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Original Article

Effects of preoperative drainage on postoperative complications in patients with periampullary tumors

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Abstract

Aim: Preoperative biliary drainage is suggested for patients with jaundice, considering that surgical operations may increase postoperative complications in the presence of jaundice. The aim of this study was to test the effect of biliary drainage on possible serious complications, deaths, or period of hospital stay.

Material and Methods: Between January 2012 and June 2016, 160 patients with operable and resectable periampullary tumors who were diagnosed with periampullary tumors underwent pancreaticoduodenectomy (Whipple's procedure) in Marmara University Pendik Training and Research Hospital, Department of General Surgery. The patients' demographics, accompanying comorbid diseases, type of biliary drainage, drainage duration, pre- and post-drainage laboratory data, emerging complications and need for re-hospitalization were recorded retrospectively from the accessible files and records.

Results: It was observed that out of 158 patients with periampullary tumors, 116 that were operated with drainage had a higher occurrence of surgical site infections and anastomotic leaks, compared to the 42 patients that were operated without drainage. Similarly, when patient results were classified according to the Clavien-Dindo complication classification, the ratio was again against the patients that were operated with drainage. Drainage patients stayed in the hospital for a longer period; however, in terms of pancreatic fistula, re-hospitalization, need for intensive care and relaparotomy ratios, and especially in terms of mortality ratios, a difference between two patient groups was not observed.

Conclusion: Investigating the data collected from patients that were operated without drainage, and specifically considering the bilirubin values of the patients who had complications, there was no threshold identified that contributed to a higher likeliness of complications. Consequently, even though there were no results to motivate recommending drainage, it was concluded that applying drainage does not create any difference in short-term prognosis, but drainage increases infectious complications.

Keywords: Periampullary cancer; obstructive jaundice; preoperative biliary drainage; postoperative complication; hyperbilirubinemia.

INTRODUCTION

Cancer-related death is the second leading cause of death in Turkey and worldwide (22%), second to cardiovascular diseases. Pancreatic cancer ranks 9th among other cancers in Turkey with an incidence of 4.5/100.000. The highest incidence rate is in the 6th and 7th decades of life and patients are diagnosed at 60-65 years of age on average (1).

According to the National Cancer Institute publications, approximately 53.000 new cases of pancreatic cancer have been expected in USA in 2016, equaling approximately 3.1% of all new cancer cases to be diagnosed. In 2016, approximately 41.780 pancreatic cancer-related deaths have also been expected, equaling approximately 7% of all cancer-related deaths. Based on the National Cancer Institute data between 2006-2012, 5-year survival rate after pancreatic cancer diagnosis is 7.7% (2).

Periampullary cancer includes tumors originating from the major papilla and 2 cm of surrounding tissues (3). Surgery is the treatment option for periampullary tumors leading to malignant obstructive jaundice (tumors of pancreatic head, distal cholangiocarcinoma, bile duct and duodenum) without metastatic findings (4). Among these tumors which usually have a poor prognosis, ampullary and duodenal carcinoma has a better prognosis compared to distal bile duct and pancreatic cancer (5).

Although surgery is the only curative treatment option, only 10-20% of the patients present with surgically

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resectable tumors. Despite surgery, many patients develop metastasis within the first year of their treatment (6).

Tumoral lesions with involvement of periampullary region cause biliary obstruction resulting in obstructive jaundice. In patients whose clinical presentation usually includes jaundice and requires pancreaticoduodenectomy (PD), preoperative biliary drainage for controlling the bilirubin levels has been discussed widely and data reporting positive and negative results has been published (7). Preoperative biliary drainage has been recommended considering that performing surgery on a patient presenting with jaundice might increase postoperative complications. It has been stated that some experimental and clinical retrospective series have shown a decrease in morbidity and mortality. However, two meta analyses have revealed more complications compared to the group receiving direct surgery and this increase has been associated with drainage (8,9).

