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ORIGINAL ARTICLE

The effect of biliary stents implanted before pancreaticoduodenectomy in periampullary tumors on postoperative results: a retrospective analysis of 106 consecutive cases at a single medical center

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Abstract

Purpose The present study evaluated the potential effects of biliary drainage before pancreaticoduodenectomy on postoperative outcomes and presented the details of a surgeon's 6 years of experience.

Methods All consecutive pancreatoduodenectomies performed from 2015 to 2021 were retrospectively analyzed. The study population was divided into two groups: the stented group (Group I) and the nonstented group (Group II). Patient demographic data and clinical characteristics were compared between the two groups.

Results This study comprised 106 individuals who underwent pancreaticoduodenectomy for periampullary tumors. The median age of the patients was 64.41 ± 11.67 years, and 65 (61.3%) were males. Sixty-seven patients (63.2%) received biliary drains (stented group), and 39 (36.8%) patients did not (nonstented group). Total bilirubin values (6.39 mg/dl) were higher in the nonstented patient group than in the stented group. The rate of total complications was significantly higher in the stented group than in the nonstented group [please check this carefully] ($p < 0.05$). The length of stay, operation time and pancreatic fistula were found to be higher in the stented group than in the nonstented group.

Conclusions Although the total bilirubin value was higher in the nonstented patient group than in the stented group, preoperative biliary drainage increased postoperative complication rates, operation time, and hospital stay. An advanced age and the presence of stents were independent risk factors influencing morbidity development according to the multivariate analysis**.**

Keywords Periampullary tumors · Jaundice · Preoperative biliary drainage · Pancreaticoduodenectomy · Postoperative outcomes

Introduction

Periampullary tumors (tumors originating in the distal biliary system, ampulla of Vater, duodenum, or pancreas head) are the most common cause of biliary blockage [1]. The majority of periampullary tumors are pancreatic malignancies. Although surgery, chemotherapy, and radiotherapy are the conventional treatments for pancreatic cancer, surgical treatment is the foundation of curative treatment. The typical surgical procedure for periampullary tumors is pancreaticoduodenectomy (PD) [2].

Patients with periampullary tumors frequently report primary illness signs, such as increasing jaundice and itching. Increased jaundice causes infection, bleeding disorders, malabsorption, digestion impairment, cardiac and renal dysfunctions, and other symptoms. As a result, cholangitis episodes often occur, causing an extension of the intended operation duration [1, 3].

For patients with resectable pancreatic head and periampullary tumors, preoperative biliary drainage (PBD) is needed to relieve biliary obstruction and stabilize the condition before surgery. The drainage procedure restores enterohepatic circulation and significantly reduces morbidity and mortality in patients with biliary obstruction [4]. However, there are studies suggesting that early surgery should be performed instead of PBD, since PBD increases the risk of perioperative infection in particular [5]. PBD has also been linked to an increased risk of leakage from the biliodigestive

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anastomosis, postoperative pancreatic fistula (POPF) rates, procedure-related complications (bleeding, cholangitis, pancreatitis, tumor seeding along the drain track), and stent-related complications (dislodgement, stent blockage) [6, 7].

Preoperative stenting is often avoided by surgeons due to its negative effects; nonetheless, a dilated channel makes anastomosis easier. Before pancreaticoduodenectomy, patients are typically referred by stenting during endoscopic retrograde cholangiopancreatography (ERCP) from various centers. Currently, biliary stents are mostly applied to patients before the surgeon evaluates them [8]. However, the need for preoperative biliary drainage in periampullary tumors is controversial [9]. Although various guidelines have been published regarding the presurgical PBD application, the exact indications have not been determined, and a common consensus has not been established [6].

The present study evaluated the potential effects of biliary drainage before pancreaticoduodenectomy on postoperative outcomes and presented the results of a surgeon's 6 years of experience.

