

# Benign biliary strictures refractory to standard bilioplasty treated using polydoxanone biodegradable biliary stents: retrospective multicentric data analysis on 107 patients

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## Abstract

**Objectives** To assess mid-term outcome of biodegradable biliary stents (BBS) to treat benign biliary strictures refractory to standard bilioplasty.

**Methods** Institutional review board approval was obtained and patient consent was waived. 107 patients (61 males, 46 females, mean age  $59 \pm 16$  years), were treated. Technical success and complications were recorded. Ninety-seven patients (55 males, 42 females, aged  $57 \pm 17$  years) were considered for follow-up analysis (mean follow-up  $23 \pm 12$  months). Fisher's exact test and Mann–Whitney *U* tests were used and a Kaplan–Meier curve was calculated.

**Results** The procedure was always feasible. In 2/107 cases (2 %), stent migration occurred (technical success 98 %). 4/107 patients (4 %) experienced mild haemobilia. No major complications occurred. In 19/97 patients (18 %), stricture recurrence occurred. In this group, higher rate of subsequent cholangitis (84.2 % vs. 12.8 %,  $p=0.001$ ) and biliary stones (26.3 % vs. 2.5 %,  $p=0.003$ ) was noted. Estimated mean time to stricture recurrence was 38 months (95 % C.I 34–42 months). Estimated stricture recurrence rate at 1, 2, and 3 years was respectively 7.2 %, 26.4 %, and 29.4 %.

**Conclusion** Percutaneous placement of a BBS is a feasible and safe strategy to treat benign biliary strictures refractory

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to standard bilioplasty, with promising results in the mid-term period.

#### Key Points

- *Percutaneous placement of a BBS is 100 % feasible.*
- *The procedure appears free from major complications, with few minor complications.*
- *BBSs offer promising results in the mid-term period.*
- *With a BBS, external catheter/drainage can be removed early.*
- *BBSs represent a new option in treating benign biliary stenosis.*

**Keywords** Biliary stricture · Percutaneous transhepatic cholangiography · Percutaneous transhepatic bilioplasty · Bioabsorbable biliary stent

## Introduction

Biliary strictures represent a frequent complication of surgical procedures involving the biliary tract, potentially resulting in obstruction to bile flow, with consequent stasis, infection, and liver damage [1, 2]. In patients with benign biliary stenosis, the first therapeutic strategy is based on endoscopic balloon dilation and stent placement [1, 3, 4]. In case of endoscopy failure or unfeasibility, a percutaneous approach has been proven to be a valuable alternative to perform a number of biliary procedures, such as percutaneous transhepatic biliary drainage (PTBD), bilioplasty, and stenting [5–10]. However, multiple sessions of bilioplasty or long-term PTBD may be required to achieve satisfactory clinical results [8–10], and the use of temporary stents remains controversial, particularly because they have to be subsequently removed [7, 11–14].

In this setting, the use of biodegradable biliary stents (BBSs) may provide the beneficial effects of stenting while avoiding the issues related to subsequent removal. BBSs have been tested in animal models, and used in humans to treat endoscopic strictures of the oesophagus, colon, and trachea [15–19]. To our knowledge, literature on BBSs to treat benign stenosis in humans is limited to a seminal technical note on two patients and to a preliminary report on ten patients [20, 21]. Thus, our aim was to assess the mid-term outcome of BBSs to treat benign biliary strictures refractory to standard bilioplasty.

## Materials and methods

Institutional review board approval was obtained and patients' consent was waived for this retrospective report.

In a prior study [21], we reported on ten patients included in the current study. The prior paper reported on preliminary results, the current study expands on this by having a larger

patient number, a longer follow-up, and including new analyses. Data of patients who underwent treatment of a benign biliary stricture by the implantation of a BBS at ten different institutions in Europe and South America were retrospectively evaluated.

## Study population

One hundred and seven patients (mean age  $59 \pm 16$  years [mean  $\pm$  standard deviation]), 61 males (aged  $61 \pm 15$  years) and 46 females (aged  $54 \pm 17$  years) were treated for a benign biliary stenosis with the percutaneous implantation of a BBS between 2007 and 2014 at ten different institutions.