Hyperbilirubinemia, clinically defined with obstructive jaundice, has impaired hepatic detoxification mechanisms resulting in deficiency of bile salts in the intestine, intestinal flora disorders and an increase in intestinal permeability. It has influenced glycogen metabolism at the hepatic tissue level, impaired mitochondrial function at the cellular level and caused hepatic reticuloendothelial system dysfunction leading to high levels of portal endotoxin circulation (10). It has been considered that TNF, IL6 and other inflammatory cytokines that increase due to Kupffer cell dysfunction might lead to bacterial infection and even metastasis (11). However, it is a well-known fact that most of these effects are related to endotoxemia rather than hyperbilirubinemia. It has been claimed that synthesis of liver-dependent coagulation factors in the presence of obstruction might be impaired and especially bleeding complications might increase in patients scheduled for surgery (12). Biliary drainage methods are used for patients with clinically significant icterus in the preoperative period in order to improve hepatic function, decrease cytokine release and endotoxemia and improve immune function. Biliary drainage is performed with stenting by percutaneous transhepatic external/internal drainage or endoscopic retrograde cholangiopancreatography (13). Both methods may have their own complications and have been shown to increase infectious complications such as pancreatic anastomotic fistula, bleeding, delayed gastric emptying, biliary fistula, gastrojejunostomy fistula, intra-abdominal abscess, wound infection, portal vein thrombosis, pneumonia and cholangitis (9).

The aim of this study is to define the complications resulting from preoperative biliary drainage performed with endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous biliary drainage (PBD) methods in patients with operable and resectable periampullary tumors who are diagnosed with high bilirubin levels as well as to determine any related factors and test the superiority of either group in comparison. In addition, the secondary objectives of the study include obtaining a threshold value from patients who develop complications in both groups, considering the preoperative bilirubin levels.

MATERIAL and METHODS

Between January 2012 and June 2016, PD (Whipple's procedure) was performed by the Marmara University Pendik Training and Research Hospital, Department of General Surgery in patients with operable and resectable periampullary tumors who were diagnosed with high bilirubin levels. The files and records of 160 patients were screened retrospectively. The patients' demographics, accompanying comorbid diseases, type of biliary drainage, drainage duration, pre- and post-drainage laboratory data, emerging complications and need for re-hospitalization were recorded from the accessible files and records.

The patients whose tumor operability was evaluated by CT without distant metastasis and involvement of portal and mesenteric vessels preventing surgery (without peripheral tumor or vessel wall disorders greater than 180 degrees) were considered eligible for surgery. The selection of patients for preoperative drainage was generally based on bilirubin levels and surgery dates. Stenting (metal or plastic) by ERCP was primarily preferred as the drainage method, switching to PBD in case of failure. Continuation of active external drainage and a decrease in bilirubin levels in weekly controls were considered as successful drainage.

All patients with insufficient bile drainage with or without cholangitis received new stents and underwent radical surgery within 4-6 weeks.

The patients who underwent surgery receiving neoadjuvant therapy as well as patients with gastric outlet obstruction were excluded from this evaluation.

All patients received perioperative antibiotic treatment and PD was performed according to the standard methods. Care was provided in accordance with the enhanced recovery after surgery (ERAS) protocols (14) without compromising patient safety and measurement of drain amylase contents as well as fistula follow-up was performed especially on Day 1, 3 and 5. Clinical follow-up in the postoperative period included intravenous fluid therapy calculated according to body weight, follow-up of input-output, postoperative analgesia, antiemetic treatment and close follow-up of blood glucose for diabetic patients. Any additional medications regularly used by the patients for their additional diseases were given orally or parenterally under close monitoring. Routine blood and biochemical parameters were monitored daily.

The Clavien-Dindo classification was used to standardize postoperative surgical complications and non-routine treatments (15). According to the classification, they were defined and recorded individually for each patient considering non-routine clinical changes and levels of treatment.

CD 1: Patients without any additional procedures except routine follow-up and treatment were categorized into this group. Patients with culture growth but without additional procedures or antibiotherapy were also included in this group.

CD 2: Patients who received blood products such as erythrocyte suspension in the postoperative period; TPN; clinical replacement of electrolytes and liquids; and drug treatments such as antibiotics, defibrillators, bronchodilators, diuretics and albumin without invasive procedures as well as patients with nasogastric (NG) tube reinsertion for TPN for an extended period due to gastric complications were included as CD 2.

