



# Percutaneous treatment of benign bilioenteric anastomotic strictures: temporary covered stent placement versus balloon dilatation

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## Abstract

**Objectives** To compare percutaneous temporary covered stent placement with balloon dilatation in the treatment of benign stricture of bilioenteric anastomosis.

**Methods** From November 2004 to August 2017, 56 patients with benign bilioenteric anastomotic strictures underwent percutaneous transhepatic treatment. A temporary covered stent designed for spontaneous migration was placed in 23 patients (stent group). Balloon dilatation was performed in 33 patients (balloon group). The technical success, percutaneous transhepatic biliary drainage (PTBD) indwelling times, stent indwelling times and patency rates were retrospectively compared between the two groups.

**Results** Technical success was achieved in all patients in the stent group and in 96.8% (32/33) of patients in the balloon group. All stents spontaneously migrated into the jejunum, and stent indwelling times were 3–9 months (median, 6 months). The PTBD indwelling time was shorter for the stent group than for the balloon group (median, 7 vs. 71 days,  $p = 0.001$ ). Recurrent strictures occurred more frequently in the balloon group than in the stent group (54.5% vs. 13.0%,  $p = 0.002$ ; hazard ratio 3.7). The 1- and 3-year primary patency rates were 90.2% and 84.9% for the stent group and 75.1% and 52.8% for the balloon group, respectively ( $p = 0.04$ ).

**Conclusions** Percutaneous temporary covered stenting is an effective treatment in patients with benign bilioenteric anastomotic strictures. It provides longer patency and shorter PTBD indwelling time compared with balloon dilatation.

## Key Points

- A temporary covered stent designed for spontaneous migration is a feasible and effective treatment for patients with benign bilioenteric anastomotic strictures.
- Percutaneous temporary covered stents provide longer patency and shorter drainage catheter indwelling time compared with conventional balloon dilatation.
- A covered stent with flared ends spontaneously migrated after 3–9 months.

**Keywords** Bile ducts · Constriction, pathologic · Stents · Dilatation

## Abbreviations

CT	Computed tomography
e-PTFE	Expanded polytetrafluoroethylene
MRCP	Magnetic resonance cholangiopancreatography
PTBD	Percutaneous transhepatic biliary drainage

## Introduction

Bilioenteric anastomotic stricture is a major complication after hepatobiliary surgery, requiring multiple hospitalisations and procedures. It is a technical problem and may be accentuated by fibrosis and scarring, with reported incidence of 2.6–24% after hepaticojejunostomy [1–3].

Treatment options for postoperative bilioenteric anastomotic strictures include surgical revision, endoscopic treatment and percutaneous transhepatic management. Surgical revision is difficult due to the shortened remaining bile duct, extensive inflammation and adhesions and patients' comorbid conditions. Endoscopic access to the stricture may be restricted due to postoperative altered bowel anatomy. Therefore,

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these patients are often referred for percutaneous transhepatic treatment [4].

Standard percutaneous treatment consists of balloon dilatation and large bore catheter placement. Strictures are dilated using 6–12 mm balloons to achieve adequate luminal patency, followed by placement of large-bore catheters (12–18 F) for extended periods [5–9]. However, this treatment requires multiple procedures and prolonged use of indwelling percutaneous catheters that are often associated with catheter-related complications and decreased quality of life [10].

Permanent metal stents are not recommended for benign biliary strictures due to high rates of stent obstruction; however, retrievable covered stents have been used [11–14]. These stents provide effective dilatation while avoiding complications associated with large-bore indwelling catheters [15, 16]. However, drainage catheters are still required for prolonged periods, and stent retrieval procedures may be technically challenging or impossible [13, 17]. Biodegradable stents may be an ideal treatment, providing the benefits of stenting without requiring removal. However, biomaterial limitations regarding expansile force and degradation profiles are still problematic; thus, they are not widely used [18].

To eliminate these disadvantages, we used covered stents designed for temporary placement in bilioenteric anastomotic strictures. We hypothesised that the stents would remain for several months before spontaneously migrating into the jejunum, without requiring removal or prolonged use of indwelling drainage catheters. This study compared the safety and efficacy of temporary covered stents with that of conventional balloon dilatation in patients with bilioenteric anastomotic strictures.

