ORIGINAL ARTICLE

Endoscopic treatment of painful chronic pancreatitis: Evaluation of a new flexible multiperforated plastic stent

Traitement endoscopique de la pancréatite chronique douloureuse : évaluation d’une nouvelle prothèse plastique souple et multiperforée

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Summary

Objectives. — Endoscopic stents are a validated treatment for painful chronic calcifying pancreatitis (CCP). Biliary-type stents are the most commonly used, but have certain drawbacks. The aim of this single-center retrospective study was to evaluate the feasibility, and the short- and medium-term efficacy of a new pancreatic stent (Johlin® model, Cook®) for pain relief.

Methods. — Thirteen patients with painful CCP were treated with a Johlin® stent. Stent specifications were studied as well as feasibility and efficacy. Success was defined as relief of pain.

Results. — There was no placement failure with the initial stent, which was 13.4 ± 2.1 cm in length and 9.8 ± 0.6 Fr in diameter. Immediate total pain relief following stenting occurred in 11 patients. The average follow-up time was 11 ± 7 months (range 1.5—24 months). Stents were left in place for 4.5 ± 3 months (range 0.5—13.5 months). At the end of follow-up, endoscopic treatment was considered effective in 12 patients. Endoscopic retrograde cholangiopancreatographic (ERCP) complications consisted of uncomplicated acute pancreatitis (10%).

Conclusion. — Pancreatic stenting using the Johlin® stent (Cook®) is feasible, has no particular adverse events and is effective for immediate as well as medium-term pain improvement.

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Introduction

The pathogenesis of chronic pancreatitis remains uncertain, but is almost certainly multifactorial [1]. Pain is the main symptom during the initial period of documented chronic calcifying pancreatitis (CCP) [2]. Endoscopy is a validated therapeutic procedure in the management of patients with painful CCP, and up to two-thirds of patients improve with endoscopic duct decompression [3]. While immediate pain relief following pancreatic duct stenting in patients with CCP is excellent (around 81%), long-term success varies from 24 to 94% (with an average of about 61%) [4–9]. In a majority of studies, the stent is a polyethylene stent similar to those used for biliary obstruction. However, these biliary stents have certain drawbacks: the entire pancreatic duct is not intubated; they are essentially inflexible and they lack sideports. In an effort to improve the pancreatic stenting procedure, a new type of plastic stent was recently developed: the Johlin-JPWS® model (Cook®). This multiperforated stent is made of flexible plastic (pellethane) and has a tapered distal tip.

The objectives of this study were to evaluate the feasibility and the short- and medium-term efficacy of the Johlin-JPWS® stent for pain relief.

Materials and methods

Patients and definitions

All patients hospitalized in our unit for painful CCP with dilatation of the main pancreatic duct, induced by obstruction due to a stricture or obstructive stones and requiring endoscopic treatment for placement of a pancreatic stent, were included in the study. The retrospective study period was from June 2003 to September 2005. Patients with previous pancreatic surgical treatment were excluded, as were those with a diagnosis or possibility of pancreatic malignancy.

The diagnosis of CCP was based on the past medical history, typical symptoms and complementary morphological data—including CT scan, magnetic resonance imaging (MRI) and endoscopic retrograde pancreatography (ERP)—with evidence of pancreatic calcifications and typical duct irregularities. Efficacy was judged on the basis of pain relief and its evolution. The clinical criteria used were the World Health Organization (WHO) grading of analgesics required for total pain relief (level 1, level 2 or level 3 analgesics or no total pain relief), and the frequency of painful events (more than one episode per month was considered frequent). Endoscopic treatment was considered successful in cases of relief of pain (defined as a decrease in analgesic dosage or level) and/or reduction in the frequency of pain. Painful relapse was defined as an increase in analgesic dosage or WHO level after an initial improvement.

