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ORIGINAL SCIENTIFIC REPORT

Clinically Relevant Late-Onset Biliary Complications After Pancreatoduodenectomy

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Abstract

Background Late-onset biliary complications (LBC) after pancreatoduodenectomy (PD) can be serious. This study aimed to clarify the frequency and risk factors of severe LBC after PD.

Methods We defined LBC as biliary complications occurring 3 months after PD and severe LBC as cases that required intensive care. A total of 318 patients who underwent PD between 2010 and 2018 with at least 1 year of postoperative follow-up were evaluated.

Results Hospitalization for severe LBC was required in 59 patients (19%), of whom 20 had liver abscesses (6.3%); 18, acute cholangitis (5.7%); 12, biliary stones (3.8%); and 21, biliary strictures (6.6%). Interventional radiological or endoscopic treatment was required in 32 patients (10%), of whom 9 had a benign primary disease with biliary stones and/or strictures. Thirteen of the remaining 23 patients with a malignant primary disease had liver abscesses and cholangitis. Significant independent risk factors for severe LBC in patients with malignant primary disease were recurrence around the hepaticojejunostomy (odds ratio 6.5, $P = 0.013$) and chemotherapy (odds ratio 13.5, $P < 0.001$).

Conclusions Severe LBC after PD may occur regardless of whether the primary disease is benign or malignant. The course of severe LBC differs according to the primary disease, and therefore, appropriate follow-up and optimal treatment should be recommended according to the condition of the patient and the disease state.

Abbreviations

DIC	Disseminated intravascular coagulation
LBC	Late-onset biliary complications
PD	Pancreatoduodenectomy
PTAD	Percutaneous transhepatic abscess drainage
PTCD	Percutaneous transhepatic cholangiodrainage

Introduction

Pancreatoduodenectomy (PD) is a highly technically challenging procedure. While advances in postoperative care and operative techniques have decreased mortality rates, early postoperative complications such as hemorrhage, pancreatic fistulae, and delayed gastric emptying are common [1–3]. Late-onset complications such as gastrointestinal hemorrhage, exocrine pancreatic insufficiency, non-alcoholic fatty liver disease, and acute pancreatitis can also occur occasionally [4–7]. In addition, late-onset biliary complications (LBC) such as acute cholangitis, biliary strictures, and biliary stones may occur repeatedly. Refractory cholangitis and biliary strictures have been reported after PD in 12–18.6% and 2.6–18% of patients,

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respectively [8–15]. LBC may be serious, requiring hospitalization or interventional treatment [9–13]. In this study, we focused on clinically relevant LBC and evaluated their frequency and risk factors based on the primary disease.

Methods

Patient selection

A total of 436 consecutive patients underwent PD at Nara Medical University between January 2010 and December 2018 (Fig. 1). Among them, 118 patients were excluded based on the following criteria: lost to follow-up (23 patients), prior hepaticojejunostomy (3 patients), and missing data (38 patients). In addition, we excluded patients who died within 1 year of PD (34 patients), to minimize the influence of impaired immunity, advanced tumor progression, and other comorbidities. We also excluded patients who were followed up for less than 1 year (20 patients). Finally, 318 patients were included in this study. Patient characteristics, preoperative data, operative techniques, postoperative data, and clinical follow-up were, retrospectively, collected from a prospective database linked to the hospital's electronic patient record system. Additionally, data regarding the type of LBC that developed after surgery, subsequent treatment methods, treatment progress, period from surgery to intervention, and the presence or absence of chemotherapy or recurrence in patients with a malignant primary disease were collected. This retrospective single-center study was approved by the Human Research Ethics Committee of Nara Medical University (Approval number: 1699).

