ORIGINAL ARTICLE

In Situ vs Ex Situ Pancreatic Duct Stents of Duct-to-Mucosa Pancreaticojejunostomy After Pancreaticoduodenectomy With Billroth I–Type Reconstruction

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Background: Pancreatic fistula is a leading cause of morbidity and mortality after pancreaticoduodenectomy, and an external stent of pancreaticojejunostomy has been recommended to prevent pancreatic fistula.

Hypothesis: Duct-to-mucosa pancreaticojejunostomy should not require placement of an external stent.

Design: Nonrandomized control study.

Setting: University hospital.

Patients: Seventy-four patients undergoing pancreaticoduodenectomy with duct-to-mucosa pancreaticojejunostomy were allocated to either the ex situ group (external pancreatic stent drainage) or the in situ group (no external drainage).

Main Outcome Measures: Operative mortality; postoperative complications, particularly pancreatic fistula; and patency of duct-to-mucosa pancreaticojejunostomy.

Results: Preoperative factors, indicated disorders, and intraoperative factors were similar for both groups. Mortality rates were 1% (1/74) overall, 3% (1 death) for the in situ group, and 0% for the ex situ group. Morbidity rates were 32% (12/37) for the in situ group and 35% (13/37) for the ex situ group. The incidence of pancreatic fistula was 5.4% and was the same for the in situ and ex situ groups. The incidence of delayed gastric emptying was similar for the in situ (19% [7/37]) and ex situ (14% [5/37]) groups. Ampullary tumors and pancreatic ducts 2 mm or less in diameter had a higher incidence of pancreatic fistula, but the incidence was similar in both treatment groups. Nasogastric tube drainage day, the median hospital stay, and pancreaticojejunostomy patency were similar in both groups.

Conclusions: The results were considered to show equivalent outcomes for ex situ and in situ pancreatic stenting of the duct-to-mucosa pancreaticojejunostomy after pancreaticoduodenectomy. The use of transanastomotic stents has to be selective according to the individual characteristics of each patient. We recommend their use with ampullary tumors or small ducts (≤2 mm).

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PANCREATICODUODENECTOMY (PD) has been used increasingly in recent years as a safe method of resection in selected patients with malignant and benign disorders of the pancreas and periampullary region. Despite a marked reduction in the mortality rate, the incidence of postoperative morbidity can approach 50%.[1,2] One common postoperative complication is leakage of the pancreaticoenteric anastomosis, the incidence of which ranges from 2.5% to 25%.[1-5] Such leakage, with subsequent delayed gastric emptying, intra-abdominal abscess, sepsis, and bleeding, remains the major cause of complications and death.[1-5]

Although numerous surgical techniques have been described to avoid such complications, no consensus has been reached regarding the pancreaticoenteric anastomosis that is safest and least prone to fistula formation. Some studies recommend temporary external stented drainage of the pancreatic juice with a polyvinyl chloride tube to protect against pancreatic fistula.[6,7] On the other hand, some achieved a low incidence of pancreaticojejunostomy without use of external stented drainage of the pancreatic duct.[1,8-10] Our group has also achieved less frequent pancreatic leakage by duct-to-mucosa pancreaticojejunostomy with temporary external stented drainage of the pancreatic duct with a polyvinyl chloride tube.[11] Theoretically, however, duct-to-mucosa pancreaticojejunostomy should not require temporary external stented drainage of the pancreatic duct. The present study tested the hypothesis that temporary external

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Table 1. Patient Characteristics and Preoperative Factors

	Pancreatic Stent		
	In Situ (n = 37)	Ex Situ (n = 37)	*P* Value
Age, y			
Mean ± SEM	63 ± 10	62 ± 12	.92
Range	42-78	32-79	
Sex, No. (%)			
Male	23 (62.2)	21 (56.8)	.47
Female	14 (37.8)	16 (43.2)	
Preoperative factors, No. (%)			
Previous abdominal surgery			
Absent	0	0	>.99
Diabetes mellitus			
Absent	9 (24.3)	10 (27.0)	>.99
Present	27 (73.0)	27 (73.0)	
Disorders, No. (%)			
Carcinoma of the head of the pancreas	11 (29.7)	8 (21.6)	.90
Carcinoma of the bile duct	13 (35.1)	15 (40.5)	
Ampullary/duodenal tumor	13 (35.1)	12 (32.4)	
Chronic pancreatitis	0	2 (5.4)	

