Initial evaluation of a new plastic pancreatic duct stent for endoscopic ultrasonography-guided placement

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Bibliography

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There are currently no plastic pancreatic duct stents that have been designed for endoscopic ultrasonography (EUS)-guided placement. This study prospectively evaluated the feasibility and efficacy of a new, single-pigtail, plastic stent. Eight patients with main pancreatic duct stricture or stenotic pancreatojejunostomy underwent EUS-guided placement of the pancreatic duct stent. The stent was placed successfully in all cases (8/8). Treatment success was achieved in all cases (8/8). A mild adverse event associated with the procedure was observed in one patient but there were no other adverse events during a mean follow-up of 7.4 months. This new pancreatic duct stent appears to be feasible and effective for EUS-guided stenting.

Introduction

Acute recurrent pancreatitis (ARP) can occur as a result of pancreatic duct obstruction from any cause. Recently, endoscopic ultrasonography (EUS)-guided pancreatic duct stent placement has been used to treat such patients when traditional endoscopic retrograde cholangiopancreatography (ERCP) has failed or is not possible because of postsurgical anatomy [1–6]. In these previous reports [2–5], the mean technical success rate was only 82%. Furthermore, adverse events such as pancreatic duct leaks, stent migration, and pancreatitis commonly occurred. We hypothesized that the low technical success and high adverse event rate may be due to lack of a dedicated pancreatic duct stent designed for EUS-guided placement. The aim of this study was to prospectively evaluate the feasibility and safety of a new, single-pigtail, plastic pancreatic duct stent for EUS-guided placement.

Patients and methods

Eight patients with ARP caused by main pancreatic duct (MPD) stricture or stenotic pancreatojejunostomy underwent EUS-guided pancreatic duct placement between August 2013 and May 2014 (Table 1).

Therapeutic echoendoscopes were used with carbon dioxide insufflation. After injection of contrast medium by 19-G or 22-G fine needles, an insulated guidewire was advanced antegrade into the duct. When possible, the wire was passed across the pancreatic duct stricture and major papilla or pancreatojejunostomy. Dilation of the needle tract and anastomotic site was carried out using a standard or tapered catheter, cautery dilator (6.5 Fr; Endoflex, Voerde, Germany), or a 4-mm-diameter dilating balloon. Finally, a newly designed, 7-Fr, pancreatic duct stent was placed. The stent has a tapered tip, four internal flanges (two in the distal end and two at the proximal end), and a single external pigtail (total length of 20 cm and an effective length of 15 cm; Gadelius Medical Co., Ltd., Tokyo, Japan) (Fig. 1, Fig. 2). When possible, the distal end of the stent was positioned across the papilla or anastomotic site. Otherwise, the distal end of the stent remained in the MPD and the proximal end remained in the stomach.

Technical success was defined as stent placement in the MPD. Treatment success was defined as complete resolution of clinical symptoms. Adverse events possibly related to the procedure were identified within 30 days. All patients provided written informed consent for the procedure. The study was approved by the institutional review board of the hospital (no.2503). The study was registered at UMIN (UMIN000012447).
Results

Eight patients (three men) with Whipple resection (n=6), middle pancreatectomy (n=1), and subtotal gastrectomy with Roux-en-Y reconstruction (n=1) underwent EUS-guided pancreatic duct stenting. The strictures were found in the pancreatojejunostomy site (n = 6) and MPD (n = 2) (Table 1). Five patients (62.5%), had previously undergone unsuccessful ERCP.

The mean MPD diameter measured by EUS at the time of puncture was 3.2 mm (range 1.6–6.0 mm) (Table 2). A 19-G needle was used in four patients and a 22-G needle was used in the remaining four patients. In all but two patients (#5 and #8), the guidewire was successfully advanced across the MPD stricture or anastomosis. All stents were easily advanced without difficulty (Fig. 3, Video 1). The distal tip of the stent was positioned in the duodenum and jejunum when the guidewire could be passed across the stricture.

The technical success rate was 100%, and mean procedure time was 37.5 minutes. One mild adverse event of self-limited abdominal pain occurred. Treatment success was achieved in all patients. There were no other adverse events during a mean follow-up of 7.4 months.

Discussion

This study reports the feasibility and efficacy of a new, plastic, pancreatic duct stent designed for EUS-guided placement. We believe that the new stent has several advantages: 1) the tapered and straight distal tip can be easily advanced via the needle tract and stricture sites; 2) the four flanges and pigtail anchor the stent and prevent outward and inward migration; 3) a 15-cm effective stent length can be used for all patients regardless of underlying anatomy; 4) relatively large apertures below the flanges and four small holes in the distal end of the stent improve ductal drainage; 5) the absence of a hole in the middle part of the stent may help to prevent pancreatic ductal leakage into the peripancreatic space (between the stomach and the pancreas).
A straight distal tip has improved ability to traverse strictures than a stent with a distal pigtail. In addition, a more tapered tip may provide better pushability than the standard pancreatic duct stents that are not tapered to the same extent. However, the straight distal stent tip may result in stent migration. To address this concern, the stent was designed with four distal flanges in combination with a pigtail at the gastric site. Although long-term outcomes are needed in order to evaluate the function of the flanges, the current study has shown that the design is sufficient to avoid stent migration after initial EUS-guided placement.

The limitations of this study were the small sample size, lack of a control group, and the inclusion of only a single operator. In conclusion, the new pancreatic duct stent designed specifically for EUS placement was feasible and effective. Further studies involving multiple centers and a large number of cases are now warranted.

**Trial registration:** UMIN000012447.

**Competing interests:** None

### Table 2  Outcome of endoscopic ultrasonography-guided pancreatic duct stenting.

<table>
<thead>
<tr>
<th>Patient #</th>
<th>Punctured MPD diameter, mm</th>
<th>Needle, G</th>
<th>Guidewire passage</th>
<th>Technical success</th>
<th>Site of distal tip of stent</th>
<th>Procedure duration, minutes</th>
<th>Acute adverse events</th>
<th>Treatment success</th>
<th>Scheduled stent exchange</th>
<th>Adverse events during follow-up period</th>
<th>Follow-up duration, months</th>
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<tbody>
<tr>
<td>1</td>
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<td>Yes</td>
<td>Yes</td>
<td>Jejunum</td>
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<td>Yes</td>
<td>No</td>
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<tr>
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<td>Yes</td>
<td>Jejunum</td>
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<td>Abdominal pain</td>
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</table>

MPD, main pancreatic duct.

1 Guidewire could advance the pancreatic duct stricture or anastomotic site, or not.

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**Fig. 3** Actual case presentation of endoscopic ultrasound (EUS)-guided pancreatic duct stent placement. 

a EUS showed a dilated pancreatic duct. 

b Pancreatogram showed obstruction of pancreatojejunalostomy and pancreatic duct stones. 

c A new 7-Fr plastic stent was placed into the pancreatic duct to the jejunum via the pancreatojejunalostomy.

d Endoscopic imaging of the proximal pigtail stent end. PD, pancreatic duct.
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