

Original Article



Biliary Stenting Prior to Pancreaticoduodenectomy and its Effects on Postoperative Outcome. Twenty Years of Experience with 805 Patients

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Abstract

Background: The aim of this study was to evaluate the potential effects of biliary drainage before pancreaticoduodenectomy on postoperative outcomes.

Methods: This study was conducted retrospectively on data from 820 cases of pancreaticoduodenectomy performed in the Gastrointestinal Surgery Department of Ankara City Hospital between April 1999 and August 2019. Twenty years of collected patient data were re-examined and 805 patients were divided into two groups as those who underwent preoperative biliary drainage (PBD) and those who did not (non-PBD). Demographic data of patients, and preoperative, operative and postoperative details, including morbidity, were collected and compared between the two groups.

Results: There were 574 (71.3%) patients in the PBD group and 231 (28.6%) patients in the non-PBD group. Total complications according to Clavien-Dindo classification were significantly higher in the PBD group ($P < 0.001$). Intraabdominal hemorrhage, delayed gastric emptying and wound infection were found to be higher in the PBD group but the rate of pancreatic fistula was similar in both groups. There was no difference between the two groups in terms of complications according to preoperative bilirubin levels. In drained patients with normal bilirubin levels, wound infections were significantly higher in a group with diameter of common bile duct > 8 mm ($P = 0.020$).

Conclusion: PBD is not associated with anastomotic leakage after pancreaticoduodenectomy. Wound infection, delayed gastric emptying and intraabdominal hemorrhage were significantly associated with PBD. Preoperative bilirubin level had no effect on these results. In subgroup analysis, in patients undergoing drainage, if bilirubin falls below 5 mg/dL, the risk of wound infection was still high in patients with bile duct diameter > 8 mm.

Keywords: Cholangiopancreatography, Endoscopic Retrograde, Pancreaticoduodenectomy, Pancreatic Neoplasms

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Introduction

Periampullary tumors (tumors originating from the head of the pancreas, ampulla Vateri, duodenum, distal biliary tract) are leading causes of biliary obstruction. These patients present with symptoms of primary disease, mostly with progressive jaundice and related pruritus. In patients with obstructive jaundice, when a resectable periampullary tumor is detected, the treatment of choice is pancreaticoduodenectomy (Whipple procedure). Because of progressive jaundice, elevated bilirubin and liver function tests, severe pruritus, frequent cholangitis attacks or prolongation of the planned surgery time, biliary stenting is a common method for drainage of obstructed biliary tract for relieving symptoms and also for relieving the undesirable effects of hepatic dysfunction. Very high bilirubin levels or prolonged obstruction of biliary tract and biliary stasis may lead to increased infection, bleeding disorders, or cardiac and renal dysfunction. Surgery in jaundiced patient could be associated with haemorrhage, septic complications or renal disorders and therefore,

preoperative drainage is considered necessary. There are publications indicating that preoperative biliary drainage (PBD) may be beneficial in certain patient groups.¹⁻³ Also, early experimental and animal models have shown improved liver function, immune response and nutritional status with internal drainage.⁴⁻⁷ But new reports have considerably conflicting results. Some show adverse effects of biliary drainage on morbidity, resulting in particularly infective conditions and some show no effect on postoperative complications.^{8,9} Although surgeons avoid stenting due to these adverse effects of preoperative stenting and the fact that dilated ducts provide more comfortable anastomosis for surgeons, biliary stenting is still common before pancreaticoduodenectomy due to referral of patients from different centers or reflex therapeutic stenting during diagnostic endoscopic retrograde cholangiopancreatography (ERCP). This procedure is still mostly performed before the surgeon evaluates the patient.¹⁰

PBD can be achieved by percutaneous transhepatic

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biliary drainage (PTD), stent placement with ERCP or less frequently, nasobiliary drainage. For whom drainage will be performed or which method will be used vary between centers. However, there is still no consensus on the total effects, benefits or harms of PBD. The aim of this study is to evaluate the potential effects of biliary drainage before pancreaticoduodenectomy on postoperative outcomes and to present the results of 20 years of experience.