Table 2. Operative Factors

	Pancreatic Stent, No. (%)		*P* Value
	In Situ	Ex Situ	
Pancreaticoduodenectomy			
Standard	24 (67)	22 (59)	.81
Pylorus preserving	13 (36)	15 (41)	
Lymph node dissection			
Standard	12 (33)	15 (41)	.63
Radical	25 (69)	22 (59)	
Portal vein resection	8 (22)	5 (14)	.54
Diameter of pancreatic duct, mm			
≤2.0	14 (39)	13 (35)	.50
2.1-4.9	15 (42)	15 (41)	
≥5.0	8 (22)	9 (24)	
Operative time and blood loss, mean ± SEM			
Operative time, min	485 ± 91	512 ± 101	.42
Blood loss, mL	1362 ± 705	1303 ± 637	.90

stented drainage of the pancreatic duct is unnecessary in duct-to-mucosa pancreaticojejunostomy after pancreaticoduodenectomy.

METHODS

A consecutive series of 74 patients underwent PD or pylorus-preserving PD with duct-to-mucosa pancreaticojejunostomy using a continuous running suture and a Billroth I–type reconstruction between April 1997 and April 2000; patients were randomly allocated to the 2 groups of external or internal stented drainage of the pancreatic duct. External stented drainage using the polyvinyl chloride tube was used in 37 of 74 patients (ex situ group), while external stented drainage of pancreatic juice was omitted in the remaining 37 patients (in situ group). Appropriate written informed consent was obtained for each patient. The patients ranged in age from 32 to 79 years; the mean±SEM/age was 62±12 years (range, 32-79 years) in the ex situ group and 63±10 years (range, 42-78 years) in the in situ group. The in situ and ex situ groups were comparable in terms of preoperative factors and the distribution of disease (**Table 1**).

The surgical procedure was described elsewhere.[11] We performed a Billroth I–type reconstruction, which entailed duodenoduodenostomy or duodenojejunostomy followed by pancreaticojejunostomy and biliary anastomosis. Pancreaticojejunostomy was conducted in end-to-side anastomosis with the use of 2 layers including duct-to-mucosa and the pancreatic parenchyma and the jejunal seromuscular layer. A 4F (1.31-mm external diameter) polyvinyl chloride tube (Sumitomo Bakelite Co, Ltd, Tokyo, Japan) was inserted into the pancreatic duct as an external stented drainage tube and fixed with sutures to the pancreatic duct. The stent tube was guided externally through the jejunal loop and biliojejunal anastomosis, and traversed the intrahepatic biliary duct, the liver parenchyma, and the abdominal wall (ex situ group). Otherwise, the stent was cut short and left in situ (in situ group) and was not fixed with sutures to the pancreatic duct or the pancreas. A tube gastrostomy was not created. The anastomotic areas of both the pancreaticojejunostomy and biliary anastomosis were drained separately with open drains.

Antibiotics were used prophylactically for 3 consecutive days before and after surgery. Intravenous hyperalimentation was administered after surgery until the patients could eat satisfactorily. The nasogastric (NG) tube was removed when the daily drainage volume was less than 200 mL on 2 consecutive days. An oral diet was resumed 2 or 3 days after NG tube removal. Wound drains were removed within 7 days after surgery when drainage was clear. Delayed gastric emptying was defined according to the criteria of Yeo and colleagues[12] as (1) NG tube left in place for 10 or more days, (2) emesis after NG tube removal, (3) reinsertion of NG tube, or (4) failure to progress with diet. The external stented drainage tube was removed 8 weeks after surgery in the outpatient clinic. The synthetic peptide octreotide acetate (Sandostatin; Novartis Pharma, Nuremberg, Germany), the first somatostatin analogue introduced for clinical use, was not used prophylactically; however, some patients with pancreatic fistula received octreotide acetate (100 µg 3 times a day).