All patients had recurrent episodes of cholangitis associated with imaging-proven biliary stricture causing bile duct dilation. The mean value of total bilirubin before stent implantation was  $8.3 \pm 9.7$  mg/100 ml. In all these patients, a percutaneous approach was chosen because of failure or unfeasibility of endoscopic treatment. BBS implantation was decided after failure of standard percutaneous treatments (bilioplasty or PTBD; median number of standard procedures prior to BBS implantation,  $n = 2$ ; interquartile range 2–3; range 1–9).

Twenty-five patients were previously operated for neoplastic disease. All these patients had negative oncologic follow-up, and were considered free from oncologic disease at the time of stent implantation. Thus, stricture was considered as related to the surgical procedure and not to the oncologic disease itself, and the patients were treated with a BBS as the stricture was considered to be benign.

Underlying disease, surgical treatment, and site of stenosis are summarized in Table 1.

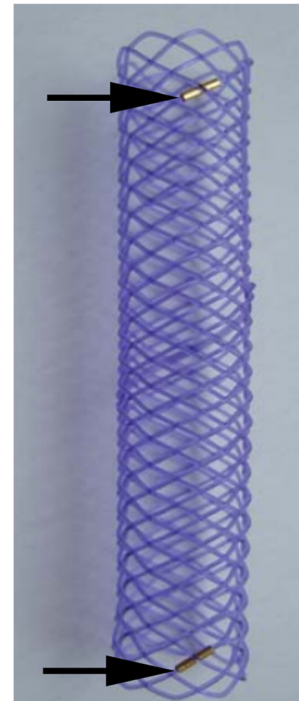
## BBS

The BBSs used in this series (Ella-DV biliary stent, ELLA-CS, Hradec Králové, Czech Republic) were made of polydioxanone (PPDX). This is a material that is degraded by hydrolytic processes in about 3–6 months. This kind of stent has also been previously tested in animal models and used in endoscopy for treating benign stenoses of the colon, oesophagus, and bile ducts, and to correct tracheal narrowing in children [15–19, 21]. Its physical features have been previously described [21, 22]. Briefly, once degraded by hydrolytic process, PPDX results in low-molecular weight species, which can be metabolized by the body [21, 22]. Some experimental studies demonstrated that degradation occurs under a zig-zag pattern, supporting the “Swiss cheese” model, so that the PPDX filaments during degradation start losing their mechanical properties but maintain their physical integrity [20]. The stents were custom manufactured in appropriate sizes from a commercially available PPDX surgical suture, which has a diameter of 0.340 mm to 0.399 mm. PPDX fibres were

**Table 1** Underlying disease, surgical treatment and site of stenosis in 107 patients with benign biliary stricture treated with biodegradable biliary stent

	No. of patients (%)
<b>Basic disease</b>	
Cholelithiasis	45/107 (42 %)
Cholecystitis	21/107 (20 %)
Pancreatic cancer	6/107 (6 %)
Inflammatory biliary stenosis	6/107 (6 %)
Cholangiocarcinoma	5/107 (5 %)
Liver metastases	5/107 (5 %)
Chronic pancreatitis	4/107 (4 %)
Neuroendocrine tumour	3/107 (3 %)
Intraductal papillary mucinous neoplasm	2/107 (2 %)
Acute pancreatitis	2/107 (2 %)
Esophago-gastric perforation	1/107 (1 %)
Gastrointestinal stromal tumour	1/107 (1 %)
Hepatocellular carcinoma	1/107 (1 %)
Mucinous carcinoma peritonei	1/107 (1 %)
Portal vein thrombosis	1/107 (1 %)
Sarcoma	1/107 (1 %)
Schwannoma	1/107 (1 %)
Trauma	1/107 (1 %)
<b>Surgical treatment</b>	
Cholecistectomy	59/107 (55 %)
Duodenocephalopancreatectomy	17/107 (16 %)
Bile duct reconstruction after iatrogenic damage	12/107 (11 %)
Surgical resection	4/107 (4 %)
Right hepatectomy	4/107 (4 %)
None	3/107 (3 %)
Bilio-digestive anastomosis	2/107 (2 %)
Liver transplantaton	2/107 (2 %)
Extensive abdominal surgery	1/107 (1 %)
Metastasectomy	1/107 (1 %)
Gastrectomy with splenectomy	1/107 (1 %)
Total gastrectomy	1/107 (1 %)
<b>Site of stenosis</b>	
Biliary–digestive anastomosis	67/107 (63 %)
Main bile duct	30/107 (28 %)
Right hepatic duct	6/107 (6 %)
Biliary confluence	4/107 (4 %)

braded to form a cylinder, similar to that of a metallic wall stent. The stents were configured with a platinum marker for X-ray visualization (Fig. 1). The stent is kept separate from the delivery system up until the time of the procedure. At this point, it has to be manually loaded onto the delivery system. Initial systems were available only with a 15-F tube sheath, while since 2012, a delivery system with an 11-F tube sheath has been commercially available. In 18 patients, two BBSs

