



Is routine drainage necessary after pancreaticoduodenectomy?

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Abstract

With the development of imaging technology and surgical techniques, pancreatic resections to treat pancreatic tumors, ampulla tumors, and other pancreatic diseases have increased. Pancreaticoduodenectomy, one type of pancreatic resection, is a complex surgery with the loss of pancreatic integrity and various anastomoses. Complications after pancreaticoduodenectomy such as pancreatic fistulas and anastomosis leakage are common and significantly associated with patient outcomes. Pancreatic fistula is one of the most important postoperative complications; this condition can cause intra-abdominal hemorrhage, septic shock, or even death. An effective way has not yet been found to avoid the occurrence of pancreatic fistula. In most medical centers, the frequency of pancreatic fistula has remained between 9% and 13%. The early detection and routine drainage of anastomotic fistulas, pancreatic fistulas, bleeding, or other intra-abdominal fluid collections after pancreatic resections are considered as important and effective ways to reduce postoperative complications and the mortality rate. However, many recent studies have argued that routine drainage after abdominal operations, including pancreaticoduodenectomies, does not affect the incidence of postoperative complications. Although inserting drains after pancreatic resections

continues to be a routine procedure, its necessity remains controversial. This article reviews studies of the advantages and disadvantages of routine drainage after pancreaticoduodenectomy and discusses the necessity of this procedure.

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Key words: Pancreaticoduodenectomy; Drainage; Suction; Fistula; Postoperative complications; Intra-abdominal infections

Core tip: Limited studies have shown that routine drainage does not produce obvious benefits for patients after pancreaticoduodenectomy. Few retrospective studies support selective drainage after pancreaticoduodenectomy, but persuasive evidence does not exist to support omitting drainage in all patients. Patients might benefit from having their drains removed shortly after pancreaticoduodenectomy; however, evidence for this assertion is lacking.

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INTRODUCTION

In the 19th century, Sims became the first surgeon to use routine drainage after gynecological surgery. Since then, most surgeons have inserted routine drainage following abdominal surgeries^[1-4]. Routine drainage is considered to be an important and effective method of reducing postoperative complications and the mortality rate, and it is widely used for various general surgeries^[5-7]. Two types of surgical drains exist: open drains and closed drains. Open drains evacuate collected fluid after the insertion of an artificial catheter into the postoperative wound.

Closed drains include the following types: a passive drain based on gravity and a suction drain that relies on negative pressure^[8-11].

Although surgical technologies have significantly progressed, abdominal drainage continues to be a routine method to avoid or reduce postoperative complications in most hospitals. The major purposes of routine drainage insertion are to manage possible leakage, provide evidence of leakage or postoperative hemorrhaging, or prevent postoperative infection by discharging blood and avoiding the formation of abdominal abscesses^[12-14]. However, certain surgeons currently believe that routine drainage can increase the incidence of intra-abdominal and wound infections, exacerbate abdominal pain, reduce lung function, and prolong hospitalization, as well as erode the hollow viscera and peripancreatic vessels^[15-18].

Although some surgeons have devoted themselves over recent decades to researching postoperative routine drainage, they have been unable to confirm the advantages of this procedure for patients after liver resection, cholecystectomy, gastrectomy, or other abdominal surgeries using randomized controlled experiments^[19-23]. The incidence of complications is not associated with routine drainage, and this procedure does not reduce the time before complications such as bile leakage and postoperative bleeding are detected. According to previous studies, certain complications were even revealed after the drains had been removed^[24-26]. Moreover, only certain types of intra-abdominal bleeding can be detected during the early stages with routine drainage, and other types must be detected *via* clinical symptoms and imaging examinations. The assessment of clinical symptoms and imaging examinations are the most effective ways to detect postoperative complications, regardless of whether routine drainage is utilized^[27-30]. Therefore, it is not apparent that routine drainage is helpful for the early detection and intervention of postoperative complications.

