Safety of Non-stented Pancreaticojejunostomy in Pancreaticoduodenectomy for Patients with Soft Pancreas

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Abstract. *Background/Aim:* It has been reported that pancreatic duct stenting for pancreaticojejunostomy in pancreaticoduodenectomy prevents postoperative pancreatic fistula. However, some reports describe severe complications associated with pancreatic duct stenting; it is controversial whether pancreatic duct stent should be used for pancreaticojejunal anastomosis in pancreaticoduodenectomy. The aim of this study was to compare the incidence of pancreatic fistula between non-stented, externally stented, and internally stented pancreaticojejunostomy in pancreaticoduodenectomy for patients with soft pancreas. *Patients and Methods:* Ninety-eight patients undergoing pancreaticoduodenectomy with soft pancreas were divided into three groups: a non-stented group (n=14), an externally-stented group (n=56), and an internally-stented group (n=28), then clinical outcomes were compared. *Results:* The frequency of clinically relevant postoperative pancreatic fistula (grade B or C) was 14% in the non-stented group, 36% in the externally-stented group, and 39% in the internally-stented group, respectively ($p=0.19$). The morbidity and mortality rates were also comparable between the three groups ($p=0.17$ and $p=0.88$, respectively). *Conclusion:* Since pancreatic duct stenting in pancreaticojejunal anastomosis for patients with soft pancreas did not reduce pancreatic fistula after pancreaticoduodenectomy, non-stented pancreaticojejunostomy for soft pancreas seems safe.

Pancreaticoduodenectomy (PD) is a standard treatment for patients with pancreatic head and periampullary tumors. Recently, the mortality rate after PD has decreased to less than 5% because of advances in surgical techniques and appropriate perioperative management (1-3). However, the morbidity rate

remains high, ranging from 30-50%, of which postoperative pancreatic fistula (POPF) is the most frequent life-threatening complication, with an incidence of 10-30% (3-7). It has been reported that pancreatic duct stenting for pancreaticojejunostomy in PD prevents POPF, and therefore pancreatic duct stent has been used in many institutions (8, 9). On the other hand, some reports describe severe complications associated with pancreatic duct stenting, such as acute pancreatitis due to occlusion or bending of the stent, anastomotic leakage or stenosis after iatrogenic injury caused by removal of an external stent (ES), and obstructive jaundice or cholangitis caused by migration of an internal stent (IS) (10-12). Several randomized control studies have controversially reported both efficacy and non-efficacy of pancreatic duct stenting for the prevention of POPF (13-16). There are some reports comparing the efficacy of external and internal stents, finding them to have equivalent outcome (10, 17). Recent meta-analyses on stenting *versus* non-stenting are contradictory (18-23). Therefore, it is still controversial whether a pancreatic duct stent should be used for pancreaticojejunal anastomosis in PD.

In pancreatic surgery, a soft pancreas is known to be a significant risk factor for POPF when compared to a hard pancreas (24, 25). Since soft pancreas is vulnerable to ischemia and actively produces exocrine secretions, bleeding, autolysis, necrosis, or pancreatic fistula can easily occur after surgical intervention (26). Therefore, it is important to treat patients with soft pancreas carefully. The aim of this study was to compare the incidence of POPF between non-stented, externally-stented, and internally-stented pancreaticojejunostomy for patients with soft pancreas.

Patients and Methods

Between January 2000 and December 2014, PD was performed for 185 patients at the Katsushika Medical Center, The Jikei University School of Medicine, or Machida Municipal Hospital, Japan. Among them, 98 patients with soft pancreas were retrospectively analyzed in this study. Soft pancreas was defined by the presence of a non-dilated main pancreatic duct (less than 3 mm) and intraoperative findings of soft pancreatic texture without fibrosis. The patients were divided into three groups: non-stented group (NS, n=14), ES

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group (n=56), and IS group (n=28). Preoperative parameters, clinical data, details of surgical procedures, and postoperative outcomes were compared between the three groups.

Surgical technique. Conventional, pylorus-preserving or subtotal stomach-preserving PD was performed according to each surgeon's preference. Reconstruction in all PD consisted of an end-to-side pancreaticojejunostomy, an end-to-side hepaticojejunostomy, and gastrojejunostomy or duodenojejunostomy using the first jejunal loop, according to Child's procedure (27). Duct-to-mucosa anastomosis of pancreaticojejunostomy was performed with eight interrupted polydioxanone sutures (5-0 PDS-II®; Ethicon, Cincinnati, OH, USA), followed by a pancreatic parenchymal-jejunal seromuscular anastomosis by polypropylene sutures (PROLENE®; Ethicon).

