ORIGINAL ARTICLE

# A biodegradable non-covered self-expandable stent to treat pancreatic duct strictures in chronic pancreatitis: a proof of principle

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**Background and Aims:** In chronic pancreatitis (CP), fibrotic pancreatic duct (PD) strictures pose a therapeutic challenge, because endoscopic dilatation requires multiple procedures with suboptimal results. Biodegradable self-expandable stents (BD-SESs) may serve as an alternative in this setting.

**Methods:** Patients with CP were eligible for this proof-of-principle study if at least 6 months of endoscopic dilatation with plastic stents had failed to resolve their PD stricture. The non-covered BD-SESs were expected to degrade within 3 to 6 months. Patients were followed at 3-monthly intervals for 1 year. Placement success and safety were the primary outcome parameters. Stricture resolution was assessed by ERCP after 6 months.

**Results:** BD-SESs were successfully placed in all 19 patients without adverse events. In 2 cases, stent occlusion with sludge and stones was treated by a balloon swipe. One stent disintegrated during this procedure, after which placement of the plastic stent was resumed. A hyperplastic response was observed in 2 patients but did not result in functional obstruction. Stricture resolution was accomplished in 11 patients (technical success rate 58%). Six patients required further treatment of their PD stricture, 4 endoscopically and 2 surgically. Three additional patients underwent surgery for other reasons: 2 Whipple procedures for CP-related adverse events and one tail resection for an intraductal papillary mucinous neoplasm. The remaining 10 patients did not require further PD drainage (clinical success rate 52%).

**Conclusions:** These preliminary results show that BD-SESs are safe to use and able to resolve fibrotic PD strictures in CP. These encouraging outcomes warrant further testing. (Gastrointest Endosc 2017;■:1-6.)

## INTRODUCTION

In chronic pancreatitis (CP), fibrotic pancreatic duct (PD) strictures are a common adverse event. Dilation is advocated in case of symptoms, because increased intraductal pressure seems to play a pivotal role in pain development. At present, endoscopic treatment consists of the sequential insertion of an increasing number of plastic stents.[1] Unfortunately, this approach often fails.[2-4] Lately, several promising publications have reported on temporary placement of self-expandable metal stents (SEMSs) in this patient group.[5-8]

SEMSs were initially developed for palliative use in malignant biliary strictures.[9] Later, fully covered

*Abbreviations: BD-SES, biodegradable self-expandable stent; CP, chronic pancreatitis; FC-SEMS, fully covered self-expandable metal stent; PD, pancreatic duct; SEMS, self-expandable metal stent.*

DISCLOSURE: *Dr Cahen has done consultancy work for Tramedico. Dr Laleman has done consultancy work for Cook Medical and Boston Scientific. Dr Poley has done consultancy work for Cook Medical, Boston Scientific, and Pentax. Dr Bruno had done consultancy work and lectured for Cook Medical and Boston Scientific. The other author disclosed no financial relationships relevant to this publication.*


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self-expandable metal stents (FC-SEMSs) became increasingly popular for treatment of benign biliary strictures.[10,11] Compared with plastic stents, FC-SEMSs have a longer patency. In addition, they may result in more effective stricture dilatation. First, their larger diameter provides a radial force that is often not achieved with plastic stent placement, because technical limitations prohibit placement of a sufficient number of plastic stents. Second, after FC-SEMS deployment, the maximal radial force is reached in hours, instead of over a period of months, as is the case with plastic stents. Despite these advantages, migration of FC-SEMS, especially proximal into the PD, is a feared adverse event.[8] The use of a biodegradable self-expandable stent (BD-SES) could potentially solve this issue. In addition, its highly biocompatible material may induce less hyper-proliferative tissue response and avoid the need for stent removal and exchange procedures. Ideally, a BD-SES would transform endoscopic PD stricture dilation into a one-step procedure.

Biodegradable stents are made of polymers, traditionally used in suture materials, which degrade over time by hydrolysis. Most experience has been obtained in endovascular and urological applications. In gastroenterology, biodegradable stents were first used for esophageal strictures, with initial encouraging results, but mucosal hyperplasia was frequently encountered.[12-16] Use of BD-SESs in the pancreaticobiliary tract has been limited because through-the-scope delivery was impossible, but a recent adaptation has solved this problem. This feasibility study was designed to investigate the use of non-covered BD-SESs in patients with CP, in whom previous endoscopic treatment with plastic stents did not resolve their fibrotic PD stricture.