Endoscopic procedure and type of stent

The procedure was similar in all cases: pancreatic sphincterotomy was performed for newly treated patients following biliary sphincterotomy, if required. Stone removal with or without lithotripsy (sometimes after extracorporeal shockwave lithotripsy) was performed. Tight strictures were treated with balloon catheter dilatation, and a Soehendra® stent retriever was used as an alternative device for dilating difficult strictures. Following catheterization, a main pancreatic duct stent was inserted.

The type of stent was the new pancreatic Johlin-JPWS® stent (Cook®) (Fig. 1). This multiperforated stent is made of flexible plastic (pellethane) and has a tapered distal tip. Two diameters are available—8.5 and 10 Fr—with lengths ranging from 8 to 22 cm. These stents were routinely changed every 3 to 4 months when they first came into use.
but, recently, they are changed every 6 or 8 months, or earlier if pain relapse occurs. Stent withdrawal has been attempted in cases of total pain relief when no residual duct strictures or obstructive stones are seen on pancreatography.

Study protocol

Study entry was defined as the day of the first stenting procedure. The end of follow-up was defined as the last hospitalization or consultation at our unit. When such information was not available, the patient or treating physician was contacted by telephone. Data collected at study entry were age, gender, etiology of CCP, main symptom revealing the CCP, duration of CCP before study inclusion, and number and types of previous endoscopic treatment. Other data collected during the study entry were the time of first re-stenting and the end of follow-up. The following clinical data were also recorded: analgesic level required to control pain and frequency; alcohol consumption; weight; diarrhea; jaundice and pancreatic supplementation. Radiological and endoscopic data included the gross pancreatic appearance, parenchymal calcifications, main pancreatic duct stones, strictures or dilatations, pancreatic pseudocyst, biliary duct stenosis or dilatation, stent diameter and length, endoscopic suspicion of stent occlusion, other associated endoscopic treatments and complications due to ERP. Finally, data collected at the end of the follow-up included overall duration of follow-up, those lost to follow-up, death, endoscopic treatment success or not, total stent number and endoscopic treatment duration.

Statistical analysis

Continuous data are reported as means ± standard deviation with ranges in parentheses. The statistical software used was SPSS® for Windows®, version 11.5.1 (SPSS Inc., Chicago, IL, USA).

Results

Patients

A total of 61 patients underwent pancreatic stenting because of painful CCP during the study. Seventeen patients who had been initially treated with standard stents and thereafter with a Johlin® stent were excluded from the analysis because of a possible bias. One patient treated with a Johlin® stent was excluded due to a subsequent diagnosis of pancreatic adenocarcinoma. Thus, the final number of patients was 43, including 13 treated exclusively with a Johlin® stent, and 30 treated exclusively with the standard, biliary-type plastic stents. Frequency of painful events and level of analgesics required were similar across both groups of patients.

Demographic and disease characteristics at the time of study entry of the 13 patients are summarized in Table 1. The cause of pancreatitis was alcohol intake in seven patients, idiopathic in three, pancreas divisum in one, hereditary in one and cystic dystrophy in an aberrant pancreas in one. An associated endoscopic treatment was performed in three patients: pancreatic duct dilatation in one patient; mechanical lithotripsy in one patient and biliary stenting in one patient.

Initial stent placement

No placement failure was seen with the first stent. Immediate total pain relief following stent insertion occurred in 11 patients, with partial pain relief in two further patients. The stent was left in place for 5 ± 3 months (range 1.5—11 months). Only one patient had a painful relapse prior to the routine stent replacement. This relapse occurred 15 days after stent insertion. Of the 13 patients, two had an occluded stent at the time of stent replacement (including the sole patient with pain relapse), and none had stent migration.

Medium-term follow-up

The average time of follow-up was 11 ± 7 months (range 1.5—24 months). Clinical data—in particular, alcohol consumption and treatment with pancreatic supplements—did not significantly change during the follow-up. However, weight did significantly increase between the beginning and end of follow-up: +3.6 ± 5.4 kg (P = 0.04).

