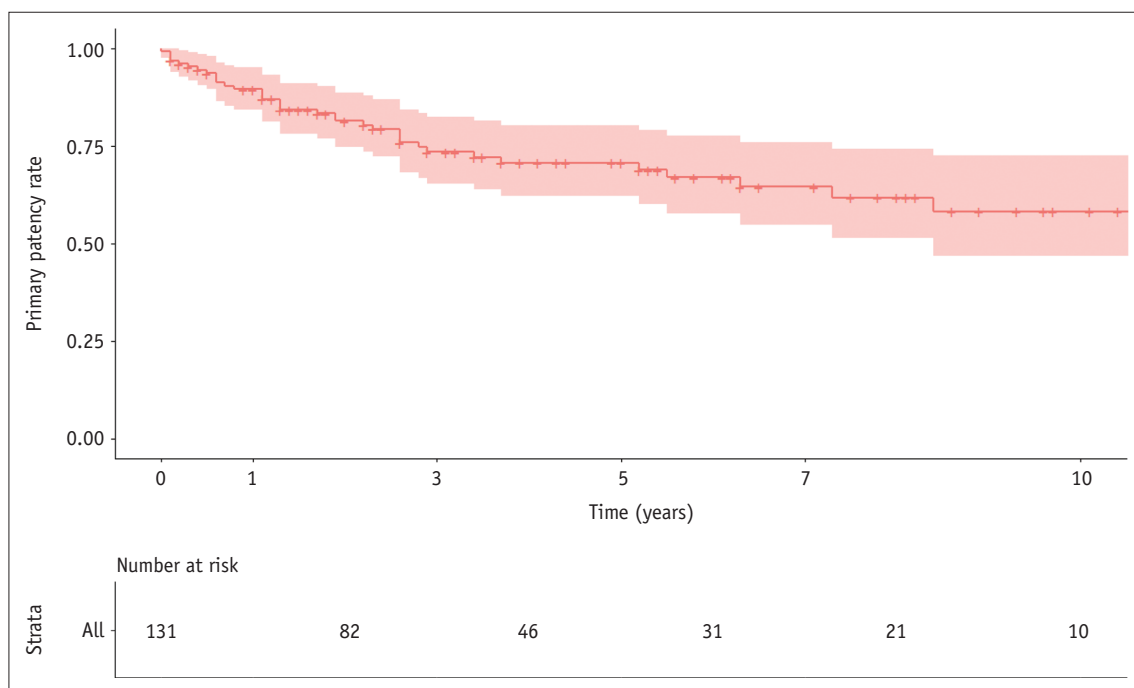
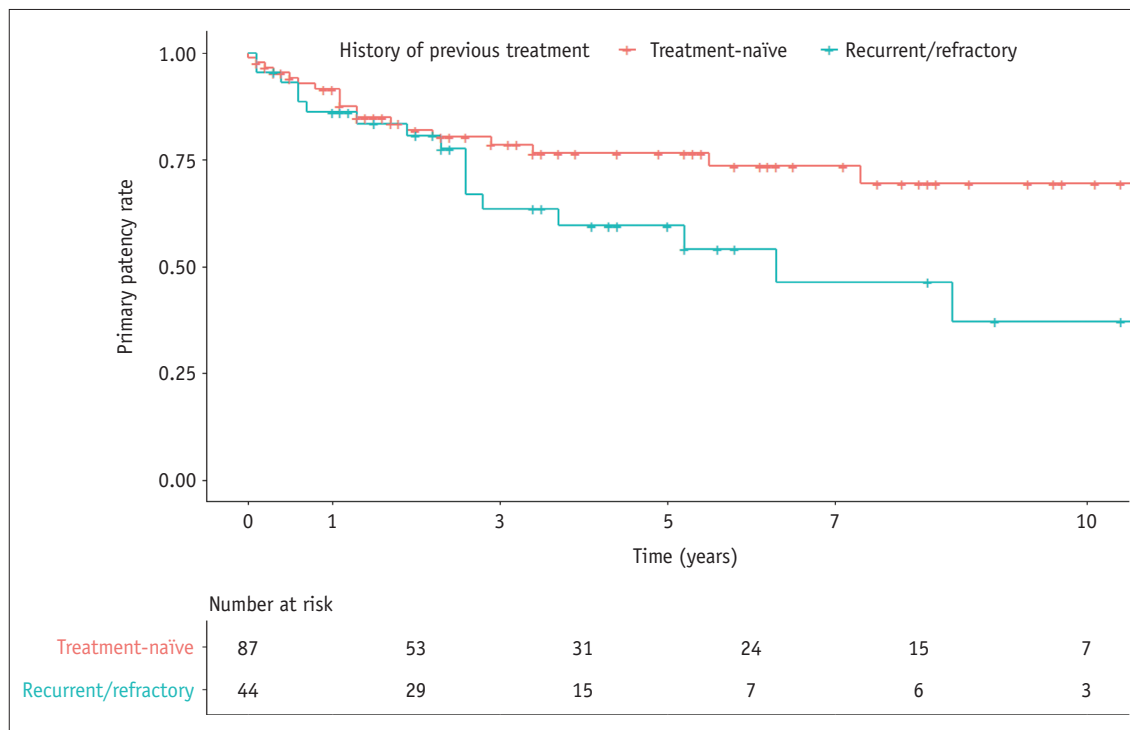


