

Research Article

Initial Experience with Biodegradable Pancreatic Stents in the Prevention of Postoperative Pancreatic Fistula after Cephalic Pancreaticoduodenectomy

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Abstract

Background: Postoperative Pancreatic Fistula (POPF) remains the most important morbidity after pancreaticoduodenectomy. There is no consensual technique for pancreatic reconstruction and many surgeons use a transanastomotic drain. Currently, the stents used are not degradable and they can cause obstruction, stricture and pancreatitis. The use of biodegradable stents that disappear a few months after the intervention could have a role in the prevention of pancreaticojejunostomy complications. The aim of the study was to evaluate technical success of implantation and safety of newly available biodegradable stents in 16 patients undergoing cephalic duodenopancreatectomy.

Materials and Methods: A single-center prospective non-randomized study was conducted with patients undergoing PD. A total of 16 patients were included. A duct-to-mucosa end-to-side anastomosis was performed for the pancreaticojejunal anastomosis and the biodegradable stent (Archimedes) was placed from the pancreatic duct to the jejunum.

Results: One of the patients developed POPF, which was successfully treated with interventional radiology drainage and somatostatin analogues. Completed degradation occurred after 3 months in all cases. There was no mortality at 30 days after PD.

Conclusion: Based on our experience, the use of resorbable internal pancreatic prostheses could be a valid alternative to prevent POPF after a pancreaticoduodenectomy, also avoiding the main complications related to the use of non-absorbable prostheses.

Keywords: Pancreatic fistula; Pancreas surgery; Pancreaticoduodenectomy; Pancreaticojejunostomy; Pancreas cancer; Pancreas surgery; Pancreatic stent

Abbreviations

POPF: Post-Operative Pancreatic Fistula; PD: Pancreaticoduodenectomy

Introduction

Pancreaticoduodenectomy (PD) is a challenge for surgeons due to the high technical demand and morbidity rate (30-50% of patients develop one or more complications). One of the most frequent complications is Postoperative Pancreatic Fistula (POPF), present in up to one third of cases [1]. Today, there is no consensual technique for pancreatic reconstruction. In order to perform this anastomosis, many surgeons use a transanastomotic drain (pancreatic internal or external stent) that facilitates the pancreatic juice drainage and keeps the pancreatic remnant permeable [2,3]. Currently, the stents used are not degradable and when these do, not migrate and get eliminated, they can cause obstruction, stricture and pancreatitis. For this reason, the use of biodegradable stents that disappear a few months after the intervention could have a role in the prevention of pancreaticojejunostomy complications. Recently, new prostheses (Archimedes stent; Amg International GmbH, Winsen, Germany)

have been used in pancreatobiliary diseases to drain obstructed biliary and pancreatic ducts by endoscopy approach with promising outcomes [4,5]. The aim of the study was to evaluate technical success of implantation and safety of newly available pancreatobiliary biodegradable stents in 16 patients undergoing cephalic PD.

Materials and Methods

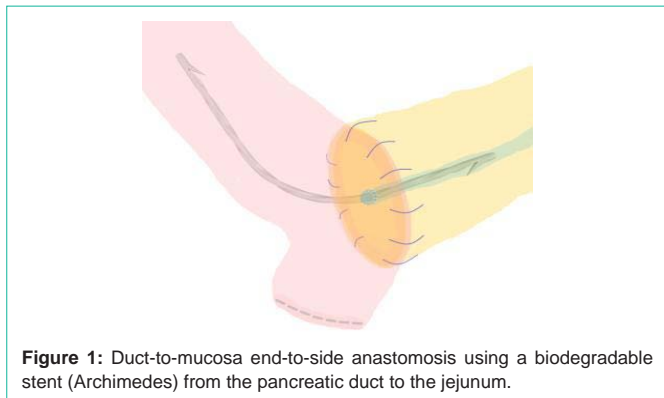
A single-center prospective non-randomized study was conducted with patients undergoing PD. Between May 2019 and December 2020, 16 patients were included in the study. The median age was 64 years and 93.8% were male patients. The main characteristics of the patients and pathology are summarized in (Table 1). A duct-to-mucosa end-to-side anastomosis was performed for the pancreaticojejunal anastomosis and the biodegradable stent (Archimedes) was placed from the pancreatic duct to the jejunum (Figure 1).

Archimedes stent

Archimedes biliary and pancreatic stents are biodegradable, polymeric prostheses with different degradation profiles. To meet different clinical needs, they have been designed to completely degrade via hydrolysis in approximately 12 days, 20 days or 11

Table 1: Patients Characteristics.

Patients characteristics	
Age	64 (IQR: 55-73.8)
Sex (male/female)	15/1 (93.8%/6.3%)
Body mass index (BMI)	22.2 (IR: 20.3-23.9)
Preoperative Ca 19.9 (U/ml)	22 (IR: 8-1.021)
Preoperative direct bilirubin (mg/dl)	4 (IR: 1-14)
Hospital stay (days)	10 (IR: 7-17)
Postoperative day 1 amilasa levels (UI/L)	306 (IR: 10-730)
Histology	
Pancreatic ductal adenocarcinoma	9 (56.3%)
Ampuloma	4 (25%)
Sarcoma	1 (6.3%)
Intrapancreatic mucinous neoplasm (IPMN)	1 (6.3%)
Chronic pancreatitis	1 (6.3%)

**Figure 1:** Duct-to-mucosa end-to-side anastomosis using a biodegradable stent (Archimedes) from the pancreatic duct to the jejunum.

weeks, depending on their composition (polymeric mixtures) and their helicoidal shape facilitates bile and pancreatic juice flow outer stent surface. We decided to use the slowest one (11 weeks), which is made of a blend of poly (lactide-co-caprolactone-co-trimethylene carbonate) and barium sulfate.