Methods

This study was approved by the Ethics Committee of Erzurum City Hospital (No: 2022/13-144). All procedures in this study involving human participants were performed in accordance with the 1964 Declaration of Helsinki and its later amendments. Patients who underwent surgery and were managed by the same experienced surgeon for periampullary tumors at the gastrointestinal surgery unit of Erzurum City Hospital between June 2015 and July 2021 were retrospectively analyzed. The data were collected from the hospital's electronic software system and patient's files.

This retrospective cohort study included all patients with distal common bile duct tumors, pancreatic head tumors, tumors of ampulla of Vater, and duodenal tumors who underwent pancreatoduodenectomy (Whipple procedure). Patients with pancreatic corpus and distal tumors, periampullary tumors deemed unresectable during surgery, and patients whose data could not be accessed were eliminated from the study.

The study population was divided into two groups: the stented group (Group I) and the nonstented group (Group II). The gastroenterology clinic sent most of the cases to us. The majority of patients with increased bilirubin levels were referred to us with a biliary stent. A few patients with jaundice who came to our outpatient clinic underwent surgery directly. Although the precise indications for stent placement are unclear, a high bilirubin level is not the only indication. Gastroenterologists understood that stents were placed during the procedure as a precaution or reflex in patients with periampullary tumors. As a result, there is no consistency in our hospital concerning the therapy of periampullary tumor patients. All patients underwent biliary decompression via endoscopic retrograde cholangiopancreatography (ERCP) by the placement of a plastic stent in the gastroenterology ERCP unit. Percutaneous biliary drainage was not used in our hospital. In our daily clinical practice, if the patient does not have any signs of cholangitis, we operate on suitable patients without applying PBD. PD (Whipple procedure) was applied to patients with a periampullary diagnosis by one experienced surgeon. The surgical technique of PD is normally carried out with or without pylorus-preserving and standard lymph node dissection, according to the ISGPS definition [10].

Patients with PBD underwent surgery at the earliest 2 weeks after the procedure. The common bile duct stents were removed from the intraoperative common bile duct mini-incision and delivered to the microbiology laboratory for culture without being stored in a sterile container. The patients were transferred to the intensive-care unit following surgery. They were admitted to the intensive-care unit for at least 1 day due to their general state. On the postoperative day (POD) 3, the nasogastric tube was removed, and oral intake was started on POD 5. Abdominal drains were removed when they fell below 40–50 cc unless any complications developed. All patients received intraoperative antibiotic prophylaxis consisting of a single intravenous shot of ceftriaxone (2/1 gr) prior to skin incision.

Patient comorbidities were measured using the American Society of Anesthesiologists (ASA) physical status classification system. Postoperative pancreatic fistula (POPF) and other pancreatic surgery-specific complications (i.e., delayed gastric emptying, chyle leak and post-pancreatectomy hemorrhage) were scored using the updated International Study Group on Pancreatic Fistula Definition. According to this definition, pancreatic leakage was accepted if the drain amylase value measured on POD 3 and afterwards was more than three times the blood amylase value [11]. Postoperative complications were scored and classified using the Clavien−Dindo Classification (CDC) [12]. Morbidity included all complications following surgery until discharge or up to 30 days.

Patient demographic and clinical characteristics were collected, including sex, age, ASA score, preoperative serum bilirubin levels, operation time, length of stay, number of lymph nodes, pathological diagnosis and postoperative complications. This study is reported in accordance with the STROBE guidelines [13].

Statistical analyses

Statistical analyses were performed with the IBM SPSS v22.0 software program (SPSS Inc., Chicago, IL, USA). The normal distribution of the variables was checked by

Kolmogorov−Smirnov and histogram tests. Descriptive data were expressed as the mean ± standard deviation (SD). Categorical variables were analyzed using the Chi-square test. Student's *t*-test was used for continuous variables with a normal distribution. The effects of risk factors on morbidity were evaluated using univariate and multivariate logistic regression analyses. A *p* value of < 0.05 was considered statistically significant.