CHARACTERISTICS OF PANCREATICODUODENECTOMY

As the use of cross-sectional imaging technology becomes more common, more pancreatic or ampulla tumors have been diagnosed, thereby resulting in the need for more pancreatic resections^[31-33]. Pancreatic resections primarily include pancreaticoduodenectomy, middle pancreatectomy, distal pancreatectomy, and local resection^[34-36]. Due to the loss of pancreatic integrity and various anastomoses, complications such as pancreatic fistula and anastomosis leakage often arise after pancreaticoduodenectomy^[37-39]. The International Study Group of Pancreatic Fistula defined this important complication after pancreaticoduodenectomy in 1995 as the output of any measurable volume of drain fluid on or after postoperative Day 3 with an amylase content greater than 3 times the upper normal serum value^[40-43]. Pancreatic fistulas can cause intraperitoneal hemorrhaging, septic shock, or death. Various clinical centers report different

rates of pancreatic fistula. Although various pancreaticojejunostomy or pancreaticogastrostomy methods can prevent the occurrence of pancreatic fistulas^[44-46], they occur in 9%-29% of patients receiving pancreaticoduodenectomies^[47-49]. In most medical centers, the frequency of pancreatic fistula has remained between 9% and 13%, and the frequency of intra-abdominal abscess is 3%-13%, such as in Massachusetts General Hospital^[50-54].

EARLY REMOVAL OF ROUTINE DRAINAGE AFTER PANCREATICODUODENECTOMY

The amylase levels of the drainage fluid on the first postoperative day may predict pancreatic fistula after pancreatic resections^[55,56]. For example, Yamaguchi and colleagues surveyed 26 patients with pancreatic resections in 2003. Twelve of these patients ultimately developed pancreatic fistulas. The researchers found that the patients who developed pancreatic fistulas had higher drainage fluid amylase levels on the first postoperative day. Thus, the drainage fluid amylase levels on the first postoperative day might predict the development of pancreatic fistulas^[57]. Molinari analyzed the data of 137 patients after pancreatic surgeries, including 101 patients after pancreaticoduodenectomies and 36 patients after distal pancreatectomies. He found that drainage fluid amylase levels ≥ 5000 U/L on the first postoperative day indicated a high risk of pancreatic fistula^[58]. In another study, however, Sutcliffe reported that it might not be appropriate to use 5000 U/L as the cut-off for the drainage fluid amylase level on the first postoperative day. This study included 70 patients after pancreaticoduodenectomies, 9 of whom eventually developed pancreatic fistulas. Three patients developed pancreatic fistulas whose drainage fluid amylase levels were > 5000 U/L on the first postoperative day. Therefore, researchers regarded 5000 U/L as an inappropriate cut-off for drainage fluid amylase levels on the first postoperative day; rather, they used 350 U/L as the cut-off^[59].

Because the drainage fluid amylase levels on the first postoperative day might predict whether patients develop pancreatic fistulas, some surgeons have questioned whether drainage should be removed soon after pancreaticoduodenectomies among patients at low risk for this complication. Kawai *et al.*^[60] divided 104 patients with routine drainage into 2 groups. The drainage in one group was removed on the fourth postoperative day, and the drainage in the other group was removed on the eighth postoperative day. The researchers extended the drainage removal time as soon as patients had developed pancreatic fistulas, bile leakage, or intra-abdominal infections. They found that the morbidity of patients whose drainage was removed on the fourth postoperative day was significantly lower than that of those whose drainage was removed on the eighth postoperative day (3.6% *vs* 23%, $P = 0.0038$). The intra-abdominal infection rate was 3.6% among pa-

tients with an earlier drainage removal, which was lower than in those whose drains were removed later (23%, $P = 0.0003$). In 2010, Bassi *et al*^[61] studied 114 patients whose drainage fluid amylase levels were > 5000 U/L on the first day after pancreatic resections. These authors excluded patients whose drain effluent had a “sinister” appearance and those with a volume of peripancreatic fluid collection > 5 cm before the third postoperative day. The researchers compared the morbidity of the postoperative complications among patients with different drainage-removal times (*i.e.*, the third postoperative day, the fifth postoperative day or longer). They found that the rate of pancreatic fistulas and intra-abdominal infections was lower among patients whose drainage was removed earlier. However, not all patients in this study underwent pancreaticoduodenectomies; 39 underwent distal pancreatectomies.