Surgical procedure

All patients underwent subtotal stomach-preserving PD or conventional PD. The bile duct was temporarily occluded with a bulldog vascular clamp to prevent potential intraabdominal infection from the bile juice. The bile duct was subsequently cut with scissors and its end was measured under the clamped portion. Bile juice was collected for intraoperative culture [14], and reconstruction was performed using the modified Child method. The jejunal limb was brought up to the pancreatic and bile duct stumps via a retrocolic route. Pancreatojejunostomy was performed in a duct-to-mucosa fashion by either a running or interrupted single-layer of 6-0 monofilament non-absorbable sutures. A 4-0 monofilament non-absorbable suture was used to close the pancreatic parenchyma and jejunal seromuscular layer in an end-to-side fashion to tightly adhere the jejunal wall to the pancreatic stump; the interrupted suture method (Kakita method) [16, 17] was used for all procedures conducted from 2010 to 2017, and the mattress suture method (modified Blumgart anastomosis) [18, 19] for those in 2018. Hepaticojejunostomy was performed using a single-layer of running 5-0 monofilament non-absorbable suture for procedures conducted until March 2018, and with a similar absorbable suture for those since April 2018. Pancreatic tube stents and retrograde transhepatic biliary drainage tubes were not used for pancreatojejunostomy and hepaticojejunostomy, respectively. Gastrojejunostomy was performed 40 cm

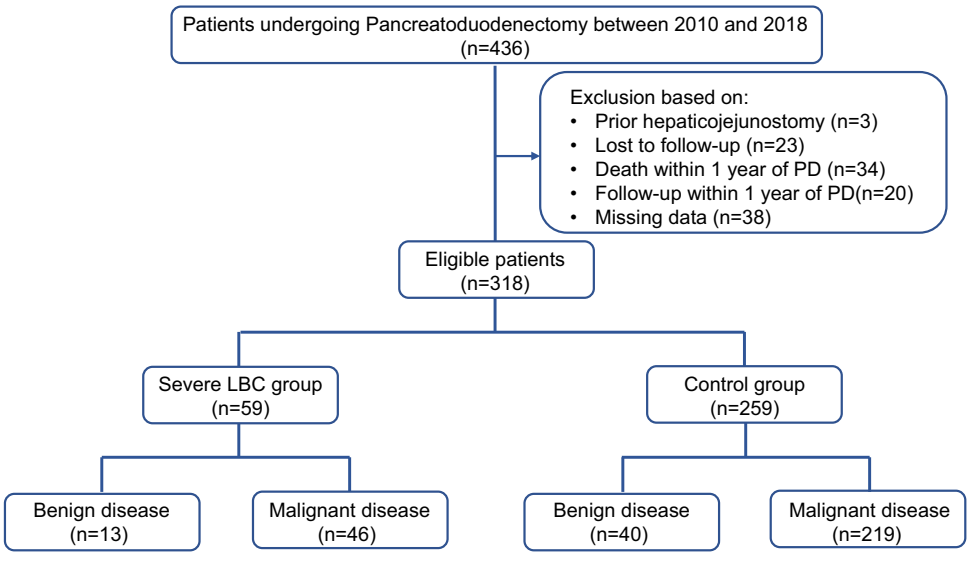

Fig. 1 Flowchart of patient selection

from the hepaticojejunostomy on the anal side using an Albert-Lembert anastomosis [20]. A closed drain was placed at the sites of pancreatojejunostomy and hepaticojejunostomy.

Adjuvant therapy

We administered a postoperative combination of high-dose 5-fluorouracil hepatic arterial infusion with systemic gemcitabine as adjuvant therapy for pancreatic cancer [21]. Until 2016, we had administered 3 cycles of gemcitabine infusion after 3 cycles of hepatic arterial chemotherapy. Since 2016, we have administered 4 cycles of S-1 oral administration instead.

Definition of LBC

Complications that occurred beyond the perioperative period were defined as late-onset complications. Among them, biliary complications, such as acute cholangitis, liver abscess, biliary stones, and biliary strictures occurring 3 months after PD, were defined as late-onset biliary complications (LBC). Severe LBC was defined as LBC that required hospitalization for intensive care, such as long-term antibiotics or interventional treatment. Acute cholangitis was diagnosed according to the Tokyo Guidelines 2018 criteria [22]. Liver abscesses and biliary stones were diagnosed by either computed tomography or magnetic resonance imaging. Biliary strictures were radiologically diagnosed by the presence of strictures showing intrahepatic biliary dilation at the site of hepaticojejunostomy. We divided the patients into two groups: the severe LBC group, which included patients requiring hospitalization for biliary complications; and the control group, which included all other patients. Some patients with biliary complications who had been treated in the outpatient clinic but later required hospitalization were included in the severe LBC group. The control group included patients who developed mild biliary complications that did not require hospitalization.

