

ORIGINAL**No-touch pylorus-resecting pancreatoduodenectomy can reduce postoperative complications even in low volume center**

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Abstract : Purposes : Pancreatoduodenectomy (PD) was performed for 6 periampullary cancer patients by using methods verified by quality randomized controlled trials (RCT) in a low-volume center (LVC). The purpose of this study was to verify the clinical results. Methods : No-touch pylorus-resecting pancreatoduodenectomy (PrPD), antecolic gastrojejunostomy, pancreatico-jejunostomy with a lost stent tube to the main pancreatic duct, and early removal of a prophylactic drain were performed. Results : The drain could be removed 4 days after operation, and no pancreatic fistula was observed in all cases. Solid food could be started on POD4 after removing the drain. Furthermore, postoperative systemic chemotherapy could be started earlier. Conclusion : Although we have only a few PD cases a year in our institution, PD can be conducted safely without complications by using the methods verified by quality RCTs. J. Med. Invest. 62 : 188-194, August, 2015

Keywords : No-touch pylorus-resecting pancreatoduodenectomy (PrPD), antecolic gastrojejunostomy, lost stent tube, early removal of drainage tube

INTRODUCTION

Our institution is a designated emergency hospital, renovated and relocated in March 2011.

From the opening of the hospital on March 1, 2011 to November 30, 2013, 119 patients with digestive organ malignancies had undergone surgery, and 23 (19.3%) of them had hepato-biliary-pancreatic malignant surgery.

To achieve radical resection (R0) with safe procedures of pancreatoduodenectomy (PD) and fewer complications after surgery, since we have only several cases in our hospital, we decided to verify our surgical procedures for cancer of the pancreatic head region, reconstruction methods and postoperative management, referring to logical reports on highly evidence-based procedures conducted in high-volume centers (HVC) in literatures.

We adopted the surgical procedures described in 'Methods' below and performed PD in 6 cases. We report case series, regarding the breakdown of the 6 cases, five cases were cancer of the pancreas and one was that of the papilla of Vater.

METHODS*1. Method of PD*

No-touch (1) pylorus-resecting pancreatoduodenectomy (PrPD) (2) with the hanging up and clamping technique (1) (Fig. 1A-D) was performed (Fig. 2). The advantages of this method are as follows,

- ① Able to operate the lesion without holding it by hand

- ② Able to prevent the leakage of cancer cells from the lesion without Kocher's mobilization

- ③ Able to resect the retroperitoneal margin (RPM) systematically by forceps traction (Fig. 3)

- ④ Able to ensure pathological exams to distinguish the nervous plexus near SMA from the lymphatic tissue

- ⑤ Able to reduce the incidence of postoperative delayed gastric emptying (DGE)

2. Reconstruction Methods (Fig. 4, 5)

- ① Pancreaticojejunostomy (Fig. 4)

- a. Inner layer : Anastomosis of the pancreatic duct to the jejunal mucosa by 8 to 11 interrupted sutures using 5-0 absorbable thread with a lost stent (internal drainage) tube (3)

- b. Outer layer : Kakita's method (4) forming a seromuscular envelope with 5 to 6 interrupted sutures using 3-0 non-absorbable thread (prolene)

- ② Hepaticojejunostomy by one layer anastomosis with interrupted sutures using 3-0 or 4-0 absorbable thread without stent placement

- ③ Antecolic gastrojejunostomy with 2-layer anastomosis (5)

- ④ Only one closed-suction tube (Jackson-Pratt tube) was placed around the pancreaticojejunostomy

3. Postoperative Management

- ① Early Removal of Jackson-Pratt tube

Amylase value of the drainage fluid was measured on POD 1 and POD 4, and after confirming that the amylase value was not more than three times that of serum, the drainage tube was removed

Abbreviations

SMA : superior mesenteric artery, SMV : superior mesenteric vein, PV : portal vein, CHA : common hepatic artery, SA : splenic artery, LGA : left gastric artery, LRV : left renal vein, IVC : inferior vena cava, IMV : inferior mesenteric vein, PHA : proper hepatic artery, RGA : right gastric artery, GDA : gastroduodenal artery, RGEA : right gastroepiploic artery, ASPDA : anterior superior pancreaticoduodenal artery

