

Stenting and the Rate of Pancreatic Fistula Following Pancreaticoduodenectomy

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Objective: To evaluate the efficacy of transanastomotic pancreatic duct internal stenting in the reduction of postoperative pancreatic fistula (POPF) after pancreaticoduodenectomy.

Design: Retrospective study.

Setting: Mayo Clinic.

Patients: Between January 1, 1999, and September 30, 2010, 553 patients underwent pancreaticoduodenectomy by a single surgeon.

Main Outcome Measures: Rates of POPF, morbidity, and mortality between stent and no-stent groups.

Results: The clinically relevant POPF (International Study Group on Pancreatic Fistula definition grade B or C) rates in the stent and no-stent groups were similar (9.6% [43 of 449 patients] and 12.5% [13 of 104 patients], respec-

tively; $P = .38$). Postoperative outcomes and morbidity were also similar between the 2 groups. Mortality was 0.7% (3 of 449 patients) for the stent group and 1.0% (1 of 104 patients) for the no-stent group. Four patients (0.9%) required endoscopic retrieval of the anastomotic stent. In subset analysis, the clinically relevant POPF rates in patients with a small pancreatic duct (≤ 3 mm; $n = 167$) were similar in the stent and no-stent groups (17.7% [23 of 130 patients] and 24.3% [9 of 37 patients], respectively; $P = .38$). In patients with a soft pancreatic gland ($n = 64$), rates of clinically relevant pancreatic fistulae were also similar in the stent and no-stent groups (31.7% [13 of 41 patients] and 17.4% [4 of 23 patients], respectively; $P = .20$).

Conclusions: Internal transanastomotic pancreatic duct stenting does not decrease the frequency or severity of POPF. The effect of stenting on long-term anastomotic patency warrants further investigation.

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MORBIDITY AFTER PANCREATICODUODENECTOMY (PD) continues to be high (30%-50%), even in high-volume centers,¹ despite a progressive reduction in mortality during the last 2 decades.² Postoperative pancreatic fistula (POPF) is the most characteristic and potentially most

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life-threatening complication.^{3,4} Pancreatic surgeons have used numerous interventions, both medical and surgical, in an effort to reduce the incidence of POPF following PD.⁵⁻⁸ Many surgeons have used transanastomotic pancreatic duct stents (internal and external) to reduce the incidence of POPF.⁹

Since the introduction of the International Study Group on Pancreatic Fistula (ISGPF) definition of POPF, 2 randomized controlled trials have evaluated inter-

nal and external stents to prevent POPF. Winter et al¹⁰ studied the efficacy of internal transanastomotic stents and reported that stenting did not affect POPF rates (21.9% in the no-stent group vs 27.0% in the stent group). Poon et al¹¹ reported that external transanastomotic pancreatic duct stents reduced pancreatic fistulae (20% in the no-stent group vs 6.7% in the stent group; $P = .03$). Rates of POPF have also been reported to be similar between internal and external transanastomotic stents.¹² With conflicting reports and heterogeneity between studies, the utility of transanastomotic pancreatic duct stenting for the reduction of POPF remains unknown.⁹

Although transanastomotic stenting may facilitate suture placement, decompress the pancreatic duct, and provide a temporary bridge between the intestine and pancreatic stump, postoperative complications associated with stenting such as stent retention or migration are well recognized.¹³ One of our patients returned 11 years following a PD for ductal carcinoma with a retained internal stent that

