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Does Preoperative Biliary Drainage Compromise the Long-Term Survival of Patients With Pancreatic Head Carcinoma?

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Background and Objectives: The aim of this study was to determine the impact of preoperative biliary drainage (PBD) on long-term survival in patients with pancreatic head carcinoma after surgical resection.

Methods: Medical records of 160 patients with pancreatic head carcinoma who underwent surgical resection were reviewed retrospectively. Clinicopathological parameters including long-term survival were compared between patients who did and did not undergo PBD.

Results: Overall survival of patients who underwent PBD (n = 93) was significantly worse than that of patients who did not (n = 67) by univariate analysis ($P = 0.030$). However, multivariate analysis revealed that PBD was not an independent prognostic factor for overall survival ($P = 0.227$). Patients who underwent percutaneous transhepatic biliary drainage (PTBD) had significantly worse survival than patients who underwent endoscopic retrograde biliary drainage (ERBD, $P = 0.038$) and patients who did not undergo PBD ($P = 0.001$). The rate of peritoneal recurrence in patients who underwent PTBD was significantly higher than that of patients who underwent ERBD ($P = 0.033$) or patients who did not undergo PBD ($P = 0.034$).

Conclusions: PBD may not affect the long-term survival of patients with pancreatic head carcinoma if ERBD is used.

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KEY WORDS: **pancreatic head carcinoma; preoperative biliary drainage; endoscopic retrograde biliary drainage; percutaneous transhepatic biliary drainage; long-term survival**

INTRODUCTION

Obstructive jaundice is one of the most common symptoms of patients with pancreatic head carcinoma. Obstructive jaundice is thought to impair nutritional, metabolic and immune function [1]. Therefore, preoperative biliary drainage (PBD) has been performed routinely for patients with pancreatic head carcinoma amenable to surgical resection at high volume centers of pancreatic surgery since nonoperative drainage procedures, including percutaneous transhepatic biliary drainage (PTBD) and endoscopic retrograde biliary drainage (ERBD), were introduced in the 1960s [2,3]. However, the benefit of PBD for patients with obstructive jaundice is controversial. With regard to short-term outcomes, several retrospective cohort studies demonstrated the usefulness of PBD, because PBD reduced postoperative morbidity and mortality [4–6]. In contrast, other retrospective series demonstrated that PBD did not influence [7–11] or increased [12,13] the incidence of perioperative complications, and a meta-analysis [14] and a recent randomized, controlled, multicenter trial [15] showed that routine PBD for jaundiced patients with resectable tumors increased the rate of perioperative complications compared with that in patients who proceeded directly to surgery, owing to the high frequency of drainage-related complications. The effect of PBD on short-term outcomes of patients with obstructive jaundice is still debatable.

In contrast, to our knowledge, few reports have determined whether PBD has a detrimental effect on the long-term survival of patients with pancreatic head carcinoma [11,16,17]. The prognostic impact of PBD on the long-term survival is still unknown. In our institution, PBD has been performed routinely for jaundiced patients with pancreatic head carcinoma. The aim of this study was to determine whether PBD was associated with compromised long-term survival of patients with pancreatic head carcinoma by assessing cases treated at our institution and analyzing the results with univariate and multivariate survival analysis.

PATIENTS AND METHODS

Study Design

This was an observational study of patients with pancreatic head carcinoma who underwent tumor resection with the aim of achieving cure at the Department of Surgery, Hiroshima University Hospital between January 1998 and June 2013. The patients were divided into two groups: patients who underwent PBD, including ERBD and PTBD, and patients who did not. Clinicopathological factors, including patient demographics, tumor characteristics, patient survival, and patterns of recurrence, were compared. Univariate and multivariate survival analyses were used to determine the effect of PBD on the long-term survival of patients with pancreatic head carcinoma. Written informed consent for surgical treatments, pathological examinations, and adjuvant chemotherapy regimens was obtained from all patients according to our

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institutional guidelines. This study was approved by our institutional review board.