## Materials and methods

### Patients

This retrospective study was approved by the Institutional Review Board, and informed consent was waived. Results of a hospital database search (November 2004–August 2017) included 298 patients with bilioenteric anastomotic stricture following hepatobiliary surgery, diagnosed using CT and/or MRCP coupled with related laboratory results and symptoms (elevated liver enzyme levels, cholangitis or jaundice). Patients with the following criteria were selected: (a) benign stricture documented on CT or MR, (b) failed endoscopic treatment and (c) attempted transhepatic recanalisation (balloon dilatation or stent placement).

### Procedures

Written informed consent was obtained from patients before procedures. Patients in the stent group were informed of the

possibilities of stent migration-related complications (recurrent stricture, stone formation, bowel obstruction) and procedures for removal of non-migrating stents. All procedures were performed by two interventional radiologists (C.J.Y and N.J.S) with 25 and 15 years of experience, respectively. Intravenous broad-spectrum antibiotics (1 g cefoperazone-sulbactam or 200 mg ciprofloxacin in allergic patients) were administered 6 h before the procedures.

The procedures were performed under conscious sedation (3–5 mg midazolam and 50–75 mg pethidine hydrochloride) and local anaesthesia (2% lidocaine).

Percutaneous transhepatic biliary drainage (PTBD) was performed under ultrasound and fluoroscopic guidance. A right or left approach was determined based on the intrahepatic duct dilatation. An 8.5 F drainage catheter (Ultrathane; COOK) was placed, and balloon dilatation or stent placement was performed 2–3 days after PTBD. After a cholangiogram confirmed the presence of an anastomotic stricture, an 8 F vascular sheath was placed. A 0.035 “hydrophilic guidewire (Radifocus; Terumo) and a 5 F angiographic catheter (Kumpe, COOK) were manipulated to cross the stricture; the guidewire was exchanged with a 0.035” hydrophilic stiff guidewire (Terumo).

In the balloon group, the anastomotic stricture was dilated with a low compliance 8 or 10 mm balloon catheter (Synergy or Mustang; Boston Scientific), based on the anastomosed bile duct diameter. The balloon was inflated until the waist disappeared, and left inflated for 5 min. In patients with bifurcated strictures, the contralateral stricture was cannulated from the initial PTBD route, and balloon dilatation was performed. If this was technically impossible, percutaneous access to the contralateral intrahepatic duct and subsequent balloon dilatation were performed. After balloon dilatation, additional local anaesthetic was injected subcutaneously and in the liver parenchymal tract. The percutaneous tract was dilated, and based on bile duct diameter, a 12 F, 14 F or 18 F drainage catheter with multiple side holes (COOK) was placed across the stricture for internal and external drainage. Patients were discharged after 24–48 h observation. Follow-up cholangiography was performed at 1-month intervals on an outpatient basis. The cholangiograms were obtained after the drainage catheter was exchanged with a same-sized sheath. If cholangiography indicated slow passage of contrast or residual stricture > 30%, the balloon dilatation was repeated, and a follow-up cholangiogram was obtained 1 month later. When ready passage of contrast with residual stricture < 30% was confirmed, the drainage catheter was positioned within the intrahepatic duct and capped for 1 week before removal.

In the stent group, a covered metal stent (Niti-S Biliary; Taewoong), designed for bilioenteric anastomotic strictures was used (Fig. 1). This stent has been approved by Korean Food and Drug Administration and commercially available in Korea. It is comprised of nitinol wires with 2 mm flaring at the

proximal (bile duct) end and 1 mm flaring at the distal (jejunal) end. The cell sizes in the stent body are irregular, resulting in different segmental radial forces and high conformability. Both flared ends are covered with silicone, whereas the body of the stent is covered with expanded polytetrafluoroethylene (e-PTFE), attached by suture, to preserve conformability. Based on bile duct diameter, an 8 or 10-mm diameter and 3-cm long stent loaded in a delivery system (8 F, 80 cm) was used. In patients with bifurcated strictures, contralateral access was made, and bilateral stent placement was performed in parallel fashion. Recanalisation of the stricture was confirmed on cholangiogram, and an 8.5 F drainage catheter was placed across the stent and capped for 2 days. After confirmation of adequate stent positioning and function using follow-up cholangiogram, the drainage catheter was removed. The patients were discharged after 24–48 h observation.