Material and Methods

This study was conducted retrospectively on data from 820 cases of pancreaticoduodenectomy performed in the Gastrointestinal Surgery Department of Ankara City Hospital (formerly Ankara Yuksek İhtisas Hospital), Turkey, between April 1999 and August 2019. These 20 years of collected patient data were re-examined and the patients were divided into two groups as those who underwent PBD (PBD group) and those who did not (non-PBD group).

Exclusion Criteria

Among these 820 patients, we excluded patients with lack of data, patients who received neoadjuvant therapy and a few patients for whom decompression was performed with nasobiliary drainage (15 patients).

Inclusion Criteria

The remaining 805 patients who underwent pancreaticoduodenectomy in the Gastrointestinal Surgery Department of Ankara City Hospital (formerly Ankara Yuksek İhtisas Hospital), Turkey, between April 1999 and August 2019 were included in the study.

All operations were performed by or under the supervision of gastrointestinal surgeons experienced in pancreatic surgery. As the center is the nationwide referral center, the majority of patients were referred from external health care facilities. Therefore, the majority of the cases were already referred with biliary stenting. Biliary drainage was performed in only three situations when the patient presented to our center with high bilirubin levels: (1) patients with frequent cholangitis attacks; (2) severe itching that causes skin injury; and (3) prolongation of planned operation time. Biliary stenting was performed via ERCP as the first choice, and PTD was administered in unsuitable cases. Other patients were directly operated. The primary surgeon decided on the type of the operation (traditional open, laparoscopic, robotic or hybrid) and pyloric sparing procedure. In the reconstruction phase of the open procedure, wirsungojejunostomy was preferred if the Wirsung duct was >5 mm, and pancreaticojejunostomy was preferred with a duct diameter of <5 mm. After pancreas anastomosis was performed, hepaticojejunostomy, antecolic gastrojejunostomy and side-by-side jejunojejunostomy (Braun anastomosis) were performed, sequentially. Those with a diameter of choledoch up to 8mm were considered normal. Laparoscopic and robotic procedures were performed in a

similar manner. The texture of the pancreas was evaluated by palpation of the pancreatic remnant tissue with hand or instrument. The diameter of the common bile duct and the Wirsung duct were measured intraoperatively.

All patients were managed in the intensive care unit for at least 1 day according to their general status. All patients received prophylactic antibiotics intraoperatively and for 24 hours postoperatively. The nasogastric catheter was removed on the 1st or 2nd postoperative day, and the drains were removed if the drainage was below 50 cc on the 4th or 5th postoperative day, unless it was impeded by any morbidity. The definition of pancreatic leak was provided according to the definition specified in the International Study Group on pancreatic fistula. Accordingly, on the 3rd postoperative day or afterwards, in patients whose drain amylase value was 3 times higher than blood amylase value, it was accepted that there was a pancreatic leak.¹¹ Likewise, delayed gastric emptying and intraabdominal hemorrhage classification were made according to the International Study Group of Pancreatic Surgery definitions. In the postoperative period, all patients underwent computed tomography (CT) to assess surgical complications and fistula on the 4th or 5th postoperative day. Complications other than fistula were assessed and recorded. Postoperative complications were classified according to Dindo and colleagues.¹²

Demographic data of patients, and data of preoperative, operative and postoperative details, including morbidity, were all collected and compared between the two groups. Since the study was designed retrospectively, informed consent was obtained from all patients only before the surgical procedure.

The data were transferred to IBM SPSS Statistics program v. 21 (IBM Corp: Armonk, NY, USA) for analysis. When evaluating the study data, frequency distribution (number and percentages) was used for categorical variables and descriptive statistics (median, minimum, and maximum) were used for numerical variables depending on the results of the Kolmogorov-Smirnov test. Continuous variables were expressed as mean \pm standard deviation or median (minimum-maximum) where applicable. Mann-Whitney U test was performed for comparing median values, and the mean differences were evaluated by student's *t* test. The chi-square test was performed to examine the relationship between two categorical variables. A *P* value <0.05 was considered statistically significant.