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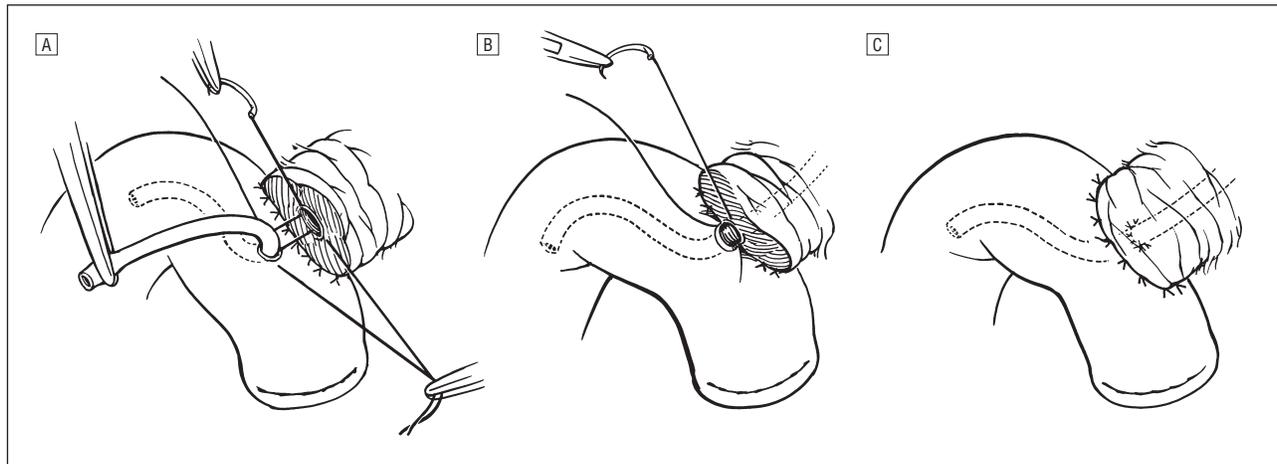


Figure. Two-layer duct-to-mucosa pancreaticojejunostomy. A, The posterior layer of the pancreas capsule and parenchyma is sutured to the seromuscular layer of the jejunum. A silastic catheter is placed. B, A duct-to-mucosa pancreaticojejunostomy is performed with 6-0 absorbable suture. C, The anterior layer of suture is placed. Reprinted with permission of Mayo Foundation for Medical Education and Research. All rights reserved.

had migrated into the biliary tree. Endoscopic removal was performed successfully. As a result of these complications and minimal data to support routine pancreatic duct stenting, we have questioned the utility of leaving an internal transanastomotic stent. These observations, coupled with our encounter with the retained stent more than a decade following operation, prompted us to change our practice to the use of a temporary stent to only guide suture placement.

The aim of this study was to evaluate the rate of POPF with and without internal transanastomotic stenting of a 2-layer duct-to-mucosa pancreaticojejunostomy after PD. We hypothesized that transanastomotic pancreatic duct stenting reduces the rate of POPF and overall postoperative morbidity of a PD.

METHODS

DESIGN, SETTING, AND PATIENTS

The study protocol was approved by the Mayo Clinic Institutional Review Board. From January 1, 1999, to September 30, 2010, 553 consecutive patients underwent PD by a single surgeon (M.B.F.) at Mayo Clinic, Rochester, Minnesota. Internal transanastomotic stenting was routine from January 1, 1999, to May 29, 2008, while in more recent years a stent was used only temporarily to facilitate construction of the pancreaticojejunostomy. Since May 29, 2008, the use of a temporary stent has been routine. In all patients thereafter, the stent was removed prior to tying the anterior row of sutures in the mucosa-to-mucosa pancreaticojejunostomy. We have retrospectively reviewed patient records and compared clinicopathologic factors between a stent group ($n=449$ [81.2%]) and a no-stent group ($n=104$ [18.8%]) to elucidate the effectiveness of transanastomotic stenting on the incidence of POPF.