### Follow-up

The patients' clinical symptoms and laboratory tests, including blood cell counts and liver function tests, were evaluated at an outpatient clinic every 3 months. A contrast enhanced CT was performed at 3-month intervals for 1 year, and every 6 months thereafter. Any symptoms, CT findings or laboratory tests suggesting recurrent stricture were further investigated using percutaneous cholangiography. Additional procedures were performed as needed.

### Definitions and analyses

The primary endpoint was primary patency, defined as the interval between drainage catheter removal and stricture recurrence. In patients with no recurrence, primary patency was assumed to be the interval between drainage catheter removal and the last follow-up. Secondary endpoints were technical and clinical success, procedure-related complications and PTBD indwelling time. Technical success was defined as patient contrast passage through a dilated or stented anastomotic stricture with < 30% residual stricture on the completion cholangiogram. Clinical success was defined as resolution of cholangitis symptoms and normalised liver function tests. The complications were classified as major and minor according to previously published guidelines [19].

Stent indwelling time was defined as the time between stent placement and the last CT with the stent in place. For example, if the stent was in place on the 6-month follow-up CT and migrated on the 9-month CT, the stent indwelling time was 6 months. Since follow-up CT was obtained at 3-month intervals for 1 year and 6-months thereafter, the stent indwelling time could be underestimated by up to 3 months within 1 year, and by up to 6 months thereafter.

Comparisons of the baseline characteristics of the stent and balloon groups were made using the Mann–Whitney *U* test for continuous variables and Fisher's exact test for categorical variables. Primary patency rates were plotted using the Kaplan–Meier estimator and were compared using a log-rank test. Cox regression analysis was used to obtain the hazard ratio for recurrent stricture between the two treatments. Firth's penalised correction was applied to reduce the monotone likelihood phenomenon that may be present in small samples [20]. All statistical analyses were performed using SPSS statistical software (SPSS Version 14.0, IBM Corp). A *p* value < 0.05 was considered statistically significant.

## Results

### Patients

Patients with malignant strictures (*n* = 228), benign strictures other than anastomotic strictures (*n* = 12) and previous treatment for bilioenteric anastomotic stricture (*n* = 2) were excluded. As a result, 56 patients (mean age, 60 years; age range, 25–91 years; male-to-female ratio, 32:24) were included. Thirty-three patients were treated with balloon dilatation (November 2004–May 2015, balloon group), and 23 patients were treated with stent placement (June 2015–August 2017, stent group) (Fig. 2). Baseline patient characteristics prior to the procedures are presented in Table 1. The two groups were not significantly different in terms of gender, age, primary disease, time interval between surgery and transhepatic treatment, type of bilioenteric anastomosis and relevant laboratory test results.

### Procedural outcomes

The PTBD catheter was initially placed in the right and left intrahepatic duct in 37 (66.1%) and 19 (33.9%) patients, respectively. Contralateral access was required in 6 patients with bifurcated strictures (balloon group [*n* = 2], stent group [*n* = 4]).

Technical success was achieved in 32 patients (97.0%) of the balloon group. Sixteen patients (51.5%) required a single balloon dilatation session to achieve technical success, but 16 other patients required two (*n* = 14, 42.4%) and three (*n* = 2, 6.0%) sessions. The remaining patient's stricture was unresponsive to three balloon dilatation sessions, and further treatment was refused. A drainage catheter was left in place in this patient. Stent placement was technically successful in all patients. Nineteen (82.6%) patients had single stent placements (8 mm [*n* = 15], 10 mm [*n* = 4]), while the remaining 4 patients with bifurcated strictures required bilateral 8 mm stent placement (Fig. 3).



**Fig. 1** A covered stent designed for bilioenteric anastomosis stricture. The stent has flared ends (2 mm at bile duct end [arrow] and 1 mm at jejunal end [arrowhead]), which is covered with silicone. The body of the stent was covered with e-PTFE at the body (curved arrow)

Clinical success was achieved in all patients with technical success in both groups (97.0% in balloon group and 100% in stent group). The PTBD indwelling time was 39–124 days (median, 71 days) for the balloon group and 6–8 days (median, 7 days) for the stent group ( $p = 0.001$ ).

Major complications occurred in 2 patients. In 1 patient of the balloon group, PTBD-related hepatic arterial bleeding occurred, which was successfully treated by coil embolisation. In 1 patient of the stent group, early stent migration (8 mm) was found on the 2-day follow-up cholangiogram. A larger

(10 mm) stent was placed, and the drainage catheter was removed after confirmation of stent patency 2 days later. Minor complications included dislodgement of drainage catheters (balloon group [ $n = 8$ ], stent group [ $n = 2$ ]), which required catheter replacement. Mortality was not associated with the procedures in either group.

