



Polysorb^R (an absorbable lactomer) staples, a safe closure technique for distal pancreatic resection

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Abstract

AIM: To investigate twenty-year experience evaluated the use of the Polysorb^R (an absorbable lactomer) staples for distal pancreatic resection.

METHODS: The data on 150 patients [92 men, 58 women, mean age 52 (24-72) years] who underwent distal pancreatectomy (DP) in the last 20 years were collected prospectively from an electronic database. The diagnosis was confirmed by endoscopic retrograde cholangiopancreatography, sonography, computed tomography and/or magnetic resonance imaging. The indications for DP were focal pancreatic necrosis, spontaneous pancreatic fistulas, abscesses, pseudocysts, segmental chronic obstructive pancreatitis in the tail, traumatic disruption, and benign (cystadenomas, insulinomas, or glucagonomas) or malignant tumours. The distal resections were performed without splenectomy in 29 of the 150 patients (19%). In the event of splenectomy, the splenic artery and vein were individually ligated, the TA-55 Auto Suture stapler, loaded with Premium Polysorb^R 55 staples (5.5 mm), was placed across the gland, and the trigger was pulled, the action of which produced two staggered absorbable suture lines. The gland distal to the stapler was

then amputated with a scalpel on the TA-55 stapler and the two rows of staples were left in the proximal pancreatic stump. After the distal resection, a drainage tube was inserted into the pancreatic bed.

RESULTS: The average duration of the operation was 150 min (range: 90-210 min) and no transfusion was indicated during the operation. After DP in one patient a type B fistula was diagnosed, which was treated successfully by conservative treatment comprising of 12-d octreotide medication (3 × 0.1 mg/d) and jejunal feeding. The incidence of postoperative pancreatic fistula was therefore 0.6%. Another 2 patients suffered postoperative pancreatitis, which was also conservatively treated. Reoperations were performed in 2 patients on the first or second postoperative day, necessitated by bleeding from the retroperitoneal region. The morbidity was 3.3% (5 patients), but no mortality occurred in the postoperative period. Overall, the postoperative period was uneventful without any complications (pancreatic fistula, abscess, bleeding or wound infection) in 145 patients. The length of the postoperative stay ranged between 8 and 16 d. For the 145 patients who had no any postoperative complications, the hospital stay was 8 or 9 d. No mortality occurred in the follow-up period (6 or 12 mo postoperatively); but 6 mo after surgery one patient suffered a pseudocyst following recurrent pancreatitis and was treated with cystojejunostomy.

CONCLUSION: Our clinical results demonstrated that the application of absorbable lactomer staples for distal pancreatic resection is a safe alternative to the standard closure technique.

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Key words: Distal pancreatic resection; Polysorb^R staples; Closure technique; Long-term experience; Pancreatic fistula

Core tip: The most common complication in distal pancreatectomy is the occurrence of a postoperative

pancreatic fistula (POPF). The fistula rate of 30% in the multicenter trial demonstrated that the currently applied techniques for closure of the pancreas remnant do not always lead to perfect results. Staples made from Polysorb^R, an absorbable lactomer, have been applied in our practice to reduce these complications. The incidence of POPF was 0.6%. Our clinical results demonstrated that the application of absorbable lactomer staples is a safe alternative to the standard closure technique and can be applied in all cases when distal pancreatic resection is indicated.

