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Postoperative Movement of an Internal Stent Placed at the Anastomotic Site of Pancreaticojejunostomy During Pancreaticoduodenectomy

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ABSTRACT

Purposes: This study aimed to investigate the postoperative movement of an internal stent placed at the anastomotic site of pancreaticojejunostomy during pancreaticoduodenectomy.
Methods: Of the 70 patients who underwent pancreaticoduodenectomy using an internal stent at the anastomotic site of pancreaticojejunostomy between January 2014 and December 2019, 64 patients (91%) were included in this study. Stent fall from the anastomotic site, stent excretion from the body, and stent migration into the pancreatic and bile duct, as well as stent-related complications were examined.
Results: The stent fall rate and excretion rate were 91% and 83%, respectively. Furthermore, migration rates into the pancreatic duct and bile duct were 5% each. There were no stent-related complications. Univariate analysis revealed that pancreatic texture and Clavien-Dindo classification differed significantly according to stent fall time ($p=0.019$, 0.045, respectively). Moreover, the Clavien-Dindo classification differed significantly according to the number of stent excretions ($p=0.023$). Additionally, patient sex, Clavien-Dindo classification, postoperative pancreatic fistula, and preoperative biliary drainage differed significantly according to stent excretion time ($p=0.014$, 0.026, 0.024, 0.044, respectively). Multivariate analysis revealed that postoperative pancreatic fistula was an independent risk factor for excretion time ($p=0.047$; HR 0.513, 95%CI; 0.266-0.992).
Conclusions: We observed the safe removal and excretion of internal stents from patients who underwent pancreaticoduodenectomy. Additionally, patients with postoperative pancreatic fistula had significantly later stent excretion time.
Key words: internal stent, pancreaticoduodenectomy, pancreaticojejunostomy

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INTRODUCTION

A pancreatic duct stent is often placed at the anastomotic site of pancreaticojejunostomy during pancreaticoduodenectomy. Two types of pancreatic duct stents exist internal and external. An internal stent is used

with the theory that it falls from the anastomotic site and is excreted spontaneously from the body because it is fixed with absorbent threads (1). However, it is unclear when the stent fall and excretion occur. Thus, we retrospectively examined the postoperative movement of an internal stent placed at the anastomotic site of pancreaticojejunostomy during pancreaticoduodenectomy.

METHODS

Patients and procedures

Between January 2014 and December 2019, 70 patients underwent pancreaticoduodenectomy at Katsushika Medical Center The Jikei University, using an internal stent at the anastomotic site of pancreaticojejunostomy. Of these, 64 patients (91%) were included in this study as they could be followed-up for over six months. Sub-stomach preserving pancreaticoduodenectomy and conventional pancreaticoduodenectomy were performed in 60 and 4 patients (94% and 4%), respectively. Reconstruction consisted of an end-to-side pancreaticojejunostomy, an end-to-side hepaticojejunostomy, and an antecolic end-to-side gastrojejunostomy according to Child's procedure (2). Duct-to-mucosa anastomosis of pancreaticojejuno-stomy was performed with polydioxanone sutures (5-0 PDS PLUS®; Ethicon), following a pancreatic parenchymal-jejunal seromuscular anastomosis with polypropylene sutures (3-0 PROLENE®; Ethicon) using the modified Blumgart method (3). The pancreatic duct stent was a polyvinyl catheter (MD-41515 pancreatic duct tube; Sumitomo Bakelite, Japan) with multiple side holes and a small knot. Using an internal stented method, a pancreatic duct stent was cut 4 cm in length and was positioned with one half in the main pancreatic duct and the other half in the jejunal lumen. The stent was fixed at the anastomotic site using the dorsal thread of the pancreaticojejunostomy. The bile duct stent in hepaticojejunostomy was not routinely used. The closed drains were placed near the sites of the pancreaticojejunal and hepaticojejunal anastomoses, and were promptly removed after confirming the absence of intra-abdominal complications. All patients were administered prophylactic antibiotics for at least three days postoperatively, postoperative prophylactic octreotide was not routinely used. Food intake started three days postoperatively after confirming the absence of intra-abdominal complications.