Statistical analysis

The correlations between severe LBC and clinicopathological parameters were analyzed using the Student *t*-test, Chi-squared test, or Fisher's exact test. Quantitative variables were expressed as the mean and standard deviation. Logistic regression analysis was used to examine the association of independent variables. Variables that were significant ($P < 0.05$) in the univariate analysis were included in the multivariate analysis. A 95% confidence interval (CI) was used, and a P-value < 0.05 was considered statistically significant. All statistical analyses were performed using JMP software version 12.0 (SAS Institute Inc., Cary, NC).

Results

Patient characteristics

A total of 318 patients were followed up for at least 1 year after PD (Fig. 1). The median length of follow-up was 37.4 months (range, 12.2–124.1 months). Pancreatic cancer and intraductal papillary mucinous adenoma were the most common malignant and benign primary diseases, respectively. Pancreatic cancer was present in 147 (55%) of the 265 patients with a malignant primary disease, and intraductal papillary mucinous adenoma was present in 42 (79%) of the 53 with a benign primary disease.

Biliary complications after PD

The types of severe LBC that developed in our cohort are listed in Table 1. Hospitalization for the treatment of LBC was required in 59 patients (19%). The median interval from PD to the required hospitalization was 14.7 months (range 3.0–60.3 months). Several patients suffered from simultaneous biliary stones and strictures, as these LBC tended to occur concurrently. Among the 18 patients with acute cholangitis, septicemia developed in 6, with one mortality, while disseminated intravascular coagulation (DIC) developed in 3. Among the 20 patients with a liver abscess, 12 underwent percutaneous transhepatic abscess drainage (PTAD). Among the 21 patients with biliary strictures, 9 had a biliary stone and 3 had a liver abscess. Only 3 patients had a biliary stone without a biliary stricture. Among the 119 patients who had a positive bile juice culture, a significant association was observed with preoperative biliary drainage ($P < 0.0001$), but not with LBC.

Hepatic artery stenosis during follow-up and recurrence around the hepaticojejunostomy were more frequent in the severe LBC group than in the control group (14% vs. 5%, $P = 0.042$ and 17% vs. 2%, $P < 0.001$, respectively) (Table 2). Furthermore, biliary complications during

Table 1 Severe late-onset biliary complications

Late-onset biliary complications	*n*
Liver abscess[a]	20
Cholangitis[b]	18
Stricture without stones[a]	12
Stricture with stones	9
Stones without stricture	3

[a]Three patients were included in both the liver abscess and stricture without stones

[b]Cholangitis does not include cholangitis with liver abscess, biliary stricture, or stones

chemotherapy, which are likely to result in serious conditions requiring hospitalization, were significantly more common in the severe LBC group ($P < 0.001$).

Risk factors for severe LBC

We evaluated the risk factors for severe LBC separately in patients with benign or malignant primary diseases given their differing backgrounds. No clinicopathological factors were associated with severe LBC in patients with a benign primary disease. In contrast, univariate analysis revealed that recurrence around the hepaticojejunostomy, hepatic arterial stenosis, and chemotherapy were significantly associated with severe LBC in patients with a malignant primary disease. The multivariate analysis revealed that recurrence around the hepaticojejunostomy (odds ratio [OR] 6.5, $P = 0.013$) and chemotherapy (OR 13.5, $P < 0.001$) were independent risk factors for severe LBC (Table 3).

Risk factors for biliary strictures and/or stones requiring hospitalization

We subsequently evaluated the risk factors for biliary strictures and/or stones. Among the 318 patients in our cohort, 24 required hospitalization for biliary strictures and/or stones; 9 had a benign primary disease, and 15 had a malignant primary disease. We divided the patients into two groups: a biliary strictures and/or stones group, which consists of patients who needed to be hospitalized for treatment; and a control group comprising all other patients. To determine the cutoff value of the bile duct diameter to predict biliary stricture and/or stones, we set and evaluated various bile duct diameters (8–10 mm) and analyzed their relation to biliary strictures and/or stones based on an area under the receiver operating characteristic curve of 0.55. As a result, we defined 9 mm as the cutoff value and classified all patients into ≤ 9 mm and > 9 mm groups. Univariate analysis revealed that only a bile duct diameter ≤ 9 mm was significantly associated with the formation of biliary strictures and/or stones ($P = 0.012$) (Table 4).