The decision on whether to use a pancreatic duct stent was also left at the surgeon's discretion. Bile-duct stent in hepaticojejunostomy and feeding tube in the jejunum were not routinely used. The pancreatic duct stent was a 5- to 6-Fr polyvinyl catheter (MD-41515 pancreatic duct tube; Sumitomo Bakelite, Tokyo, Japan) with multiple side holes. As an ES method, the tip of the pancreatic duct stent was inserted through the pancreaticojejunal anastomosis into the main pancreatic duct, then the other end of the tube was extracted through a stab incision both in the jejunal and abdominal wall. As an IS method, the tip of pancreatic duct stent, 5-cm in length, was positioned one half in the main pancreatic duct and the other half in the jejunal lumen. The decision on whether to use fibrin glue for preventing leakage around the anastomotic site was also left at the surgeon's discretion. Surgical drains were placed in the sites of the pancreaticojejunal and hepaticojejunal anastomoses in all patients.

Perioperative management. All patients were given preoperative and postoperative prophylactic antibiotics for at least 3 days after the operation. Postoperative prophylactic octreotide acetate was not administered, and oral intake was routinely started 3 to 7 days after surgery when there was no evidence of intra-abdominal complications. Amylase levels in serum and drainage fluid were measured on days 1, 3 and 5 after surgery. Intra-abdominal drains were removed as soon as possible, between postoperative day 4 and 7, after confirming the absence of clinically relevant (CR) POPF. ES were removed around 3 to 4 weeks postoperatively if there was no evidence of CR-POPF.

Definitions. CR-POPF was defined as grade B and C according to the International Study Group on Pancreatic Fistula grading system (7). Complications were classified in accordance with Clavien's classification (28).

Statistical analysis. Continuous data are expressed as the mean±SD. Comparisons of continuous variables between the three groups were performed using the Kruskal–Wallis test. A *p*-value of less than 0.05 was judged to be statistically significant.

Results

Patient characteristics and clinical diagnoses of the three groups are summarized in Table I. There were significant differences in age and co-morbidity between the three groups. The patients of ES were younger than those of the other groups (*p*=0.002), and the co-morbidity rate of ES was less

Table I. Patient characteristics and clinical diagnosis.

Preoperative parameter	No stent (n=14)	External stent (n=56)	Internal stent (n=28)	<i>p</i> -Value
Age (years)	72.7±8.4	66.9±6.8	73.1±7.1	0.002
Sex (male/female)	11/3.	38/18.	22/6.	0.502
BMI (kg/m ²)	23.1±2.6	22.4±3.2	22.8±3.5	0.324
Co-morbidity	12 (86%)	27 (48%)	20 (71%)	0.013
Hypertention	9	16	12	
Diabetes mellitus	5	10	12	
Cardiac disease	2	0	1	
Pulmonary disease	0	0	3	
Cerebral disease	1	1	2	
Diagnosis				0.642
Malignant diseases	11 (79%)	47 (84%)	25 (89%)	
Pancreatic carcinoma	1	5	1	
Cholangiocarcinoma	6	14	14	
Ampullary carcinoma	2	20	8	
IPMN	4	8	2	
Other	1	9	3	

BMI: Body mass index; IPMN: intraductal papillary mucinous neoplasm. Data are the mean±SD, or number (%).

Table II. Intraoperative variables for patients undergoing pancreaticoduodenectomy (PD).

	No stent (n=14)	External stent (n=56)	Internal stent (n=28)	<i>p</i> -Value
Procedure				<0.001
PD	1	35	1	
PPPD	12	19	19	
SSPPD	1	8	8	
Operative time (min)	397±80	470±119	397±60	<0.001
Blood loss (ml)	1670±739	1764±1470	1307±1103	0.149
Blood transfusion	5 (36%)	24 (43%)	12 (43%)	0.882
Use of fibrin glue	13 (93%)	29 (52%)	22 (79%)	<0.001

PPPD: Pylorus-preserving PD; SSPPD: subtotal stomach-preserving PD. Data are the mean±SD, or number (%).

than those of the other groups (*p*=0.013). The malignancy rates of primary disease were comparable between the three groups (*p*=0.642). There were statistically significant differences between the three groups in procedure, operative time, and the use of fibrin glue (Table II). The number of conventional PDs in patients of the ES group was greater than those of the other two groups (*p*<0.001). The operative time for ES was longer than those of the other groups (*p*<0.001). The use of fibrin glue in patients of the NS group was more frequent than those of the other groups (*p*<0.001). There were no significant differences between the three groups in morbidity and mortality (Table III).

Table III. Postoperative outcomes of patients who underwent pancreaticoduodenectomy.