## PATIENTS AND METHODS

### Study design

This prospective intervention trial was performed between January 2013 and July 2015 in 2 tertiary referral centers. After BD-SES placement, patients were followed at 3-monthly intervals for 1 year. Stent degradation was assessed by MRCP after 3 months and stricture resolution by ERCP after 6 months. The study was approved by the local ethics review boards and conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization of Good Clinical Practice. All participants provided written informed consent before participation.

### Patients

Patients were recruited from the outpatient clinic of the Departments of Gastroenterology and Hepatology of the Erasmus University Medical Center in Rotterdam, the Netherlands, and the University Hospital in Leuven, Belgium. Inclusion criteria were (1) a diagnosis of CP, based on clinical symptoms in combination with morphological changes and/or pancreatic functional insufficiency; (2) a benign fibrotic pancreatic duct stricture; and (3) previous endoscopic plastic stent insertions for at least 6 months failed to accomplish any sign of stricture resolution. Exclusion criteria were patients younger than 18 years with a contraindication for endoscopy (Roux-en-Y reconstruction), suspected pancreatic malignancy, a limited life expectancy (<1 year), and pregnancy. Intraductal stones, suitable for endoscopic removal, were not considered to be an exclusion criterion.

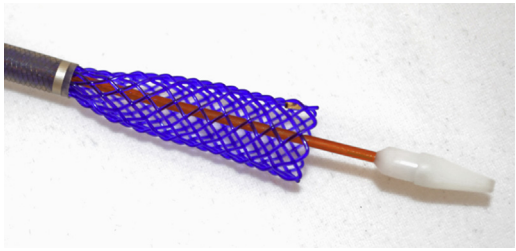

**Figure 1.** Uncovered biodegradable self-expandable stent (ELLA-CS) loaded on the delivery system.

### Stent placement

The non-covered BD-SES used in this series (Ella-DV biliary stent, ELLA-CS, Hradec Králové, Czech Republic) is made of polydioxanone fibers. The model resembles a metallic expandable stent (Fig. 1) with a diameter of 6 mm and a length of either 3 or 4 cm. Before use, the stent was manually loaded onto the delivery system. Platinum markers ensure radiologic visualization. The stent is designed to degrade within 3 to 6 months.

All stents were placed by experienced endoscopists. ERCP was performed with a duodenoscope (Olympus TJF-Q160/180V) with the patient under general anesthesia. The decision to dilate the stricture was at the discretion of the endoscopist. The BD-SES was introduced under fluoroscopic control over a guidewire. The shortest stent was chosen, bridging the stenosis by at least 1 cm at either end. After stent placement, patients were admitted for observation overnight (Fig. 2).

### Outcome measures

Placement success and safety were the primary outcome measures. Adverse events were classified as placement related, stent related, and disease related (meaning other adverse events related to CP). Secondary outcome measures were technical success (stricture resolution), defined as complete runoff of contrast and easy passage of an extraction balloon or retrieval basket through the stricture during ERCP after 6 months, and clinical success, defined as no need for further treatment of the PD stricture during the 1-year follow-up. In addition, stent degradation on MRCP was assessed as a secondary outcome measure. Follow-up information was collected every 3 months