CD 3: Patients who underwent endoscopic procedures, invasive procedures with ultrasound or CT and angiographic procedures were included.

CD 4: Patients requiring intensive care follow-up due to single or multiple organ failure despite treatments were included.

As no patients died under department follow-up during first hospitalization or death occurred under intensive care follow-up, no patients were included in the CD 5 group. As the procedures were performed under sedation in the CD 3 group and the transition from single to multiple organ failure was very fast in the CD 4 group, categorization into "a" and "b" was not approved. Because all patients were under close follow-up after discharge, the attached "d" section was not used.

Pancreatic Fistula

Several definitions were used in the literature to define a pancreatic fistula (PF) (16). The definition of PF was standardized in 2005 by the International Study Group on Pancreatic Fistula [ISGPF] and defined as an amylase level in drainage fluid 3 times higher than serum amylase level on postoperative Day 3 or later. Based on the clinical condition, the grade was classified as A, B and C (17).

Other Complications

Re-hospitalization: They were recorded considering whether re-hospitalization occurred within one month after discharge.

Intensive care admittance: The number of days were recorded for patients requiring intensive care in the postoperative period.

As the NG tube was retracted at the end of Day 2 at the latest (Hour 48) in routine follow-up; NG tubes staying in place more than 3 days, NG tubes inserted after postoperative Day 3 due to persistent nausea-vomiting as well as NG tubes kept inserted for more than 7 days were defined as "delayed gastric emptying". Patients who could not tolerate oral intake by Day 2 and did not receive any NG tubes were recorded as delayed gastric emptying. NG tubes inserted at any time during hospitalization and kept in place for more than one day were also recorded as complications (18).

Statistical Analysis

IBM SPSS Statistics 23 software was used for statistical analysis. Two-tailed chi-square or Fisher exact tests were used to compare categorical variables. Independent 2-sample t-test or Mann-Whitney U test was used for continuous variables. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 160 patients who underwent PD surgery between January 2012 and June 2016 were determined to be hyperbilirubinemia in the preoperative period. Data obtained from 2 patients receiving preoperative chemotherapy was excluded from the analysis.

Among 158 patients included in the study, 39.2% were female (n=62) and 60.8% were male (n=96) with a mean age of (±SD) 61±9 years. The most prominent finding in patient presentations was jaundice in both patient groups. In a cohort of 158 patients in total, 60% of the patients presented with jaundice followed by 43% presenting with pain. Approximately 10% of 158 patients had no current complaint at presentation. However, some cases in which the same patient had multiple complaints like jaundice, pain and itching were observed. The mean age in the drainage group was 63±8 years compared to 58±8 years in the non-drainage surgery group, with a significant difference between these age groups (p=0.019). Considering comorbid diseases, the most common diseases were hypertension and diabetes mellitus, respectively (43.7%-36.7% in total). Distribution of patient demographics by group is shown in Table 1.

It was observed that the operated patients had mostly tumors of pancreatic head and ampulla in both groups and most of the patients had adenocarcinoma as determined by pathological examinations (Table 1). There was no significant difference between diagnosis of malignancies and anatomic location of malignancies.

Patients with cystic neoplasia such as intraductal papillary mucinous neoplasm, neuroendocrine tumors and gastrointestinal stromal tumors were considered in "other diagnosis" group and lesions located between the periampullary region and mid-common bile duct were considered in "other location" group. Although a statistically significant difference was observed between the drainage and non-drainage groups in terms of "other location", this difference was not interpreted as clinically significant due to intra-group heterogeneity. However, when evaluating all malignancies, the cause of drainage for distal bile duct tumors might be associated with patients' presentation with prominent jaundice and especially with performance of diagnostic internal drainage (ERCP).

An analysis of the TNM grades of the patients diagnosed with adenocarcinoma showed that both groups had T3 tumors at the highest rate (59.0% in the drainage group and 51.6% in the non-drainage surgery group).