**Fig. 1** Bioabsorbable biliary stent 8 mm×60 mm. The stent is made by polydioxanone and is provided with two platinum markers (arrows) to allow for fluoroscopic visibility

were used. Thus, a total of 125 BBSs were implanted. Their diameter was 7 mm ( $n=4$ ), 8 mm ( $n=18$ ), 9 mm ( $n=9$ ), 10 mm ( $n=89$ ), and 12 mm ( $n=2$ ). The mean diameter was  $9.7 \pm 0.7$  mm. The median stent length was 45 mm (range 30–80 mm).

### Implantation procedure

All patients underwent percutaneous transhepatic cholangiography under local anaesthesia and conscious sedation with ultrasound and/or fluoroscopic guidance, using the standard micropuncture technique [21]. Operator experience in biliary procedures ranged between 3 and 30 years (median 20 years, interquartile interval 15.25–27). To perform biliary duct puncture, a right intercostal approach was used in 75/107 (70 %) patients, a left subcostal approach was used in 16/107 (15 %) patients, and a bilateral approach was used in 16/107 (15 %) patients. Before stent placement, balloon dilation was performed in 78/107 (73 %) cases. A 15-F delivery system was used in 53/107 (50 %) patients, while an 11-F delivery system was used in 54/107 (50 %) patients. Stent release at the desired level was performed by a pull-back system under fluoroscopic control. After stent placement, balloon dilation was performed in 82/107 (76 %) cases in our series. After a final cholangiography to demonstrate correct stent expansion, a biliary internal–external drainage catheter or a 4-F angiographic catheter was left in place for 24–48 hours to retain access to the biliary system for further control. After this period, cholangiography

was performed and in case stricture resolution was confirmed, the catheter was removed. Patients were then discharged after 24–48 hours of observation.

### Endpoints and data analysis

The number of cases in which it was possible to cross the stenosis with the delivery system and deploy the stent at the site of the stenosis was recorded. Technical success was considered as the resolution of the stricture at the final cholangiography. In case of technical success, the immediate result was further categorized as optimal or suboptimal according to operator judgement of stent expansion. Immediate and late complications were recorded.

Episodes of cholangitis, episodes of altered hepatic functional tests (e.g. increased serum levels of gamma-glutamyl transferase [GGT], alkaline phosphatase [ALP], and bilirubin) without clinical symptoms of cholangitis, episodes of development of biliary stones, and development of imaging demonstrated biliary stricture recurrence and time to development of imaging demonstrated biliary stricture recurrence were recorded. Stricture recurrence was defined as the presence of an imaging-demonstrated stricture at the level of the previous stent implantation. In case symptoms were present in the absence of an imaging demonstrated recurrence, they were separately analysed and referred to reasons other than recurrence. Only patients with at least a 6-months follow-up ( $n = 97$ ) were considered for this analysis.

### Statistical analysis

Sex distribution, immediate result of cholangiography, development of subsequent cholangitis, episodes of increased serum levels of GGT/ALP/bilirubin without clinical symptoms of cholangitis, and biliary stones in patients who developed stricture recurrence were compared to those in patients who did not develop stricture recurrence using Fisher's exact test. Age, operator's years of experience, stent diameter in patients who developed stricture recurrence, and patients who did not develop stricture recurrence in the same two groups were compared using the Mann–Whitney  $U$  test. Time-to-event data analysis for the mean time to stricture recurrence was performed by calculating the Kaplan–Meier curve. Analysis was performed using GraphPad Prism 5 software (Graph-Pad, La Jolla, CA, USA). A  $p$  value less than 0.05 was considered as statistically significant.