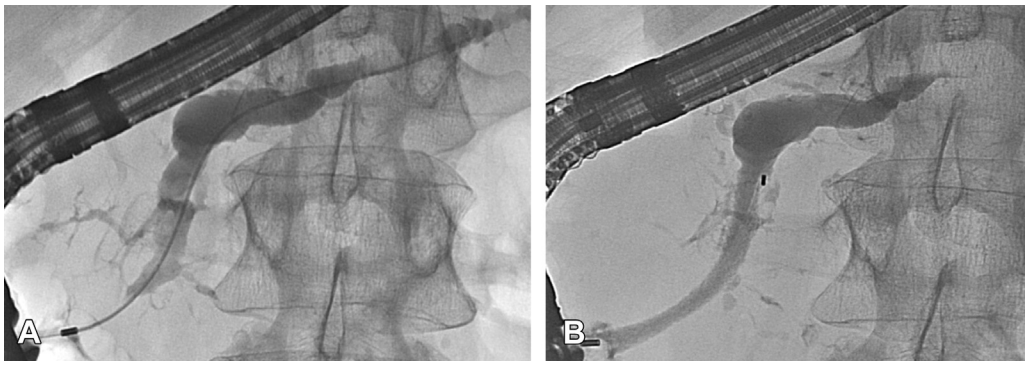


**Figure 2.** Radiologic images of pancreatic duct stricture, before (**A**) and after (**B**) stent placement.

**TABLE 1. Baseline demographic and disease characteristics**

| Characteristic | Value |
|---|---|
| No. of patients | 19 |
| Age (years), median (IQR) | 55 (49-61) |
| No. of males (%) | 10 (53) |
| Disease duration (years), median (IQR) | 4 (2-8) |
| Cause of pancreatitis, n (%) | |
| Alcoholic | 13 (68) |
| Idiopathic | 5 (26) |
| Other | 1 (5) |
| Ongoing alcohol abuse,-n (%) | 3 (16) |
| Previous stent duration (months), median (IQR) | 10 (6-18) |
| Previous cumulative French, median (IQR) | 10 (7-10) |
| Izbicki pain score, median (IQR) | 76 (54-88) |

*IQR*, Interquartile range.

**TABLE 2. Stricture and stent placement characteristics**

| Variable | Value |
|---|---|
| Stricture length (mm), median (IQR) | 10 (10-20) |
| Stricture location, n (%) | |
| Head | 15 (79) |
| Neck | 2 (11) |
| Corpus | 2 (11) |
| Sphincterotomy, n (%) | 17 (90) |
| Dilatation, n (%) | 9 (47) |
| Stone removal, n (%) | 3 (16) |
| Stent length, n (%) | |
| 3 cm | 10 (53) |
| 4 cm | 9 (47) |
| Stent placement, n (%) | |
| Transpapillary | 16 (84) |
| Intraductal | 3 (16) |

*IQR*, Interquartile range.

during the first year. In addition to a standardized evaluation of complaints and adverse events, the Izbicki pain score was obtained.[17]

## Statistical analysis

Depending on the distributional properties of the outcome measures, data are expressed as means ± standard deviation or as medians with the interquartile range. Analyses were performed using SPSS 22.0 (IBM SPSS Inc, Chicago, Ill).

# RESULTS

## Patients and stent placement

Stents were placed in 19 patients; the demographic and disease characteristics of the patients are listed in Table 1. Patients had previously undergone stent placement for a median of 10 months (range, 6-12 months). Details regarding the stricture and BD-SES placement procedure are given in Table 2. Stent placement was successful in all cases (placement success 100%). In 3 patients, the stent position was optimized after deployment by pulling the stent distally with an extraction balloon or biopsy forceps.

## Adverse events

**Placement-related adverse events.** Adverse events are summarized in Table 3. No serious periprocedural adverse events were encountered. One patient was admitted for 4 days after stent placement because of self-limiting pain, without abnormal results for laboratory tests or on imaging. Another patient with severe atherosclerosis and peripheral arterial disease underwent surgery for jejunal perforation 6 days after stent insertion. This patient also underwent extracorporeal shock wave lithotripsy for pancreatic stones. Intestinal ischemia was identified as

**TABLE 3. Adverse events**

| Adverse event | No. of patients (%) |
|---|---|
| Procedure- and stent-related | 4 (21) |
| Admittance for post-procedural pain | 1 |
| Stent occlusion | 2 |
| Cholecystitis | 1 |
| Migration | - |
| Disease-related (chronic pancreatitis) | 8 (42) |
| New PD stricture (proximal to BD-SES) | 1 |
| Flares | 6 |
| Post-ERCP pancreatitis (after second ERCP at 6 months) | 1 |
| Cholecystitis | 1 |
| Splenic vein thrombosis | 1 |
| CBD stricture | 2 |
| Gastric outlet obstruction | 1 |
| SEMS migration | 1 |

*PD*, Pancreatic duct; *BD-SES*, biodegradable self-expandable stent; *CBD*, common bile duct; *SEMS*, self-expandable metal stent.