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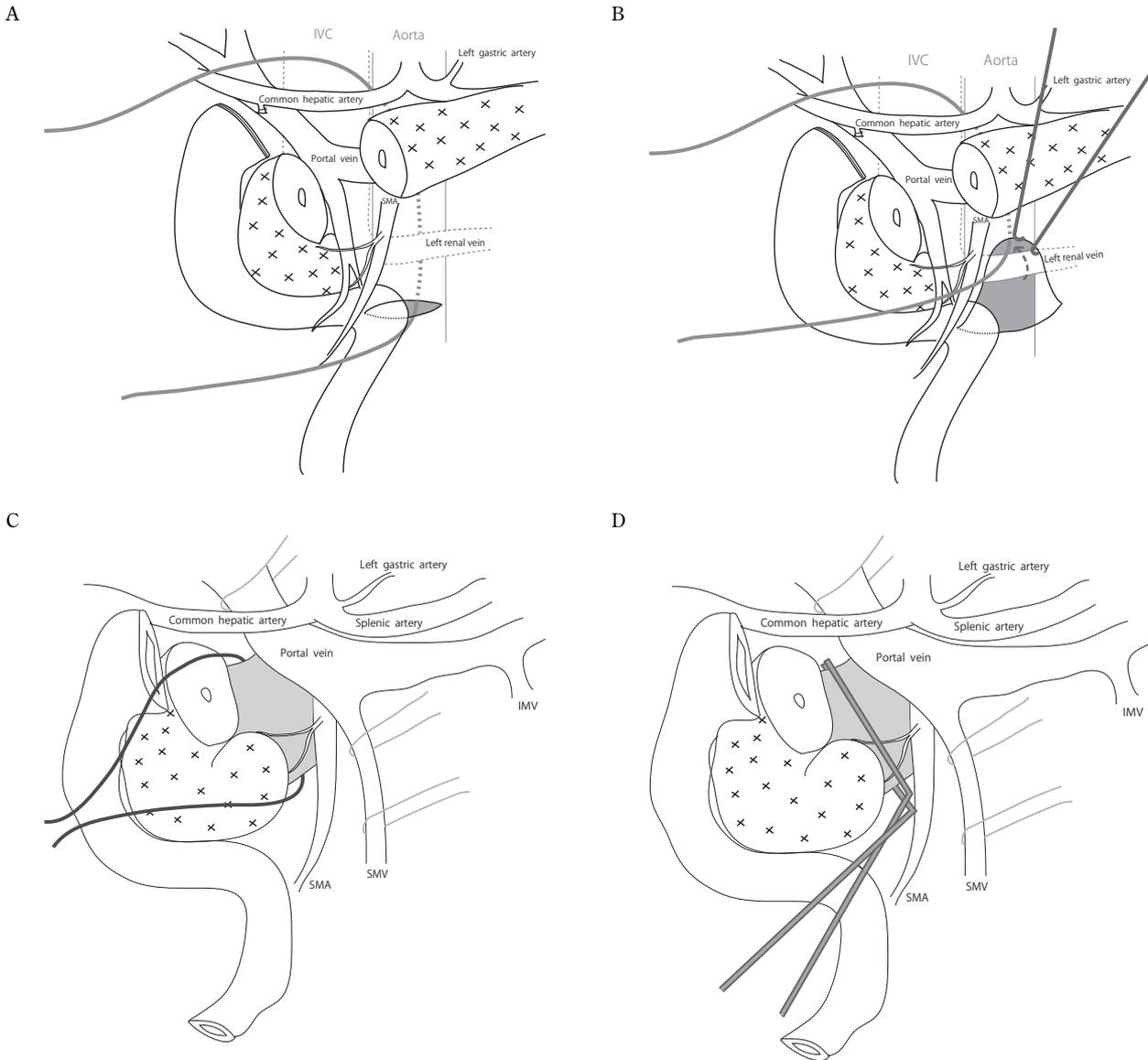


Fig. 1 No-touch pancreatoduodenectomy using the hanging up and clamping technique.
 A. The anterior surfaces of the aorta is dissected bluntly to permit the passage of a tap
 B. Since the left renal vein (LRV) is visible to the near comparatively when you pull the incised Treitz' ligament with retractor, a position of the tape is changed into the ventral side of LRV from the dorsal side
 C. The tape is repositioned to the pancreatic side of the common hepatic artery and the SMV-PV cranially, and to the pancreatic side of the left renal vein and mesocolon caudally
 D. Under traction of the vascular clamp, retroperitoneal margin is transected along with the right surface of SMA