Results

Throughout the 6-year study period, 106 consecutive patients were operated on for the diagnosis of periampullary tumors in the gastrointestinal surgery department. The median age of the patients was 64.41 ± 11.67 years, and 65 (61.3%) were males. The patients were divided into 2 groups: stented group (Group I; $n = 67$, 63.2%); and nonstented group (Group II; $n = 39$, 36.8%). Preoperative biliary drainage was performed with ERCP in all patients, and plastic stents were placed in all patients. The patient characteristics are shown in Table 1.

When the preoperative patients were evaluated according to the ASA scoring system, 6 patients were ASA I, 56 were ASA II, and 44 were ASA III. No statistically significant difference was observed between the groups in terms of the ASA score ($p = 0.249$).

The median total bilirubin level before surgery was significantly higher in the nonstented group than in the stented group (6.39 mg/dL vs. 3.47 mg/dL, $p = 0.017$). In addition, the direct bilirubin level was significantly higher in the nonstented group than in the stented group (4.71 ± 5.02 mg/dL vs. 2.34 ± 4.02 mg/dL, $p = 0.009$). The number of lymph nodes removed was 22.68 ± 8.13, and no significant difference was observed between the groups ($p = 0.958$).

The indications for PD were pancreatic ductal adenocarcinoma in 84, intraductal papillary mucinous neoplasms in 7, pancreatic adenoma in 6, pancreatic neuroendocrine tumor in 2, mucinous cystic neoplasm in 4 (1 adenoma, 3 adenocarcinoma), serous cystic neoplasm in 1, chronic pancreatic in 1, and mixed adenoneuroendocrine carcinoma in 1.

Neoadjuvant therapy, which was provided at another hospital, was given to two patients without a stent. The majority of patients we sent for neoadjuvant therapy did not return to our hospital. Therefore, the number of patients in this group was less than expected.

Of the 106 PD operations, 104 were performed in an open setting, 1 was laparoscopic, and 1 was robotic. A single experienced gastrointestinal surgeon performed the procedures on the patients. In 78 patients, pancreatic anastomosis was performed using the Blumgart technique, and in 28 cases, the Heidelberg Wirsung jejunostomy approach was used. In 69 individuals, pyloric-sparing gastric anastomosis was performed, while in 37 patients, the usual approach was used. After pancreas anastomosis was performed, hepaticojejunostomy, antecolic gastrojejunostomy, and side-by-side jejunojejunostomy (Braun anastomosis) or duodenojejunostomy were performed sequentially.

In terms of the age, sex, ASA score, and total number of lymph nodes removed following surgery, there were no significant differences between the patient groups ($p > 0.05$). However, the stented group had a considerably longer hospital stay and a longer operation time than the nonstented group ($p < 0.05$) (Table 1).

A growth rate of 92.3% was observed in the stent cultures sent intraoperatively. The most commonly reproducing microorganisms were *Klebsiella pneumonia* 23.43%,

Table 1 Patient's demographic features and clinical characteristics

Variables	Group I ($n = 67$)	Group II ($N = 39$)	All patients	*p* value
Sex				
Female	24 (22.6%)	17 (16.0%)	41 (38.7%)	0.535
Male	43 (40.6%)	22 (20.8%)	65 (61.3%)	
Age (years)	65.49 ± 10.93	62.08 ± 12.48	64.41 ± 11.67	0.144
ASA I	2 (1.9%)	4 (3.8%)	6 (5.66%)	0.249
ASA II	35 (33.0%)	21 (19.8%)	56 (52.83%)	
ASA III	30 (28.3%)	14 (13.2%)	44 (41.5%)	
Preoperative total bilirubin level (mg/dl)	3.47 ± 5.65	6.39 ± 6.48	4.55 ± 6.1	0.017*
Preoperative direct bilirubin level (mg/dl)	2.34 ± 4.02	4.71 ± 5.02	3.21 ± 4.53	0.009*
Total number of lymph nodes removed	22.66 ± 8.64	22.74 ± 7.29	22.68 ± 8.13	0.958
Operation time (min)	335.67 ± 44.90	312.3 ± 42.89	327.07 ± 45.4	0.010*
Length of hospital stay/day	13.72 ± 5.54	9.87 ± 2.48	12.3 ± 5	0.001*

ASA American Society of Anesthesiologists

*$p<0.05$

Escherichia coli 21.8%, *Enterococcus faecium* 20.3%, and *Enterococcus faecalis* 9.3%.