Evaluation

We routinely performed abdominal computed tomography (CT) seven days postoperatively. After the patient was discharged, a follow-up CT was performed every three or four months. The fall of the stent from the anastomotic site of the pancreaticojejunostomy and excretion of the stent from the body were confirmed by CT examination. Serum amylase levels and drainage fluid volume were measured on postoperative days 1, 3, and 5. Postoperative pancreatic fistula was defined according to the International Study Group on Pancreatic Fistula (ISGPF) (4). The severity of other early complications was categorized according to the Clavien-Dindo classification (5). This study was approved by the Ethics Committee of the Jikei University School of Medicine. The approval number is 30-322(9343).

Statistical analysis

Univariate analyses were performed using the Mann-Whitney U-test or Chi-square test. Multivariate analyses were performed using a logistic regression analysis. All data were analyzed using JMP Pro version 12 (SAS Institute Inc.). Statistical significance was set at $p<0.05$, and data are expressed as mean ± standard deviation.

RESULTS

Patient characteristics and operative variables are shown in *table 1*. The mean postoperative follow-up period was 24.1 ± 15.3 months (6-69). There were 42 males (66%) and 22 females (34%), mean age=68.9 ± 11.3 (31-87); mean body mass index=22.2 ± 4.2 kg/m^2 (15.2-33.3). The primary diseases were pancreatic carcinoma (n=21, 33%), bile duct carcinoma (n=18, 28%), intraductal papillary mucinous neoplasm (n=10, 16%), duodenal carcinoma (n=5, 8%), ampulla of Vater carcinoma (n=3, 5%), transverse colon carcinoma with duodenal invasion (n=2, 3%), neuroendocrine tumor (n=2, 3%), chronic pancreatitis (n=1, 2%), mucinous cyst neoplasm (n=1, 2%) and pancreatic duct adenoma (n=1, 2%). Forty-three patients (67%) had comorbidities, including hypertension (n=39, 61%), diabetes mellitus (n=18, 28%), hyperlipidemia (n=16, 25%), ischemic heart disease (n=7, 11%), and respiratory disease (n=1, 2%). The mean diameter of the main pancreatic duct was 2.7±1.8 mm (1-10). The pancreatic texture was soft and hard in 24 and 40 patients (38% and 62%), respectively. The stent size was 5, 6, and 7.5 Fr in 48, 13, and 3

Table 1 - Patient characteristics and operative variables

	Mean±SD or n (%)	range
Patients' characteristics		
Age (years)	68.9±11.3	31-87
Sex (male/female)	42 / 22 (66% / 34%)	
Body mass index (kg/m^2)	22.2±4.2	15.2-33.3
Type of Disease		
Pancreatic carcinoma	21 (33%)	
Bile duct carcinoma	18 (28%)	
Intraductal papillary mucinous neoplasm	10 (16%)	
Duodenal carcinoma	5 (8%)	
Ampulla of Vater carcinoma	3 (5)	
The others	7 (11%)	
Co-morbidity	43 (67%)	
Hypertension	39 (61%)	
Ischemic heart disease	7 (11%)	
Hyperlipidemia	16 (25%)	
Diabetes Mellitus	18 (28%)	
Pulmonary disease	1 (2%)	
Pancreatic texture (soft/hard)	40 / 24 (63% / 37%)	
Operative factors		
Procedure (SSPPD/PD)	60 / 4 (94% / 6%)	
Portal vein resection	7 (11%)	
Preoperative biliary drainage	38 (59%)	
Operation time (min)	449±70	294-616
Intraoperative blood loss (ml)	1,043±750	222-3,862
Transfusion	12 (19%)	
Mortality	0	
POPF (Grade B/C)	13 (20%)	
Clavien-Dindo classification III≥	18 (28%)	
Postoperative hospital stay	25.2±16.9	9-93
Reoperation	3 (5%)	
Diameter of main pancreatic duct	2.7±1.8	1-10
Stent size (5Fr/6Fr/7.5Fr)	48/13/3 (75%/20%/5%)	
Suture number of duct to mucosa anastomosis (4/5/6/8/10/12)	34/1/1/24/3/1 (53%/2%/2%/38%/5%/2%)	