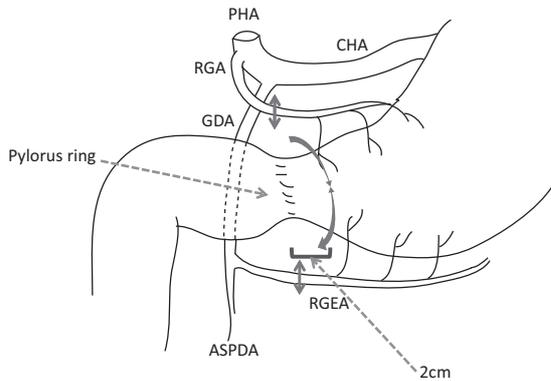


Fig. 2 The stomach is divided at 2cm oral of the pylorus ring, and so more 90% of the stomach can be preserved.

on POD 4.

② Introduction of enhanced recovery after surgery (ERAS)

Postoperative management was performed with ERAS method. A nasogastric tube was not inserted intra- and postoperatively. Post-operative pain was treated with a short-acting anesthetic and epidural analgesia. Fluid was taken orally the next day, followed by solid food intake on POD 3 and 4, and early mobilization and walking were encouraged.

RESULTS

During 33 months from the opening of our new hospital, PD had been performed in 6 patients. Table 1 describes the preoperative characteristics of the 6 patients. The average age was 62.8 ± 11.7 years old, and both the number of male patients and that of female

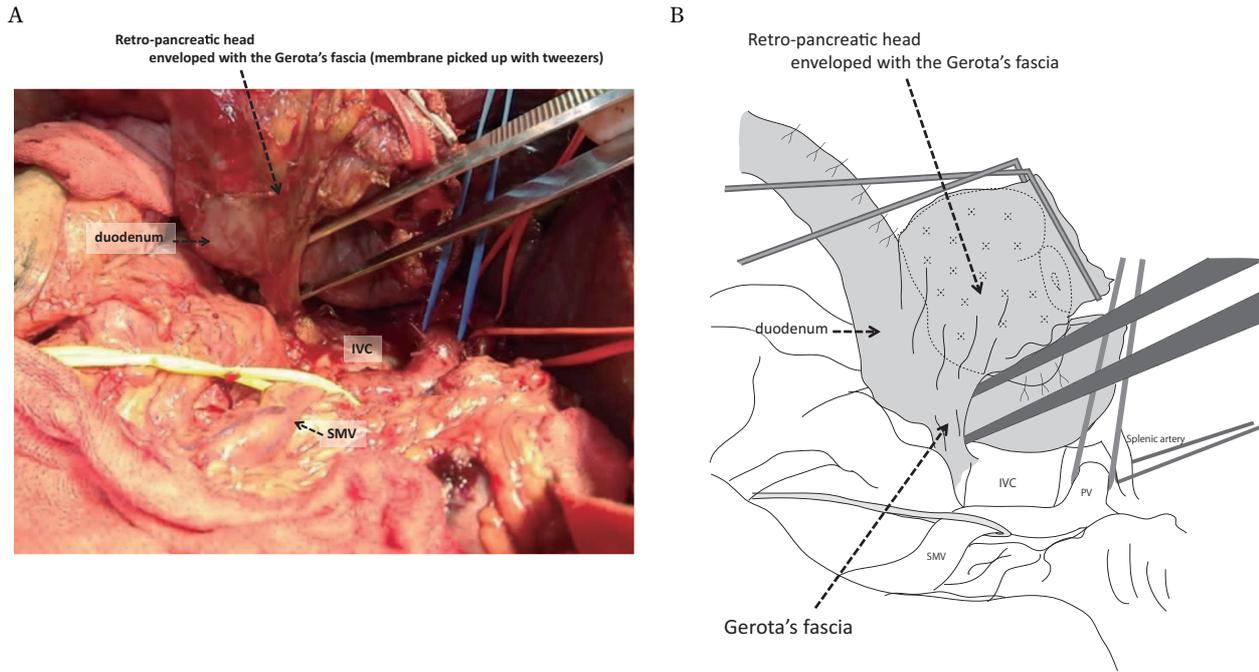


Fig. 3A. B The last procedure of the resection includes reversed Kocher's mobilization. The posterior plane of the Gerota's fascia is dissected medial to lateral direction.