Patient Selection

All consecutive patients with pancreatic head carcinoma who underwent surgical resection entered the study. All patients underwent R0 or R1 tumor resection and had a confirmed pathological diagnosis. Patients with pancreatic ductal adenocarcinoma derived from an intraductal papillary-mucinous neoplasm or a mucinous cystic neoplasm were excluded from this study [18]. Pylorus-preserving pancreatoduodenectomy was usually performed for patients with pancreatic head carcinoma. Patients with tumors close to the duodenal bulb in the superior pancreatic head underwent conventional pancreatoduodenectomy. Patients with tumors that invaded the whole pancreas underwent total pancreatectomy. Partial resection of the portal vein (PV) or superior mesenteric vein (SMV) was performed if separation of the tumor from the PV or SMV was not possible at surgery [19]. All patients underwent regional and para-aortic lymph node dissection. Intraoperative pathological findings of distal pancreatic margins were assessed on frozen tissue sections. If any pancreatic margin was positive for cancerous cells, further resection of the pancreas was performed to the maximum extent possible. For reconstruction of the alimentary tract, the Billroth I type or the Roux-en Y type reconstruction with pancreaticogastrostomy was performed [20].

Postoperative adjuvant chemotherapy for patients with pancreatic carcinoma was instituted in 2002. Patients who received postoperative adjuvant chemotherapy had two options after surgical resection: intravenous chemotherapy alone or intravenous and oral chemotherapy. Intravenous chemotherapy consisted of gemcitabine 700 mg/m^2 administered bi-weekly for 30 min by intravenous drip infusion. Patients who received intravenous and oral chemotherapy were given intravenous gemcitabine 700 mg/m^2 on day 1 and oral S-1 50 mg/m^2 for 7 consecutive days; this cycle was repeated every 14 days [21–23]. No patient received radiation therapy during the study period.

Definitions

Local or distant tumor extension was assessed by computed tomography. A tumor was considered unresectable if computed tomography revealed distant metastases, including liver metastasis, peritoneal dissemination, or apparent para-aortic lymph node metastasis [24]. Tumors that encased the celiac or superior mesenteric artery were usually considered unresectable. However, tumor abutment of the celiac or superior mesenteric artery and involvement of the PV or SMV alone was not a contraindication to radical resection. ERBD was performed for all patients who had preoperative obstructive jaundice to reduce cholestatic liver damage. However, if ERBD failed technically, PTBD was performed.

Pancreatic fistula was classified according to the criteria of the International Study Group on Pancreatic Fistula (ISGPF), and was defined as grade B or C pancreatic fistula [25]. Postoperative complications were graded according to the classification of surgical complications proposed by Dindo et al. [26], and were defined as grade III, IV, or V complications.

After tumor resection, all specimens were evaluated pathologically, and each tumor was classified as well-differentiated, moderately differentiated, or poorly differentiated tubular adenocarcinoma or adenosquamous carcinoma according to the predominant pathology. Specimens were also examined pathologically for anterior serosal invasion, retropancreatic tissue invasion, choledochal invasion, duodenal invasion, portal vein invasion, and lymph node metastasis. Surgical margins were considered positive if infiltrating adenocarcinoma was present at the proximal or distal pancreatic transection line or in the dissected peripancreatic soft tissue margins. The final stage of pancreatic carcinoma was assessed pathologically according to the TNM classification system of malignant tumors published by the International Union Against Cancer (UICC), 7th edition [27].

Data Collection

The collected data included sex, age, date of surgery and last follow-up, type of biliary drainage, operative procedure, PV/SMV resection, operative time, blood loss, blood transfusion, postoperative complication, 30-day mortality, postoperative adjuvant chemotherapy, tumor size, pathological diagnosis, lymph node status, surgical margin status, UICC pT factor, and UICC stage. Postoperative patients were followed every 3–6 months in the outpatient clinics with computed tomography and blood tests. For patients who died, survival time after surgery and cause of death were recorded. For survivors, postoperative survival time and status of recurrence were recorded.

Study Outcomes

The primary endpoint was whether PBD was an independent prognostic factor for overall survival in patients with pancreatic carcinoma. Additional endpoints were to compare overall survival and initial sites of recurrent between patients who underwent ERBD and PTBD.