Success after each stent placement

During the follow-up period, 31 Johlin® stents were inserted, and only in one case pancreatic pain was not successfully improved, and this was a stent replacement. The 30 other stents improved pancreatic pain and were left in place for 4.5 ± 3 months (range 0.5—13.5 months). At the time of stent removal, five stents (16%) were obstructed and two (6%) had migrated. Endoscopic retrograde cholangiopancreatographic (ERCP) complications consisted of uncomplicated acute pancreatitis in three cases (10%).
Global success of the endoscopic treatment

Endoscopic treatment was considered ineffective in only one case: this patient is currently being treated with pancreatic stents, but requires level 3 analgesics as associated treatment. Among the 12 patients (92%) for whom endoscopic treatment was effective, one was lost to follow-up, one died of a nonpancreatic cause after 11 months of follow-up, and one had a definitive stent withdrawal after 12 months of treatment and three consecutive stent placements. At the end of follow-up, the nine other patients still required main pancreatic duct intubations in our unit.

Discussion

The major goal in the management of CCP is the treatment of pain. Mechanisms of pain remain incompletely understood, but are probably multifactorial and involve high pancreatic duct pressure of neurogenic origin [10,11]. Many studies have demonstrated the efficacy of endoscopic stents in improving pain [4–9,12]. Immediate pain relief has been observed, on average, in about 80% of patients, although the figure dropped to about 61% at a mean follow-up of around 30 months [4–9,12].

Our study analyzed the technical success, and early and mid-term efficacy with respect to pain relief, of a new plastic pancreatic stent (Johlin-JPWS® stent; Cook®). The results showed its feasibility and effectiveness for immediate and medium-term pain improvement. The feasibility of the initial stent insertion in our patients was similar to the highest rates reported in the literature, with no placement failures: 100% versus 96–99% [7,8]. Clinical efficacy of the initial endoscopic treatment was effective in all of our patients, which is also comparable to the best published series (70–94%) [6,8,9,12]. Clinical success rates at the end of the follow-up was 91% overall, with 92% for the Johlin® stent group on follow-up and 70–87% for the endoscopic stenting published series [6,12]. The fact that a single experienced operator performed both the initial treatment and the routine stent replacement before pain relapse in the majority of cases could explain the high technical success rate.

The retrospective design of our study does not allow for advanced statistical comparisons with those treated with the standard biliary stents. However, a few points may be discussed in relation to the technical advances of the Johlin® stent—namely, its use of a new material (pellethane), the multiperforated design and the tapered distal tip.

Deviere wrote in an editorial [13] that the ideal pancreatic stent would be without side holes, as they could reduce the duration of stent patency because of internal surface irregularities that promote adhesion and occlusion, as observed by Farnbacher et al. [14]. The Johlin® stent is made with pellethane, which is more flexible and smoother than polyethylene, so reducing surface irregularities. Furthermore, there is no flap in the device. Another potential advantage of the Johlin® stent is the possibility of draining the accessory ducts via lateral holes. Many studies have demonstrated altered pancreatic duct morphology following polyethylene stent therapy [15–17]. One hypothesis is that duct alterations lead to focal pancreatitis due to the exclusion of accessory ducts via lateral holes. Many studies have demonstrated that the material that clogs pancreatic stents is usually composed of albumin and its degradation products, whereas pancreatic juice is usually albumin-poor [14,18]. The authors suggest that the stents led to local inflammatory reactions to protein exudation and stent obstruction [14,18].