Results

A total of 805 cases were included in the study after the patients with missing data, patients receiving neoadjuvant therapy and the few cases of nasobiliary drainage were excluded. Of these, 86.3% were operated for malignancy and the rest for other reasons. A total of 574 (71.3%) of these patients were in the PBD group while the remaining 231 (28.6%) patients were in the Non-PBD group. Table 1 presents the demographic features, pre-drainage and preoperative bilirubin levels, preoperative albumin levels,

Table 1. Demographic Data and Preoperative and Intraoperative Findings of the Patients

Variables	Total (805 Patients)	PBD (574 Patients)	None-PBD (231 Patients)	P Value
Mean age±SD	59.37±11.74	59.43±11.27	59.24±12.87	0.83
Gender				
Male	499 (62%)	368 (64.1%)	131 (56.7)	0.05
Female	306 (38%)	206 (35.9%)	100 (43.3)	
ASA				
I	118 (14.7%)	91 (15.9%)	27 (11.7%)	0.02
II	413 (51.3%)	299 (52.1%)	114 (49.4%)	
III	261 (32.4%)	177 (30.8%)	84 (36.4%)	
IV	13 (1.6%)	7 (1.2%)	6 (2.6%)	
Median preoperative bilirubin (mg/dL) (min-max)	2 (0.11–34)	2 (0.18–34)	1 (0.11–28)	0.009
Median present bilirubin (mg/dL)	3.98 (0.11–48)	6.10 (0.11–48)	1 (0.19–28)	<0.001
Mean present albumin (mg/dL)	3.72±0.69	3.64±0.69	3.92±0.65	<0.001
Pancreatic texture				
Firm	462 (57.6%)	344 (59.9%)	118 (51.1%)	0.02
Soft	342 (42.6%)	230 (40.1%)	113 (48.9%)	
Median common bile duct diameter (mm) (min-max)	10 (5–27)	11 (5–27)	10 (5–25)	<0.001
Median Wirsung duct diameter (mm) (min-max)	4 (1–18)	4 (1–18)	4 (1–15)	0.49
Operative time (min)	360 (160–750)	360 (160–750)	360 (210–660)	0.52

and intraoperative findings (pancreatic texture, diameter of the common bile duct, diameter of the Wirsung duct and operation time). The groups were comparable and there was no significant difference between them regarding age and gender ($P=0.835$ and $P=0.051$, respectively). However, ASA (American Society of Anesthesiologists) I and II patients were significantly more frequent in the PBD group ($P=0.023$). The median bilirubin level at the time of admission was significantly higher in the PBD group (6.10 mg/dL vs. 1 mg/dL, $P<0.001$). Most of the patients presented after biliary drainage and stenting as mentioned before. Plastic stents were placed in all patients. Although normalization was achieved in most of the preoperative drainage group patients, median bilirubin level was still statistically higher in the PBD group (2 mg/dL vs. 1 mg/dL, $P=0.009$). In addition, preoperative albumin level was significantly higher in the non-PBD group ($P<0.001$). Pancreatic texture was significantly firmer in patients in the PBD group (59.9% vs. 51.1%, $P=0.022$). While the diameter of the common bile duct was greater in the PBD group ($P<0.001$), no significant difference was observed in the diameter of the Wirsung duct ($P=0.491$). Operation times were similar between the two groups ($P=0.526$).

When the postoperative outcomes of these patient groups were evaluated (Table 2), it was seen that the complications according to Clavien-Dindo classification were significantly higher in the PBD group ($P<0.001$). When these complications were considered only for categories III, IV and V, this significant difference persisted.

When the complications were evaluated separately, no significant difference was found between the groups

in terms of the most important complications of pancreatic anastomosis leakage and hepaticojejunostomy anastomosis leakage, and preoperative drainage had no effect on either of them ($P=0.189$, $P=0.520$, respectively). Similarly, there was no significant difference between the two groups in terms of abdominal collection ($P=0.820$). However, intraabdominal hemorrhage, delayed gastric emptying and wound infection were found to be higher in the PBD group and this difference was statistically significant ($P<0.001$, $P=0.008$, $P<0.001$, respectively). Despite this, there was no difference between the two groups in terms of postoperative hospital stay ($P=0.074$).