Statistical Analysis

Data were expressed as median (range). Clinicopathological factors were compared between the two groups with the Chi-square test or Fisher's exact test. Survival curves were constructed via the Kaplan–Meier method, and differences in survival curves were compared by univariate log-rank (Mantel-Cox) analysis. Factors found to be significant on univariate analysis were subjected to multivariate analysis with a Cox proportional hazards model. Differences were considered significant at $P < 0.05$. Statistical analysis was performed with JMP statistical software version 9.0.2 (SAS Institute, Cary, NC).

RESULTS

Patient Demographics and Tumor Characteristics

A total of 160 patients with pancreatic head carcinoma entered the study. Patient demographics and tumor characteristics are shown in Table I. The 160 eligible patients included 84 men (53%) and 76 women (47%) with a median age of 69 years (range, 38–88 years). Preoperative maximum serum total bilirubin level ranged from 0.3 to 29.7 mg/dl (median, 1.9 mg/dl), and PBD was performed for 93 patients (58%), ERBD for 73 patients (46%) and PTBD for 20 patients (12%). Postoperative complication occurred in 28 patients. The most common complication was pancreatic fistula (n = 7), followed by wound infection (n = 6), chylous ascites (n = 6), biliary fistula (n = 5), intra-abdominal abscess (n = 3), and miscellaneous complications (n = 3).

Comparison of Clinicopathological Factors Between Patients With and Without PBD

A comparison of clinicopathological factors between the 93 patients who underwent PBD and the 67 patients who did not is shown in Table II. Among the 160 patients, PBD was performed more frequently in patients who received blood transfusions ($P = 0.027$) or who had higher serum total bilirubin levels ($P < 0.001$), larger tumors ($P = 0.043$), and more advanced pT factor ($P = 0.044$). However, there were no significant differences in the use of adjuvant chemotherapy, tumor differentiation, lymph node status, surgical margin status, and UICC stage between the two groups.

TABLE I. Patient Demographics and Tumor Characteristics (n = 160)

Factor	No. of patients	%
Age, years		
Median (range)	69 (38–88)	
Gender		
Male	84	53
Female	76	47
Preoperative maximum total bilirubin level, mg/dl		
Median (range)	1.9 (0.3–29.7)	
Preoperative biliary drainage		
PTBD	20	12
ERBD	73	46
No	67	42
Operative procedure		
Pylorus-preserving pancreatoduodenectomy	144	90
Conventional pancreatoduodenectomy	12	8
Total pancreatectomy	4	2
PV/SMV resection		
Yes	77	48
No	83	52
Operative time, min		
Median (range)	382 (235–650)	
Blood loss, ml		
Median (range)	1,300 (190–8,345)	
Blood transfusion		
Yes	51	32
No	109	68
Postoperative complications		
Yes	28	17
No	132	83
Postoperative adjuvant chemotherapy		
Yes	113	71
No	47	29
Tumor size, cm		
Median (range)	3.0 (0.2–10.0)	
Pathology		
Tubular adenocarcinoma		
Well-differentiated	62	39
Moderately differentiated	77	48
Poorly differentiated	15	9
Adenosquamous	6	4
Lymph node metastasis		
Yes	114	71
No	46	29
Surgical margin		
Positive	56	35
Negative	104	65
UICC pT factor		
pT1	8	5
pT2	5	3
pT3	145	91
pT4	2	1
UICC stage		
IA	7	4
IB	2	1
IIA	36	23
IIB	87	55
III	2	1
IV	26	16

PTBD, percutaneous transhepatic biliary drainage; ERBD, endoscopic retrograde biliary drainage; PV/SMV, portal or superior mesenteric vein; UICC, International Union Against Cancer.