Fig. 5. Kaplan-Meier curve of the primary patency rate in 131 patients achieving clinical success.



**Fig. 6.** Kaplan-Meier curves of the primary patency rate for treatment-naïve (n = 87) and recurrent/refractory (n = 44) groups.

were censored without clear indications of recurrent biliary ductal stricture (although their stricture status was not clearly known). During the mean follow-up period of 60.2 months (median period, 52.7 months; range, 1.6–146.1 months), 20 patients died of causes unrelated to the biliary stricture. The remaining 99 patients were alive until the end of the study.

The primary patency rates at 1, 3, 5, 7, and 10 years after removal of biliary stent and catheter were 88.2%, 70.0%, 66.2%, 60.5%, and 54.5%, respectively (Fig. 5). Patency rates for treatment-naïve and recurrent/refractory strictures are shown in Figure 6. During the follow-up period, 37 (31.1%) of 119 patients had a recurrence of clinically significant strictures at 0.5–124.5 months (median, 16.1 months). For ten patients, the decision was made to resort to surgery; four patients underwent endoscopic treatments, and in 23 patients, nine patients received a retrievable covered stent, and 14 patients were treated with repeat balloon dilatation with a large-bore catheter.

According to the multivariable Cox proportional hazard regression analysis, sex, age, underlying disease (benign versus malignant), relation to surgery (non-postsurgical versus surgical), stricture type (simple versus complex), combined biliary stones, history of previous treatment (treatment-naïve versus recurrent/refractory), and stricture

site (anastomotic versus non-anastomotic) were not significantly associated with primary patency (Table 2).

## DISCUSSION

In the present study, the primary patency rates at 1, 3, 5, 7, and 10 years after removal of biliary stent and catheter were 88.2%, 70.0%, 66.2%, 60.5%, and 54.5%, respectively. We determined the probability of a patient not having clinically significant recurrence over the long-term (as long as 12.2 years) after retrievable stent treatment. In the previous studies, the primary patency rates at 1 and 3 years were 82.6%–91% and 69.3%–87%, respectively [16–19]. Although it is difficult to compare with prior findings, the short-term primary patency rates we observed were similar to those reported in previous studies using percutaneous placement of temporary covered stents. Most previous studies included only patients who underwent temporary covered stent placement for treatment-naïve biliary strictures. In the present study, we also evaluated the efficacy of retrievable stent placement for recurrent/refractory benign biliary strictures in a relatively large number of patients with long follow-up periods. Notably, nearly half of the patients in the present study had recurrent/refractory strictures. Our study did not reveal