Drainage can be safely removed from patients who have even developed grade A pancreatic fistulas (biochemical fistulas without clinical signs). Hiyoshi analyzed the postoperative data of 176 patients receiving pancreaticoduodenectomies. He found that patients who underwent pancreaticoduodenectomies were more likely to have clinical pancreatic fistulas when they had drainage fluid amylase levels ≥ 750 IU/L, serum C-reactive protein (CRP) levels ≥ 20 mg/dL, and temperatures ≥ 37.5 °C compared with patients without this complication on the third postoperative day. Other patients did not develop clinical pancreatic fistulas even with grade A pancreatic fistulas. Therefore, drainage could be removed safely from patients with drainage fluid amylase levels < 750 IU/L, serum CRP levels < 20 mg/dL, and temperatures < 37.5 °C on the third postoperative day^[62-66]. Currently, no appropriate index exists to precisely predict the early incidence of pancreatic fistulas.

SELECTIVE ROUTINE DRAINAGE AFTER PANCREATICODUODENECTOMY

Pancreatic texture and the diameter of the major pancreatic duct are the primary factors associated with the occurrence of pancreatic fistulas^[67-69]. El Nakeeb *et al*^[70] surveyed 471 patients undergoing pancreatic resections and analyzed the risk factors for developing pancreatic fistulas. They compared the clinicopathological factors (*e.g.*, age, sex, smoking, body mass index, preoperative albumin, preoperative bilirubin, preoperative biliary drainage, liver status, mass mean size, site, pancreatic duct diameter, pancreatic consistency, and others) of 57 patients with pancreatic fistulas with those of 414 patients without pancreatic fistulas. A soft pancreatic texture and a pancreatic duct diameter less than 3 mm were risk factors for pancreatic fistula. The incidence of pancreatic fistula among patients with pancreatic ducts ≤ 3 mm (28.6%) was significantly higher than that among patients with larger duct diameters (4.9%, $P = 0.0001$). Patients with a hard pancreatic texture also had a lower incidence of pancreatic fistulas (7.9% *vs* 14.3%,

$P = 0.04$). In another study, Pratt found that the potential for developing clinically relevant pancreatic fistulas among patients with soft pancreatic textures was more than 3 times that seen among patients with hard pancreatic textures (OR = 3.28, 95%CI = 1.08-9.93, $P = 0.036$). When the pancreatic duct diameter was less than 3 mm, patients had a greater chance of developing pancreatic fistulas than those with a normal (4-5 mm) or dilated (≥ 6 mm) pancreatic duct. In addition, the ratio of pancreatic fistulas increased by 68% when the pancreatic duct diameters decreased by 1 mm^[71].

In light of the low risk of pancreatic fistulas among patients with hard pancreatic textures, dilated pancreatic ducts, or both, safely foregoing routine drainage among these patients is possible. Lim *et al*^[72] chose not to insert routine drainage in 27 patients after pancreaticoduodenectomies between July 2009 and June 2011. Most of these patients had either a hard pancreas or a dilated (≥ 3 mm) main pancreatic duct. These patients were matched with 27 patients with routine drainage over the same period. All patients had similar demographic data, surgical indications, and primary risk factors for pancreatic fistula. The overall morbidity rate among the patients without drainage was 56%, whereas this figure for the patients with drainage was 70% ($P = 0.04$). The incidence of pancreatic fistula among patients without drainage (0%) was significantly less than that among those with drainage (22%, $P = 0.009$). Therefore, omitting drainage might be preferable among patients at low risk for pancreatic fistula.