Biliary drainage was performed on 116 patients: PBD for

47 patients (40.5%) and ERCP for 69 patients (59.6%). Biliary drainage procedures were successful for 105 patients (90.5%) and jaundice-related complaints decreased within 10 days. 11 patients with ERCP underwent subsequent PBD due to postprocedural stent dysfunction (9.5%). Bilirubin levels remained elevated in 9 patients despite drainage (7.7%). Among these patients, 1 patient developed acute renal failure and underwent dialysis (0.9%). Bilirubin levels remained elevated in 1 of 9 patients due to cholangitis and decreased below 2 mg/dL on postoperative Day 8 (0.9%). Complications related to preoperative drainage were determined using the patient records: stent dysfunction, cholangitis, acute renal failure, bleeding and pancreatitis. Following drainage, no conditions that could prevent surgery (stones, metastasis, additional diseases, etc.) were observed.

Surgery was performed after 15 days post-diagnosis on average for the non-drainage group and after 25 days on average for the drainage group.

No surgery-related complications were observed in 19 of 116 drainage patients (16.4%) and 9 of 42 non-drainage surgery patients (21.4%). The complications including anastomotic leakage and surgical site infection were more common in drainage surgery patients compared to the non-drainage patients and these differences were considered statistically significant. When other complications were reviewed, there was no significant difference between two groups (Table 2).

Median number of days of hospitalization was 9 days (min 5, max 45 days) in the drainage group compared to 7 days (min 4, max 24 days) in the non-drainage surgery group and the duration of hospitalization was observed to be significantly shorter in the non-drainage surgery group (p=0.012).

Postoperative pancreatic fistula (POPF) was found in 91 patients in the drainage group (78.4%) compared to 32 patients in the non-drainage group (76.3%). In terms of fistula grading, Grade A was found in 19%, Grade B in 45.7% and Grade C in 13.8% in the drainage group compared to Grade A in 31%, Grade B in 31% and Grade C in 14.3% in the non-drainage surgery group. Chylous fistula persisting for more than 3 weeks was detected when drainage triglyceride levels were measured in four patients. When postoperative complications were classified according to CD, it was shown that CD 1 and CD2 patients constituted the majority in both groups. The drainage group had a re-hospitalization rate of 31.9% within 1 month due to deterioration of general condition, infection and intra-abdominal collection while this rate was 23.8% in the non-drainage surgery group. 10.3% of the drainage group and 16.7% of the non-drainage surgery group were re-operated due to bleeding, evisceration, intra-abdominal abscess, etc. The PD procedure of one patient was completed by total pancreatectomy. During the early postoperative period, 25% of the drainage group and 21% of the non-drainage surgery group were monitored in the intensive care unit. Fistula formulation by patient stage, CD classifications, re-hospitalization, re-laparotomy rates and intensive care rates were detailed in Table 2.

The 1-month mortality rate was calculated as 9.5% (n=11) in the operated group with drainage compared to 7.1% (n=3) in the group without drainage and there was no statistically significant difference between the groups (p=0.760).

When the complications of patients with post-drainage surgery were grouped according to the PBD and ERCP procedures, there was no statistically significant difference between the groups with preoperative PBD and ERCP.

The last median total bilirubin level of the patients with drainage was 11.9 mg/dL (min=0.3 - max=42 mg/dL) and the direct bilirubin level was 9.1 mg/dL (min=0.3 - max=34 mg/dL). The bilirubin levels of 9 patients did not change following drainage and the last median bilirubin level of the remaining patients as measured in the preoperative period was 2.2 mg/dL (min=0.2 - max=22 mg/dL) for total bilirubin and 1.2 mg/dL (min=0.1 - max=15 mg/dL) for direct bilirubin. It was observed that the bilirubin levels of 9 patients without bilirubin level changes decreased below 2 mg/dL between postoperative Day 7 and 10. The last median bilirubin level of the patients without drainage as measured in the preoperative period was 1.1 mg/dL (min=0.2 - max=21 mg/dL) for total bilirubin and 0.3 mg/dL (min=0.1 - max=16 mg/dL) for direct bilirubin. The total bilirubin level of the drainage group was 11.9 mg/dL, with a significant difference compared to the non-drainage group (1.1 vs. 11.9 mg/dL, p<0.001).