**Table 2. Cox Regression Analysis of the Association between Various Variables and the Primary Patency**

Variables	Univariable Analysis			Multivariable Analysis		
	HR	95% CI	P	HR	95% CI	P
Sex (male* vs. female)	1.42	0.74–2.73	0.3			
Age ( $\leq 60$ years* vs. $> 60$ years)	0.50	0.25–1.01	0.052	0.56	0.28–1.14	0.11
Underlying disease (benign* vs. malignant)	0.49	0.22–1.13	0.10	0.72	0.29–1.80	0.5
Relation to surgery (non-postop.* vs. postop.)	0.50	0.25–0.99	0.045	0.68	0.32–1.43	0.3
Stricture type (simple* vs. complex)	1.41	0.66–3.01	0.4			
Biliary stone (no* vs. yes)	1.35	0.66–2.76	0.4			
Treatment-naïve* vs. recurrent/refractory	1.87	0.97–3.60	0.62	1.43	0.70–2.93	0.3
Non-anastomotic* vs. anastomotic	0.76	0.36–1.57	0.5			

In the multivariable model, only variables with  $p < 0.2$  in the univariable analysis were included. \*Reference category. CI = confidence interval, HR = hazard ratio, op = operative

significant differences between the treatment-naïve and recurrent/refractory groups in terms of the primary patency rate. We also found that among the 44 patients who underwent retrievable stent placement and removal for recurrent/refractory strictures after repeated balloon dilatation, 25 patients (56.8%) showed improvement of the strictures until the end of the study period (mean, 44.9 months after catheter removal). Therefore, in addition to the use of temporary covered stents in patients with benign biliary strictures, retrievable stents may also provide sufficient relief from strictures even in cases that had proven recurrent/refractory to previous treatments, including repeated balloon dilatation or large-bore catheters, although the difference between the two groups would require further investigation in a larger sample.

Ideally, covered stents for benign biliary strictures should demonstrate a persistent dilatation effect and be easily removed. From this perspective, fully covered stents were closest to the ideal in our study. Among several available covered metallic stents, the e-PTFE-covered stent is considered the most effective choice for benign biliary strictures [12–14] because the completely e-PTFE-covered material serves as an effective mechanical barrier to tissue ingrowth and as a relatively friction-free surface, which is particularly suitable for removal without being incorporated into the bile duct wall [21,22]. In addition, because a nitinol stent can recompress to a small volume, it facilitates its removal through a relatively narrow channel without requiring an increase in the diameter of the tract [14].

There are two concerns associated with the placement of covered stents. First, the placement of covered stents across the bilioenterostomy anastomosis may cause cholangitis in the ipsilateral or contralateral bile duct.

In the present study, cholangiographic occlusions of the ipsilateral or opposite intrahepatic bile ducts by stents were observed in 35 of 148 patients. Except for three patients who underwent stent removal 1–3 days after stent placement due to markedly elevated liver enzymes, the stents were placed in situ in the remaining 32 patients because their liver enzymes were within the normal range despite cholangiographic occlusion. Gwon et al. [16] suggested that cholangiographic occlusion of the bile ducts by an e-PTFE-covered retrievable stent did not represent functional occlusion. Petersen et al. [12] also observed a flow of contrast material between the bile duct wall and the PTFE-covered stent for as long as 4–6 months following stent placement. Therefore, we suggest that blockage of the intrahepatic bile ducts by an e-PTFE-covered retrievable stent may not result in major complications, although close follow-up is necessary in such cases.

Second, migration and dislocation during or after stent placement remain major concerns. Previous studies have reported 6%–21% migration rates following percutaneous transhepatic placement of retrievable covered stents [12,14,16,19]. In the present study, the stent migration rate was 18.9% (28 of 148 patients). Positioning the pigtail-shaped tip of the catheter beneath the distal margin of the stent did not completely prevent stent migration. To prevent stent migration, a few anti-migration designs have been tested, including stents with anti-migration fins and percutaneous fixation strings. Ye et al. [18] reported that a transhepatic fixation string could prevent distal stent migration in 25 of 26 patients. Wang et al. [23] used a covered stent with anchoring fins; however, they found mucosal ulceration of the bile duct due to anchoring fins of the stents. Therefore, innovative stent design modifications are required to ensure the ability to remove stents and to

prevent their migration and dislocation.