In 1992, Jeekel^[73] indicated that patients without routine drainage did not develop more serious complications than those with routine drainage after pancreatoduodenectomy. However, this study only included 22 patients without drainage, and the researchers inserted drainage into patients with diffuse bleeding. Heslin *et al*^[74] conducted a retrospective study in 1998 of 38 patients without drainage and 51 patients with drainage, and they compared the rates of postoperative complications between these groups of patients. The pancreatic fistula and intra-abdominal abscess rates were not more frequent among patients without routine drainage, and neither were the rate of CT-guided percutaneous drainage or necessity of reoperation. Patients without drainage had a briefer anesthesia time in this study ($P = 0.0001$), which might be related to the surgical decision of whether to use drainage. Recently, Correa-Gallego *et al*^[75] collected the data of 1122 patients who underwent pancreatic resections, including 739 patients who underwent pancreatoduodenectomies at the Memorial Sloan-Kettering Cancer Center between 2006 and 2011. Different surgeons operated on these patients who were divided into groups of routine drainers (operative drains placed in $> 95\%$ of patients), selective drainers (drains placed in approximately 50% of patients), and routine non-drainers (drains placed in $< 15\%$ of patients). The incidence of pancreatic fistulas was lower among patients without drainage after pancreatoduodenectomy (17% *vs* 27%, $P = 0.001$). In addition,

Table 1 Citations of routine drainage studies

Preference	Ref.	Country	Study design	n	PD
Removed early	Kawai <i>et al</i> ^[60] , 2006	Japan	Time cohort	104	104
Selective routine drainage	Jeekel <i>et al</i> ^[73] , 1992	Netherlands	Prospective case report	22	22
	Heslin <i>et al</i> ^[74] , 1998	United States	Retrospective	89	89
	Lim <i>et al</i> ^[72] , 2013	France	Case-control analysis	54	54
	Mehta <i>et al</i> ^[93] , 2013	United States	Retrospective	709	709
	Correa-Gallego <i>et al</i> ^[75] , 2013	United States	Retrospective	1122	739
No routine drainage	Van Buren <i>et al</i> ^[79] , 2013	United States	Randomized prospective	137	137

the incidence of overall complications was also lower among patients without drainage (48% *vs* 54%, $P = 0.03$). Bile duct diameter, blood loss, and operation time also influenced the surgical decisions regarding selective drainers. These researchers also discovered that the frequency of drainage use had decreased annually in their center, especially among selective drainers and non-drainers. However, randomized controlled trials (RCTs) were not conducted to confirm the selection criteria of the non-drainers after pancreatoduodenectomy.

NO ROUTINE DRAINAGE AFTER PANCREATICODUODENECTOMY

Omitting drainage among patients at low risk of pancreatic fistula might be safer. However, whether drainage benefits patients at high risk for pancreatic fistula or whether drainage should be omitted among all patients after pancreatoduodenectomies remains unknown. Conlon *et al*^[76] conducted an RCT in 2001; these authors selected 179 patients with either pancreatic or peripancreatic carcinomas, including 139 patients who had undergone pancreaticoduodenectomies and 40 who had undergone distal pancreatectomies. These patients were randomly assigned to two groups. Routine drainage was placed in the patients of one group but omitted from those of the other group. The incidence of complications among the drainage group was 63%, whereas the rate among the no-drainage group was 57% ($P = 0.5$). Eleven patients with drainage developed pancreatic fistulas, whereas none of the patients without drainage did so. Patients with routine drainage were more likely to develop serious intra-abdominal abscesses, intra-abdominal fluid collection, and pancreatic fistulas (19 *vs* 8, $P < 0.02$). These results were enlightening; unfortunately, however, these researchers did not analyze the results of patients undergoing pancreatoduodenectomies and distal pancreatectomies separately. In 2011, Fisher conducted a time cohort study on pancreatic resections without routine intraperitoneal drainage. The complication rate was 65% among patients with routine drainage, which was higher than that among those without routine drainage (65% *vs* 47%, $P = 0.020$). Moreover, the incidence of pancreatic fistula was also higher among patients with routine drainage (44% *vs* 11%, $P < 0.0001$). However, this patient cohort included 153 patients who had undergone pancreatoduodenectomies and 73 patients who had undergone

distal pancreatectomies, and the effect of the different types of pancreatic resections on pancreatic fistula was not investigated^[77,78].