patients (75%, 20% and 5%), respectively. The number of duct-to-mucosa anastomosis sutures was four in 34 patients (53%), five in 1 patient (2%), six in 1 patient (2%), eight in 24 patients, ten in 3 patients (5%), and twelve in 1 patient (2%). The mean operation time was 449 ± 70 min (294-616), and the mean intraoperative blood loss was 1,043 ± 750 mL (222-3,862). Transfusion was performed in 12 patients (19%), portal vein resection in 7 patients (11%), and preoperative biliary drainage in 38 patients (59%). The morbidity and mortality rates were 44% and 0%, respectively. Clavien-Dindo classification (≥) and postoperative pancreatic fistula (Grade B/C) occurred in 18 and 13 patients (28% and 20%), respectively. Reoperations were performed in 3 patients (5%) due to necrosis of the transverse colon, perforation of the transverse colon and internal hernia. The mean postoperative hospital stay was 25.2 ± 16.9 days (9-93). Postoperative movement of the stent is shown in *table 2*. The stent fell from the anastomotic site in 58 patients (91%), while the stent remained in the anastomotic site in 6 patients (9%), one

Table 2 - The postoperative movement of internal stent

	mean±SD, or n (%)
Stent fall from the anastomotic site	58 (91%)
Fall time (months)	4.9±2.0
Fall within one month	1 (2%)
Fall within six months	42 (66%)
Fall within one year	58 (91%)
Dead without fall	1 (2%)
Stent excretion from the body	53 (83%)
Excretion time (months)	6.4±2.9
Excretion within one month	0
Excretion within six months	28 (44%)
Excretion within one year	51 (80%)
Dead without excretion	4 (6%)
Stent migration into pancreatic duct	3 (5%)
Stent migration into bile duct	3 (5%)
Postoperative pancreatitis	0
Postoperative high serum amylase	11 (17%)

of whom died. The shortest stent fall time was on postoperative day seven, and the stent fell within one year in all patients. The mean stent fall time was 4.9 ± 2.0 months. The stent was excreted from the bodies of 53 patients (83%), while the stent remained in 11 patients (17%), four of whom died without excretion. The mean excretion time was 6.4 ± 2.9 months. Meanwhile, stents were excreted within six months and one year postoperatively from 28 and 50 patients (44% and 78%), respectively. Stent migration into the pancreas occurred in 3 patients (5%): One had a stent that was spontaneously excreted, one remained with a migrated stent, and one died with a migrated stent. Stent migration into the bile duct occurred in 3 patients (5%), all of whom subsequently were excreted spontaneously. There were neither stent-related complications (such as pancreatitis and cholangitis) postoperatively nor after the patients were discharged. Eleven patients (17%) had hyperamylasemia during follow-up; however, all were asymptomatic.

The relationship between clinical variables and postoperative internal stent movement is shown *tables 3-5*. Univariate analysis revealed that pancreatic texture and Clavien-Dindo classification (≥) differed significantly according to stent fall time (p=0.019, 0.045, respectively), Clavien-Dindo classification (≥) differed significantly according to the number of stent excretions (p=0.023). Additionally, patient sex, Clavien-Dindo classification (≥), postoperative pancreatic fistula, and preoperative biliary drainage differed significantly according to stent excretion time (p=0.014, 0.026, 0.024, 0.044, respectively).

Multivariate analysis revealed that postoperative pancreatic fistula was an independent risk factor for stent excretion time (p=0.047; HR 0.513, 95%CI; 0.266-0.992), as shown *table 6*.