TABLE II. Comparison of Clinicopathological Factors of Patients Who Did and Did Not Undergo Preoperative Biliary Drainage

	No. of patients, biliary drainage		
Factor	No (n = 67)	Yes (n = 93)	*P*-Value
Gender			
Male	37	47	0.558
Female	30	46	
Age, years			
<70	31	50	0.349
≧70	36	43	
Preoperative maximum total bilirubin level, mg/dl			
<3.0	66	22	<0.001
≧3.0	1	71	
PV/SMV resection			
Yes	29	48	0.298
No	38	45	
Operative time, min			
<380	31	48	0.505
≧380	36	45	
Blood loss, ml			
<1,300	35	43	0.454
≧1,300	32	50	
Blood transfusion			
Yes	15	36	0.027
No	52	57	
Postoperative complications			
Yes	11	17	0.759
No	56	76	
Postoperative adjuvant chemotherapy			
Yes	47	66	0.911
No	20	27	
Tumor size, cm			
<3.0	36	35	0.043
≧3.0	31	58	
Tumor differentiation			
Well-differentiated	30	32	0.185
Moderately or poorly differentiated	37	61	
Lymph node metastasis			
Yes	44	70	0.187
No	23	23	
Surgical margin			
Positive	21	35	0.409
Negative	46	58	
UICC pT factor			
pT 1, 2	9	4	0.044
pT 3, 4	58	89	
UICC stage			
IA	4	3	0.234
IB	2	0	
IIA	16	20	
IIB	37	50	
III	1	1	
IV	7	19	

PV/SMV, portal or superior mesenteric vein; UICC, International Union Against Cancer.

Survival and Prognostic Factors

There were no lost patients to follow up in this series. Of the 160 patients, 89 patients have died at the time of this writing. Median follow-up time of the 160 patients was 15 months (range, 1–109 months), and median follow-up time of 71 survived patients was 23.3 months (range, 1–95 months). Overall 1-, 2-, and 5-year survival rates for the 160 patients were 73%, 50%, and 25%, respectively (median survival time, 22.1 months). Univariate and multivariate survival analyses were performed to clarify the prognostic impact of PBD in patients with pancreatic head carcinoma who underwent surgical resection. Univariate analysis revealed that the preoperative maximum serum total bilirubin level ($P = 0.016$), PBD ($P = 0.030$), PV/SMV resection ($P = 0.018$), operative time ($P = 0.002$), blood loss ($P < 0.001$), blood transfusion

($P < 0.001$), postoperative complications ($P = 0.002$), postoperative adjuvant chemotherapy ($P < 0.001$), tumor differentiation ($P = 0.003$), lymph node status ($P < 0.001$), surgical margin status ($P < 0.001$), and UICC stage ($P = 0.043$) were significantly associated with overall survival. Overall survival curves of patients with and without PBD are shown in Figure 1A. Overall 5-year survival rates for patients with and without PBD were 20% and 33%, respectively (median survival time, 16.2 months vs. 32.5 months). Thus, these 10 significant factors were entered into a multivariate survival analysis with a Cox proportional hazards model. Multivariate analysis demonstrated that postoperative complications ($P = 0.046$), postoperative adjuvant chemotherapy ($P = 0.008$), tumor differentiation ($P = 0.010$), and lymph node status ($P = 0.004$) remained independently associated with overall survival. PBD was not an independent prognostic factor for overall survival in patients with pancreatic head carcinoma ($P = 0.509$, Table III). UICC stage was not entered into multivariate survival analysis to avoid a confounding effect of other factors including UICC pT factor and lymph node status. A further analysis was performed to determine the effects of ERBD and PTBD on long-term survival. There was no significant difference in overall survival between patients who underwent ERBD and patients who did not undergo PBD ($P = 0.168$). However, patients who underwent PTBD had significantly worse survival compared with patients who underwent ERBD ($P = 0.038$) and patients who did not undergo PBD ($P = 0.001$, Fig. 1B). Patients who underwent PTBD were significantly older than patients who underwent ERBD ($P = 0.022$). However, there were no significant differences in other clinicopathological factors, including tumor characteristics and the use of adjuvant chemotherapy between patients who underwent ERBD and patients who underwent PTBD (Table IV).