There was a significant difference in preoperative bilirubin level and the common bile duct diameter between the two groups ($P<0.001$). The effect of these factors on the results was also evaluated. When the patients with preoperative bilirubin level under 5 mg/dL or over 5 mg/dL were evaluated, there was no difference between the two groups in terms of complications. This showed that preoperative bilirubin level had no effect on postoperative results. Only delayed gastric emptying and intraabdominal hemorrhage were approaching statistical significance ($P=0.050$ for both) (Table 3). Similarly, there was no difference in postoperative complications between patients with bile duct diameter above and below 8 mm in the whole group ($P>0.053$). Therefore, a subgroup analysis was performed. The effects of common bile duct diameter (<8 mm, >8 mm) on complications were evaluated in patients who underwent preoperative stent placement and reduced bilirubin levels below 5 mg/dL. Although bilirubin was normalized, wound infections were significantly higher in the group >8 mm ($P=0.024$).

Table 2. Postoperative Outcomes

Variables	Total (805 Patients)	PBD (574 Patients)	None- PBD (231 Patients)	P Value
Total complication (Clavien Dindo) grade				
I	207 (25.7%)	163 (28.4%)	44 (19%)	<0.001
II	164 (20.4%)	128 (22.3%)	36 (15.6%)	
III	104 (12.9%)	78 (13.6%)	26 (11.3%)	
IV	11 (1.4%)	8 (1.4%)	3 (1.3%)	
V	65 (8.07%)	50 (8.71%)	15(6.49%)	
Severe complications (III-V)	180 (22.36%)	134 (23.34%)	44(19.4%)	<0.001
Pancreatic leakage				
Grade A	143 (17.8%)	106 (18.5%)	37 (16%)	0.19
Grade B	72 (8.9%)	55 (9.6%)	17 (7.4%)	
Grade C	42 (5.2%)	31 (5.4%)	11 (4.8%)	
Hepaticojejunostomy leakage	26 (3.2%)	20 (3.5%)	6 (2.6%)	0.52
Abdominal collection or abscess	84 (10.4%)	59 (10.3%)	25 (10.8%)	0.82
Wound infection	174 (21.6%)	144 (25.1%)	30 (13%)	<0.001
Delayed gastric emptying	22 (2.7%)	17 (3%)	5 (2.2%)	0.008
Intraabdominal Hemorrhage	45 (5.6%)	32 (5.6%)	13 (5.6%)	<0.001
Others	46 (5.71%)	40 (6.96%)	6 (2.59%)	
Median postoperative hospital stay (day)	16 (2–150)	17 (2–150)	14 (6–144)	0.41

Table 3. Impact of Preoperative Bilirubin Level on Outcome (Postoperative Data)

Variables	Bilirubin <5 mg/dL (n = 614)	Bilirubin ≥5 mg/dL (n = 191)	P Value
Total complication (Clavien Dindo) grade			
I	164 (26.7%)	43 (22.5%)	0.75
II	127 (20.7%)	37 (19.4%)	
III	75 (12.2%)	29 (15.2%)	
IV	10 (1.6%)	1 (0.5%)	
V	48 (7.8%)	17 (8.9%)	
Severe complications (III-V)	133 (21.6%)	47 (24.6%)	0.89
Pancreatic leakage			
Grade A	113 (18.4%)	30 (15.7%)	0.70
Grade B	58 (9.4%)	14 (7.3%)	
Grade C	30 (4.9%)	12 (6.3%)	
Hepaticojejunostomy leakage	20 (3.3%)	6 (3.1%)	0.93
Abdominal collection or abscess	70 (11.4%)	14 (7.3%)	0.10
Wound infection	137 (22.3%)	37 (19.4%)	0.38
Delayed gastric emptying	13 (2.1%)	9 (4.7%)	0.05
Intraabdominal hemorrhage	29 (4.7%)	16 (8.4%)	0.05
Others	31 (4.05%)	15(8.6%)	

(Table 4). This suggests that the large diameter of the common bile duct may be effective on wound infection in patients with stent placement.