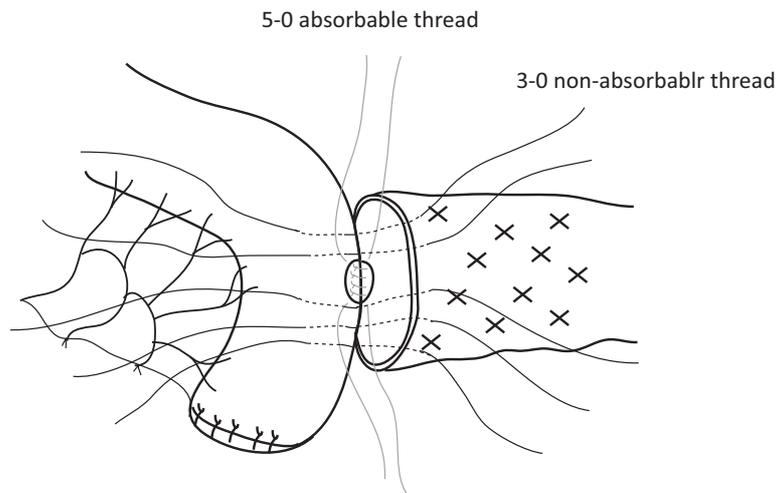


Fig. 4 Pancreaticojejunostomy was performed by duct-to-mucosa, end-to-side anastomosis in all patients.

patients were 3. As for the preoperative performance status (PS), PS 0 is five people and PS 2 is one. Preoperative biliary drainage was conducted in 5 patients who had jaundice. The surgical details are shown in Table 2. The type of resection was PrPD in all cases, the operative time was 371.2 ± 57.53 min. The average bleeding volume was $464.6 \text{ ml} \pm 123.1$ and the intra-operative red cell transfusion of 3 ± 1.7 unit underwent in four cases. But blood transfusion was not done in two cases. Table 3 describes the state of intra-operative pancreas. The texture of the pancreas was hard with the diameter of the main pancreatic duct (MPD) to be 4 or 3.5 mm in 2 cases, and soft with the diameter of MPD to be 2 mm or 3.5 mm in 2 cases, respectively. Pancreatic transection was performed with ultrasonic scalpel (SonoSurg[®]) and surgical knife around the main

pancreatic duct.

The breakdown of the intra- and post-operative findings is as follows (Table 4). Cancer infiltration to the nervous plexus around SMA was not verified histologically in all 6 cases, but cancer infiltration of the dissected peripancreatic tissue margin was recognized in 3 of 6 cases. Therefore, the residual tumor was supposed to be evaluated as R1 but not R0 for advanced cancer in these 3 cases.

Postoperative amylase levels in serum and drainage fluid are shown in Table 5. The serum levels on POD 4 were restored to the normal range except one which had no measurement. The amylase level of drainage fluid on POD 4 was lower than on POD 1 in 4 cases. Although the level on POD 4 was slightly higher than on POD 1 in 2 cases, they were almost in the normal range. According

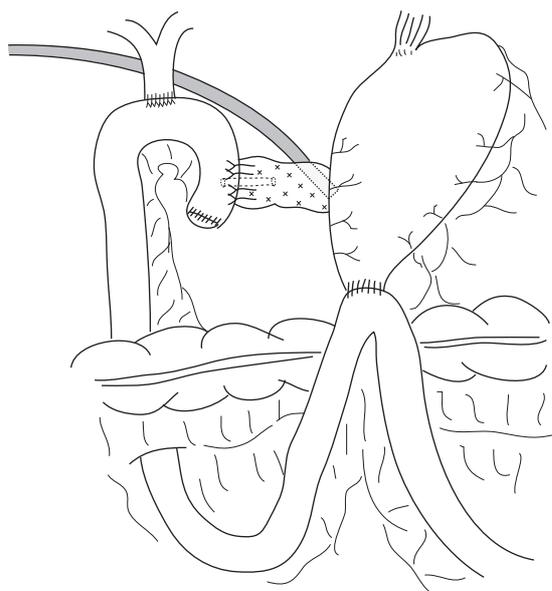


Fig. 5 Reconstruction after pylorus-ring resection PD.