Clinicopathologic features were evaluated by comparing these 2 groups, and perioperative outcomes were sought. Patient clinical records were reviewed for age, sex, comorbidities, American Society of Anesthesiologists classification, operative procedure, operative time, operative blood loss, number of transfusions, texture of pancreatic remnant, pancreatic duct size, pathologic diagnosis, and 30-day morbidity and mortality. Pancreatic duct diameter was measured prospectively by sounding the duct in the remnant pancreas with a

series of Bakes dilators after pancreatic head resection and prior to reconstruction. Pancreatic texture was graded by a single surgeon (M.B.F.) using a scale of 1 to 10, with pancreata of grades 1 through 3 categorized as soft. Pancreatic duct size and pancreatic remnant texture were prospectively documented as part of the operative record. Rates of pancreatic anastomotic failure (POPF) and delayed gastric emptying were determined using the ISGPF definitions.¹

Previous studies have demonstrated that a small pancreatic duct (≤ 3 mm) and soft pancreatic gland are independent risk factors of POPF after pancreaticojejunostomy.⁴ Based on these reports, we performed subset analysis for groups with a small pancreatic duct (≤ 3 mm) and a soft pancreatic gland.

OPERATIVE PROCEDURE

Patients underwent a conventional or pylorus-preserving PD, with a standard or extended lymph node harvest as previously described.¹⁴ Vagotomy, tube gastrostomy, and feeding jejunostomy were not performed. On completion of the PD, the proximal 2 to 3 cm of the pancreatic body remnant was mobilized in preparation for the pancreaticojejunal anastomosis. The jejunal limb was brought through the transverse mesocolon by the retrocolic route. A 3.5F to 8.0F silastic catheter (SF Medical) was cut to a length of 4 to 6 cm and served as a transanastomotic pancreatic duct stent. This stent was left in place with the expectation that it would pass spontaneously in the stool. In the no-stent group, a temporarily placed stent was used to facilitate construction of the pancreaticojejunostomy and was removed prior to completing the anastomosis. Using $\times 2.5$ loupe magnification, an end-to-side pancreaticojejunostomy was performed in 2 layers: an inner duct-to-mucosa layer with 6-0 absorbable suture and an outer layer with interrupted 4-0 silk suture (**Figure**). A single-layer hepaticojejunostomy was performed 8 to 10 cm downstream from the pancreaticojejunostomy. The duodenojejunostomy or gastrojejunostomy was constructed in an antecolic fashion. A single 15F, round, closed-suction drain was placed posterior to the pancreaticojejunostomy and hepaticojejunostomy and brought out through the right anterior abdominal wall.

PERIOPERATIVE MANAGEMENT

Perioperative management was standardized. All patients were given perioperative prophylactic antibiotic and antiemetic medi-

Table 1. Patient Characteristics in the Groups With and Without Transanastomotic Pancreatic Duct Stenting

Variable	No. (%)		P Value
	Stent (n=449)	No Stent (n=104)	
Age, median (IQR), y	65 (56-72)	65 (55-73)	.87
Male	246 (54.8)	62 (59.6)	.37
History			
Alcohol use	49 (10.1)	5 (4.8)	.20
Smoking	126 (28.1)	15 (14.4)	.21
Comorbidities			
Cardiac	95 (21.2)	26 (25.0)	.37
Pulmonary	55 (12.2)	11 (10.6)	.63
Diabetes	103 (22.9)	27 (26.0)	.53
Hypertension	169 (37.6)	41 (39.4)	.74
Obesity ^a	103 (22.9)	27 (26.0)	.71
Preoperative data			
Pancreatitis	79 (17.6)	19 (18.3)	.84
Jaundice	258 (57.5)	66 (63.5)	.27
Endoscopic CBD stent	232 (51.7)	64 (61.5)	.07
Endoscopic MPD stent	17 (3.8)	6 (5.8)	.38
ASA classification			.15
1	40 (8.9)	10 (9.6)	
2	194 (43.2)	51 (49.0)	
3	209 (46.5)	43 (41.3)	
4	6 (1.3)	0	
Operative procedure			<.001
PD	97 (21.6)	4 (3.8)	
PPPD	352 (78.4)	100 (96.2)	
Operative time, median (IQR), min	371 (335-416)	332 (291-402)	<.001
EBL, median (IQR), mL	600 (350-800)	650 (350-900)	.20
Transfusion of RBCs	127 (28.3)	22 (21.2)	.73
Texture of pancreas ^b			.12
Soft	41 (15.8)	23 (23.0)	
Not soft	219 (84.2)	78 (77.0)	
Pancreatic duct size, median (IQR), mm	4 (3-6)	4 (3-6)	.43
Pathologic diagnosis			
Pancreas			
Ductal adenocarcinoma	213 (47.4)	56 (53.8)	.12
IPMN	76 (16.9)	15 (14.4)	.42
Islet cell tumor	17 (3.8)	2 (1.9)	.22
Chronic pancreatitis	20 (4.5)	4 (3.8)	.78
Other	12 (2.7)	5 (4.8)	.38
Bile duct			
Adenocarcinoma	13 (2.9)	5 (4.8)	.44
Other	3 (0.7)	3 (2.9)	.21
Ampullary			
Adenocarcinoma	55 (12.2)	10 (9.6)	.54
Other	2 (0.4)	2 (1.9)	.28
Duodenal			
Adenocarcinoma	9 (2.0)	2 (1.9)	.88
Other	10 (2.2)	0	.10
Missing	19 (4.2)	0	.02