	No stent (n=14)	External stent (n=56)	Internal stent (n=28)	p-Value
Complication (Clavien-Dindo ≥ 3)	2 (14%)	23 (41%)	10 (36%)	0.174
Pancreatic fistula	5 (36%)	28 (50%)	14 (50%)	0.338
Grade A	3 (21%)	8 (14%)	3 (11%)	0.5
Grade B	2 (14%)	14 (25%)	9 (32%)	0.422
Grade C	0 (0%)	6 (11%)	2 (7%)	0.413
Grade B+C (CR-POPF)	2 (14%)	20 (36%)	11 (39%)	0.195
Mortality	1 (7%)	3 (5%)	1 (4%)	0.877
Reoperation	1 (7%)	6 (11%)	2 (7%)	0.832
Postoperative hospital stay (days)	21.3 $\pm$ 12.3	33.5 $\pm$ 22.9	31.9 $\pm$ 28.5	0.054

CR-POPF: Clinically relevant postoperative pancreatic fistula. Data are the mean $\pm$ SD number (%).

The rate of overall POPF was 36% in NS, 50% in ES and 50% in IS, respectively ($p=0.338$). The rate of CR-POPF was 14% in NS, 36% in ES and 39% in IS, respectively ($p=0.195$). The overall morbidity (Clavien's classification 3 or more) rate was 14% in NS, 41% in ES and 36% in IS ($p=0.174$). Although surgical or radiological treatment regarding postoperative complications was required in one patient (7%) in the NS group, six patients (18%) in the ES group, and two patients (8%) in the IS group, there was no statistically significant difference ($p=0.832$).

Hospital mortality rate was 7% in the NS, 5% in the ES, and 4% in the IS group without a statistically significant difference ($p=0.877$). One patient died 49 days after surgery in the NS group due to progression of malignant lymphoma of the duodenum. The reasons for three deaths in the ES group were intra-abdominal hemorrhage following CR-POPF in two and deterioration of co-morbidity with chronic renal failure in one patient, respectively. These patients died 33, 31, and 70 days after surgery, respectively. Another patient in the IS group died 58 days after surgery due to intra-abdominal hemorrhage following CR-POPF. Therefore, all three deaths (3.1%) due to POPF were in the stented groups, and none in the NS group. Postoperative hospital stay was comparable ($p=0.054$), and postoperative hospital stay of the NS group tended to be shorter than that for the other groups. Ninety-eight PDs were performed by a total of 23 surgeons, eight of which were senior and 15 of which were junior surgeons. The clinical outcomes when compared by surgeon are shown in Table IV. The number of NS cases operated on by senior surgeons was more than those of ES and IS ($p<0.001$). The operative time performed by junior surgeons was longer than that of senior surgeons ($p=0.003$). The CR-POPF rate was

Table IV. Clinical outcomes compared by surgeon type.

Surgeon	Senior (n=39)	Junior (n=59)	p-Value
No stent	13	1	<0.001
External stent	19	37	0.171
Internal stent	7	21	0.058
Operative time (min)	402 $\pm$ 95	452 $\pm$ 94	0.003
Blood loss (ml)	1484 $\pm$ 1374	1601 $\pm$ 1185	0.535
CR-POPF	13	20	0.954
Mortality	5	0	0.005

CR-POPF: Clinically-relevant postoperative pancreatic fistula. Data are the mean $\pm$ SD number (%).

Table V. Summary of recent meta-analyses.

Author (Ref)	Year	No. of cases	PO PF		p-value
			NS	S	
Xiong <i>et al.</i> (19)	2012	1,726	28%	22%	0.13
Markar <i>et al.</i> (20)	2012	732	26%	20%	0.13
Wang <i>et al.</i> (21)	2013	793	22%	29%	0.02
Hong <i>et al.</i> (22)	2013	416	33%	19%	0.001
Zhou <i>et al.</i> (18)	2013	724	11%	14%	0.31
Patel <i>et al.</i> (23)	2014	416	38%	19%	0.0001

POPF: Postoperative pancreatic fistula, NS: no-stented group, SG: stent group.

comparable between senior and junior surgeons ($p=0.954$). Mortality rate of those treated by senior surgeons was higher than for those treated by junior surgeons ($p=0.005$).

Discussion

POPF is a common and life-threatening complication after PD (13-17). Various techniques have been advocated and evaluated to reduce POPF by many surgeons. Influenced by the reports in which pancreatic duct stent for pancreaticojejunostomy in PD prevents POPF (8, 9), pancreatic duct stent is routinely used in many Institutions. In six recent meta-analyses, three reports demonstrated that a pancreatic duct stent was useful for preventing POPF (21-23) (Table V). On the other hand, the other three meta-analyses demonstrated that such stenting did not reduce POPF (18-20). Moreover, some prospective randomized trials and retrospective studies demonstrated that the POPF rate of NS was equal to that of the stented group (13, 15, 29). Winter *et al.* reported that the POPF rate was 11.3% in the stented group and 7.6% in the NS group ($p=0.10$) (13), Pessaix *et al.* reported that the CR-POPF rate was 24.7% in the ES group and 35.8% in the NS group ($p=0.13$) (15), and