Discussion

Although they began in the 1980s, studies on the effects of PBD have peaked since 2000. Srivastava et al reported that high bilirubin level increased the complications associated with bleeding, while infective morbidity was high in

patients who underwent PBD.¹³ After that, studies with similar results (long operative time, high wound infection and intraabdominal abscess rate) have appeared.¹⁴⁻¹⁶ Also, some prospective trials, like that of van der Gaag et al and Arkadopoulos et al revealed the increased rate of serious complications in patients with biliary drainage and do not recommend biliary drainage even for patients with severe jaundice.^{17,18} In contrast, results showing that PBD has no effect on early and late term results have been reported.¹⁹⁻²⁵

Table 4. Impact of Peroperative Common Bile Duct Diameter on Postoperative Outcome in Preoperative Biliary Drainage Positive Patients Group Who Had Bilirubin Levels Under 5 g/dL Preoperatively

Variables	Diameter of the Common Bile Duct <8 mm (n=99)	Diameter of the Common Bile Duct >8 mm (n=325)	P Value
Total complication (Clavien Dindo) grade			
I	22 (22.2%)	101 (31.3%)	0.08
II	17 (17.2%)	78 (24.1%)	
III	15 (15.2%)	37 (11.5%)	
IV	1 (1%)	7 (2.2%)	
V	10 (10.1%)	25 (7.7%)	
Severe complications (III-V)	27 (27.2%)	69 (21.23%)	0.07
Pancreatic leakage			
Grade A	19 (19.2%)	61 (18.9%)	0.10
Grade B	5 (5.1%)	38 (11.8%)	
Grade C	4 (4%)	16 (5%)	
Abdominal collection or abscess	8 (8.1%)	40 (12.4%)	0.23
Wound infection	17 (17.2%)	92 (28.5%)	0.02
Delayed gastric emptying	2 (2%)	8 (2.5%)	0.79
Intraabdominal Hemorrhage	4 (4%)	14 (4.3%)	0.9
Hepaticojejunostomy leakage	2 (2%)	13 (4.0%)	0.34

These studies have suggested that biliary drainage can be used safely when necessary, but discussions about necessary situations have continued. Also, the results of the meta-analyses do not differ. Saleh et al and Sewnath et al showed no evidence for positive or adverse effects of preoperative endoscopic biliary stent placement^{26,27} while Smith et al and Wang et al concluded that presence of jaundice at the time of resection has an adverse impact on infectious complications or early postoperative survival.^{28,29} A study group in France strongly advised PBD with biliary stenting in patients with severe jaundice and reported severe morbidity and decreased long-term survival with high bilirubin levels.³⁰ In general, most of the studies agree that preoperative drainage does not increase postoperative major complications and does not affect survival but creates infective morbidities. Therefore, these studies suggest that biliary drainage should be performed in the required patient group only – cholangitis, prolongation of operation, etc).³¹⁻³³ We have adopted a similar approach in our own clinical practice.

These results raised new questions about the source of infection. Bile infection is thought to be the cause of increased postoperative infective morbidity in patients who undergo PBD.³⁴⁻³⁶ However, this is controversial. Grizas et al and other studies showed bile infection in patients undergoing drainage but indicated that this did not increase postoperative septic complications.^{37,38} Considering these results, we believe that appropriate antibiotic prophylaxis should be considered in patients with biliary drainage who will undergo resection and specific antibiotic treatment based on bile culture is required to prevent infectious morbidity. The studies by Kondo et al and Sudo et al confirm this view.^{39,40} In addition, elimination of biliary stasis and normalization

of bilirubin levels do not prevent the increase in infection. In our subgroup analysis, even when bilirubin levels approach normal, the risk of infection is still high if the common bile duct diameter is still dilated. This risk is minimized in patients with common bile duct diameter returning to under 8 mm.

Pancreatic fistula, one of the most common complications of the Whipple procedure, may be associated with PBD and cholangitis or other infective morbidities. In the retrospective evaluation by Yanagimoto et al, the rate of pancreatic fistula was higher in patients who had cholangitis after biliary drainage.⁴¹ Also, Fujii et al showed high fistula rate in patients with preoperative biliary stents.⁴² In the literature, there is a majority of publications that advocate otherwise and this relationship is still unclear. In our study, no correlation was found between preoperative stent placement and anastomotic leakage.