Table 3 - The relationship between clinical variables and stent fall

		n (%)	Number of fall (%)	p-value	Fall time (months)	p-value
Age (years)	70≥	36 (56%)	31 (86%)	0.160	4.5	0.101
	70<	28 (44%)	27 (96%)		5.4	
Sex	male	42 (66%)	38 (90%)	0.955	5.2	0.116
	female	22(34%)	20 (91%)		4.4	
Diameter of main pancreatic duct (mm)	3≥	41 (64%)	37 (90%)	0.889	5.2	0.271
	3<	23 (37%)	21 (91%)		4.5	
Pancreatic texture	soft	40 (63%)	36 (90%)	0.825	5.4	0.019
	hard	24 (37%)	22 (92%)		4.1	
Suture number of duct to mucosa anastomosis	4	34 (53%)	31 (95%)	0.872	5.3	0.157
	5≥	30 (37%)	27 (90%)		4.5	
Stent size (Fr)	5	48 (75%)	43 (90%)	0.620	5.1	0.383
	6 or 7.5	16 (25%)	15 (93%)		4.5	
Clavien-Dindo classification	III≥	18 (28%)	18 (100%)	0.107	5.7	0.045
	III<	46 (72%)	40 (87%)		4.6	
Postoperative pancreatic fistula	No or BL	51 (80%)	45 (88%)	0.194	4.7	0.075
	B or C	13 (20%)	13 (100%)		5.8	
Co-morbidity	Yes	43 (67%)	37 (86%)	0.072	4.9	0.746
	No	21 (33%)	21 (100%)		5.0	
Body mass index (kg/m^2)	25≥	14 (22%)	12 (86%)	0.476	4.6	0.491
	25<	50 (78%)	46 (92%)		5.0	
Procedure	SSPPD	60 (94%)	54 (90%)	0.506	5.0	0.670
	PD	4 (6%)	4 (100%)		4.5	
Intraoperative blood loss (ml)	1000<	39 (61%)	34 (87%)	0.238	4.9	0.962
	1000≥	25 (39%)	24 (96%)		4.9	
Operative time (min)	480<	43 (67%)	38 (88%)	0.376	4.9	0.739
	480≥	21 (33%)	20 (95%)		5.1	
Transfusion	Yes	12 (19%)	12 (100%)	0.216	5.0	0.865
	No	52 (81%)	46 (88%)		4.9	
Portal vein resection	Yes	7 (11%)	7 (100%)	0.367	4.9	0.930
	No	57 (89%)	51 (91%)		4.9	
Preoperative biliary drainage	Yes	38 (59%)	34 (89%)	0.702	4.6	0.144
	No	26 (41%)	24 (92%)		5.4	

Table 4 - The relationship between clinical variables and stent excretion

		n (%)	Number of excretion (%)	p-value	Excretion time (months)	p-value
Age (years)	70≥	36 (56%)	29 (81%)	0.587	6.2	0.569
	70<	28 (44%)	24 (86%)		6.7	
Sex	male	42 (66%)	35 (83%)	0.879	7.1	0.014
	female	22(34%)	18 (82%)		5.2	
Diameter of main pancreatic duct (mm)	3≥	41 (64%)	35 (85%)	0.470	6.2	0.560
	3<	23 (37%)	18 (78%)		6.8	
Pancreatic texture	soft	40 (63%)	34 (85%)	0.549	6.6	0.600
	hard	24 (37%)	19 (79%)		6.1	
Suture number of duct to mucosa anastomosis	4	34 (53%)	28 (82%)	0.917	6.3	0.674
	5≥	30 (37%)	25 (83%)		6.6	
Stent size (Fr)	5	48 (75%)	40 (83%)	0.848	6.6	0.460
	6 or 7.5	16 (25%)	13 (81%)		5.9	
Clavien-Dindo classification	III≥	18 (28%)	18 (100%)	0.023	7.7	0.026
	III<	46 (72%)	35 (76%)		5.7	
Postoperative pancreatic fistula	No or BL	51 (80%)	40 (78%)	0.066	5.8	0.024
	B or C	13 (20%)	13 (100%)		8.3	
Co-morbidity	Yes	43 (67%)	35 (81%)	0.667	6.3	0.667
	No	21 (33%)	18 (86%)		6.6	
Body mass index (kg/m^2)	25≥	14 (22%)	11 (79%)	0.634	5.6	0.282
	25<	50 (78%)	42 (84%)		6.6	
Procedure	SSPPD	60 (94%)	49 (82%)	0.347	6.3	0.619
	PD	4 (6%)	4 (100%)		7.5	
Intraoperative blood loss (ml)	1000<	39 (61%)	31 (79%)	0.378	6.5	0.916
	1000≥	25 (39%)	22 (88%)		6.4	
Operative time (min)	480<	43 (67%)	34 (79%)	0.256	6.8	0.208
	480≥	21 (33%)	19 (90%)		5.8	
Transfusion	Yes	12 (19%)	12 (100%)	0.080	6.2	0.732
	No	52 (81%)	41 (79%)		6.5	
Portal vein resection	Yes	7 (11%)	6 (86%)	0.829	4.7	0.101
	No	57 (89%)	47 (82%)		6.6	
Preoperative biliary drainage	Yes	38 (59%)	32 (84%)	0.720	5.8	0.044
	No	26 (41%)	21 (81%)		7.4	