Cases requiring interventional treatment

Among the 59 patients with severe LBC, 32 (54%) underwent interventional radiologic or endoscopic treatment; 9 had a benign primary disease, and 23 had a malignant primary disease (Supplementary Table S1). The median interval from surgery to interventional treatment for LBC was 13.4 months (range 3.0–60.6 months). All patients with a benign primary disease who underwent interventional treatment had biliary stones or strictures. Of those with a malignant primary disease who underwent interventional treatment, 13 had biliary stones and/or strictures and 13 had liver abscesses and cholangitis. Development of a liver abscess and biliary stricture occurred in 3 patients, who received treatment for both LBC. Of the 23 patients with a malignant primary disease, 16 developed LBC during chemotherapy and 5 required multiple interventions for repeated LBC. In summary, in all patients with benign diseases, interventional treatments were performed for biliary stricture or stones, whereas in patients with malignant diseases, approximately 60% of treatments were administered for infectious diseases such as cholangitis and liver abscesses.

Radiologic or endoscopic treatment for either biliary stone removal or dilatation of the hepaticojejunostomy anastomosis was performed in 22 patients. Endoscopic treatment for biliary stones and/or strictures was successful in 10 patients. Percutaneous transhepatic cholangiodrainage (PTCD) was performed in 4 patients who had multiple bilateral biliary stones that could not be entirely removed by endoscopy. None of the patients required surgical intervention.

Discussion

LBC after PD can develop regardless of whether the primary disease is benign or malignant [15]. There were no significant risk factors for severe LBC in patients with a primary benign disease. In contrast, chemotherapy and recurrence around the hepaticojejunostomy were independent risk factors for severe LBC in patients with a malignant primary disease. Infectious LBC during chemotherapy may have been associated with cancer-induced immunosuppression and/or chemotherapy-induced myelosuppression. Our results indicate that the cause of severe LBC after PD may depend on the primary disease, and therefore, the therapeutic strategy for LBC may need to differ accordingly.

LBC requiring interventional treatment is a major concern in clinical practice. In our study, more than half of the hospitalized LBC patients required interventional radiologic or endoscopic treatment. For patients with a benign primary disease, interventional treatment was required for biliary strictures and/or stones. Among patients with a malignant primary disease, 13 of the 23 patients requiring intervention had a biliary stricture and/or stones. A common bile duct diameter of ≤ 9 mm was the only factor significantly associated with developing biliary strictures or stones. Previous studies have reported that a thin bile duct, with a cut-off diameter of 4–6 mm, is a risk factor for biliary complications [8, 23–25]. The difference in the cut-off values between previous reports and this study may be

Table 2 Comparison of patient characteristics between the severe LBC group and the control group