When intra-group complication rates were compared to the bilirubin threshold value in the non-drainage surgery group that underwent surgery without postoperative drainage, the threshold value was specified as the mean value of total bilirubin of 4.5 mg/dL and complications were observed in 10 patients (23.8% of the non-drainage surgery group). When the threshold value was specified as the median value of total bilirubin of 1.1 mg/dL, complications were observed in 17 of 22 patients in the non-drainage surgery group who had higher bilirubin levels (40.5% of the non-drainage surgery group). However, the analysis performed in the non-drainage group revealed no difference between bilirubin levels in patients with or without complications (p>0.05) and thus no cut-off (threshold) value to cause an increase in morbidity was found upon analysis of the relation between complications and bilirubin values.

Bacterial growth was observed in the drainage catheter, wound site and blood cultures from 38 patients in the patient groups classified as POPF grade B and C in the postoperative period of 1 month. The rate of 32 patients with growth in the drainage group was 27.6% and the rate of 6 patients with growth in the non-drainage surgery group was 14.3% (p<0.005).

Table 1. Distribution of demographics and malignancies by group

		With drainage N=116		Without drainage N=42		P
		N	%	N	%	
Gender – n (%)						
	Female	45	(38.9)	17	(40.8)	0.02
	Male	71	(61.2)	25	(59.5)	
Age (mean ±SD)						
	Year	62.59 (±8.27)			57.74 (±8.76)	0.019
Comorbidity* – n (%)						
	Diabetes	41	(35.3)	17	(40.5)	0.55
	HT	52	(44.8)	17	(40.5)	0.82
	CHF - Heart Failure	19	(16.4)	4	(9.5)	0.28
	COPD	8	(06.9)	3	(7.1)	1.0
	Other	6	(05.2)	12	(28.6)	0.32
	No	25	(21.6)	14	(33.3)	
Smoking – n (%)						
	Yes	45	(38.8)	9	(21.4)	0.042
	No	71	(61.2)	33	(78.6)	
Alcohol – n (%)						
	Yes	7	(06.0)	1	(2.4)	0.68
	No	109	(94.0)	41	(97.6)	
BMI (mean ±SD)		N=60		N=27		
kg/m²		26.72 (±3.36)			27.65 (±3.98)	0.3
Location of malignancy – n (%)						
	Pancreatic head	50	(43.1)	19	(45.2)	0.74
	Ampulla	35	(30.2)	8	(19.0)	0.17
	Distal bile duct	19	(16.4)	0	(0)	0.005
	Duodenum	0	(0)	4	(9.5)	-
	Other location	12	(10.3)	11	(26.2)	<0.001
Pathological diagnosis – n (%)						
	Adenocarcinoma	104	(89.7)	28	(66.7)	0.086
	Other diagnosis	12	(10.3)	14	(33.3)	0.157

HT: Hypertension, CHF: Congestive heart failure, COPD: Chronic obstructive pulmonary disease, SD: Standard Deviation, BMI: Body Mass Index, *Patients may have multiple comorbidities

Table 2. Postoperative complications and classifications of complications in pancreaticoduodenectomy patients