**TABLE 4. Management according to stricture resolution**

| Stricture resolution | No, n = 8 (42%) | Yes, n = 11 (58%) | All, n = 19 (100%) |
|---|---|---|---|
| Additional PD drainage | | | |
| None | 2 | 8 | 10 (53) |
| Endoscopic | 4* | – | 4 (21) |
| Surgery | 2† | 3‡ | 5 (26) |

*Ongoing plastic stent placement, 3; self-expandable metal stent for 2 weeks, 1.
†Pancreaticojejunostomy and Whipple procedure (the latter for a new stricture, proximal to the biodegradable self-expandable stent).
‡Two Whipple procedures; ongoing chronic pancreatitis with gastric outlet obstruction and common bile duct obstruction. One tail resection for and intraductal papillary mucinous neoplasm.

**TABLE 5. Overall outcomes**

| Outcomes | n (%) |
|---|---|
| Placement success | 19 (100) |
| Adverse events (procedure-/stent-related) | 4 (21) |
| Technical success (stricture resolution) | 11 (58) |
| Clinical success (no further treatment) | 10 (53) |

the underlying cause (especially because a second perforation occurred later). A relationship with the placement procedure was considered highly unlikely, given the location of the perforation, several meters distal to the ampulla.

**Stent- and disease-related adverse events.** In 3 patients, ERCP was performed within 3 months because of persisting pain. In one patient, the BD-SES was found to be patent after 2 months. Nevertheless, it was cleared with a balloon, and some sludge was removed. In another patient, obstruction of the stent by sludge or hyperplasia was suspected 2 weeks later. This time, a balloon swipe resulted in disintegration of the BD-SES. As the stricture was still present, a plastic stent was inserted. A third patient was found to have developed a new stricture after 3 months, proximal to the BD-SES, for which a plastic stent was inserted.

In a fourth patient, ERCP was performed because of cholecystitis and suspected choledocholithiasis after 3 months. During this procedure, bile duct stones were not observed, but the BD-SES seemed occluded with sludge and was cleared by a balloon swipe. Stent migration was not observed. However, other CP-related adverse events were frequently encountered (Table 3).

## Technical outcomes: stent and stricture resolution

At MRCP after 3 months, stent degradation was complete in 14 patients and partial in 5. On ERCP, 3 months later, a hyperplastic response was noticed at the site of the ampulla in 2 patients. However, functional obstruction was absent however. Both of these patients had a close to normal caliber PD (4 mm) on EUS and MRCP and have remained asymptomatic without further treatment throughout the follow-up period. Overall, stricture resolution was achieved in 11 of 19 patients (technical success 58%; Tables 4 and 5).

## Clinical outcomes and further management

Eight patients had a resilient PD stricture, 2 of whom have remained asymptomatic and have not required further treatment. Six patients required subsequent treatment, 4 endoscopically and 2 surgically. In 1 patient, a metallic SES was placed, but this stent had to be removed within 2 weeks because of migration. During this procedure, the pancreatic sphincterotomy was extended, and this patient has not required treatment since. In 3 patients, stent therapy was continued for a symptomatic persistent stricture. One of these patients subsequently withdrew consent and refused further follow-up. Another patient has remained stent dependent, because he refused surgery. Two patients underwent surgery for a resilient PD stricture; the patient who had developed a new stricture underwent a Whipple procedure after 7 months. A second patient underwent a pancreaticojejunostomy for a persistent stricture after 9 months.

Of the 11 patients in whom stricture resolution was accomplished, 3 underwent surgery for other CP-related adverse events; one underwent a Whipple procedure after 9 months because of groove pancreatitis and gastric outlet obstruction, another after 11 months for a common bile duct stricture and recurrent flares. Both of these patients had a normal-caliber PD at the time of surgery. A third patient developed a new stricture after 11 months,

proximal to the original stricture and stent location. Brush cytology was suspect for malignancy, and a tail resection was performed. The final pathologic diagnosis showed an intraductal papillary mucinous neoplasm of the main pancreatic duct. After a median follow-up of 12 months (interquartile range, 8-12 months), 10 of the 19 patients did not require further endoscopic or surgical PD drainage (clinical success 53%; Tables 4 and 5).