	Severe LBC (n = 59) (%)	Control (n = 259) (%)	P value
Male/female	34:25	151:108	1.000
Age (years)[a]	67.4 ± 10.7	68.5 ± 9.0	0.427
Pathology			0.343
Benign	13 (22)	40 (15)	
IPMA	8 (14)	34 (13)	
Others	5 (8)	6 (2)	
Malignant	46(78)	219 (85)	
Pancreatic cancer	31 (53)	116 (45)	
Bile duct cancer	8 (14)	29 (11)	
Ampullary carcinoma	1 (2)	33 (13)	
IPMC	3 (5)	15 (6)	
Others	3 (5)	26 (10)	
Preoperative biliary drainage	29 (49)	118 (46)	0.665
MS	5 (8)	18 (7)	
EBS	17 (29)	75 (29)	
ENBD	3 (5)	16 (6)	
PTCD	4 (7)	9 (3)	
Bile juice culture positive	25 (42)	94 (36)	0.456
Preoperative cholangitis	16 (27)	58 (22)	0.495
Galle stone (past history)	5 (8)	11 (4)	0.189
Neoadjuvant CRT	19 (32)	64 (25)	0.252
Neoadjuvant treatment	20 (34)	80 (31)	0.645
DM	13 (22)	68 (26)	0.620
PNI < 45	19 (32)	82 (32)	1.000
Operating time (min)	346 ± 95.4	324 ± 80.5	0.067
Estimated blood loss (ml)[a]	620 ± 791.6	432 ± 543.0	0.088
Blood transfusion	11 (19)	34 (13)	0.301
Absorbable suture material (hepaticojejunostomy)	5 (8)	29 (11)	0.646
Common bile duct size (mm)[a]	10.7 ± 5.5	10.7 ± 5.0	0.995
Bile duct			0.170
1 orifice	56 (95)	254 (98)	
2 orifices	3 (5)	5 (2)	
Bile leakage	1 (2)	13 (5)	0.480
Pancreatic fistulae	10 (17)	62 (24)	0.302
Abdominal abscess	8 (14)	28 (11)	0.505
Severity of complication[b]			0.337
Grade 0–II	46 (78)	185 (71)	
Grade III–V	13 (22)	74 (29)	
Hepatic artery stenosis	8 (14)	14 (5)	0.042
Hepatic arterial infusion	18 (31)	67 (26)	0.515
During chemotherapy	30 (51)	21 (8)	< 0.001
Recurrence around the hepaticojejunostomy	10 (17)	4 (2)	< 0.001

IPMA, intraductal papillary mucinous adenoma; IPMC, intraductal papillary mucinous carcinoma; MS, metal stent; EBS, endoscopic biliary stenting; ENBD, endoscopic nasobiliary drainage; PTCD, percutaneous transhepatic cholangial drainage; CRT, chemoradiotherapy; DM, diabetes mellitus; PNI, prognostic nutritional index

[a]Data are expressed as mean ± standard deviation

[b]Severity was defined according to the Clavien–Dindo classification

Table 3 Risk factors for severe LBC in patients with a malignant primary disease

	Severe LBC (n = 46)	Control (n = 219)	Univariate	Multivariate		
			P-value	Odds ratio	95% CI	P-value
Preoperative cholangitis						
Yes	15	57	0.369			
No	31	162				
Preoperative biliary drainage						
Yes	27	117	0.513			
No	19	102				
Bile juice infection (intraoperative)						
Yes	23	88	0.222			
No	23	131				
Suture material						
Absorbable 4		24	0.643			
Non-absorbable 42		195				
Neoadjuvant treatment						
Yes	20	80	0.380			
No	26	139				
Neoadjuvant radiation						
Yes	19	64	0.115			
No	27	155				
Common bile duct size						
$\leq$ 10 mm	28	120	0.358			
$>$ 10 mm	17	99				
Bile leakage						
Yes	1	10	0.425			
No	45	209				
Pancreatic fistulae						
Yes	8	51	0.371			
No	38	168				
Hepatic arterial infusion						
Yes	18	67	0.266			
No	28	152				
During chemotherapy						
Yes	30	21	$<$ 0.001	13.5	6.18–29.67	$<$ 0.001
No	16	198				
Recurrence around the hepaticojejunostomy						
Yes	10	4	$<$ 0.001	6.5	1.49–28.09	0.013
No	36	214				
Hepatic arterial stenosis						
Yes	8	13	0.018	2.5	0.74–8.24	0.141
No	38	206				
DM						
Yes	12	61	0.807			
No	34	158				
PNI						
$<$ 45	19	79	0.507			
$\geq$ 45	27	140				

Table 3 continued

	Severe LBC (n = 46)	Control (n = 219)	Univariate	Multivariate		
			P-value	Odds ratio	95% CI	P-value
Liver cyst						
Yes	10	33	0.280			
No	36	186				

LBC, late-onset biliary complication; CI, confidence interval; DM, diabetes mellitus; PNI, prognostic nutritional index

Table 4 Risk factors for biliary stricture and/or stones requiring hospitalization