Although it is generally thought that preoperative stent procedure increases postoperative infective morbidity, Jagannath et al stated that this is the case in patients with stent-related complications or long-term stents, and that morbidity and mortality do not change in uncomplicated stents.⁴³ Mezhir et al achieved similar results in their case-control study and did not recommend routine use of biliary drainage.⁴⁴ This is one of the limitations of the study. There are no data about the complications related to preoperative stent placement or on how long after stent placement the patients were operated. The main reason for this is that the patients were mostly admitted from external centers.

Routine ERCP in patients with obstructive jaundice and stent placement as a therapeutic reflex may have decreased in recent years due to the preference of diagnostic magnetic resonance imaging (MRI). With this non-

invasive imaging method, it is possible to diagnose with the same accuracy as ERCP and also to perform staging. In addition, complications that may occur due to ERCP are prevented. With the more widespread use of MRI in pancreatic cancer, ERCP can be performed only when necessary and with indications. This will reduce the rate of therapeutic reflex stent placement. Also, percutaneous biliary drainage may be a preferred option instead of ERCP for selected patients and thus, stent-related infective morbidities can be avoided. Park et al found a lower frequency of catheter-related complications for percutaneous drainage and proposed this method as an alternative.⁴⁵ Similar study results continue to emerge.⁴⁶⁻⁴⁸ However, we believe that more studies should be conducted on this subject. Recently, Uemura et al showed worse prognosis in pancreatic adenocarcinoma patients with preoperative percutaneous biliary drainage.⁴⁹ As another method of drainage, Sugiyama et al evaluated the decompression method with preoperative nasobiliary drainage and showed no difference with stenting.⁵⁰ Also, Zhang et al suggested nasobiliary drainage as an optimal method for biliary obstruction.⁵¹ Another limitation of our study was that two drainage and stent placement methods were evaluated together.

Another limitation of the study is the large number of variables that need to be evaluated besides the stent. It should be remembered that many variables such as vascular resection, different organ resection, pyloric protection, types of anastomosis, suture materials used, etc. may affect the results. This can only be prevented by standardized prospective studies. In addition, ASA, pancreatic consistency and albumin levels differed between our two study groups. One might argue that this could affect the results. ASA I-II and firm pancreas texture were more frequent in the PBD group and the complication rate was expected to be low with these results, but the complications were significantly higher in this group. Also, even if albumin levels seem different, median values are very close to each other. Despite this difference, there was no difference in terms of anastomotic leakage.

According to the results of our study, PBD is not associated with anastomotic leakage after pancreaticoduodenectomy. However, wound infection, delayed gastric emptying and intraabdominal hemorrhage were significantly associated with PBD. Bilirubin level has no effect on these results. Only late gastric emptying and intraabdominal hemorrhage approached statistical significance with bilirubin levels > 5 mg/dL. The diameter of the common bile duct has no effect on these results, but on subgroup analysis, in patients undergoing drainage, if bilirubin falls below 5 mg/dL, the risk of wound infection was high in patients with bile duct diameter > 8 mm. It is still a mystery whether preoperative drainage should be performed in patients scheduled for Whipple, and the final point is that drainage can be performed in the selected patient group. However, many already drained patients still refer to

surgeons. Our study showed that infective complications were more common in these patients, and this result is similar to the literature. Differently in our study, we showed that these infective complications decreased in patients with a common bile duct diameter < 8 mm after drainage, and in our opinion, this is the strongest point of the study. We suggest that the diameter of the common bile duct together with the bilirubin level may be an indicator of infective complications after biliary drainage.

Authors' Contributions

Study conception and design: Colakoglu MK, Oter V. Acquisition of data: Özgün YM, Aksoy E, Piskin E, Aydın O, Bostancı EB. Analysis and interpretation of data: Colakoglu MK, Oter V, Bostancı EB. Drafting: Özgün YM, Aksoy E, Piskin E, Aydın O. Critical revision: Colakoglu MK, Oter V, Bostancı EB.

Conflict of Interest

The authors declare that they have no conflict of interest.

Ethics Approval

Informed consent was obtained from all patients at the time of admission to the hospital that their data, laboratory and imaging results could be used for scientific purposes. The ethics committee of the hospital stated that no further approval is required for retrospective analysis. Patient records and patient data were anonymized before evaluation, and care was taken to hide identity information.

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