Recently, Van Buren *et al*^[79] conducted a randomized prospective trial and found no evidence to support abandoning routine drainage in all patients after pancreaticoduodenectomy. In this multicenter trial, 137 patients were randomly assigned to two groups: the drain group and the no-drain group.

The patients in these groups were similar with regard to demographics, pancreatic duct size, pancreas texture, and surgical technique. Patients in the no-drain group demonstrated higher rates of intra-abdominal fluid collection and intra-abdominal abscess (10% *vs* 25%, $P = 0.027$). More patients in the no-drain group required postoperative cutaneous drains. Moreover, the mortality of patients without routine drainage was higher than that of patients with routine drainage after a 90-d follow-up evaluation (12% *vs* 3%, $P = 0.097$); thus, this trial was ended early. The 30-d mortality rate in this study was also higher than that of several centers (6% *vs* 3%)^[79-81].

DISCUSSION

As surgical techniques, perioperative support care, the use of antibiotics, imaging techniques, and non-operative treatment have developed, the complications following pancreatic surgeries have been detected earlier and managed more effectively^[82-86]. Radiological interventions can be used to manage abdominal collection and abscesses after pancreaticoduodenectomies without reoperation^[87-91]. Therefore, the importance of routine drainage is decreasing^[92]. Some surgeons forego the routine insertion of drainage and deem it useless for reducing and managing postoperative complications. However, the evidence needed to verify the disadvantage of routine drainage after pancreaticoduodenectomy (*e.g.*, RCTs) is lacking.

We conducted a search for citations concerning drainage after pancreaticoduodenectomy using Ovid Medline and PubMed. Table 1 presents the study characteristics. Only one retrospective study examined the early removal of drainage following pancreaticoduodenectomy. In this study, the rates of pancreatic fistulas and other complications were significantly lower among patients whose drains were removed early, regardless of the criteria for removing drainage^[60]. Other studies (*e.g.*, Kurahara *et al*^[94] and Nissen *et al*^[95]) attempted to find a connection between drainage

Table 2 Studies comparing selective routine drainage with selective no-drainage *n* (%)

Ref.	Patients	Drain	No drain	Pancreatic fistula			Complications			Possible reasons for drainage
				Drain	No drain	<i>P</i> value	Drain	No drain	<i>P</i> value	
Heslin <i>et al.</i> ^[74]	89	51	38	3 (6)	1 (3)	0.30	23 (45)	15 (39)	0.60	Anesthesia time
Lim <i>et al.</i> ^[72]	54	27	27	6 (22)	0 (0)	0.009	13 (48)	6 (22)	0.09	Hard pancreas and dilated main pancreatic duct
Mehta <i>et al.</i> ^[93]	709	251	458	61 (24)	48 (11)	< 0.0001	171 (68)	248 (54)	< 0.0001	Operation type and blood loss
Correa-Gallego <i>et al.</i> ^[75]	739	386	353	104 (27)	59 (17)	0.001	NA	NA	NA	Bile duct diameter, blood loss, and operation time

NA: Not available.