DISCUSSION

Pancreaticoduodenectomy is a standard procedure for peri-ampullary tumors. However, postoperative morbidity and mortality rates remain higher in pancreaticoduodenectomy (40%-45%, 1.6%-3.6%, respectively) than in other procedures (6-8). Pancreaticoenteric anastomosis in pancreaticoduodenectomy includes pancreaticojejunostomy and pancreaticogastrostomy. While pancreaticogastrostomy is associated with lower rates of postoperative pancreatic fistula than pancreaticojejunostomy (9,10), pancreaticogastrostomy is associated with an increased risk of postoperative intraluminal hemorrhage (11). Thus, pancreaticojejunostomy is commonly performed worldwide.

A pancreatic duct stent is commonly used to bridge pancreaticoenteric anastomosis because it diverts pancreatic juice from the anastomosis site, decompresses the remnant pancreas, and maintains the patency of the main pancreatic duct (12,13). Furthermore, pancreatic duct stents reduce the rate of postoperative pancreatic fistula (14-16). However, recent reports have indicated that stenting and non-stenting methods are comparable for preventing postoperative pancreatic fistula (17-19). Therefore, whether a pancreatic stent reduces postoperative pancreatic fistula remains controversial. Moreover, an internal stent is believed to be more useful than an external stent because hospital stay is shorter with use of former than latter. This is because the occurrence of injury during external stent removal is sometimes related to pancreatitis or late-onset stenosis of the pancreatic duct (1,20-22).

Moreover, some stent-related complications (including small bowel perforation, cholangitis, liver abscess, pancreatitis, and osteomyelitis) are due to enterospinal fistula (12,13,23-26). For example, a report of death due to multiple organ failure following biliary obstruction was related to stent migration into

Table 5 - The relationship between clinical variables and migration into pancreatic/bile duct

		n (%)	Migration into pancreatic duct	p-value	Migration into bile duct	p-value
Age (years)	70≥	36 (56%)	1 (3%)	0.412	3 (8%)	0.118
	70<	28 (44%)	2 (7%)		0 (0%)	
Sex	male	42 (66%)	1 (2%)	0.228	3 (7%)	0.199
	female	22(34%)	2 (9%)		0 (0%)	
Diameter of main pancreatic duct (mm)	3≥	41 (64%)	2 (5%)	0.923	1 (2%)	0.256
	3<	23 (37%)	1 (4%)		2 (9%)	
Pancreatic texture	soft	40 (63%)	2 (5%)	0.879	1 (3%)	0.285
	hard	24 (37%)	1 (4%)		2 (8%)	
Suture number of duct to mucosa anastomosis	4	34 (53%)	1 (3%)	0.482	1 (3%)	0.482
	5≥	30 (37%)	2 (7%)		2 (7%)	
Stent size (Fr)	5	48 (75%)	1 (2%)	0.088	3 (6%)	0.306
	6 or 7.5	16 (25%)	2 (13%)		0 (0%)	
Clavien-Dindo classification	III≥	18 (28%)	0 (0%)	0.267	1 (6%)	0.837
	III<	46 (72%)	3 (7%)		2 (4%)	
Postoperative pancreatic fistula	No or BL	51 (80%)	3 (6%)	0.370	2 (4%)	0.566
	B or C	13 (20%)	0 (0%)		1 (8%)	
Co-morbidity	Yes	43 (67%)	1 (2%)	0.201	3 (7%)	0.215
	No	21 (33%)	2 (10%)		0 (0%)	
Body mass index (kg/m^2)	25≥	14 (22%)	0 (0%)	0.348	1 (7%)	0.623
	25<	50 (78%)	3 (6%)		2 (4%)	
Procedure	SSPPD	60 (94%)	3 (5%)	0.647	3 (5%)	0.647
	PD	4 (6%)	0 (0%)		0 (0%)	
Intraoperative blood loss (ml)	1000<	39 (61%)	2 (5%)	0.835	2 (5%)	0.835
	1000≥	25 (39%)	1 (4%)		1 (4%)	
Operative time (min)	480<	43 (67%)	3 (7%)	0.215	2 (5%)	0.984
	480≥	21 (33%)	0 (0%)		1 (5%)	
Transfusion	Yes	12 (19%)	1 (8%)	0.507	0 (0%)	0.394
	No	52 (81%)	2 (4%)		3 (6%)	
Portal vein resection	Yes	7 (11%)	0 (0%)	0.534	0 (0%)	0.534
	No	57 (89%)	3 (5%)		3 (5%)	
Preoperative biliary drainage	Yes	38 (59%)	2 (6%)	0.792	1 (3%)	0.347
	No	26 (41%)	1 (4%)		2 (8%)	