Abbreviations: ASA, American Society of Anesthesiologists; CBD, common bile duct; EBL, estimated blood loss; IPMN, intraductal papillary mucinous neoplasm; IQR, interquartile range; MPD, main pancreatic duct; PD, pancreaticoduodenectomy; PPPD, pylorus-preserving pancreaticoduodenectomy; RBCs, red blood cells.

^aObesity is defined as a body mass index (calculated as weight in kilograms divided by height in meters squared) higher than 30.

^bOwing to missing data, the sample sizes are 275 in the stent group and 101 in the no-stent group.

cations. Prophylactic octreotide was not administered. Drain volumes were recorded daily. The amylase level in the drained body fluid was evaluated on postoperative day 3 and repeated prior to drain removal. Drains were discontinued in stable patients with low levels of amylase in the drained body fluid (<3 times the upper limit of normal serum levels). Postoperative pancreatic fistulae not controlled adequately with the drain placed at operation were managed with percutaneous computed tomography- or ultrasonography-guided drainage.

STATISTICAL ANALYSIS

Continuous data were expressed as median and interquartile range. Comparisons of categorical and continuous variables were performed using the Fisher exact test and Mann-Whitney test, respectively. $P < .05$ was considered statistically significant. All statistical analyses were performed using SPSS for Windows version 18.0 statistical software (SPSS Inc).

Table 2. Rate of Postoperative Pancreatic Fistula

POPF Grade ^a	No. (%)		P Value
	Stent	No Stent	
All patients ^b			.21 ^c
No	385 (85.7)	84 (80.8)	
A	21 (4.7)	7 (6.7)	
B	39 (8.7)	8 (7.7)	
C	4 (0.9)	5 (4.8)	
Patients with small main pancreatic duct, ≤ 3 mm ^d			.10 ^e
No	99 (76.2)	23 (62.1)	
A	8 (6.2)	5 (13.5)	
B	20 (15.4)	5 (13.5)	
C	3 (2.3)	4 (10.8)	
Patients with soft remnant pancreatic gland ^f			.60 ^g
No	24 (58.5)	15 (65.2)	
A	4 (9.8)	4 (17.4)	
B	10 (24.4)	3 (13.0)	
C	3 (7.3)	1 (4.3)	

Abbreviation: POPF, postoperative pancreatic fistula.

^aGraded according to the International Study Group on Pancreatic Fistula definition.¹

^bThe sample sizes are 449 in the stent group and 104 in the no-stent group.

^cNo POPF vs any POPF (grade A, B, or C). For no POPF and grade A vs grade B or C, $P=.38$.

^dThe sample sizes are 130 in the stent group and 37 in the no-stent group.

^eNo POPF vs any POPF (grade A, B, or C). For no POPF and grade A vs grade B or C, $P=.38$.

^fThe sample sizes are 41 in the stent group and 23 in the no-stent group.