	Biliary stricture and/or stones (n = 24)	Control (n = 294)	Univariate	
			Odds ratio	P-value
Preoperative biliary drainage				
Yes	12	135	1.2	0.700
No	12	159		
Preoperative cholangitis				
Yes	5	69		0.769
No	19	225	1.2	
Bile juice infection (intraoperative)				
Yes	7	112		0.387
No	17	182	1.5	
Bile duct				
$\leq$ 9 mm	17	127	3.2	0.012
$>$ 9 mm	7	169		
Suture material (hepaticojejunostomy)				
Absorbable	1	33		0.304
Non-absorbable	23	261	2.9	
Bile leakage				
Yes	1	13		0.953
No	23	281	1.1	
POPF				
Yes	3	69		0.227
No	21	225	2.1	

LBC, late-onset biliary complication; POPF, postoperative pancreatic fistula

due to the method used to measure the bile duct diameter. In our study, we accurately measured the cut end of the bile duct intraoperatively instead of through preoperative imaging. The method or material used for suturing the hepaticojejunostomy may also be involved in the development of LBC. In most cases, we performed hepaticojejunostomy with a single-layer of running monofilament thread. We did not find any associations between the use of absorbable or non-absorbable sutures and the development of LBC. Various suturing methods are available, such as interrupted or running sutures, as well as various suturing materials, such as monofilament, polyfilament, absorbable, and non-absorbable sutures. However, the optimal suturing method to prevent biliary stricture formation has not yet been established. Therefore, further studies are required.

The most common LBC in this study was liver abscess, which occurred in 20 patients, of whom 7 were treated with antibiotics. The remaining 13 patients had malignant primary diseases and required radiological intervention, including PTCD and PTAD. The second most common LBC was biliary stenosis and/or stones; 13 patients required interventional treatment, among which 8 patients

underwent interventional radiological treatment. Endoscopic treatment is increasing due to the development of double-balloon endoscopy, and it can even be performed even for biliary complications after biliary reconstruction [26]. Although endoscopy is the first choice of treatment, radiological intervention is still needed in some cases, especially for complex LBC. Radiological treatment often requires multiple interventions and extended hospital stays. These are critical issues, especially in patients with malignant primary diseases who have to discontinue chemotherapy for the treatment of LBC. In our study, 16 out of the 23 malignant patients requiring interventional treatment developed severe LBC during chemotherapy, of whom 13 were on chemotherapy for recurrence. LBC itself may cause DIC and sepsis, and can be fatal. In addition, discontinuation of chemotherapy may indirectly affect patient prognosis. Therefore, if LBC can be detected at an early stage before they become severe, conservative or endoscopic treatment may be possible, and the need for discontinuation of chemotherapy may be minimized. Early detection, intervention, and prevention of LBC may help avoid interventional treatment; this should be kept in mind during follow-up, especially in patients with a malignant primary disease.

Finally, the median interval from surgery to hospitalization for LBC was 14.2 months (range, 3.0–60.3 months) in patients with a malignant primary disease and 17.3 months (range, 4.2–39.7 months) in patients with a benign primary disease. There were no statistically significant differences between the two groups. Therefore, long-term follow-up is required, even for patients with benign diseases, especially in cases of thin biliary ducts.

There are several limitations to this study. First, the study was performed retrospectively at a single institution. Second, the admission of patients with LBC was at the discretion of individual attending physicians; however, the diagnosis of LBC was based on the Tokyo Guidelines or imaging findings [22]. Furthermore, the sample size was relatively small. However, to the best of our knowledge, this is the first study to address late-onset LBC after PD. Therefore, our data may provide useful new information for better treatment of this complication that occasionally occurs after PD.

To conclude, LBC may occur after PD, regardless of whether the primary disease is benign or malignant. Furthermore, since LBC can occur more than one year after PD, long-term follow-up is necessary in patients with both benign and malignant diseases. In the case of patients with malignant primary disease, LBC may interfere with the treatment for recurrence, thereby influencing the prognosis. Therefore, early diagnosis and intervention for LBC may be critical. On the other hand, for symptomatic patients with benign primary disease, careful evaluation and management should be considered to prevent repeated LBC.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00268-022-06511-2.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval This study was approved by the Human Research Ethics Committee of Nara Medical University (Approval number: 1699), and all procedures were performed according to the principles of the Declaration of Helsinki.

Informed consent Opt-out consent was obtained from all patients or their family members.

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