fluid amylase levels and postoperative complications, especially pancreatic fistula. These studies identified criteria that might support the early removal of drainage after pancreaticoduodenectomy^[94-96]. Five studies supported the selective use of drainage; these studies each failed to discover the benefits of drainage for selected patients. The rates of pancreatic fistulas and other complications were higher among the drainage group in certain studies (Table 2). Only Lim *et al.*^[72] provided criteria for omitting drainage, but most of this study's patients had hard pancreases and dilated main pancreatic ducts, regardless of their treatment group. Researchers of other studies found that a prolonged operative time, a large amount of blood loss, or a dilated main pancreatic duct usually prompted surgeons to insert drainage in pancreatic resections. This procedure is considered to be relatively conservative and potentially safe among surgeons. Therefore, drainage was usually selectively omitted in most retrospective studies. Only two studies evaluated the outcomes after pancreatic resections (including pancreaticoduodenectomies and distal pancreatectomies) without routine drainage. Routine drainage did not show a benefit for non-selective patients. Fisher found that blood loss and transfusions clearly decreased over time due to the development of surgical techniques; however, no significant differences were observed with regard to pancreatic texture or the main pancreatic duct between the two groups. Conlon *et al.*^[76] conducted a prospective randomized study on routine drainage after pancreatic resection. However, they did not analyze important factors such as pancreatic texture and pancreatic duct diameter; furthermore, their sample size was likely insufficient. Van Buren *et al.*^[79] provided more persuasive evidence. Although no significant difference was observed in the rates of pancreatic fistulas between patients with or without routine drainage, the higher mortality rate among patients without routine drainage encouraged surgeons to use caution when considering whether to abandon routine drainage after pancreaticoduodenectomy.

Pancreaticojejunostomy and pancreaticogastrostomy might be different regarding pancreatic fistulas. Four randomized controlled trials and 22 observational clinical studies were included in a meta-analysis and systematic review in 2013. Patients in the pancreaticogastrostomy group had a significantly lower incidence of pancreatic fistulas, but higher rate of intra-luminal hemorrhage^[46].

Moreover, pancreatic fistula rates were significantly lower and less severe in two recent RCTs, and there was no significant difference in the incidence of postoperative hemorrhage^[44,84].

Closed drainage was believed to reduce the risk of retrograde microbial contamination compared with open drainage, though bacterial migration may also occur with closed drainage. Sarr *et al.*^[97] showed patients with closed-suction drainage had a lower incidence of wound infection than patients with open drainage after cholecystectomy in 1987. However, Sánchez-Ortiz *et al.*^[98] found no significant difference in relevant complications between a closed-suction drainage group and an open drainage group after partial nephrectomy. There has been no evidence to show that closed drainage is better than open drainage after pancreaticoduodenectomy, but most surgeons choose closed drainage in light of the possibility of increased risk of retrograde microbial contamination. Some surgeons believe that negative pressure might increase the risk of pancreatic fistulas or lead to delayed hemorrhage at the time of drain removal^[98]. However, there has also been no obvious evidence to prove the harm of closed-suction drainage. Most surgeons insert closed-suction drainage for full draining after pancreaticoduodenectomy.

Fluid collections have been related to fistulas of pancreaticojejunostomy anastomosis after pancreaticoduodenectomy^[86]. Thus, drainage tubes were often placed in the vicinity of the pancreatic anastomosis^[84], but some surgeons placed one drainage tube in the right subhepatic space, and others in the retroperitoneal area adjacent to the pancreatic anastomosis^[44]; it is still unknown which method is better. Shrikhande *et al.*^[12] compared perioperative outcomes between a one-drain group and a two-drain group after gastric and pancreatic resections. They found two drains were no better than one drain, but evidence is still lacking. One or more drains were inserted after pancreaticoduodenectomy, and two drains were usually inserted.

In conclusion, most of the limited studies in this review did not reveal an obvious benefit for routine drainage among patients following pancreaticoduodenectomy. Only some of the retrospective studies supported the use of selective drainage after pancreaticoduodenectomy, and no persuasive evidence exists to support the omission of drainage among all patients. On the contrary, level 1 data

discouraged surgeons from abandoning drainage among all patients, although only one trial was conducted^[79]. Early drainage removal following pancreaticoduodenectomy might benefit patients; however, the evidence to support this supposition is lacking. Therefore, more studies, especially RCTs, are needed to verify the advantages and disadvantages of using drainage after pancreaticoduodenectomy. Adequate numbers of cases should be enrolled and randomized in the RCTs. Moreover, there should be no differences in the factors (*e.g.*, demographics, comorbidities, pancreatic duct size, pancreas texture, operative technique or others) which could influence the incidence of pancreatic fistulas between two groups. The postoperative management should also be consistent.

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