Postoperative outcomes are shown in Table 2. The overall morbidity rate was 54.7%, and complication rates were 64.17% in Group I and 38.46% in Group II, with significant differences ($p = 0.01$). The perioperative mortality rate was 1.88% (2/106); both of these patients were in the stented group, and bacteria grew on the stents. The cause of death in these patients was sepsis secondary to pneumonia.

Although pancreatic leakage was detected at a higher rate in Group I than in Group II, no statistically significant difference was found between the groups ($p = 0.471$) (Table 2).

The effect of sex, operation time, age, presence of stent, total bilirubin, direct bilirubin, total lymph node count, positive lymph node count, and postoperative surgical stage on morbidity development was studied using univariate and multivariate logistic regression analyses (Tables 3 and 4). In the univariate analysis, advanced age, male sex, presence of a stent, and duration of operation time were associated with postoperative complications ($p = 0.046$, $p = 0.018$, $p = 0.038$, $p = 0.021$, respectively) (Table 3). The multivariate analysis indicated that the morbidity rate increased 1.063 times with increasing age ($p = 0.008$; 95% confidence interval [CI] for Exp (B): 1.016–1.112). In addition, morbidity was 4.332 times higher in those with common choledochal stents ($p = 0.011$; 95% CI for Exp (B): 1.407–13.336). Advanced age and the presence of a stent were independent risk factors for postoperative complications (Table 4).

Table 2 Postoperative complications

Variables	Group I ($n = 67$)	Group II ($n = 39$)	Total	p value
CD 1	30 (%)	11 (%)	41 (38.68%)	0.01*
CD 2	7 (%)	4 (%)	11 (10.37%)	
CD 3	6 (%)	0 (%0)	6 (5.66%)	
Wound infection	17	1	18	
Only pancreatic leakage (*n*)	9	9	18	
Sepsis (*n*)	6	1	7	
Atelectasis (*n*)	4	2	6	
Pneumonia (*n*)	3	0	3	
Bleeding (*n*)	1	2	3	
Intraabdominal collection (*n*)	1	0	1	
Pleural effusion (*n*)	1	0	1	
Hypoglycemia (*n*)	1	0	1	
Pancreatic leakage	32.83%	25.64%	30.18%	0.471
Biochemical leak	18	10	28 (26.41%)	
Grade B	2	0	2 (1.88%)	
Grade C	2	0	2 (1.88%)	
Deaths	2	0	2 (1.88%)	0.530

CD Clavien–Dindo

*$p < 0.05$

Table 3 Risk factors affecting the development of morbidities (results of a univariate logistic regression analysis)

Variables	*B*	SE	Exp *B*	95% CI for EXP (*B*)		p value
				Lower limit	Upper limit	
Age	– 0.058	0.029	0.944	0.892	0.999	0.046*
Sex	– 1.145	0.484	0.318	0.123	0.822	0.018*
Stent presence	– 1.336	0.643	0.263	0.075	0.926	0.038*
Operation time	– 0.016	0.007	0.984	0.971	0.998	0.021*
Total bilirubin	– 1.168	0.805	0.311	0.064	1.508	0.147
Direct bilirubin	1.324	1.018	3.760	0.511	27.656	0.193
Total number of LNs removed	0.022	0.029	1.022	0.964	1.083	0.464
Number of positive LNs	0.074	0.154	1.077	0.797	1.455	0.631

B logistic regression coefficient, *SE* standard error, Exp (*B*) odds ratio, *CI* confidence interval, *LN* lymph node

*$p < 0.05$

Table 4 Risk factors affecting the development of morbidities (results of a multivariate logistic regression analysis)