the bile duct (13). Additionally, some reports describe small bowel perforation due to pancreatic stents, one of which occurred 19 years postoperatively (12,26). Therefore, long-term follow-up is necessary for patients whose stents have not been excreted from the body.

In our study, there were no stent-related complications. High serum amylase levels were found in 11 patients (17%) postoperatively, but all patients were asymptomatic. Therefore, the internal stented method is considered safe.

Similarly, Yoshimi et al. reported that internal stents were excreted in all patients by postoperative day 176 (1). Moreover, Kadowaki et al. reported that stent fall rate was 75% with a mean fall time of 13.1 months, excretion rate was 61% with a mean excretion of 15 months, and 41% of the stents were excreted within one year (13). In comparison, our patients had a mean fall time of 4.9 months, and mean stent excretion time of 6.4 months. Within one year, 91% of stents fell from the anastomotic site, and 80% of stents were excreted

Table 6 - Multivariate analysis of risk factor according to stent excretion time

	p-value	Hazard Ratio	95% Confidence interval
Sex	0.156	0.635	0.338-1.193
Clavien-Dindo classification	0.789	0.895	0.297-2.520
Postoperative pancreatic fistula	0.047	0.513	0.266-0.992
Preoperative biliary drainage	0.297	1.368	0.759-2.466

from the body. Multivariate analysis showed that the stent excretion time was significantly delayed in patients with grade B/C postoperative pancreatic fistula. We believe this is because pancreatic fistula may enhance intra-abdominal adhesion and reduce intestinal peristalsis due to inflammation.

Furthermore, Kadowaki et al. reported that the stent migration rates into the remnant pancreas and bile duct were 18.6% and 7.0%, respectively (13). In other reports, the migration rate into the bile duct was between 1.4% and 16.8 % (23,24). In our study, the migration rates into the pancreas and bile duct were both 5%. However, because stent length, thread type, and evaluation period differed between our study and previous studies, an exact comparison was difficult.

We used CT images to evaluate stent fall and excretion. However, as there is a time lag between CT imaging and confirmation of stent fall or excretion, the exact fall and excretion time remain unclear. Nonetheless, we show that internal stents are safe. However, there are some patients whose stents remained fixed at the anastomotic site and migrate into the remnant pancreas; therefore, careful follow-up is necessary. Considering the risk of stent-related complications, no stented method is desirable, and the development of a bioabsorbable stent is expected.

CONCLUSION

We observed the safe removal and excretion of internal stents from patients who underwent pancreaticoduodenectomy. Additionally, patients with postoperative pancreatic fistula had significantly later stent excretion time.

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Disclosure statement

The authors have no conflicts of interest to declosure.

Ethical approval

This study was conducted in accordance with the Declaration of Helsinki and ethical guidelines for clinical study in Japan under approval of the institutional review board of Katsushika Medical Center Jikei University. The approval number is 30-322(9343).

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