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INTRODUCTION

Left pancreatectomy is the standard operation for tumours located in the body and the tail of the pancreas and for selected patients with chronic pancreatitis. The indications for distal pancreatectomy (DP) include complications of acute pancreatitis and a traumatic injured pancreas. DP can be combined with a multivisceral approach to achieve a radical tumour resection; most commonly the stomach and the left-side colon are the adjacent organs removed during this procedure^[1]. Pancreatic surgery is technically challenging and requires a high level of experience. Today, low mortality and morbidity rates below 5% can be achieved in high-volume institutions^[2]. The most common complication in DP is the occurrence of a postoperative pancreatic fistula originating from the cut margin of the pancreatic remnant, which is reported with an incidence between 6% and 30%^[3,4]. The definition of a postoperative pancreatic fistula (POPF) has been standardized by the International Study Group on Pancreatic Fistula (ISGPF)^[5]. To avoid POPF development, safe closure of the pancreas is the crucial step of the operation. Procedures that have been recommended with a view to diminishing the risk of a pancreatic leak include direct duct ligation^[6], enteric drainage^[7,8], injection of prolamine or the use of fibrin glue^[9,10]. Among the techniques that have proved useful for management of the transected parenchyma is hand-sewn parenchymal closure^[11,12] with a coverage procedure applying the falciform ligament^[13] and the use of stainless steel staples with or without mesh reinforcement following transection of the parenchyma^[14,15]. Almost 10 years ago, our initial clinical experience with the application of absorbable copolymer lactomer staples made from Auto Suture Premium Polysorb^R 55 (Tyco Healthcare Group LP, Norwalk, CT, United States) for closure of the transected margin of the pancreas was published^[16] and we now summarize our 20-year experience with this safe closure

technique for DP.

MATERIALS AND METHODS

The data on 150 patients [92 men, 58 women, mean age 52 (24-72) years] who underwent DP in the last 20 years were collected prospectively from an electronic database. DP was followed by closure of the resection surfaces with absorbable lactomer clips. The diagnosis was confirmed by sonography, endoscopic retrograde cholangiopancreatography (ERCP), computed tomography (CT) and/or magnetic resonance imaging (MRI). The indications for DP (with or without splenectomy) were spontaneous pancreatic fistulas, pseudocysts, abscesses, traumatic disruption, focal pancreatic necrosis, segmental chronic obstructive pancreatitis in the tail, and benign (insulinomas, glucagonomas or cystadenomas,) or malignant tumours (Table 1).

The operating procedure was as follows: after division of the gastrocolic ligament with visualization of the pancreas, the spleen was removed and the distal pancreas was mobilized. If the spleen could be saved, it was left in place and the distal pancreas was prepared along the splenic artery and vein. The distal resections were performed without splenectomy in 29 of the 150 patients (19%). In the event of splenectomy, the splenic artery and vein were individually ligated, the TA-55 Auto Suture stapler, loaded with Premium Polysorb^R 55 staples (5.5 mm), was placed across the gland, and the trigger was pulled, its action producing two staggered absorbable suture lines. The gland distal to the stapler was then amputated with a scalpel on the TA-55 stapler and the two rows of staples were left in the proximal pancreatic stump. There was generally no bleeding on the resection surface; if it is observed, a suture of no. 3/0 Vicryl^R (Ethicon) may be used to oversee these bleeding points and the suture lines. No patients participated in the hand-sewn method in our clinical work, but if the ERCP proved stenosis, obstruction of the papilla Vateri or a dilated main duct of the pancreas, or in the event of a bulky tail of the pancreas with a dilated pancreatic duct or stenotic papilla Vateri, a bypass operation (pancreato-jejunostomy) was used. In patients with firm pancreatic tissue, the stapler was also applied successfully without any complications. After the distal resection, a drainage tube was inserted into the pancreatic bed. The drain was removed after postoperative day 4 or 5, depending on the amylase activity assessed in the drain fluid and the quantity of the fluid discharge. In accordance with the ISGPF definition, a pancreatic fistula was defined as an amylase content > 3 times the upper normal serum value in the drain fluid on or after postoperative day 3 (normal serum value 100 U/L in our laboratory). The fistula type was defined according to the ISGPF classification^[5]. The ISGPF criterion was also adopted for patients who were operated on before 2005. The prospective data on these patients are available in our computer database.

Before the operation, prophylactic antibiotic (ceftriaxone, 2 g, *z.z.*) was administered and in the early postopera-

Table 1 Pathology

Diagnosis	n (%)
Focal pancreatic necrosis	9 (5)
Spontaneous pancreatic fistulas	10 (6)
Abscess in the tail	12 (8)
Pseudocyst	22 (15)
Traumatic disruption	3 (2)
Segmental chronic obstructive pancreatitis	22 (15)
Cystadenoma	18 (12)
Insulinoma	7 (5)
Glucagonoma	2 (1)
Adenocarcinoma	39 (26)
Connected with total gastrectomy or left side colectomy	4 (3)
	2 (1)