^gNo POPF vs any POPF (grade A, B, or C). For no POPF and grade A vs grade B or C, $P=.20$.

RESULTS

PATIENT POPULATION

The study included 553 patients who underwent PD by a single surgeon (M.B.F.), of whom 449 (81.2%) had transanastomotic stenting (stent group) and 104 (18.8%) had no stenting (no-stent group). Patient characteristics are summarized in **Table 1**. Stented patients were more likely to undergo PD with distal gastrectomy rather than pylorus-preserving PD and have a longer operative time because between 1997 and 2004 we were conducting a prospective randomized trial comparing standard and extended lymphadenectomy. All patients enrolled in the extended lymphadenectomy trial had PD with distal gastrectomy (n=63 [11.4%]).

COMPARISON OF POPF BETWEEN STENT AND NO-STENT GROUPS

The overall postoperative pancreatic fistula rate was 15.2% for grade A, B, or C fistulae and 10.1% for grade B or C fistulae. There was no significant difference in the fistula rate between the stent and no-stent groups (**Table 2**). Subset analysis for patients with a 3-mm or smaller pancreatic duct showed that patients in the stent group were more likely to have lower rate of grade B or C POPF but no statistically significant overall difference in the POPF rate

Table 3. Postoperative Course in the Stent and No-Stent Groups

Variable	Stent (n=449)	No Stent (n=104)	P Value
Median (IQR), d			
Postoperative length of stay	10 (8-14)	9 (7-15)	.32
Time until unlimited oral intake	7 (5-11)	7 (5-12.5)	.47
NG tube removal	1 (1-4.5)	1 (1-2)	.11
No. (%)			
Postoperative transfusion	41 (9.1)	11 (10.6)	.22
Bile leak	13 (2.8)	5 (4.8)	.35
Intra-abdominal abscess	30 (6.7)	4 (3.8)	.25
Percutaneous drainage	57 (12.7)	14 (13.5)	.84
Intra-abdominal bleeding	17 (3.8)	3 (2.9)	.65
Reoperation	11 (2.4)	2 (1.9)	.74
Readmission	39 (8.7)	7 (6.7)	.50
Death <30 d after operation	3 (0.7)	1 (1.0)	.92
DGE grade ^a			.53 ^b
No	220 (49.0)	47 (45.2)	
A	126 (28.1)	33 (31.7)	
B	81 (18.0)	18 (17.3)	
C	22 (4.9)	6 (5.8)	

Abbreviations: DGE, delayed gastric emptying; IQR, interquartile range; NG, nasogastric.

^aGraded according to the International Study Group on Pancreatic Fistula definition.¹

^bNo DGE vs grade A, B, or C. For no DGE and grade A vs grade B or C, $P=.84$.

(**Table 2**). In subset analysis of patients with a soft pancreas, patients in the stent group were more likely to have a higher rate of grade B or C POPF, although there was no statistically significant difference in the POPF rate (**Table 2**).

POSTOPERATIVE MORBIDITY AND MORTALITY

No difference in the postoperative course was identified in the stent and no-stent groups (**Table 3**). Endoscopic retrieval of the retained or migrated pancreatic transanastomotic stent was required in 4 of 449 patients (0.9%).

COMMENT

In this retrospective study of 553 patients undergoing PD with or without an internal transanastomotic stent, no benefit was observed with stenting. Patients had similar morbidity and mortality. However, late stent-related complications were noted in 0.9% of stented patients. In subset analysis of the patients with a small pancreatic duct (≤ 3 mm), a trend was observed toward decreased POPF in the stent group but was not statistically significant. In subset analysis of patients with a soft pancreas, a trend was observed toward increased POPF in the stent group but was not statistically significant. Therefore, even in patients at increased risk for POPF, the benefit of internal transanastomotic stenting was not apparent.