## DISCUSSION

This study is the first to report on endoscopic use of biodegradable stents in the human pancreatic duct. It shows that non-covered BD-SESs are a feasible and safe treatment option for fibrotic PD strictures in patients with CP. Six months after plastic stent placement, BD-SESs had resolved more than half of the strictures without need for further endoscopic interventions.

SEMs attain a higher dilation force than conventional stents, in which the radial force is gradually increased and dependent on successful insertion of multiple stents. Also, their larger diameter ensures a better long-term patency. In recent years, several groups have reported on the use of fully covered SEMSs in the treatment of PD strictures.[5-8,18] In 2008, Park et al[8] were the first to evaluate the use of SEMSs for benign PD strictures in humans and found migration to be a frequent and limiting adverse event. Addition of an anti-migration flap eliminated this problem in a second study but created stent-induced ductal hyperplasia in 16% as a trade-off.[5] Giacino et al[6] inserted 10 SEMSs and achieved 90% technical success rate but also encountered hyperplasia in 20% of cases.

The obvious advantage of BD-SESs over metal stents is the redundancy of removal. In addition, metal stents require covering to allow removal, which may induce pancreatitis by blockage of side branches and facilitate migration. For biliary and pancreatic duct applications, biodegradable stents have been evaluated in several in vitro and animal studies, which proved the stents to be safe and well tolerated.[19-24] They provided an adequate radial force and resulted in complete stricture resolution within several months. Moreover, recently, 2 case reports described the first endoscopic application of a BD-SES in the human bile duct.[25,26] The stent applied in these studies was identical to the one used in the present study. It was inserted in a patient with leakage of the cystic duct and in 2 patients with common bile duct strictures due to gallstone disease. The BD-SES was well tolerated and effective in all cases.

Stents were well tolerated in our study. Ductal hyperplasia had been our most feared adverse event, because it was encountered frequently with use of similar BD-SES in the esophagus.[12-16] After PD insertion in animals, no signs of hyperplasia or integration in the epithelium were seen. Moreover, the BD-SESs seemed to have a self-clearing effect on attached sludge[20] and a more beneficial pattern of expression of proteins associated with tissue healing.[24] In our study, we did not encounter functional obstruction by hyperplasia, although a hyperplastic response was noticed at the site of the ampulla in 2 patients. Both of these stents had been placed transpapillary, and perhaps this response may be prevented by placing the BD-SES intraductally. Stent occlusion was rarely encountered, and clearance of the stent by a balloon swipe was proven possible, but only at an early stage of stent degradation. BD-SES migration did not occur, similar to the more recent reports on metal stents with anti-migratory adaptations.[5]

The expected degradation time of the BD-SES was 3 to 6 months, yet after 3 months, most of the stents had degraded on MRCP. Likely, the microenvironment of the pancreatic ductal system, dominated by enzyme and bicarbonate production, stimulates the hydrolytic degradation process. Similar to SEMSs, BD-SESs may require less time to achieve stricture resolution.

The reported technical and clinical outcomes are promising. In our own prospective randomized study, the clinical success rate of endoscopic treatment with plastic stents was a mere 32%, but this involved a selected group of patients with advanced disease and complex pathology.[2] Other studies have shown variable success rates, up to 85%.[3,27] In addition, the absence of stricture recurrence in the present study is favorable, because, in a similar group of 10 patients treated recently by FC-SEMS, the PD stricture recurred in 38%.[7]

An ideal biodegradable pancreatic duct stent should serve as a 1-step treatment. It must be easy to place, have a strong radial force, and an optimal indwelling time; long enough to resolve the stricture, yet short enough to prevent ductal injury and hyperplastic changes.[28] These preliminary results show the feasibility of this idea and indicate the need for a prospective trial in which native strictures will be randomly allocated to biodegradable or plastic stent treatment, as currently advocated by the European Society of Gastrointestinal Endoscopy (ESGE). We plan to undertake this study.

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