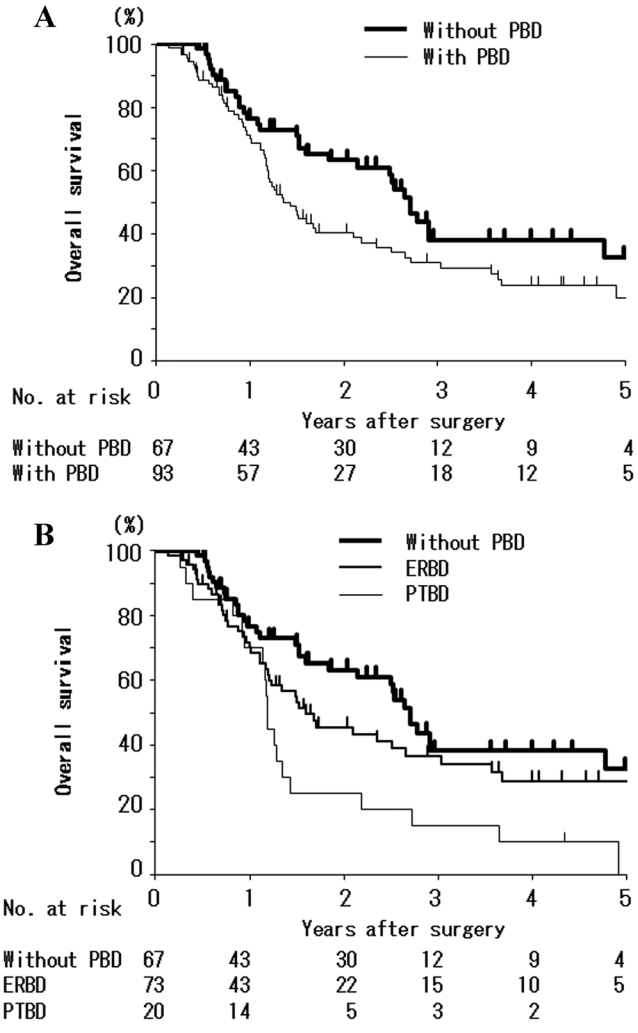

Fig. 1. **A**: Survival curves of patients who did or did not undergo PBD ($P = 0.030$). **B**: Survival curves of patients who did not undergo PBD, patients who underwent ERBD, and patients who underwent PTBD (without PBD vs. ERBD, $P = 0.168$; without PBD vs. PTBD, $P = 0.001$; ERBD vs. PTBD, $P = 0.038$). PBD, preoperative biliary drainage; ERBD, endoscopic retrograde biliary drainage; PTBD, percutaneous transhepatic biliary drainage.

Recurrence

At the time of this writing, recurrence had occurred in 39 (58%) of 67 patients who did not undergo PBD, 48 (66%) of 73 patients who underwent ERBD, and 19 (95%) of 20 patients who underwent PTBD. The specific sites of initial recurrence in the three groups are shown in Figure 2. There were no significant differences in the incidences of hepatic, pulmonary, or locoregional recurrence among the three groups. However, the rate of peritoneal recurrence in patients who underwent PTBD was significantly higher than that of patients who underwent ERBD ($P = 0.033$) and that of patients who did not undergo PBD ($P = 0.034$).

DISCUSSION

PBD is usually performed for patients with resectable pancreatic carcinoma who develop obstructive jaundice, because immediate surgery is not often feasible owing to a full surgical schedule at high-volume centers for pancreatic surgery. However, there are few reports concerning the effect of PBD on the long-term survival of patients with pancreatic carcinoma [11,16,17]. The current study demonstrated that PBD was not an independent prognostic factor for overall survival in patients with pancreatic carcinoma by multivariate analysis, although there was a significant difference in overall survival between patients who did and did not undergo PBD by univariate analysis. In addition, among patients who underwent PBD, the overall survival of those who underwent PTBD was significantly worse than that of patients who underwent ERBD, while patients who underwent ERBD had the same overall survival rate as patients who did not undergo PBD. The results of this study suggest that PBD does not affect the overall survival of patients with pancreatic carcinoma, if ERBD is used for PBD.

With regard to the effect of PBD on long-term survival, Martignoni et al. [11] analyzed 190 patients with pancreatic and ampullary carcinoma, and reported that there was no significant difference in overall survival between patients who underwent PBD and patients who did not. Smith et al. [17] reported that in a retrospective analysis of 155 patients with resected pancreatic carcinoma, no significant difference in overall survival was found between patients who underwent PBD and patients who did not. In addition, a randomized controlled study that compared short-term outcomes between patients who underwent PBD and patients who underwent early surgery demonstrated that the delay in surgery associated with PBD did not affect overall survival in patients with pancreatic head carcinoma [16]. The results of the previous reports were consistent with those of our study.