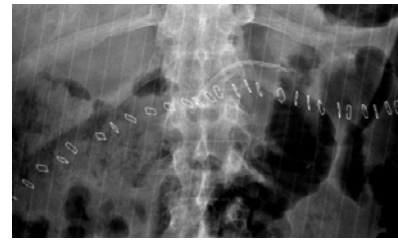
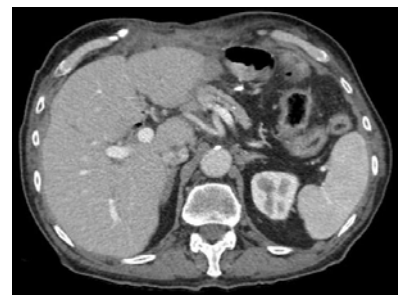
Outcomes and follow-up

The primary outcome of the study was the evaluation of the presence of POPF in the postoperative period. POPF was defined as drainage fluid amylase value of >5000U/L on the first day after surgery as it has been described by other groups [6].

The secondary outcome of the study was the evaluation of the position and degradation time of the stents. An abdominal radiograph was performed to assess well-positioning of the stent on postoperative day 7. To evaluate the degradation after three months we used the CT scan we perform by protocol as part of the follow up in patients who underwent PD. A complete degradation was defined as <25% of stent length or stent fragments visible at CT.

Results

One of the patients developed POPF in the postoperative period. In this case, the highest drain fluid amylase was 31157UI/L on postoperative day 7 and it was successfully treated with interventional radiology drainage and somatostatin analogues. There was no

**Figure 2:** Postoperative day 7 abdominal radiograph, which shows pancreatic stent.**Figure 3:** CT scan after 1 month. Biodegradable stent is well-positioned in the pancreaticojejunostomy.**Figure 4:** CT scan after 3 months with complete degradation of the stent. A small stent fragment remains (<25%) in the pancreatic duct.

mortality at 30 days after PD.

Evaluation of stent degradation was performed as described. An abdominal radiograph and a CT scan showed well-positioned stent on the postoperative first week and first month respectively (Figure 2 and 3). Completed degradation occurred after 3 months in all cases (Figure 4).

Discussion

POPF is possibly the most feared complication after a PD. Several pancreatic reconstruction techniques have been described in order to prevent POPF, with no current standardized method.

The two most widely accepted risk factors for its development are the presence of a soft pancreas and the small diameter of the pancreatic duct stump, suggesting that the integrity of the pancreaticojejunal anastomosis and its susceptibility to failure is of vital importance in preventing this complication.

The use of transanastomotic stents to facilitate drainage of pancreatic juice has been supported by several randomized prospective studies. Motoi et al. [7] found that the incidence of clinically significant pancreatic fistula decreased with the use of an external

pancreatic prosthesis. Pessaix et al. [8] evaluated the placement of an external prosthesis in high-risk patients and found that the incidence of pancreatic fistula was significantly reduced among prosthetic wearers, also associating significantly lower morbidity compared to the non-prosthetic group. However, the usefulness of pancreatic prostheses does not seem so clear according to other studies such as Kuroki et al. [3], who found no significant differences in the incidence of pancreatic fistula and the use of prostheses.

The prospective randomized controlled clinical trial conducted by Tani et al. [9] found no difference between the type of pancreatic prosthesis used (external or internal) in the overall incidence of postoperative complications, including pancreatic fistula (26% internal vs. 20% external, $p>0.05$).

Despite this controversy, in a more recent meta-analysis, Patel et al. [10] demonstrated that the placement of an external prosthesis in the pancreatic duct significantly reduces the incidence of pancreatic fistula and hospital stay. In theory, the use of externalized drains would prevent premature migration or occlusion (more frequent with internal prostheses), also allowing a more complete evacuation of pancreatic juice and preventing the activation of pancreatic enzymes by bile. Some of the main problems of their use are the greater loss of fluids (evacuation outside the pancreatic juice instead of the intestinal lumen, and consequent malabsorption), risk of peritonitis after their withdrawal and complications related to manipulation (torsion, obstruction, etc.).

The use of resorbable internal stents (like Archimedes stent) would allow combining the advantages of one type of drainage and the other: the pancreatic drainage would be maintained in the intestinal lumen and being resorbable in the short term would avoid complications related to its migration or obstruction. According to this theory, we started to use Archimedes stents in 2018 and, to our knowledge, this is the first study in which these prostheses are used in patients undergoing PD. In the present paper, high levels of amylase in ascites fluid were detected in only one patient. This patient developed POPF in the postoperative period and was successfully treated with interventional radiology drainage and somatostatin analogues. Likewise, there was no complication in relation to the prostheses and its correct position, and its disappearance was verified by abdominal radiograph and CT after 7 days, 1 and 3 months respectively (Figures 2, 3 and 4).

This study has some limitations. It is a non-randomized study with a small cohort of patients. These preliminary data suggest promising results, but future multicenter randomized studies are necessary to assess the efficacy of biodegradable stents.

Conclusion

Based on our experience, the use of resorbable internal pancreatic prostheses could be a valid alternative to prevent the development of pancreatic fistula after a pancreaticoduodenectomy, also avoiding the main complications related to the use of non-absorbable internal or external prostheses.

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