With the establishment of a POPF definition by the ISGPF, we have been able to compare POPF rates between studies.¹ Four previous studies have evaluated the utility of stenting the pancreatic anastomosis using the ISGPF POPF definition (**Table 4**). These studies per-

Table 4. Studies of Transanastomotic Pancreatic Duct Stenting for Pancreaticoduodenectomy^a

Source	Study Design	Stent	Patients, No.	Grade A, B, or C POPF (Grade B or C POPF), %			P Value ^b	Superior
				All	Stent	No Stent		
Winter et al, ¹⁰ 2006	Prospective	Internal	238	24	27	22	.3	Equal
Poon et al, ¹¹ 2007	Prospective	External	120	13 (9)	7 (3)	20 (15)	.032 (.027)	Stent
Satoi et al, ¹⁵ 2010	Retrospective	External	129	32 (11)	44 (14)	27 (6)	.0004 (NS)	No stent
Smyrniotis et al, ¹⁶ 2010 ^c	Prospective	Internal	82	4 (2)	5 (2)	2 (2)	NS (NS)	Equal
Current study	Retrospective	Internal	553	15 (10)	14 (10)	19 (12)	.21 (.38)	Equal

Abbreviations: NS, not significant; POPF, postoperative pancreatic fistula.

^aOnly studies that use the International Study Group on Pancreatic Fistula definition of pancreatic fistula are included. Duct-to-mucosa pancreaticojejunostomy was performed in all studies.

^bThe *P* values are for stent vs no stent and are expressed as *P* value for grade A, B, or C POPF (*P* value for grade B or C POPF).

^cReconstructed using isolated jejunal loop.

formed a duct-to-mucosa pancreaticojejunostomy, with 2 studies using internal stenting and 2 using external stenting.^{10,11,15,16} Three were prospective studies and 1 was a retrospective study. The overall rate of POPF (including the current study) was 17.8% (200 of 1122 patients) for grade A, B, or C and 9.3% (82 of 884 patients) for grade B or C. Only Poon et al¹¹ demonstrated a decreased rate of POPF with external transanastomotic stenting.

Proponents of using an external stent cite several reasons why it may improve outcomes following a pancreaticoenterostomy. First, the external stent creates a controlled pancreaticocutaneous fistula by diverting pancreatic secretions away from the anastomosis. This may encourage anastomotic healing and improve long-term pancreatic duct patency. Second, the stent may decompress the afferent limb and provide improved local control of secretions in the instance of an anastomotic leak. Third, the stent can facilitate precise suture placement. In a study of 120 randomized patients, Poon et al¹¹ concluded that external stenting decreased the rate of POPF. On the other hand, Satoi et al¹⁵ reported that external stenting increased POPF in a retrospective study of 129 patients. In an 85-patient study that did not use the ISGPF definition of POPF, Roder et al¹⁷ reported that the POPF rate was 7% in patients with an external pancreatic duct stent compared with 29% in patients without a pancreatic duct stent (*P* = .007).

Several studies have investigated the benefit of internal transanastomotic stents for PD, but results are mixed.^{9,10,18,19} In a prospective randomized trial of 238 patients by Winter et al,¹⁰ internal transanastomotic stenting did not reduce the incidence of POPF. Although multivariate analyses in this study did adjust for surgeon and anastomotic technique, the study did not report POPF rates in subgroups with duct-to-mucosa vs invagination-type pancreaticojejunostomy, making it difficult to compare with other studies. In a canine model, Biehl and Traverso²⁰ evaluated internal pancreatic duct stenting after pancreaticojejunal anastomosis. Biehl and Traverso performed the procedure in 3 experimental groups: stent, no stent, and temporary stent removed after the pancreaticojejunal anastomosis was complete. The study evaluated the development of pancreatic fistulae as well as long-term outcomes of duct occlusion and stenosis. Although not statistically significant, pancreatic duct stenosis (at

1-month necropsy) was 0% in the stent group, 25% in the temporary-stent group, and 30% in the no-stent group. Our study was not designed to analyze long-term anastomotic patency, although this has been suggested as one of the benefits of stenting.