### Results

In all cases (107/107), it was possible to complete the procedure, to cross the stenosis, and to deploy the stent. In 3/107 cases (3 %) performed with the 15-F delivery system,

difficulties in retracting the system after stent deployment were reported. In 2/107 cases (2 %), migration of the stent occurred immediately after deployment (technical success 98 %). These two cases were managed with standard PTBD positioning and were not considered for further analysis. In 105 cases with correct stent deployment, final cholangiography demonstrated resolution of the stenosis and restoration of the bile flow through the previous stricture. The operator judged the result as optimal in 94/105 cases (90 %) and suboptimal in 11/105 cases (10 %). In 4/107 (4 %) cases, immediate mild haemobilia occurred. No further treatment was needed for managing this complication. No major complications occurred.

Ninety-seven patients (mean age  $57 \pm 17$  years), 55 males (mean age  $61 \pm 15$  years) and 42 females (mean age  $55 \pm 18$  years), had at least six months of follow-up. Thirty-three patients had at least 1 year of follow-up, 22 patients had at least two years of follow-up, and 23 had at least three years of follow-up. The mean follow-up time was  $23 \pm 12$  months (median 16.0 months, range 6–49 months). In the considered period, 19 treated patients (18 %) experienced a stricture recurrence. Mean time-to-stricture recurrence for the 19 patients who experienced this event was  $15.4 \pm 8.3$  months. The estimated mean time to stricture recurrence calculated with Cox regression for all treated patients was 38 months (95 % CI 34–42 months). The estimated stricture recurrence rates at 1, 2, and 3 years were, respectively, 7.2 %, 26.4 %, and 29.4 %. The Kaplan–Meier curve is shown in Fig. 2. Of the patients with stricture recurrence, 6/19 (31 %) were treated with sustained dilation with PTBD, 3/19 (16 %) underwent surgical repair, 3/19 (16 %) were treated with bilioplasty and PTBD, in 3/19 (16 %), an additional BBS was implanted, in 2/19 (10 %), a retrievable stent was implanted, 1/19 (5 %) decided to be treated at a different hospital, and 1/19 (5 %) died due to acute pancreatitis. Subgroup analysis regarding patients who developed stricture recurrence and patients who did not develop stricture recurrence is reported in Table 2.

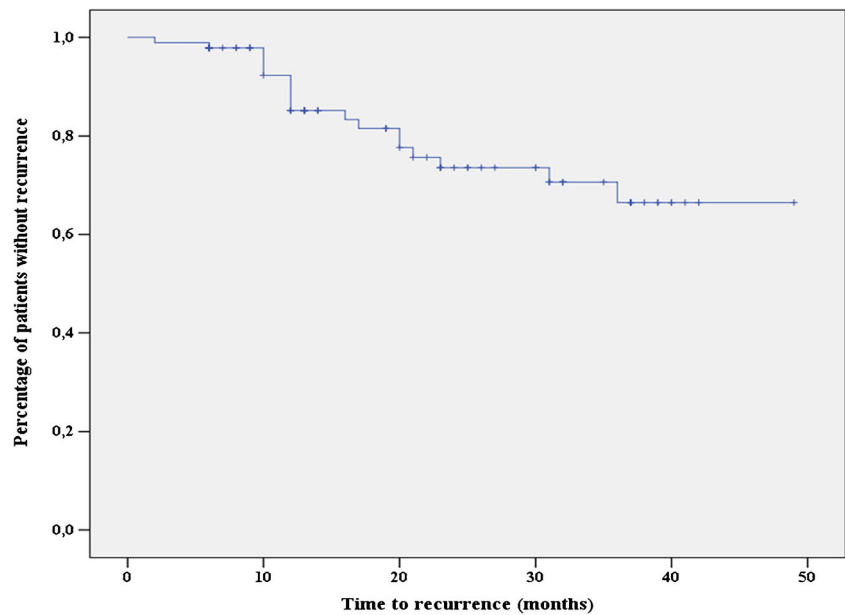
A case of a patient treated with a BBS for the treatment of a benign biliary stenosis is shown in Fig. 3.

### Discussion

Our analysis on a larger series of patients demonstrated that percutaneous implantation of a BBS is feasible, safe, and effective in the treatment of benign biliary strictures with a mean follow-up of 2 years.