Table 1 Preoperative Characteristics of 6 Patients

Age (yr)	62.8± 11.7
Gender (M/F)	3/3
Performance Status (0/1/2)	5/0/1
Diabetes (yes/no)	2/4
Preoperative biliary drainage (yes/no)	5/1
Total bilirubin at hospitalization (mg/dl)	13.02± 12.0
Total bilirubin at just before operation (mg/dl)	2.49± 1.24
Serum amylase level (IU/ML)	89.17± 53.43

Table 2 Surgical Details

Type of Resection	PrPD in 6 cases
Operation time (min. ± SD)	371.2± 57.53
Bleeding Volume (ml± SD)	464.6± 123.1
Intraoperative Red Cells Transfusions (yes/no)	4/2
	(U± SD) 3± 1.7

Table 3 State of Residual Pancreas

No	Case	Location of cancer	Size of Tumor mm (TS)	Texture	Diameter of MPD	Number of Interrupted Sutures in	
						Duct-to-duct Anastomosis	Seromuscular Anastomosis*
1	60s M	Ph	32x35x35 (TS2)	hard	4 mm	9	6
2	60s F	Ph	58x30x21 (TS3)	hard	3.5 mm	9	6
3	40s M	Up	55x25x21 (TS3)	soft	2 mm	8	6
4	70s F	Ph	50x35x25 (TS3)	soft	3.5 mm	9	6
5	70s M	Ph	40x37x21 (TS2)	soft	3.5 mm	11	5
6	60s F	Papilla Vater	23x16	soft	2 mm	9	6

Ph : Head of Pancreas, Up : Uncinate Process, MPD : main pancreatic duct , *Kakita method : forming a seromuscular envelope

to The International Study Group of Pancreatic Surgery (ISGPS), all patients were without an amylase level higher than 3 times the serum amylase level, so all were not defined it as postoperative pancreatic fistula (POPF).

Since the amylase levels of drainage fluid were not more than three times those of serum, the drainage tube was removed on POD 4 in all cases. And all patients didn't need any surgical or radiological therapy, so all were Grade I of The Clavien-Dindo Classification. The median hospital stay was 22 days.

No postoperative complications including pancreatic fistula, intra-abdominal infection, and biliary leakage were observed in all cases and there was no postoperative mortality as shown in Table 6.

Table 7 shows the prognosis of 6 cases with PD. Adjuvant systemic chemotherapy could be started on POD 35 and earlier (24.5 days on average) in the 4 patients.

Although the case 1 was Stage III with R1 resection, he survived for 39 months by the postoperative adjuvant chemotherapy. The causes of the death were local recurrence, portal vein obstruction, atrophy of the liver, and ascites. Two other patients with R1 resection died of recurrence around SMA or liver metastasis after 26 months and 10 months from the operation, respectively. In Case 4, the patient who had R0 resection but developed N2 lymph node metastasis died after 18 months from the operation due to recurrence around SMA. In Case 5, the patient developed dementia postoperatively and went home on foot without permission (the distance was around 20 minutes on foot) on the 6th day after surgery. Therefore, although it was Stage IVa, adjuvant chemotherapy was not performed, and he died of local recurrence around SMA after 6 months from the surgery.

The results were summarized as follows ;

1. The drain could be removed 4 days after operation, and the pancreatic fistula was not seen in all cases.
2. Solid food could be started on POD 4 after removing the drain.
3. Postoperative systemic chemotherapy could be started earlier.
4. Although we have a few PD cases a year in our institution, PD could be conducted safely without complications by using the methods verified by quality RCT.

DISCUSSION

PD is an only effective treatment method for cancer of the pancreatic head region. Even for patients who underwent radical resection (R0), which was supposed to be curative, survival analysis has revealed a poor survival rate because of cancer recurrence. The most of the postoperative recurrent cases are due to hepatic metastasis, local recurrence, and peritoneal dissemination. One of the reasons for these is that cancer cells may be squeezed and shed into the portal vein, peritoneal cavity or retroperitoneum after duodenal mobilization during operation by holding the pancreatic head

Table 4 Description of Findings in 6 cases with PrPD

No	Case	Disease	Ca. Inf. to SMA's NP	Ca. Inf. to DPM	Stage (TNM)	Assessment of Residual Tumor
1	60s M	Ca. of Ph	no	+	Stage III (T3N1M0)	R1
2	60s F	Ca. of Ph	no	+	Stage IVa (T3N2M0)	R1
3	40s M	Ca. of Up	no	+	Stage IVb (T4N2M0)	R1
4	70s F	Ca. of Ph	no	-	Stage IVa (T3N2M0)	R0
5	70s M	Ca. of Ph	no	-	Stage IVa (T3N2M0)	R0
6	60s F	Ca. of Papilla Vater	no	-	Stage III (T3N0M0)	R0