As mentioned above, the current study demonstrated that patients who underwent ERBD had a more favorable overall survival rate compared with patients who underwent PTBD. To our knowledge, no previous reports have demonstrated a survival difference between patients with pancreatic head carcinoma who underwent PTBD and ERBD. Recently, Hirano et al. [28] demonstrated an oncological benefit of ERBD compared with PTBD in patients with resected hilar

TABLE III. Univariate and Multivariate Survival Analysis of Prognostic Factors for Patients With Pancreatic Head Carcinoma

	Univariate analysis			Multivariate analysis		
Factor	No. of patients	Median survival time (months)	*P*-Value	Hazard ratio	95% CI	*P*-Value
Gender						
Male	84	18.2	0.152			
Female	76	30.4				
Age, years						
<70	81	20.1	0.685			
≧70	79	28.2				
Preoperative maximum total bilirubin level, mg/dl						
<3.0	88	31.7	0.016	1.0		0.806
≧3.0	62	17.2		1.08	0.59–2.12	
Preoperative biliary drainage						
Yes	93	16.2	0.030	1.25	0.63–2.38	0.509
No	67	32.5		1.0		
PV/SMV resection						
Yes	77	16.1	0.018	1.11	0.69–1.81	0.647
No	83	30.2		1.0		
Operative time, min						
<380	79	34.9	0.002	1.0		0.885
≧380	81	16.1		1.04	0.61–1.78	
Blood loss, ml						
<1,300	78	36.9	<0.001	1.0		0.354
≧1,300	82	16.1		1.30	0.74–2.28	
Blood transfusion						
Yes	51	11.1	<0.001	1.55	0.91–2.65	0.110
No	109	32.5		1.0		
Postoperative complications						
Yes	28	12.9	0.002	1.75	1.01–2.93	0.046
No	132	30.2		1.0		
Postoperative adjuvant chemotherapy						
Yes	113	32.5	<0.001	1.0		0.008
No	47	11.5		2.10	1.22–3.58	
Tumor size, cm						
<3.0	71	32.5	0.066			
≧3.0	89	16.1				
Tumor differentiation						
Well-differentiated	62	34.9	0.003	1.0		0.010
Moderately or poorly differentiated	98	16.1		1.82	1.15–2.94	
Lymph node metastasis						
Yes	114	17.9	<0.001	2.14	1.27–3.74	0.004
No	46	57.3		1.0		
Surgical margin						
Positive	56	12.1	<0.001	1.17	0.71–1.91	0.545
Negative	104	30.4		1.0		
UICC pT factor						
pT 1, 2	13	57.3	0.055			
pT 3, 4	147	20.1				
UICC stage						
IA, IB	9	NA	0.043			
IIA, IIB, III, IV	151	20.4				

PV/SMV, portal or superior mesenteric vein; CI, confidence interval; UICC, International Union Against Cancer; NA, not available.

cholangiocarcinoma. In a retrospective analysis of 67 patients who underwent PTBD and 74 patients who underwent ERBD, the overall survival rate of patients who underwent ERBD was significantly higher than that of patients who underwent PTBD, and PTBD was one of the independent factors predictive of poor overall survival by multivariate analysis.

The reason for the poorer survival of patients who underwent PTBD is likely that spillage of bile juice, which contains cancer cells, during PTBD placement and catheter exchange easily induces peritoneal recurrence in patients who undergo PTBD. Hirano et al. [28] reported that patients who underwent PTBD more frequently developed peritoneal dissemination compared with patients who underwent ERBD after surgical resection of hilar cholangiocarcinoma, and PTBD was the only independent factor predictive of peritoneal recurrence by multivariate analysis. Similarly, the frequency of peritoneal recurrence in patients who underwent PTBD was significantly higher than that in patients who underwent ERBD or that in patients who did not undergo PBD in the current study. Several reports have demonstrated the risk of PTBD-related catheter tract recurrence [29–31] or peritoneal dissemination [32,33] in bile duct