The diameter of the pancreatic duct was measured from endoscopic retrograde cholangiopancreaticographic films or abdominal ultrasound scans. Postoperative pancreatic fistula was diagnosed from local findings, ie, skin excoriation around the drain site, and was defined as a high concentration of amylase, ie, more than 3 times the serum concentration in drainage fluid or leakage demonstration on fistulography or computed tomography. Bilioenteric anastomotic leakage was documented by radiograms. The end points were operative mortality; postoperative complications, particularly pancreatic fistula; and duct-to-mucosa pancreaticojejunostomy patency. The patency was examined by magnetic resonance imaging 1 year after surgery.

Data are presented as the mean±SEM. Statistical analysis was performed with the program StatView J-5.0 (SAS Institute Inc, Cary, NC). The χ^2, Fisher exact, and Mann-Whitney tests were used. A *P* value less than .05 was considered statistically significant.

RESULTS

Intraoperative factors such as the rate of standard or pylorus-preserving PD, the extent of lymph node dissection, the rate of portal vein resection, pancreatic duct diameter, operation time, and blood loss were similar for both groups (**Table 2**).

There was 1 death (3%) in the in situ group and none in the ex situ group. The overall mortality rate was 1%

(1/74). The morbidity rate was 32% (12/37) for the in situ group and 35% (13/37) for the ex situ group, and the overall morbidity rate was 34% (25/74). The overall incidence of pancreatic fistula was 5% (4/74). The incidence of pancreatic fistula was 5% and was the same for the in situ and ex situ (5.4%) groups. Delayed gastric emptying was observed in 12 patients (16%) overall, excluding the patients with pancreatic fistula; the incidence was similar for the in situ (19% [7/37]) and ex situ (14% [5/37]) groups. The incidence of delayed gastric emptying was higher in pylorus-preserving PD than in standard PD (36% [10/28] vs 4% [2/46]), but was similar in pylorus-preserving PD for the in situ (38% [5/13]) and ex situ (33% [5/15]) groups. Minor biliary anastomotic leakage occurred in 1 patient in the in situ group and healed spontaneously without reoperation. Intra-abdominal hemorrhage and abscess were seen in 1 patient each in both groups. One patient in each group required reoperation. Reoperation in one patient was for intra-abdominal hemorrhage due to pancreatic fistula and in the other was for portal vein thrombosis (**Table 3**). Upper gastrointestinal tract hemorrhage or anastomotic marginal ulcer was not observed.

The mean duration of the NG drainage was not significantly different between the in situ and ex situ groups. The mean length of postoperative hospital stay was also similar in both groups. The mean time to removal of the biliary and pancreatic stents was 28±7 postoperative days in the ex situ group. Patients with anastomotic leakage had longer duration of the NG tube drainage, as well as later resumption of oral intake, longer postoperative hospital stay, and later removal of the pancreatic stents. Two patients (5%) experienced localized peritonitis after removal of the external stent tube in the ex situ group, whereas the pancreatic duct stents in the in situ group spontaneously dropped out within 1 month. The duct-to-mucosa pancreaticojejunostomy was patent in all patients regardless of pancreatic duct stents. An anastomotic stricture was seen in 1 patient in the ex situ group who had repeated alcholic pancreatitis (**Table 4**).

The overall incidence of pancreatic fistula was 5% (1/19) in pancreatic cancer, 4% (1/28) in bile duct cancer, and 8% (2/25) in ampullary tumor. The incidence of pancreatic fistula in ampullary tumor was a little bit higher compared with other disorders, but the incidence was the same for the in situ (8%) and ex situ (8%) groups. No pancreatic fistula was observed in patients with gallbladder cancer, gastric cancer, colon cancer, or chronic pancreatitis (**Table 5**).

The incidence of pancreatic fistula when the pancreatic duct diameter was less than or equal to 2.0 mm and 2.1 to 4.9 mm was 11% (3/27) and 3% (1/30), respectively. The incidence of pancreatic fistula was higher in the in situ group (14% [2/14]) than in the ex situ group (8% [1/13]) in patients with a pancreatic duct of 2.0 mm or less. No pancreatic fistula was seen in patients with pancreatic ducts 5.0 mm wide or larger (**Table 6**).