**Follow-up**

The median follow-up period was 1168 days for the balloon group (range, 174–3965 days) and 603 days for the stent group (range, 180–2169 days) ( $p = 0.01$ ). Four patients (7.1%) were lost to follow-up (balloon group [ $n = 3$ ], stent group [ $n = 1$ ]). Three patients in the balloon group died of causes unrelated to the procedure (pneumonia [ $n = 2$ ], lung cancer [ $n = 1$ ]).

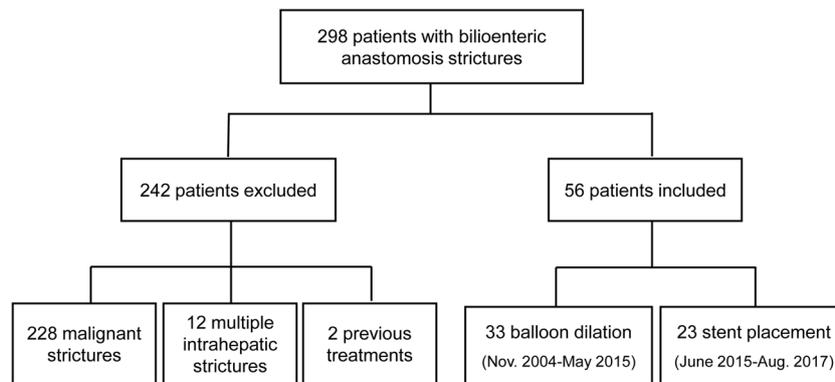
All stents remained at the stricture on the 3-month CT, and had migrated into the jejunum on CT at 6 months ( $n = 7$ ), 9 months ( $n = 13$ ) and 12 months ( $n = 3$ ). Therefore, stent indwelling time was 3–9 months (median, 6 months). All patients confirmed that the migrated stents passed rectally and asymptotically.

Recurrent strictures occurred in 18 patients in the balloon group and 3 patients in the stent group (54.5% vs. 13.0%, respectively;  $p = 0.002$ ). The stent indwelling time for these 3 patients was 3 months. The 21 patients were treated with repeat balloon dilatation ( $n = 14$ ) or stent placement ( $n = 5$ ). The 1-

**Table 1** Baseline characteristics of 56 patients included in this study

Characteristic	Balloon group ( $n = 33$ )	Stent group ( $n = 23$ )	$p$ value
Gender			0.117
Male	16	16	
Female	17	7	
Mean age $\pm$ SD	59.58 $\pm$ 17.28	60.52 $\pm$ 14.14	0.829
Primary disease for surgery			0.344
Benign	20 (60.6)	11 (47.8)	
Malignant	13 (39.4)	12 (52.2)	
Bilioenteric anastomosis			0.177
Simple hepaticojejunostomy	27	19	
Double right and left hepaticojejunostomy	6	4	
Time of onset from operation			0.911
< 6 months	11 (33.3)	8 (34.8)	
$\geq$ 6 months	22 (56.7)	15 (65.2)	
Laboratory tests (mean $\pm$ SD)			
WBC	8075.4/ $\mu$ L $\pm$ 2620.3	8151.1/ $\mu$ L $\pm$ 3011.2	0.455
ALP	339.8 IU/L $\pm$ 207.5	320.6 IU/L $\pm$ 162.0	0.712
Total bilirubin	2.6 mg/dL $\pm$ 3.1	2.6 mg/dL $\pm$ 2.5	0.858
AST	75.3 IU/L $\pm$ 90.3	83.1 IU/L $\pm$ 71.0	0.650
ALT	71.5 IU/L $\pm$ 69.1	79.8 IU/L $\pm$ 75.6	0.845
$\gamma$ -GT	355.1 IU/L $\pm$ 287.5	315.3 IU/L $\pm$ 253.3	0.710

WBC white blood cells, ALP alkaline phosphatase, AST aspartate aminotransferase, ALT alanine aminotransferase,  $\gamma$ -GT  $\gamma$ -glutamyl transferase