		With drainage N=116		With N=42		P	Total N=158	
		N	%	N	%			
Complications								
Bleeding		32	(27.6)	8	(19.0)	0.280	40	(25.3)
Anastomotic leakage		57	(49.1)	12	(28.6)	0.021	69	(43.7)
Delayed gastric emptying		12	(10.3)	5	(11.9)	0.780	17	(10.8)
Surgical site infection		46	(39.7)	8	(19.0)	0.016	54	(34.2)
Eventration		3	(2.6)	1	(2.4)	1.000	4	(2.5)
Pulmonary complication		10	(8.6)	1	(2.4)	0.290	11	(7.0)
Renal failure		2	(1.7)	1	(2.4)	1.000	3	(1.9)
Fistula		91	(78.4)	32	(76.2)	0.760	124	(78.5)
No complications		19	(16.4)	9	(21.4)	0.460	28	(17.7)
Clavien-Dindo								
	CD 1	48	(41.4)	26	(61.9)	0.017	74	(46.8)
	CD 2	50	(43.1)	10	(23.8)	0.021	60	(38.0)
	CD 3	6	(5.2)	3	(7.1)	0.700	9	(5.7)
	CD 4	12	(10.3)	3	(7.1)	0.760	15	(9.5)
Postoperative pancreatic fistula – n (%)								
	No	25	(21.6)	10	(23.8)	0.760	35	(22.2)
	A	22	(19.0)	13	(31.0)	0.110	35	(22.2)
	B	53	(45.7)	13	(31.0)	0.097	66	(41.8)
	C	16	(13.8)	6	(14.3)	0.940	22	(13.9)
Re-hospitalization – n (%)								
	Yes	37	(31.9)	10	(23.8)	0.430	47	(29.7)
	No	79	(68.1)	32	(76.2)		111	(70.3)
Re-laparotomy – n (%)								
	Yes	12	(10.3)	7	(16.7)	0.280	19	(12.0)
	No	104	(89.7)	35	(83.3)		139	(88.0)
	Yes	29	(25.0)	9	(21.4)	0.640	38	(24.1)
	No	87	(75.0)	33	(78.6)		120	(75.9)

DISCUSSION

Preoperative biliary drainage is usually performed in patients with malignant pancreatic head tumors. Despite its theoretical advantages, it is controversial whether it causes perioperative complications or it has superior clinical benefits. In the current analysis, morbidity of biliary drainage was higher compared to the non-drainage group regarding the parameters of anastomotic leakage, surgical site infection (including intra-abdominal abscess) and duration of hospitalization. A meta-analysis including 15 retrospective studies that compared the morbidity rates of preoperative post-drainage surgery and non-drainage surgery showed that especially infectious complications had a higher rate in patients with drainage (9).

There was no significant difference between the drainage group and non-drainage group in terms of fistula development. High frequency of pancreatic fistula development were explained with measurement of current amylase values as of Day 1. The majority of patients with fistula were assessed and treated as grade B. Although the rate of infection with fistula complication was higher in the drainage group among the patients with grade B and C fistula, no statistical difference was observed. This data revealed that drainage had no impact on fistula development; however, it was also demonstrated that drainage had a negative impact on bacterial contamination upon fistula development. A study showed that bacteria were isolated in 15% of drainage surgeries and 9.4% in non-drainage surgeries (8,9).

There was no difference in mortality between the groups: mortality rate was 6.9% in the drainage group and 7.1% in the non-drainage surgery group. In a meta-analysis comparing the mortality rate of patients with periampullary tumors who underwent PD after biliary drainage with that of the non-drainage surgery group, mortality was 15.1% in the drainage group compared to 13.3% in the non-drainage surgery group (8).Van der Gaag et al. found a mortality rate of 14.7% in the drainage group compared to 12.8% in the non-drainage group (7).On the other hand, mortality rates of 2-4% were also reported following PD in the literature (19,20) and this difference was considered related to the extensive heterogeneity in jaundice levels. The higher number of patients being treated for metastatic diseases may be responsible for the high rate of mortality. The mortality rates in our study were also included in the range of different mortality rates reported in the literature.

The mechanism of biliary drainage leading to complications is unknown. Some studies correlated short-term drainage with surgery without sufficient drainage in patients with advanced jaundice. Optimal duration was not definite. According to the published literature, even though the bilirubin level returns to normal, full recovery of hepatic synthesis and clearance function as well as mucosal intestinal barrier function is only possible after 4-6 weeks (9). It was also not definite whether restoration of hepatic functions would be fully reflected in postoperative clinical data. This time period (4-6 weeks) was taken into consideration in the presented data and the schedule of surgery was maintained except for the patients developing drainage complications such as cholangitis. More comprehensive studies are required to determine preoperative drainage duration to further reduce morbidity rates.