Variables	*B*	S.E.	Wald	*p* value	Exp (*B*)	95% CI for EXP (*B*)	
						Lower limit	Upper limit
Age	0.061	0.023	6.954	**0.008***	1.063	1.016	1.112
Sex	– 0.339	0.496	0.468	0.494	0.712	0.269	1.883
Stent presence	1.466	0.574	6.528	**0.011***	4.332	1.407	13.336
Operation time	0.006	0.006	1.087	0.297	1.006	0.995	1.017
Total bilirubin	– 0.153	0.426	0.129	0.719	0.858	0.372	1.977
Direct bilirubin	0.109	0.577	0.035	0.851	1.115	0.360	3.453
Total LN count	– 0.003	0.031	0.007	0.935	0.997	0.939	1.060
Positive LN count	– 0.049	0.111	0.196	0.658	0.952	0.766	1.184
Constant	– 6.786	2.636	6.625	0.01	0.001		

B logistic regression coefficient, *SE* standard error, Exp (*B*) odds ratio, *CI* confidence interval, *LN*, lymph node

*$p<0.05$

Discussion

One of the most prevalent clinical symptoms in periampullary tumors is obstructive jaundice (90%). Obstructive hyperbilirubinemia is harmful and can impede the liver function, causing biliary bacterial colonization and hypotension development. The need for preoperative biliary drainage in patients with jaundice is debatable, and it has yet to be determined which patients require this surgery [14]. PBD may aid a subset of jaundiced patients, but the ideal patient population and procedure timing are unclear [9]. Severe jaundice, long waiting times for surgery, cholangitis, and the use of neoadjuvant therapy, which is a rapidly emerging indication for longer term PBD, can be considered the main basic indications [15].

Let us examine the positive and negative elements of PBD in light of current research. In patients with proximal malignant obstructive jaundice, PBD reduces surgical complications [16]. A large-patient-volume study found that PBD was associated with bactobilia and wound infection but did not increase the length of stay or rates of death, severe complications, delayed gastric emptying, or pancreatic or biliary fistula [4].

The unfavorable consequences of PBD have been highlighted relatively explicitly, particularly in surgical publications. There are issues with the PBD operation itself as well as unfavorable consequences of PBD on surgery. Direct PBD complications include cholangitis, pancreatitis, stent blockage, duodenum or bile duct perforation, and bleeding from PBD-related perforation [15]. PBD has also been associated with an increased risk of abdominal collections and surgical site infection and an extended operative time [9, 17–19]. Again, certain prospective trials have found that biliary drainage increases the risk of major consequences, and PBD is not indicated in these investigations, even in cases with severe jaundice [5, 20]. If performed, percutaneous biliary drainage should be favored over ERCP. As a result, quick biliary decompression is possible, and the risk of catheter-related problems is reduced [21]. PBD should not be routinely recommended for obstructive jaundice. If this technique can be improved and the complication rate and hospital stay associated with PBD can be reduced, then PBD may be considered [22]. Clinically, the duration between PBD and surgery is estimated to be around 4 to 6 weeks. PBD-related post-pancreatectomy problems are twice as common as in other individuals, and they extend the patient's operation time and induce tumor stage progression [9, 24].

Regarding the need for PBD, it is a procedure applied before surgery in many patients. The rate of its use in studies varies between 35.5 and 55% [6, 9, 25, 26]. The current study's relatively high rate of PBD (63.2% of patients) may be due to a lack of understanding the guideline recommendations. Alternatively, it may be due to gastroenterologist's stenting reaction when performing ERCP on patients with periampullary pathology.

One of the most common complications after PD (Whipple procedure) is pancreatic fistula [1]. When the effect of PBD on pancreatic fistula is examined, the information in the literature on this subject is diverse. It has been reported that pancreatic fistula occurs more frequently following PBD [27, 28]. On the other hand, recent research has revealed that there is no relationship between PBD and pancreatic fistula [1, 4]. However, it was found to be higher in patients with intra-abdominal bleeding, wound infection, delayed stomach emptying, and PBD in the same study [1]. Although the rate of pancreatic fistula was higher in the stented group in the present study, no statistically significant difference was observed.