One of the main advantages of BBS implantation is the possibility of sparing the patient the task of carrying a biliary drainage for a long period, as, after biodegradable stent placement, the drainage catheter can be removed after 24–48 hours. This is different from what happens with a standard strategy or

**Fig. 2** Kaplan–Meier curve showing recurrence-free survival of 89 patients who underwent percutaneous treatment of a benign biliary stenosis using a bioabsorbable stent



with retrievable stents *ceteris paribus*, where an external drainage is generally left in place for a long period [8–10,

**Table 2** Comparison of patients who developed stricture recurrence with patients who did not develop stricture recurrence in 97 patients treated with biodegradable biliary stent for the treatment of a benign biliary stenosis

	Stricture recurrence		p value
	No n = 78 (72 %)	Yes n = 19 (18 %)	
Male/female	41/37	14/5	0.123**
Age (years)*	61 ± 15	55 ± 18	0.223***
Site of stenosis (anasthomotic/ non-anasthomotic)	48/30	8/11	0.194**
Previous malignancy (yes/no)	22/55	3/16	0.383**
Operator experience (years)*	21 7	17 ± 7	0.074***
Stent diameter (millimeters)*	9.8 ± 0.7	9.3 ± 0.9	0.017***
Cholangiographic result (optimal/suboptimal)	72/6	11/8	0.001**
Subsequent cholangitis (yes/no)	10/68	16/3	0.001**
Subsequent event of increased serum levels of GGT/ALP/bilirubin without symptoms of cholangitis (yes/no)	12/66	5/14	0.313**
Subsequent development of biliary stones (yes/no)	2/76	5/14	0.003**
Mean time to stricture recurrence (months)*	N/A	15.4 ± 8.3	

\* data are mean ± standard deviation

\*\* Fisher's exact test

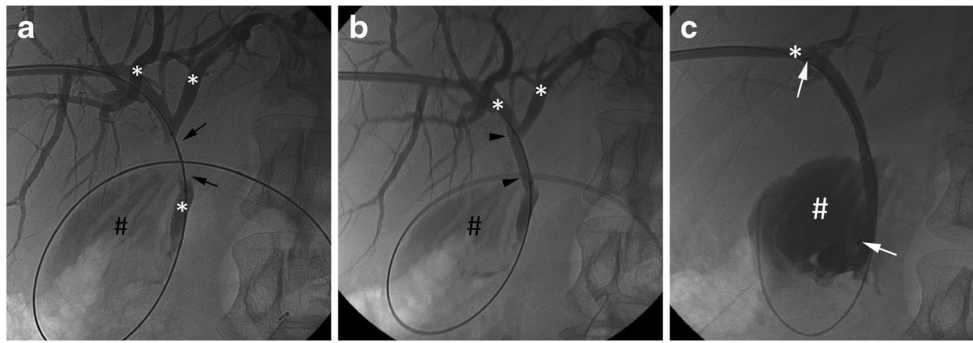
\*\*\* Mann–Whitney U test

N/A = not applicable

13, 14]. Moreover, the implantation of a BBS may be theoretically not only an effective option when other strategies have failed, but may also represent an alternative first option to be offered to patients in order to avoid the discomfort of long-term external drainage.

Percutaneous transhepatic procedures have been demonstrated to be an effective alternative to surgery in a number of conditions, in particular to treat postsurgical biliary complications when endoscopy is not feasible or fails [5, 6, 23, 24]. When percutaneous transhepatic strategy is employed in patients with a benign biliary stricture, the treatment is mainly based on PTBD and bilioplasty [8–10]. Cantwell et al. [8] reported the outcomes of a 30-year experience with balloon dilation of benign biliary strictures in 75 patients with 100 % technical success and 75 % successful management during follow-up with 30.6 % patients requiring more than one treatment. Their probability of not having clinical significant stricture recurrence at 5 years dropped from 0.52 after the first treatment to 0.43 after second treatment. In a series of 44 patients with benign anastomotic stricture treated with PTBD, Weber et al. [9] reported 61.4 % treatment success and the biliary drainage was successfully removed after 19.9 ± 16.1 months. In the same report, 10 patients had to carry a permanent drainage device. In this setting, the use of stents in the treatment of benign biliary stenosis has been postulated due to the higher expansion force and larger diameter compared to the indwelling catheters and of the sustained dilation effect [12–14]. In particular, retrievable covered stents have been reported as an effective treatment for benign biliary strictures. Gwon et al. [14] reported the use of retrievable covered stents in the treatment of 68 patients with benign biliary strictures. The stent was correctly deployed in all cases, with stent migration occurring in 16.2 % of cases. They reported a 20 %





**Fig. 3** Use of biodegradable biliary stent to treat a stricture of the main biliary duct. (a) Percutaneous transhepatic cholangiography showing the biliary tree (*asterisks*), a stricture of the main biliary duct (*black arrows*) and the presence of contrast medium in the bowel (*hash*). (b) Pre-

dilation is performed at the level of the stricture by a biloplasty balloon (*arrowheads*; *asterisks* = biliary tree, *hash* = bowel). (c) Biodegradable biliary stent is positioned across the stricture (*white arrows* = radiopaque markers, *asterisk* = biliary tree, *hash* = bowel)

rate of re-stenosis at a mean follow up of 36 months. In this group of patients, the mean indwelling period of the drainage catheter was 5.8 months.