How long temporary stents should be left in place remains to be determined. A short stent indwelling period might result in insufficient resolution of the strictures, whereas a longer indwelling period may not be desirable because of its association with stent-related complications, such as stent occlusion or cholangitis. In the present study, the mean indwelling period was 2.4 months (median period, 2.3 months; range, 0.2–7.7 months). In previous studies, the mean indwelling period for retrievable stents was 2.5–4 months [15,16,18,19]. Due to the long-term period of the present study, the target duration of stent placement varied slightly, but the mean duration was close to that reported in previous studies. We also found that complete stent occlusion due to sludge was observed in one patient with a stent indwelling period of 7 months. Unfortunately, no current materials exhibit 100% resistance in the hostile environment of the liver and bowel. The membrane is exposed to bile and potentially to gastric acid, which results in membrane degradation. Previous studies reported that polyurethane and silicone membranes may be degraded by bile, pancreatic juice, or gastric juice [21,22]. Moreover, the e-PTFE membrane was more resistant to acids and alkalis. However, Bang et al. [24] reported that e-PTFE showed higher tensile and tear strengths and tended to form biofilms more frequently than polyurethane and silicone during bile exposure. Gwon et al. [25] reported that intact e-PTFE coverings with clean stent lumens as well as intact drawstrings and nylon loops were observed in the removed stents after up to 64 days. Petersen et al. [12] reported that moderate luminal narrowing (50%–60%) was observed at 5–6 months and one stent was occluded at 9 months. Tomishima et al. [26] reported that stent fracture occurred in two cases (7.7%) in which the retrievable covered stents were placed for more than 6 months. According to these previous studies and our outcomes, leaving covered stents in situ for 6 months seems to be acceptable for benign biliary diseases in terms of stent durability and safety, although there is anecdotal evidence that some stents remain intact for a significantly longer period.

The present study has several limitations. First, this study was retrospective and was conducted at a single center with a nonrandomized design, which may have decreased its statistical strength. Some unpredictable dropouts were due to unsuspected diagnoses of anastomotic tumor recurrence (4.1%) during follow-up, but only 2.7% of patients were lost to follow-up during the stenting period, while 4.1%

of the patients were lost during follow-up after catheter removal. However, the patients were consecutively enrolled, and long-term follow-up data were obtained from most patients. Nevertheless, it is possible that the sequential nature of the study may have introduced some bias. Second, the study participants did not undergo homogeneous treatment. Prior to retrievable stent treatment, 50 of 148 patients with recurrent/refractory benign biliary strictures despite prolonged catheter interposition after balloon dilatation were included in this study. However, because the patients had different causes, locations, and types of strictures, it was not possible to apply a homogeneous treatment regimen.

In conclusion, the long-term outcomes of the present study suggest that percutaneous treatment of benign biliary strictures using temporary placement of retrievable PTFE-covered stents may be a clinically effective method.

#### Availability of Data and Material

The datasets generated or analyzed during the study are not publicly available due to privacy and ethical concerns, but are available from the corresponding author on reasonable request.

#### Conflicts of Interest

Dong Il Gwon who is on the editorial board of the *Korean Journal of Radiology* was not involved in the editorial evaluation or decision to publish this article. All remaining authors have declared no conflicts of interest.

#### Author Contributions

Conceptualization: Dong Il Gwon. Data curation: Dong Il Gwon. Formal analysis: Byung Soo Im, Dong Il Gwon. Investigation: Byung Soo Im, Dong Il Gwon. Methodology: Dong Il Gwon. Project administration: Dong Il Gwon, Hee Ho Chu, Jin Hyoung Kim, Gi-Young Ko. Resources: Dong Il Gwon, Gi-Young Ko. Supervision: Hyun-Ki Yoon. Validation: Dong Il Gwon, Hee Ho Chu, Jin Hyoung Kim, Gi-Young Ko. Visualization: Byung Soo Im, Dong Il Gwon. Writing—original draft: Byung Soo Im. Writing—review & editing: all authors.

#### ORCID iDs

Byung Soo Im

<https://orcid.org/0000-0002-0187-9286>

Dong Il Gwon

<https://orcid.org/0000-0002-3121-2853>

Hee Ho Chu

<https://orcid.org/0000-0002-3903-0026>

Jin Hyoung Kim

<https://orcid.org/0000-0002-7300-6396>

Gi-Young Ko

<https://orcid.org/0000-0003-4617-1799>

Hyun-Ki Yoon

<https://orcid.org/0000-0002-8346-6599>

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