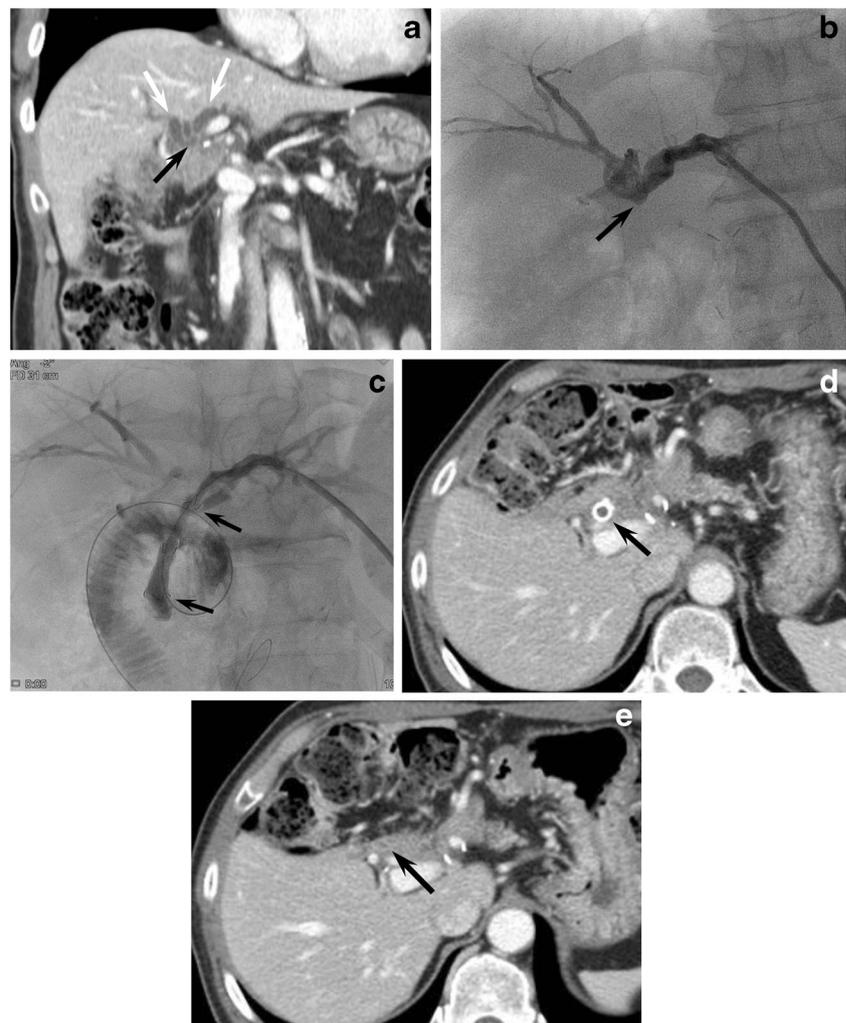
**Fig. 2** Flow chart showing included and excluded patients

and 3-year primary patency rates were 75.1% and 52.8% for the balloon group and 90.2% and 84.9% for the stent group, respectively ( $p = 0.04$ ) (Fig. 4). Cox regression analysis with Firth's correction indicated a higher incidence of stricture recurrence in the balloon group than in the stent group at all time points (hazard ratio 3.7; CI 0.05–0.90;  $p = 0.03$ ) (Table 2).