Table 2 Intra- and post-operative patient factors n (%)

Median operation time	150 min
Pancreas tissue texture	
Soft	75 (50)
Hard	66 (44)
Not assessed	9 (6)
Additional organ resection	
Splenectomy	121 (81)
Total gastrectomy	4 (3)
Left colon resection	2 (1)
Re-operation	2 (1)
POPF Grade B	1 (0.6)
Morbidity	5 (3.3)
Mortality	0
Median hospital stay	9 d

tive period all of the patients received standard supportive treatment, consisting of total parenteral nutrition for 4 d, a proton pump antagonist (pantoprazole), suppression of TNF synthesis (pentoxifylline) and octreotide medication ($3 \times 0.1 \text{ mg/d}$)^[17]. Oral nutrition was started 5 d after surgery.

RESULTS

The average duration of the operation was 150 min (range 90-210 min) and no transfusion was indicated during the operation. The median drain discharge on postoperative day 1 was 50 mL (range: 30-90), but had fallen by postoperative day 4 to 20 mL (range: 10-30). The amylase concentrations on postoperative days 1 and 4 were $450 \pm 120 \text{ U/L}$ and $140 \pm 90 \text{ U/L}$, respectively. Five days after the surgery the drainage tube was usually removed. No ISGPF type A fistula developed in any of the operated patients at all, but in one case, an ISGPF type B fistula was diagnosed, which was treated successfully by conservative treatment comprising 12-d octreotide medication ($3 \times 0.1 \text{ mg/d}$) and jejunal feeding. The incidence of POPF was therefore 0.6%. Another 2 patients suffered postoperative pancreatitis, which was also conservatively treated. Reoperations were performed in 2 patients on the first or second postoperative day, necessitated by bleeding from the retroperitoneal region. The morbidity was 3.3% (5 patients), but no mortality occurred in the postoperative period. There were no postoperative complications (no bleeding, wound infection, abscess or pancreatic fistula) in 145 cases. The duration of postoperative hospitalization varied from 8 to 16 d. For the 145 patients who had no postoperative complications, the hospital stay was 8 or 9 d. All of the patients were followed up for one year postoperatively. During this period, no patients died, but 6 mo after surgery one patient suffered a pseudocyst following recurrent pancreatitis and was treated with cystojejunostomy. In the follow-up period, 18 of the 150 patients displayed new-onset insulin-dependent diabetes (Table 2).

DISCUSSION

There have been a marked improvement in the past few

years as concerns the clinical results after pancreatic surgery, the postoperative levels of morbidity and mortality having fallen appreciably^[2,18,19]. Nevertheless, POPF is still a relatively frequent and clinically significant finding after DP, its incidence having been reported in the range between 6% and 30%^[4,20]. Moreover, POPF may be accompanied by intraabdominal abscesses, sepsis, pancreatic fluid collection and wound infection^[21]. It is well known that advanced age, an inadequate poor nutritional status, a high BMI, duct obstruction and soft pancreatic tissue are risk factors for POPF^[22,23]. The surgical management of the pancreas stump is crucial, and various operative modifications have therefore been introduced in efforts to prevent POPF, though without conclusive results. No significant differences were observed between the most common procedures of suture closure and stapling with stainless steel staples with respect to the POPF or intraabdominal abscess after DP^[24], and a further meta-analysis confirmed this^[25]. The recent DISPACT trial found no evidence that stapler closure was superior to manual suturing. The 30% fistula rate revealed by this multicenter trial demonstrated that the currently applied techniques for closure of the pancreas remnant do not always lead to perfect results. There is therefore a need for new approaches, among them new operative procedures, with a view to decreasing the rate of POPF^[26]. The meta-analysis by Jensen *et al.*^[27] of bioabsorbable staple line reinforcement and the risk of fistula following DP concluded that reinforced staples may be a preferred method of pancreatic stump closure following DP, reducing the fistula rate to 17%. Our present study, on 150 patients, evaluated a simple and safe closure technique for DP with the use of Polysorb^R staples (Auto Suture), and indicated a morbidity of 3.3% and a POPF incidence of 0.6%.