Table 3. Postoperative Courses and Pancreaticojejunostomy Patency*

	In Situ (n = 37)	Ex Situ (n = 37)	*P* Value
NG drainage day, mean ± SEM			
PD	6.0 ± 1.6	4.0 ± 1.1	.96
PPPD	6.0 ± 1.5	3.7 ± 1.5	
Hospital stay, mean ± SEM, POD			
PD	34 ± 11	32 ± 9.4	.91
PPPD	42 ± 12	40 ± 12	
Removal of the stent, mean ± SEM, POD	. . .	28 ± 7	. . .
Stent tube trouble, No.	0	2	.49
Pancreaticojejunostomy, No.			
Patency >1 y after surgery	37	37	>.99
Stricture	0	1	>.99

*Excluding the patients with pancreatic leaks or delayed gastric emptying. Patients with anastomotic leakage had longer duration of nasogastric (NG) tube drainage, resumed oral intake later, had longer postoperative hospital stay, and had later removal of the biliary and pancreatic stents. PD indicates pancreaticoduodenectomy; PPPD, pylorus-preserving PD; and POD, postoperative day.

COMMENT

This study determined that the morbidity (particularly pancreatic fistula), mortality, NG drainage days, hospital stay, and duct-to-mucosa pancreaticojejunostomy patency in the group that received in situ pancreatic duct stents were comparable with those in the ex situ group. In situ and ex situ pancreatic stenting of the duct-to-mucosa pancraticojejunostomy were equivalent options. Although the present study was not a definitive prospective randomized controlled trial, it is important to note that the pancreaticojejunostomy and reconstruction performed in this study used the single method of a Billroth I–type reconstruction with duct-to-mucosal pancreaticojejunostomy with the use of a continuous running suture, thereby indicating no outcome advantage for either group.[11] The data in the present study showed that duct-to-mucosa pancreaticojejunostomy may not require temporary external stented drainage of the pancreatic duct after pancreaticoduodenectomy, and in situ stents are adequate. The use of transanastomotic stents in duct-to-mucosa pancreaticojejunostomy should be selective, according to the individual characteristics of each patient.

There is no agreement as to the best reconstruction method of pancreaticojejunostomy, and many variations of the procedure have been reported,[3-10] including orientation (end vs side), the type of anastomosis (invagination vs duct-to-mucosa), the use of isolated Roux-en-Y limbs, and the use of pancreatic duct stenting (external vs internal drainage and complete drainage of pancreatic juice vs incomplete). Stenting of the pancreatic duct after pancreaticoduodenectomy has been evaluated by several other authors. Some have observed lower rates of fistulas and death with external stented drainage of the pancreatic duct.[13-17] A previous prospective observational study showed that temporary stenting and external drainage of the pancreatic duct reduced the rate of pancreatic leakage.[7] That study, however, can be criticized for using 3 different methods of pancreaticojejunostomy: end-to-side invagination anastomosis, end-to-side anastomosis, and duct-to-mucosa anastomosis. Duct-to-mucosa anastomosis is less prone to pancreatic fistula,[6,18,19] and the incidence of pancreatic fistula has

Table 4. Postoperative Mortality and Morbidity*

	Total, No. (%)	Pancreatic Stent, No. (%)		*P* Value
		In Situ	Ex Situ	
Mortality	**1** (1.4)	1(2.7)	0	>.99
Morbidity	**25** (33.8)	12 (32.4)	13 (35.1)	.81
DGE	**12** (16.2)	7 (18.9)	5 (13.5)	
PD	**2** (4.3)	2 (8.3)	0	.54
PPPD	**10** (35.7)	5 (38.5)	5 (33.3)	
Pancreatic leakage	**4** (5.4)	2 (5.4)	2 (5.4)	
PD	**2** (4.3)	1 (4.2)	1 (4.5)	>.99
PPPD	**2** (7.1)	1 (7.7)	1 (6.7)	
Lethal leakage	**1** (1.4)	1 (2.7)	0	>.99
Bile leakage	**1** (1.4)	1 (2.7)	0	>.99
Repeat laparotomy	**3** (4.1)	1 (2.7)	2 (5.4)	>.99
Hemorrhage	**2** (2.7)	1 (2.7)	1 (2.7)	>.99
Abscess	**2** (2.7)	1 (2.7)	1 (2.7)	>.99
Ascites	**1** (1.4)	0	1 (2.7)	>.99
Portal vein thrombosis	**1** (1.4)	0	1 (2.7)	>.99
Tube trouble	**2** (5.4)	0	2 (5.4)	.49

*DGE indicates delayed gastric emptying; PD, pancreaticoduodenectomy; and PPPD, pylorus-preserving PD.