Although wound infection is the most common complication after PD, the most common reason for reoperation is bleeding (80%). After PD, hemorrhagic consequences occur at a rate of 5–20%. In hyperbilirubinemia patients, hepatic dysfunction, cholestasis, and coagulation abnormalities result in hemorrhagic diathesis, known as post-pancreatectomy hemorrhage (PPH) [9]. Although PPH developed in 3 patients (2.8%) in our study, the need for reoperation did not arise. Although two of the patients had jaundice, neither had a stent.

The transfer of microorganisms to the biliary tree following internal biliary drainage is one of the most prominent explanations for the increase in the rate of infection after BD. *Escherichia coli* has always been the most prevalent bacteria in bile cultures. The presence of *Enterococcus faecalis* increases when PBD is used [6]. In another study, while *Enterococcus* was the most abundant bacteria, *Klebsiella* species were the most abundant Gram-negative bacteria [4]. Growth was observed in the stent cultures of PBD patients at a rate of 94–95.23%, with *Enterococcus* being the most commonly growing bacterium [4, 6]. As the number of bile cultures grows, so does the number of surgical site infections (SSIs). The risk of SSI can be reduced by decreasing the intraoperative bile exposure time by closing the bile duct and performing peritoneal lavage at the end of surgery [29, 30]. According to these findings, adequate prophylactic antibiotics or antibiotic therapy based on stent culture results can reduce infection morbidity in patients who receive preoperative drainage. This perspective is supported by the findings of other studies [1, 31, 32]. In our study, stent culture growth was observed in 92.3% of patients with stents, similar to the literature. Despite the fact that *Escherichia coli* and *Enterococcus* were the most commonly reproducing bacteria, in line with the literature, *Klebsiella* species were found to be on the rise, demonstrating that the bacterial spectrum had shifted in patients with stents, allowing *Klebsiella* species to emerge.

Complication rates after PD are considerably high. In the literature, the complication rate after PD was reported to be 46.4–59.9%, and the mortality rate was 1.7–2.06% [6, 16, 33]. Although the stented group had a higher complication rate than the nonstented group in our study, the total complication rate was 54.7%, and the mortality rate was 1.88%, which is consistent with the literature. The number of studies on factors influencing morbidity is limited, and large-volume prospective studies on this topic are needed. Advanced age and the presence of stents were identified as factors influencing morbidity development in our study.

Several limitations associated with the present study warrant mention. First, it was carried out using a prospectively maintained database, but it was retrospectively analyzed. Second, the PBD indication was determined by different gastroenterologists, with no fundamental guideline followed. Third, PBD-related consequences were unclear, and their impact on postsurgical complications was not thoroughly distinguished. Fourth, there was a relatively low number of patients included in the study. Finally, neither the short- nor long-term effects of PBD on the survival have been established.

Despite these limitations, we believe that our study has certain strengths. The experience of the surgeon, anastomosis techniques, and preoperative and postoperative patient care can influence surgical outcomes. As a result, since all the patients were managed by a single surgeon, the effect of multiple techniques and the surgeon on complications was eliminated. The number of studies using logistic regression analyses is limited in the literature. An important aspect of the present study is that the factors affecting morbidity were also specified.

Conclusions

In most cases of obstructive jaundice, gastroenterologists install a stent during the ERCP procedure in periampullary tumors. Preoperative stenting complicates surgery and increases postoperative complications. In many cases, this procedure is unnecessary. Further studies are needed to confirm the indication of PBD. Although the total bilirubin level was higher in the nonstented group than in the stented group, the postoperative complication rate, operation time, and hospital stay were higher in the stented group. An advanced age and the presence of a stent were factors found to have influenced the morbidity development.

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Declarations

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

Ethical approval All the procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments. Approval for this study was obtained from the Research Ethics Committee of Erzurum City Hospital (No: 2022/13–144).

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