TABLE IV. Comparison of Clinicopathological Factors Between Patients Who Undergo ERBD and PTBD

Factor	No. of patients, biliary drainage		*P*-Value
	ERBD (n = 73)	PTBD (n = 20)	
Gender			
Male	34	12	0.322
Female	39	8	
Age, years			
<70	44	6	0.022
≧70	29	14	
Preoperative maximum total bilirubin level, mg/dl			
<3.0	15	7	0.235
≧3.0	58	13	
PV/SMV resection			
Yes	36	11	0.802
No	37	9	
Operative time, min			
<380	39	9	0.616
≧380	34	11	
Blood loss, ml			
<1,300	36	7	0.316
≧1,300	37	13	
Blood transfusion			
Yes	25	10	0.203
No	48	10	
Postoperative complication			
Yes	12	5	0.513
No	61	15	
Postoperative adjuvant chemotherapy			
Yes	56	11	0.089
No	17	9	
Tumor size, cm			
<3.0	26	9	0.448
≧3.0	47	11	
Tumor differentiation			
Well differentiated	26	6	0.792
Moderately or poorly differentiated	47	14	
Lymph node metastasis			
Yes	57	13	0.251
No	16	7	
Surgical margin			
Positive	26	9	0.448
Negative	47	11	
UICC pT factor			
pT 1, 2	3	1	1.000
pT 3, 4	70	19	
UICC stage			
IA	2	1	0.743
IB	0	0	
IIA	14	6	
IIB	40	10	
III	1	0	
IV	16	3	

ERBD, endoscopic retrograde biliary drainage; PTBD, percutaneous transhepatic biliary drainage; PV/SMV, portal or superior mesenteric vein; UICC, International Union Against Cancer.

carcinoma. ERBD, but not PTBD, should be selected for patients with pancreatic head carcinoma who have obstructive jaundice when practical to prevent postoperative peritoneal recurrence.

The current study limited in that it is a retrospective analysis based on a relatively small number of patients. Therefore, the statistical power to detect clinically relevant details is relatively low. Prospective studies on larger numbers of patients are needed to confirm the results of this study.

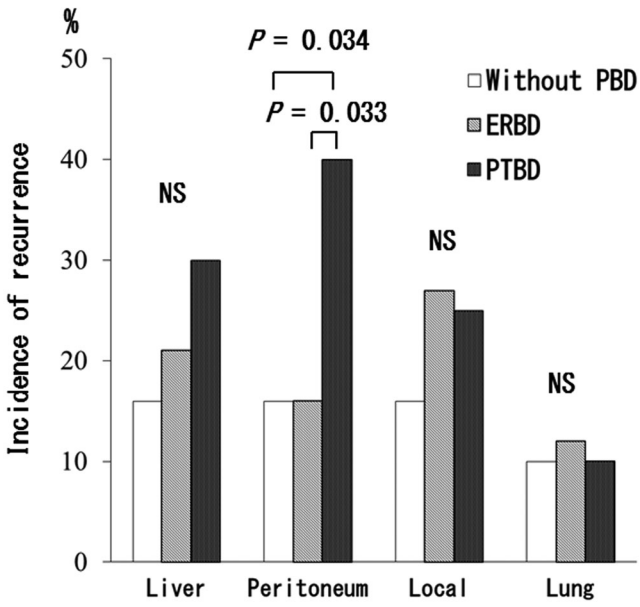

Fig. 2. Initial site of recurrence in patients who did not undergo PBD, patients who underwent ERBD, and patients who underwent PTBD. PBD, preoperative biliary drainage; ERBD, endoscopic retrograde biliary drainage; PTBD, percutaneous transhepatic biliary drainage; NS, not significant.

CONCLUSIONS

In conclusion, the current study demonstrated that PBD was not an independent prognostic factor for overall survival among patients with resected pancreatic head carcinoma. However, PTBD compromised overall survival, compared with ERBD. Patients who underwent PTBD developed peritoneal recurrence more frequently than those who underwent ERBD. ERBD is recommended for jaundiced patients with pancreatic head carcinoma to prevent peritoneal recurrence.

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