PrPD : Pylorus-resecting Pancreatoduodenectomy,

Ca. : cancer, Inf. : Infiltration, Ph : Head of Pancreas, Up : Uncinate Process,

SMA : Superior Mesenteric Artery, NP : Nerve Plexus, DPM : Dissected peripancreatic tissue Margin

Table 5 Amylase levels in Serum and Drainage Fluid

No	Case	Amylase levels (IU/ML) Serum*/Drainage Fuluid		Rempved Day of Drainage Tube	Hospital Stay (Days)
		POD 1	POD 4		
1	60s M	157/109	125/169	4	33
2	60s F	NM/229	50/106	4	14
3	40s M	79/2888	20/53	4	23
4	70s F	54/24	20/11	4	21
5	70s M	146/398	24/69	4	15
6	60s F	496/37	NM/65	4	80
					Median hospital stay 22 days

* Normal range : 42~158 IU/ NM : not mesure

Table 6 Postoperative Complications (n=6)

Complications	Number of Cases
Pancreatic fistula	0
Biliary leakage	0
Intra-abdominal infection	0
Wound infection	0
Delayed gastric emptying	0
Mortality	0

that contains tumors with the surgeon's hand.

No-touch PD using the hanging up and clamping technique by Hirota M, *et al.* (1) is considered to be a logical surgical method, since this procedure needs no duodenal mobilization or holding the pancreatic head. Therefore, we decided to adopt this method (Fig 1).

Recently, Hirota M (6) reported good results that the 5-year survival rate of patients who received PD was 44%, and those of JPS-stage III was 57%.

PpPD with preservation of the entire stomach had been popularized in the late 1970s since the report on the treatment of chronic pancreatitis by Traverso (7). The results of several randomized controlled trials (RCT) or meta-analyses comparing PpPD and PD had been reported, and the two procedures were equivalent in regard to morbidity, mortality, and survival for the treatment of periampullary cancer (8-13). Moreover, PpPD has been reported to reduce

Table 7 Postoperative chemotherapy and Prognosis

No	Case	Stage	Location of ca.	Assessment of Residual Tumor	Chemotherapy Drug & start date		Reccurence and Prognosis	
					Drug	Days (POD)	Reccurence site	Prognosis
1	60s M	Stage III	Ph	R1	GEM+S1	14	Paraaorta LN (19 month)	39 month dead
2	60s F	Stage IVa	Ph	R1	GEM+S1	28	PL sma (12 month)	26 month dead
3	40s M	Stage IVb	Up	R1	GEM+S1	35	Liver metastasis (2 month)	10 month dead
4	70s F	Stage IVa	Ph	R0	S1	21	PL sma (18 month)	18 month alive
5	70s M	Stage IVa	Ph	R0	-	-	PL sma (5 month)	6 month dead
6	60s F	Stage III	Papilla Vater	R0	-	-	-	8 month alive

Ph : Head of Pancreas, Up : Uncinate Process, GEM : Gemcitabine,

S1 : S1-tegafur-oxonate combination LN : Lymph node, PL sma : Plexus of superior mesenteric artery

dumping, diarrhea, and bile reflux gastritis after gastrectomy and improved the nutritional status of patients compared with PD with distal gastrectomy (8, 11, 14). Therefore, PpPD had been generally accepted as a surgical procedure for periampullary cancer and also pancreatic cancer.

However, the reported overall incidence of delayed gastric emptying (DGE) according to new definition from the International Study Group of Pancreatic Surgery (ISGPS) is 33% to 46% (15-18) and DGE is a frustrating complication. A RCT on whether PrPD could reduce the incidence of DGE compared with PpPD was performed by Kawai M, *et al.* (2), and showed that PrPD significantly reduced the incidence of DGE compared with PpPD. And then, a RCT conducted by Tani M, *et al.* (5) on whether antecolic duodenojejunostomy during PpPD could reduce the incidence of DGE compared with retrocolic anastomosis showed that antecolic reconstruction for duodenojejunostomy decreased DGE. Therefore, our institution decided to employ PrPD and antecolic gastrojejunostomy.