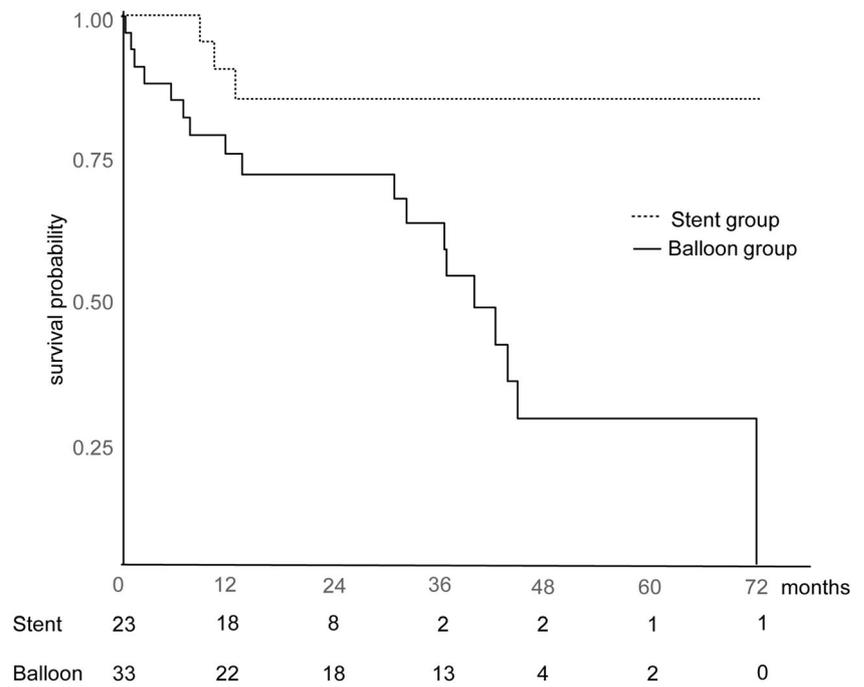
## Discussion

Retrievable covered stents have been used to treat benign biliary strictures with promising results, potentially providing better long-term patency than conventional balloon dilatation [11–14]. However, previous studies

**Fig. 3** A 30-year-old woman with bilioenteric anastomosis stricture following Whipple operation. **a** A contrast enhanced CT coronal image demonstrates stricture of hepaticojejunostomy (black arrow) and diffuse intrahepatic duct dilation (white arrows). **b** A radiograph obtained immediately after PTBD shows complete obstruction of the hepaticojejunostomy. **c** A radiograph obtained immediately after stent placement shows patent contrast passage through partially expanded covered stent. Note radiopaque markers at mid and both ends of the stents (arrows). **d** A contrast enhanced CT obtained 6 months after stent placement demonstrates patent stent (arrow) with decompression of intrahepatic bile ducts. **e** A 9-month follow-up CT shows disappearance of the stent (arrow) suggesting migration. Otherwise, there was no abnormal finding on CT and laboratory tests suggestive of recurrent biliary obstruction. The migrated stent was passed out through the anus without causing any specific symptom



**Fig. 4** Primary patency of balloon and stent group estimated by Kaplan–Meier method. The stent group shows longer patency than balloon group ( $p = 0.04$ , log-rank test)



included strictures of various causes such as intra-operative injury, anastomotic stricture (bilioenteric and duct-to-duct), chronic cholangitis, pancreatitis, trauma and sclerosing cholangitis. Those strictures may be different in their location, extent, pathologic nature and response to treatment, precluding the generalised application of those results to specific strictures. Furthermore, to our knowledge, only one study has compared covered stents with conventional percutaneous treatment [13]. Therefore, this study compared covered stenting with balloon dilatation in patients with bilioenteric anastomotic strictures.

Bilioenteric anastomotic strictures are characteristically different from other benign biliary strictures. Endoscopic access is not feasible in most patients due to altered enteric anatomy. Therefore, percutaneous treatment is often the first option. They are typically tight, focal strictures that are occasionally difficult to cross with a guidewire and cause frequent

stent migration due to the “soap bar” effect, where pressure from a short, tight stricture on the rigid stent results in a propulsive force [21].

To avoid stent retrieval issues, our goal in this study was to use a temporary indwelling stent that would spontaneously migrate after several months. The combination of high conformability and a flared end is proposed to reduce early stent migration; therefore, a covered stent with these anti-migration properties was used. The 2-mm flaring was determined by our previous experiences, in which stents with no flared ends and 1-mm flared ends spontaneously migrated within 2 weeks and 1–2 months after placement, respectively (data not included in this study). Therefore, we hypothesised that stents with 2 mm-flared ends would remain for more than 3 months and spontaneously migrate after stricture remodeling. As a result, all stents migrated 3–9 months after placement (by study definition) and passed rectally without causing bowel obstruction. However, if the stent does not migrate as

**Table 2** Procedural and follow-up outcomes

	Balloon group ( $n = 33$ )	Stent group ( $n = 23$ )	$p$ value
Technical/clinical success	32 (97.0%)	23 (100%)	1.0
PTBD indwelling, median (range)	71 (39–124)	7 (6–8)	0.001
Complications			
Major	1 (3.0%)	1 (4.3%)	1.0
Minor	8 (24.2%)	2 (8.7%)	0.17
Follow-up, median (range)	1168 (174–3965)	603 (180–2169)	0.01
Recurrent stricture	18 (54.5%)	3 (13.0%)	0.002

planned, a long-term indwelling of the stent may be associated with complications such as stent obstruction, stone formation and cholangitis, and require removal when these complications occur. If required, we planned to push the stent into the jejunum using an 8 F curved sheath through a percutaneous biliary access. This is technically feasible and less traumatic than percutaneous retrieval, based on our experience.