Patients presented in this report represent a case series and no direct comparisons with other treatments have been performed. However, no other consistent experiences on BBS placement are present in the literature. We can somewhat compare our results to those reported using other strategies. In our series, we were able to perform the procedure and deploy the stent at the level of the stenosis in all cases, with 2 % incidence of immediate stent migration. This rate is comparable to what has been reported for retrievable stents [12–14]. No migration was observed during the 24–48 hours of observation time. However, maintaining a catheter in place may help to perform the standard PTBD procedures in case of delayed migration. Of note, BBS migration is potentially a minor issue, as, differently from metallic stents, they are hydrolysed both in the biliary tract and in the bowel.

The 4 % incidence rate of mild haemobilia might be due to the still quite rudimentary and large introductory system, and is similar to what has been reported in other series about percutaneous treatment of biliary stenoses [8–13]. Another issue that could be related to this was that in 3 cases, we experienced difficult removal of the introductory system. However, each was regarded as a minor complication and we cannot hypothesize any real implication on the outcome of patients. For these issues, further improvement of the delivery system may lead to decreased complication incidence.

During a mean follow-up of 2 years, stricture recurrence occurred in about 20 % of patients in our series. This result is similar to that reported in a previous series with the use of standard balloon dilation/PTBD [8, 9] and retrievable covered stents [14]. However, in our series, patients had the biodegradable stent implanted after a median of two previously failed percutaneous treatments. It is known that the probability of having a clinically significant stricture recurrence increases after experiencing previous failure of percutaneous

procedures [8]; therefore, most patients included in our series were at a high risk of developing a stricture recurrence. Thus, we think BBSs may represent a valuable treatment for patients in whom standard strategies failed. As could be expected, in the group of patients with biliary stricture recurrence, a significantly higher incidence of cholangitis and development of biliary stones was observed in comparison with the group of patients who did not develop biliary stricture recurrence. About 15 % of our patients developed cholangitis or an episode of increased serum levels of GGT/ALP/bilirubin without clinical symptoms of cholangitis or biliary stones without imaging evidence of stricture recurrence. These events may be related to the effects of previous surgery (e.g. presence of a bilio-digestive anastomosis), to the degradation process of the stent with stent fragment migration [20, 21], or to inflammatory mucosal reaction [23]. However, further studies are needed to better clarify this issue, as we do not have enough data to support such hypotheses.

In our series, a suboptimal immediate cholangiographic result was significantly associated with stricture recurrence. This emphasizes the fact that immediate optimal results are crucial for achieving a good subsequent clinical outcome.

Some limitations of this study have to be taken into account. First, data were collected retrospectively in different centres around the world, thus selection of cases suitable for BBS implantation was based on each centre preference, also because guidelines on BBS indications are still missing. Then, patient selection was heterogeneous, and a number of different basic diseases were included in the study. However, the majority of stenoses in our series derived from similar kind of hepato-pancreato-biliary surgery and not from the basic disease itself. Moreover, a standardized follow-up protocol was not established and it differed widely among centres. This is also the reason why a number of patients were lost after 6 months of follow-up. Furthermore, our results are based on a mean follow-up time of approximately 2 years. As recurrence might occur after this period, our results might have

been overestimated. Furthermore, we considered as recurrence only those cases in which the stricture recurrence was visible on imaging, while patients with symptoms without imaging evidence of recurrence were considered as not having a stricture recurrence. This might determine an overestimation of our results. Lastly, we do not have any direct comparison with patients who were treated with other strategies.

In summary, percutaneous placement of BBSs is a feasible and safe strategy to treat benign biliary strictures, offering promising results during the mid-term period, potentially representing a further option for treating patients in whom standard percutaneous therapy failed, and a strategy for sparing the patient a long-lasting treatment. Long-term results should be awaited and further randomized controlled trials comparing the outcome of BBSs to that of other procedures are warranted to better clarify these issues.

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