Cartridges of Polysorb^R, an absorbable lactomer copolymer of glycolic acid and lactic acid, are commercially available^[28]. Following insertion, these copolymer staples undergo slow hydrolysis, involving progressive depolymerisation and metabolization to carbon dioxide and water. Their break-down begins around 2 wk postoperatively and then are fully absorbed by 6 to 8 wk with no inflammatory reactions^[29,30]. These results were confirmed

by our experimental work on DP in an animal model (mongrel dogs). Four weeks after operation, no fistula and no abscess formation was noted and histologically the clips were gradually absorbed with no reaction^[31]. Following first successful use in gynaecology^[32] absorbable lactomer staples were utilized after left pancreatectomy in 32 patients: only minimal complications were reported^[33]. Absorbable lactomer staples have similarly proved effective for skin graft stapling in burn patients^[34].

We have made use of such staples in 150 patients with various indications for DP (with or without splenectomy): spontaneous pancreatic fistulas, pseudocysts, abscesses, traumatic disruption, focal pancreatic necrosis, segmental chronic obstructive pancreatitis in the tail, and benign (insulinomas, glucagonomas or cystadenomas,) or malignant tumours and multivisceral resection following DP. The inclusion criteria and operative data correspondent closely to those in published series. The median age, the sex distribution and the splenectomy rate were balanced, but the median operation time, the morbidity and mortality, the rate of POPF and the median hospital stay confirmed significantly better results than those of other large series^[11,12,35]. Our good clinical results may be ascribed to the facts that the staples applied are absorbable, larger than metallic ones and correctly close the resected surface. ERCP and CT are essential preoperatively to check on the normal flow of pancreatic juice through the Vater papilla, should the pancreatic duct prove abnormal (stenotic, irregular or dilated) or if the whole gland is involved by hard calcified pancreatitis, only pancreaticojejunostomy is indicated after DP.

Our results allow the conclusion that absorbable lactomer staples may safely be applied to close the transected margin of the pancreas in all cases when DP is indicated for benign or malignant disorders, or a traumatically injured pancreatic gland. 150 operated patients appears to be a reasonably acceptable number as concerns confirmation of the effectiveness of this surgical method. However, for verification of our clinical results, a multicentre randomized study is clearly needed.

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COMMENTS

Background

Left pancreatectomy is the standard operation not only for tumours located in the body and the tail of the pancreas, but also for selected patients with chronic pancreatitis. The indications for distal pancreatectomy include complications of acute pancreatitis and a traumatic injured pancreas. The most common complication in distal pancreatectomy is a postoperative pancreatic fistula. The fistula rate of 30% in the multicentre trial demonstrated that the currently applied techniques for closure of the pancreas remnant do not always lead to perfect results.

Research frontiers

The definition of a postoperative pancreatic fistula (POPF) has been standardized by the International Study Group on Pancreatic Fistula (ISGPF). To avoid POPF development, safe closure of the pancreas is the crucial step of the op-

eration. The success achieved with absorbable lactomer staples in gynaecology was followed by their use to close the pancreatic remnant after left pancreatectomy, only minimal complications arising.

Innovations and breakthroughs

The authors have utilized absorbable lactomer staples for DP in 150 cases with indications of spontaneous pancreatic fistulas, pseudocysts, abscesses, traumatic disruption, focal pancreatic necrosis, segmental chronic obstructive pancreatitis in the tail, and benign (insulinomas, glucagonomas or cystadenomas,) or malignant tumours.

Applications

This study demonstrated that the incidence of POPF was 0.6% and the application of absorbable lactomer staples is therefore a safe alternative to the standard closure technique in all cases when distal pancreatic resection is indicated.

Terminology

In accordance with the ISGPF definition, a POPF represents a healing/sealing failure of a pancreatic-enteric anastomosis or a parenchymal leak not directly related to an anastomosis. Absorbable lactomer staples are made from a copolymer of glycolic acid and lactic acid, which undergoes slow hydrolysis after application with progressive depolymerization and metabolization to carbon dioxide and water.

Peer review

This is an important study showing experience of using Polysorb staples for closing the distal stump after pancreatic resection. Regarding the consistency of the pancreas, which did not change the option to use the technique. One criticism is that the indications for pancreatectomy are very varied, which has relation with the risk of fistula.

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