Based on the evaluation of periampullary malignancies, there is no prospective randomized or retrospective randomized study comparing bilirubin levels of the patients with drainage or evaluating complications by bilirubin levels. During the review of meta-analyses comparing the patients undergoing surgery with or without drainage, the threshold bilirubin values compared with complications were not observed (8).In many published studies, different bilirubin levels were accepted as the threshold value for drainage requirements (7,8,10,4,21). In our study, there was a significant difference between the median bilirubin level measured before drainage in the drainage group (11.9 mg/dL) and the median bilirubin level of the non-drainage group (1.08 mg/dL). However, no significant correlation was found between the complications rates and bilirubin levels. The post-drainage bilirubin levels were reviewed and any reduction was interpreted as an indicator of efficacy. However, it is difficult to decide an optimal level or a threshold value. For this purpose, an analysis of both median and mean data of different bilirubin levels obtained from non-drainage patients was performed, revealing no threshold value that could lead to reduced morbidity or increased morbidity in non-drainage surgery. Further studies are required to clarify the relationship between bilirubin levels and prognosis in order to obtain this data.

Either internal or external drainage may be preferred as the biliary drainage method. Although internal drainage was used as the first choice in the data, 11 patients were switched to external drainage in the case of insufficient internal drainage. It was reported in the literature that internal drainage had more complications compared to external drainage (22). In this study, there was no statistically significant difference between the PBD group and internal ERCP group in terms of complications. Although external drainage was known to be a method reducing patients' comfort, both groups had bleeding, infectious complications, pulmonary and renal complications and fistula complications without any statistically significant difference.

When the complications developed by the drainage and non-drainage groups were analyzed according to the Clavien-Dindo classification, CD 1 and CD 2 rates were significantly higher in the non-drainage group whereas there was no difference in complications of CD 3 and CD 4. It was concluded that treatments provided according to the ERAS protocols in the non-drainage group showed a smaller deviation from the routine.

In our study, no difference was observed between the groups in terms of bleeding, delayed gastric emptying, eventration, pulmonary complications specifically aggravated with postoperative atelectasis, multiple

organ failure, and renal failure as a precursor of sepsis. Bleeding was usually analyzed as a fistula complication in the literature and had a higher rate in drainage groups (7). Renal and pulmonary complications also caused by preoperative comorbid diseases were reviewed in the studies comparing postoperative morbidity and mortality of PD irrespective of drainage and had a higher rate in patients over 65 years of age with comorbid diseases (23).

Based on the comparison of demographics between the groups, there was a significant difference in terms of age, with the non-drainage surgery group being younger than the drainage group. In a study analyzing complication parameters according to the age groups, it was observed that complication rates were higher in the group aged 70 and above compared to younger groups. However, no significant difference was observed when the age factor was evaluated together with the drainage method (24). In our study, it was also considered to have an impact on the complication rates in the non-drainage surgery group. Consequently, preoperative drainage is a very challenging decision to make in case of periampullary tumors which already have a poor prognosis, considering the fact that age-related comorbid diseases can also affect mortality and morbidity in elderly patients with hyperbilirubinemia. The difficulty experienced by surgeons is usually caused by the fact that the clinical response of an elderly patient following hyperbilirubinemia and drainage as well as postoperative clinical course after PD cannot be anticipated easily in elderly patients. Similarly, when the bilirubin levels of both groups were compared, the bilirubin levels of the group operated without drainage was significantly lower than the other group. When complication rates are interpreted accordingly, it has become more difficult to decide whether the complications in the drainage group result from high bilirubin levels or the drainage itself. Based on the evaluation according to the literature, higher number of infectious complications in the drainage group and lack of a bilirubin threshold value resulting in an increase in complications have suggested that high complication rates can be related to the drainage.

Similarly in a meta-analysis study evaluating preoperative biliary drainage, it was reported that postoperative complications such as anastomotic leakage, bleeding, surgical site infection, and relaparotomy were less common in drainage patients compared to non-drainage patients. However, duration of hospitalization and mortality rates were similar (25).

CONCLUSION

As a conclusion of the study, there was no clinically significant difference between the short-term mortality and morbidity following periampullary tumor surgery with or without drainage. Although no data has been obtained to recommend routine drainage, drainage should not be considered as a procedure to avoid, as the same early mortality and morbidity rates have been observed in the non-drainage group. Non-drainage surgery can easily be performed in the presence of obstructive icterus and jaundice is not a contraindication for PD.

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