Moriya *et al.* reported that the CR-POPF rate was 9.6% in the stented group and 12.5% in the NS group ($p=0.38$) (29). On the other hand, Sachs *et al.* retrospectively evaluated clinical outcomes between NS ($n=385$) and the stented groups ($n=59$) and reported that the CR-POPF rates were 11% and 29% ($p<0.001$), respectively (30). They also concluded that the use of pancreatic duct stent does not reduce the incidence of CR-POPF. Imaizumi *et al.* demonstrated that pancreatic duct stenting was unnecessary if the duct-to-mucosa anastomosis was performed properly (26). Suzuki *et al.* also insisted there was no need for use of a pancreatic duct stent in pancreaticojejunostomy (31), and we also do not consider that a pancreatic duct stent is necessary for all patients.

Soft pancreas is a risk factor for POPF after PD because a soft pancreas is very vulnerable to ischemia and actively produces exocrine secretion (31). There are some reports with regard to POPF in soft pancreas (13, 16, 18, 26, 29) (Table VI). In a meta-analysis, Zhou *et al.* reported that the POPF rate with soft pancreas was 22.9% in the stented group as compared to 36.6% in the NS group ($p=0.05$) (18). In a randomized study, Motoi *et al.* reported that CR-POPF (pancreatic duct < 3 mm) was 10% in the stented group as compared to 40% in the NS group ($p<0.05$) (16). On the other hand, there are some reports that the POPF rate for NS with soft pancreas was equivalent to that of stented PD. Winter *et al.* reported that POPF with soft pancreas was 21.1% in the stented group and 10.7% in the NS group ($p=0.10$) (13). Imaizumi *et al.* reported that POPF with soft pancreas was 7.7% in the stented group and 7.3% in the NS group, with no significant difference (26). Moriya *et al.* reported that POPF with soft pancreas was 23.8% in the IS and 37.8% in the NS groups ($p=0.20$). Moreover, they reported that CR-POPF with soft pancreas was 17.7% in the IS and 24.3% in the NS groups ($p=0.38$) (29). Suzuki *et al.* reported that it was important to maintain the patency of the anastomosis in pancreaticojejunostomy in order to prevent POPF, for which non-stented pancreaticojejunostomy was useful (31). Therefore, it is also controversial whether a pancreatic duct stent should be used for pancreaticojejunal anastomosis in patients with soft pancreas.

In our retrospective study, there were no significant differences in the incidence of POPF and CR-POPF between the three groups. In addition, morbidity and mortality rates were also similar. Clinical outcomes of the stented groups were comparable, and NS pancreaticojejunostomy with soft pancreas was acceptable. Based on the current study, it may not be necessary to use a pancreatic duct stent for patients with soft pancreas. However, several biases exist in the current study, such as the age of patients, co-morbidity rate, subtypes of procedure, operative time, and use of fibrin glue. Because most NS pancreaticojejunostomies were performed by senior surgeons and many stented pancreaticojejunostomies were performed by junior surgeons, operative time of the stented groups was longer than that of the NS group.

Table VI. Reports on postoperative pancreatic fistula (POPF) for patients with soft pancreas.

Author (Ref)	Year	PO PF		p-Value
		NS	S	
Imaizumi <i>et al.</i> (26)	2002	7.30%	7.70%	NS
Winter <i>et al.</i> (13)	2006	10.70%	21.10%	0.1
Motoi <i>et al.</i> (16)	2012	40%	10%	<0.05
Moriya <i>et al.</i> (29)	2012	24.30%	17.70%	0.38
Zhou <i>et al.</i> (18)	2013	37%	23%	0.05

NS: No-stented group, SG: stent group, ns: no significance.

Moreover, it cannot be evaluated that good outcomes of the NS group were the result of operations by senior surgeons because all cases of mortality were associated with surgery by senior surgeons (as shown in Table IV).

In the current study, we had two complications caused by pancreatic duct stenting: local peritonitis due to accidental removal of stent and cholangitis due to migration of internal stent into the bile duct in one case. Besides, anastomotic leakage in a patient with hard pancreas immediately after removal of an external stent can occur. Furthermore, self-removal of a stent is a serious concern in elderly patients with delirium. Therefore, we do not consider that a pancreatic duct stent should be used in all patients. In the future, it is necessary to examine what kind of patients with soft pancreas need pancreatic duct stenting in a large-scale prospective study.

Conclusion

Since pancreatic duct stenting for soft pancreas did not reduce POPF after PD in the current study, we conclude that non-stented pancreaticojejunostomy for patients with a soft pancreas seems safe.

Disclosure

The Authors declare that they have no conflict of interest in regard to this study.

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