This study found that temporary covered stent placement provides longer patency compared with balloon dilatation. The 3-year primary patency rates were 84.9% for the stent group vs. 52.8% for the balloon group, and recurrent strictures requiring re-intervention were 3.7-fold more frequent in the balloon group. These results support previous studies using percutaneous temporary covered stenting [11, 13, 22]. Kim et al placed retrievable covered stents in 35 benign biliary strictures, which were electively removed after 0.5–5 months. Similarly, the stent group had longer patency rates than the balloon group at 3 years (87% vs. 44%, respectively). These results suggest that stents provide “prolonged dilatation” as well as induce stretching and remodelling of bilioenteric anastomoses [5].

Previous studies have reported various stent indwelling times (6–12 months), with no consensus regarding the optimal interval. Several endoscopic studies suggest longer indwelling time is associated with better patency [23, 24]. However, due to its association with stent-related complications, a longer indwelling time may not be always desirable. In this study, 3 out of 7 patients with 3-month indwelling times experienced recurrent strictures. In contrast, the other 16 patients with 6- or 9-month indwelling times had no recurrent strictures. One endoscopic study found no benefit from stenting beyond 1 year [25]. Therefore, in our opinion, optimal stent indwelling time is between 6 and 12 months.

In this study, PTBD indwelling time was significantly reduced in the stent group compared with the balloon group (median, 7 vs. 71 days, respectively). Moreover, the indwelling time was markedly shorter than those in previous studies using retrievable stents [11, 13] where drainage catheters were left in place to prevent stent migration, requiring indwelling PTBD for 2.5–5.8 months. In our study, spontaneous stent migration eliminated the need for prolonged percutaneous drainage, and patients were discharged with no external access a few days after stent placement. We believe that reduced PTBD indwelling time improves the patient’s quality of life [10]. Given its longer patency and shorter PTBD indwelling time compared with balloon dilatation, covered stents should be the preferred option for patients with benign bilioenteric anastomotic strictures, and is the standard treatment at our institution.

The main limitation of this procedure is that the stent migration time cannot be controlled, resulting in variable stent indwelling times (3–9 months). A biodegradable stent may be

the solution. The concept of biodegradable stents is similar to the spontaneously migrating stents used in this study; they provide the benefits of stenting (longer patency and shorter PTBD indwelling) without requiring removal. In a recent study of benign biliary strictures treated with biodegradable stents, early stent migration and recurrent strictures occurred in 2% and 18% of patients, respectively [26]. The 1- and 3-year patency rates were 92.8% and 70.6%, respectively, comparable to the results of this study. However, the degradation time of this stent (3–6 months) [27] is less than optimal, based on the results of this study. More research on biomaterials with longer degradation times is warranted.

Several study limitations should be addressed. First, there are inherent limitations in a retrospective observational design. Second, the number of patients was relatively small. Third, historical controls were used for comparisons. The stent placements were performed more recently than the balloon dilatations; thus the follow-up period was significantly shorter for the stent group, precluding long-term outcome comparisons. In addition, it is possible that the stent group received more advanced medical care. Fourth, the stent indwelling times were not exact, only estimated using follow-up imaging; the indwelling times could be underestimated by up to 3 months. A randomised, controlled trial using a larger population and longer follow-up is warranted to confirm the results of this study.

In conclusion, percutaneous placement of a temporary covered stent designed for spontaneous migration is an effective treatment in patients with benign bilioenteric anastomotic strictures. It provides longer patency and shortens drainage catheter indwelling time compared with balloon dilatation.

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## Compliance with ethical standards

**Guarantor** The scientific guarantor of this publication is Chang Jin Yoon.

**Conflict of interest** The authors declare that they have no conflict of interest.

**Statistics and biometry** No complex statistical methods were necessary for this paper.

**Informed consent** Written informed consent was waived by the Institutional Review Board.

**Ethical approval** Institutional Review Board approval was obtained.

## Methodology

- Retrospective
- Experimental study
- Performed at one institution

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