Table 1 Main characteristics of the study patients at inclusion. Caractéristiques principales des patients à l’inclusion.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All (n=43)</th>
<th>Johlin® stent (n=13)</th>
<th>Standard stent (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender (%)</td>
<td>81</td>
<td>77</td>
<td>83</td>
</tr>
<tr>
<td>Age (years)</td>
<td>51±12</td>
<td>58±12</td>
<td>47±11</td>
</tr>
<tr>
<td>Alcohol-related etiology (%)</td>
<td>55</td>
<td>50</td>
<td>57</td>
</tr>
<tr>
<td>Duration of chronic pancreatitis (years)</td>
<td>5±7</td>
<td>5±6</td>
<td>5±7</td>
</tr>
<tr>
<td>Previous endoscopic treatments (%)</td>
<td>28</td>
<td>15</td>
<td>33</td>
</tr>
<tr>
<td>Pancreatic sphincterotomy (%)</td>
<td>28</td>
<td>15</td>
<td>33</td>
</tr>
<tr>
<td>Stone extraction (%)</td>
<td>7</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Extracorporeal lithotripsy (%)</td>
<td>9</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Number of previous treatment sessions</td>
<td>1.6±0.8</td>
<td>1.5±0.7</td>
<td>1.6±0.8</td>
</tr>
<tr>
<td>Efficacy of class 1 or 2 analgesics (%)</td>
<td>77</td>
<td>69</td>
<td>80</td>
</tr>
<tr>
<td>Initial weight (kg)</td>
<td>62±12</td>
<td>68±14</td>
<td>60±10</td>
</tr>
<tr>
<td>Parenchymal calcifications (%)</td>
<td>71</td>
<td>55</td>
<td>77</td>
</tr>
<tr>
<td>Intraduct stones (%)</td>
<td>74</td>
<td>77</td>
<td>73</td>
</tr>
<tr>
<td>Duct stenosis (%)</td>
<td>44</td>
<td>39</td>
<td>47</td>
</tr>
<tr>
<td>Duct dilatation (%)</td>
<td>91</td>
<td>100</td>
<td>87</td>
</tr>
<tr>
<td>Pancreatic pseudocysts (%)</td>
<td>40</td>
<td>15</td>
<td>50</td>
</tr>
<tr>
<td>Common bile duct stenosis (%)</td>
<td>19</td>
<td>31</td>
<td>13</td>
</tr>
<tr>
<td>Stent length (cm)</td>
<td>8.8±3.5</td>
<td>13.4±2.1</td>
<td>6.8±1.5</td>
</tr>
<tr>
<td>Stent diameter (Fr)</td>
<td>8.6±1.6</td>
<td>9.8±0.6</td>
<td>8±1.6</td>
</tr>
<tr>
<td>Associated endoscopic treatment (%)</td>
<td>26</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Post-ERCP complications (%)</td>
<td>14</td>
<td>15</td>
<td>13</td>
</tr>
</tbody>
</table>
Lateral holes could decrease this inflammatory reaction by providing better drainage of the accessory ducts. The tapered distal tip could also improve the tolerability of the stent by allowing an easier progress through the main pancreatic duct during the ERP procedure, and may promote fewer microtraumas. In addition, the tapered tip, the flexibility of the stent and its length (8—22 cm) probably result in a more complete intubation of the main pancreatic duct and, thus, no accumulation of stones in the distal main duct above the stent.

Given the heterogeneous nature of the published reports that are retrospective and the frequent lack of a study protocol, it is difficult to compare results and determine the average lifetime of the stent. In our study, it was impossible to determine this duration because of the routine, scheduled stent replacements even when the patients were asymptomatic. Details concerning the duration to indwelling stents are lacking and, otherwise, there appears to be no consensus. Some studies advise routine stent replacement every 3 or 6 months with clinical follow-up [7,19,20] while others recommend changing the stent only in symptomatic patients [6,12], with similar clinical results. As a result of the present study, we have changed our standard practice as the rate of painful relapse appears to be reduced with the Johlin® stent and the risk of obstruction tends to be lower. As a consequence, it may be possible to reduce the frequency of stent replacements. In fact, we now schedule changing stents every 8 to 10 months, with no adverse events.

Conclusion

Pancreatic stenting using the Johlin® stent (Cook®) is feasible with no particular adverse events and is effective for immediate and medium-term pain relief. In the endoscopic management of painful CCP, the use of the Johlin® stent may permit less frequent stent replacements.

References