PD is an aggressive surgery occasionally associated with pancreatic fistula and postoperative mortality. Pancreatic fistula, in particular, is a severe complication of PD and may cause intra-abdominal hemorrhage and postoperative mortality due to the autolytic activity of pancreatic juice. Thus, our institution started to use pancreaticojejunostomy with 2-layer anastomosis to prevent pancreatic fistula. The inner layer anastomosis of the pancreatic duct to the jejunal mucosa is performed and Kakita's method (4) is used for the outer layer anastomosis. Many surgeons have used an external stent across pancreaticojejunostomy into the MPD to prevent pancreatic fistula. In a RCT, Poon *et al.* (19) found that patients with an external tube had a significantly lower pancreatic fistula rate compared with the non-stented group, and the pancreatic texture did not affect the incidence of pancreatic fistula. By contrast, another RCT showed that pancreatic duct stenting did not decrease the occurrence of pancreatic fistula in patients who underwent PD, compared with non-stented patients (20). A RCT conducted by Tani M, *et al.* (3) on whether internal drainage with pancreaticojejunostomy is better than external drainage with pancreaticojejunostomy showed that the incidence of postoperative complications including pancreatic fistula was not significantly different between internal and external drainage. However the median postoperative hospital stay in the internal drainage group was significantly shorter than the external drainage group.

The International Study Group of Pancreatic Surgery (ISGPS) has proposed a consensus on the definition and clinical grading of postoperative pancreatic fistula (POPF). Actually, POPF represents a failure of healing/sealing of a pancreatic-enteric anastomosis or a parenchymal leak which is not directly related to an anastomosis since distinguishing the two conditions is difficult. Thus, the all-inclusive definition is a drain output of any measurable volume of fluid on or after POD 3 with an amylase level higher than 3 times the serum amylase level. Pancreatic fistula is also defined as follows : Grade A, called "transient fistula," which has no clinical impact on postoperative course ; Grade B, required a change in management or adjustment in the clinical pathway ; Grade C, a major change in clinical management or deviation from the normal clinical pathway (21, 22).

Then, to assess the value of prophylactic drainage, Kawai M, *et al.* (23) prospectively assigned the patients into 2 groups : In group 1 (n=52), the drain was removed on POD 8 ; In group 2 (n=52), the drain was removed on POD 4. Postoperative complications in the 2 groups were compared, and it was showed that the rate of pancreatic fistula was significantly lower in PDO 4 group (3.6%) than POD 8 group (23%), (p=0.0038). In addition, Grade C was not seen in POD 4 group. Also, a RCT on early versus late drain removal after PD was performed by Bassi C *et al.* (24). Early drain removal (on POD 3) in group A (n=57) and late drain removal (POD 5 or beyond) in group B (n=57) were allocated at random

and compared. The rate of pancreatic fistula was 1.8% (Grade B in 1 case) in Group A versus 26.6% (Grade C in 15 cases, Grade B in 1 case, and Grade A in 7 cases) in Group B (p=0.0001). They concluded that an intra-abdominal drain can be safely removed on POD 3 after PD, and a prolonged period of drain insertion is associated with a higher rate of postoperative complications with increased hospital stay and costs.

According to the Pancreatic Cancer Clinical Practice Guidelines (2013 Japanese version, Japan Pancreas Society) (25), complications tend to be fewer in the facilities where there are more than a certain number of treatment cases and specialists. In addition, those facilities conduct better management of complications, and are recommended as Grade B. However, there is no clear description about 'a certain number' of operations. In one paper, medical institutions with 19 or less cases in a year are determined to be a low-volume center (LVC), and those with 20 or more cases in a year to be high-volume center (HVC), and there is another paper that determined medical institutions with 4 or less cases to be LVC, those with 5 to 18 cases to be medium-volume center (MVC), and those with 19 or more cases to be HVC. There seems to be no formal and common definition for LVC, MVC and HVC. Some institutions have specialists even if they are LVC.

Although we have a few PD cases a year in our institution, PD can be conducted safely without complications by using the methods verified by the quality RCTs mentioned above. This indicates that even if a medical institution is not HVC, PD can be performed safely.

CONFLICT OF INTEREST STATEMENT

Hitomi Kamo and other co-authors have no conflict of interest.

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