Table 5. Pancreatic Fistula in Relation to Underlying Disorders

Disorders	No./Total (%)	Pancreatic Stent, No. (%)		*P* Value
		In Situ	Ex Situ	
Carcinoma of the head of the pancreas	**1/19** (5.3)	1/11 (9.1)	0/8	.89
Carcinoma of the bile duct	**1/28** (3.6)	0/13	1/15 (6.7)	
Ampullary/duodenal tumor	**2/25** (8.0)	1/13 (7.7)	1/12 (8.3)	
Chronic pancreatitis	**0/2**	0/0	0/2	

Table 6. Pancreatic Fistula in Relation to Diameter of Pancreatic Duct

Pancreatic Duct Diameter, mm	No./ Total (%)	Pancreatic Stent, No. (%)		*P* Value
		In Situ	Ex Situ	
≤2.0	**3/27** (11.1)	2/14 (14.2)	1/13 (7.7)	.22
2.1-4.9	**1/30** (3.4)	0/15	1/15 (6.7)	
≥5.0	**0/17**	0/8	0/9	

also been reported to be lower (10%) than with other methods.[7] On the other hand, some investigators[1,8-10] have achieved a low incidence of pancreaticojejunostomy without use of external stented drainage of the pancreatic duct and have seen no advantages of stented pancreatectomy; some[20,21] have warned of the potential dangers associated with the use of a stent. The results of this study concur with the latter. However, to confirm the data of the present study, a prospective randomized controlled trial must be performed with 3 treatment groups: ex situ, in situ, and a group with no stenting of the duct.

A prospective randomized experimental study,[22] comparing stent-in, stent-out, and no-stent groups, showed that the use of internal stenting had lower rates of leak, occlusion, and stenosis and better patency of pancreaticoenteric anastomoses. However, proponents of complete external drainage of pancreatic juice during healing have noted some potential advantages.[23-25] First, complete drainage might prevent activation of pancreatic enzymes by bile soon after surgery. However, creation of a Roux-en-Y loop for the pancreatic anastomoses, which diverts pancreatic juice far away from the rest of the anastomosis, is the only method to prevent activation of the pancreatic enzyme. Second, the stent tube may decompress the denervated jejunal segment. Third, stenting of the pancreatic duct may allow more precise placement of sutures, thus protecting the pancreatic duct from suture injury and reducing the risk of iatrogenic pancreatic duct occlusion. We used a 4F (1.31 mm in external diameter) tube, a smaller diameter than the pancreatic duct, and did not aim to completely drain pancreatic juice. Otherwise, the stent was cut short and left in situ (in situ group). The third advantage is present in both the in situ and ex situ groups of pancreatic duct stents despite loss of the first 2 advantages. The results of this study suggest that preventing the activation of pancreatic enzymes and decompression of the denervated jejunal segment may not be important factors in preventing pancreatic fistula. Furthermore, patency of duct-to-mucosa pancreaticojejunostomy was good, and the incidence of stricture of the anastomosis was low.

Factors significantly increasing the risk of pancreatic fistula are ampullary or duodenal disease, soft pancreatic texture, and lower surgical volume.[3,5,6,8,26] The overall incidence of pancreatic fistula in ampullary tumor was a little bit high (8%) compared with other diseases, whereas the incidence was similar for the in situ and the ex situ groups. Furthermore, the incidence of pancreatic fistula

tended to be higher for the in situ group (14%) compared with the ex situ group (8%) in patients with a pancreatic duct diameter of less than 2.0 mm. Another strategy must be proposed as a means of reducing the incidence of pancreatic fistula after pancreaticoduodenectomy for ampullary or duodenal tumors with a pancreatic duct diameter of 2.0 mm or less. Our results indicate that ex situ and in situ pancreatic stenting of duct-to-mucosa pancraticojejunostomy are equivalent options. The use of transanastomotic stents should be selective according to the individual characteristics of each patient.

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