Two previous studies have compared POPF outcomes with external and internal transanastomotic stenting. Tani et al¹² conducted a prospective, randomized, controlled trial of internal vs external transanastomotic stents and showed equivalent outcomes (grade A, B, or C POPF: external, 20%; internal, 26%). In this study of 100 patients, they concluded that internal stenting can simplify postoperative management and might shorten the postoperative stay for PD. In a nonrandomized study of 74 patients, Ohwada et al⁸ reported equivalent outcomes for patients with internal stents and those with external stents but did not use the ISGPF definition of POPF. Neither study compared POPF outcomes with a no-stent group.

Few studies have investigated the use of pancreatic duct stents in patients at increased risk for POPF (small duct and/or soft gland). The rate of POPF for patients with a soft pancreas ranges from 18% to 41% in studies using the ISGPF grading system.^{10,11,21} Similar to previous studies, we did not identify a difference in POPF with use of pancreatic duct stenting in patients with a soft pancreas. Interestingly, based on univariate analysis, Poon et al¹¹ reported that a soft pancreas was not a risk factor for POPF (*P* = .08) but that pancreatic duct stenting did reduce the rate of POPF in this subgroup.

In our study, a small pancreatic duct (≤ 3 mm) resulted in an overall higher rate of POPF in both the stent and no-stent groups (24% and 38%, respectively). The tendency for stenting to decrease the POPF rate was recognized, although a statistical difference was not present. Similarly, Poon et al¹¹ reported an increased risk of pancreatic fistula in patients with a small pancreatic duct (≤ 3 mm) (*P* = .03), but the reduction in POPF with the use of a pancreatic stent was not statistically significant. Winter et al¹⁰ reported that a larger pancreatic duct (≥ 5 mm) decreased the risk of POPF independent of pancreatic duct stenting (odds ratio = 0.2; *P* < .05). Ohwada et al⁸ found an equivalent outcome regarding pancreatic fistula rates when internal or external stents were used for pancreatic ducts smaller than 2 mm.

Although our study does not identify a benefit of internal transanastomotic stenting, the benefit of using a stent may still exist. In our practice, a stent is used to guide suture placement and is removed prior to completing the anastomosis. The pancreatic anastomoses analyzed in this study were performed by an experienced surgeon or by a trainee with the guidance of an experienced surgeon. It may be that accurate suture placement in the hands of an experienced pancreatic surgeon is more important than leaving a stent in place.

The retrospective design of this study limits our ability to conclusively state that transanastomotic stents do not decrease the rate of POPF. Similarly, this study is a historical comparison with patients in the study prior to the establishment of the ISGPF definition of POPF. Moreover, our study was not designed to assess long-term anastomotic patency, which may be influenced by stent use. Acknowledging these limitations, this is currently the largest study to our knowledge to investigate the utility of internal transanastomotic stents in the prevention of POPF. All patients underwent a duct-to-mucosa anastomosis performed similarly by or under the guidance of a single experienced pancreatic surgeon, thereby reducing variation.

In conclusion, this retrospective study of 553 patients demonstrated that routine use of an internal transanastomotic pancreatic duct stent was not associated with a decrease in the pancreatic fistula rate after PD. Also, stenting did not affect the morbidity and mortality associated with PD. In subgroup analysis of high-risk patients with a small pancreatic duct diameter (≤ 3 mm) or a soft pancreatic gland, the use of pancreatic duct stenting did not significantly change the rate of pancreatic fistulae. Importantly, the only identifiable difference in morbidity associated with routine use of a pancreatic stent was the occurrence of delayed complications directly associated with stenting. In our cohort, although rare, 4 patients (0.9%) required endoscopic retrieval of their transanastomotic stent owing to stent migration or obstruction of the pancreatic duct. While transanastomotic stenting does not affect short-term outcomes in PD, stenting may influence the long-term patency of the pancreaticojejunal anastomosis and warrants future investigation.

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