Original Article

Preoperative endoscopic retrograde biliary drainage increases postoperative complications after pancreaticoduodenectomy compared to endoscopic nasobiliary drainage

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Background: Preoperative biliary drainage prior to pancreaticoduodenectomy (PD) by percutaneous transhepatic biliary drainage (PTBD) or endoscopic biliary drainage (EBD) is performed to improve liver functions, including immunity and coagulation that affect postoperative recovery in patients with jaundice. EBD can be performed through endoscopic retrograde biliary drainage (ERBD) or endoscopic nasobiliary drainage (ENBD). There is no clear consensus about which drainage is more suitable for preoperative EBD. The purpose of this study was to compare the postoperative outcomes of ENBD and ERBD performed prior to PD.

Methods: Data were collected retrospectively from the medical records of 3 hospitals: Chuncheon, Kangdong and Kangnam Sacred Heart hospitals. From January 2007 to April 2019, PD was performed in 230 patients, among whom, 88 patients had undergone preoperative EBD. These 88 patients were divided into two groups according to the method of preoperative biliary drainage: ENBD versus ERBD. We compared clinical data and postoperative complications after PD between ENBD and ERBD.

Results: The overall complication rates in the ENBD group were significantly lower than in the ERBD group (26.1% *vs.* 57.1%, P=0.003). Postoperative pancreatic fistula (POPF) rates (11.1% *vs.* 38.1%, P=0.003) and postpancreatectomy hemorrhage (PPH) rates (2.2% *vs.* 14.3%, P=0.036) in the ENBD group were also lower than in the ERBD group.

Conclusions: Our study provides further evidence that patients undergoing ERBD before PD are more likely to suffer POPFs and PPHs. This suggests that ENBD should be preferred in order to minimize the risk of POPFs and PPHs in patients with biliary obstruction prior to undergoing PD.

Keywords: Pancreaticoduodenectomy (PD); endoscopic nasobiliary drainage (ENBD); endoscopic retrograde biliary drainage (ERBD)

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Introduction

Pancreaticoduodenectomy (PD) is curative treatment for periampullary and pancreatic disease (1). Obstructive jaundice is the most common symptom in patients with periampullary cancer. It can exacerbate the risk of infectious complications and mortality post PD (2). Thus, preoperative biliary drainage was introduced to reduce the negative effects of obstructive jaundice in patients with periampullary neoplasms (3). Preoperative biliary drainage by percutaneous transhepatic biliary drainage (PTBD) or endoscopic biliary drainage (EBD) is performed to improve liver functions, including immunity and coagulation, that affect perioperative recovery in jaundiced patients (4). EBD has been shown to be superior to PTBD. PTBD is more invasive. In addition, PTBD has a higher rate of catheter tract metastases and complications (5). EBD can be performed through endoscopic retrograde biliary drainage (ERBD) or endoscopic nasobiliary drainage (ENBD). ENBD decompresses biliary obstruction by draining bile outside the body, avoiding regurgitation of the intestinal contents. The common drawback of ENBD is the loss of body fluid which may affect the recovery of hepatic function and immunity (6). ERBD normalizes bile flow in digestive tract which is important for improving metabolic and immune function and preventing bacterial translocation (7). Some studies have suggested that ENBD may be superior to ERBD in terms of perioperative morbidity (8,9). In that study, ERBD had a significantly higher risk for dysfunction than ENBD. In addition, pancreatic fistula rate was significantly lower in the ENBD group than in the ERBD group. However, there are few reports detailing the postoperative outcomes of ENBD and ERBD; and hence there is no clear consensus about which drainage is more suitable. Therefore, the purpose of this study was to compare the postoperative outcomes of ENBD and ERBD performed prior to PD. We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/gs-20-711).

Methods

Study design

Data from the medical records of 3 hospitals, Chuncheon, Kangdong, and Kangnam Sacred Heart hospitals, were collected retrospectively. From January 2007 to April 2019, PD was performed in 230 patients, among whom, 88 patients had undergone EBD. Endoscopists perform ENBD or ERBD based on personal opinion, hospital stay duration, economic costs, bile duct stenosis and equipment conditions. These 88 patients were divided into two groups according to the method of preoperative biliary drainage: ENBD versus ERBD. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board (IRB No. 2019-09-004-002) and individual consent for this retrospective analysis was waived.

Clinicopathological characteristics

Patient demographics included age, gender, preoperative symptoms, body mass index (BMI), comorbidities, history of abdominal surgery, American Society of Anesthesiologists (ASA) score, and preoperative serum bilirubin level. Intraoperative variables including operating time, blood loss, and blood transfusion were evaluated. Size of the tumor, margin status, and pathologic diagnosis were analyzed. Postoperative complications such as postpancreatectomy hemorrhage (PPH), delayed gastric emptying (DGE), and postoperative pancreatic fistula (POPF) were evaluated. POPF was defined by the International Study Group on Pancreatic Fistula definition (10). DGE was defined by the International Study Group on Pancreatic Surgery criteria (11). PPH was defined by the International Study Group on Pancreatic Surgery definition (12). The Clavien-Dindo classification was used to classify postoperative complications (13).

Statistical analysis

Categorical variables are presented as percentages. Continuous variables are presented as medians and ranges. Analysis was performed using the Student *t*-test or Mann-Whitney test for continuous variables and the Chi-squared test or Fisher's exact test for categorical variables. The risk factors were evaluated by univariate and multivariate analyses with odds ratios and 95% confidence intervals using logistic regression. Statistical significance was defined as value of $P<0.05$.

Results

Clinicopathological characteristics

In the study, 88 patients underwent EBD prior to PD, of whom 42 (48.7%) underwent ERBD and 46 (52.3%) underwent ENBD. The characteristics of the 88 patients are summarized in *Table 1*. There were no significant differences between the two groups.

Table 1 Clinicopathological characteristics of patients (n=88)

Characteristics	ENBD (n=46)	ERBD (n=42)	P value
Age, median [range], year	67 [43–82]	65 [41–81]	0.529
Gender (male:female)	23 (50.0%):23	25 (59.5%):17	0.370
BMI, median [range], kg/m^2	23.34 [16.29–32.08]	23.50 [15.82–33.48]	0.538
ASA class (minimal/moderate/severe)	3/36/7	2/36/4	0.538
Symptom			0.492
Abdominal pain	14 (30.4%)	14 (33.3%)	
Jaundice	19 (41.3%)	21 (50.0%)	
General weakness	6 (13.0%)	2 (4.8%)	
Dysphagia	2 (4.3%)	3 (7.1%)	
Comorbidity			
Hypertension	22 (47%)	19 (45.2%)	0.808
Diabetes mellitus	16 (34.8%)	12 (28.5%)	0.385
Pulmonary disease	3 (6.5%)	1 (2.4%)	0.292
Cardiovascular disease	4 (8.7%)	1 (2.4%)	0.201
Abdominal surgical history	6 (13.0%)	9 (21.4%)	0.296
Preoperative bilirubin, median [range], mg/dL	1.6 [0.2–12.0]	1.3 [0.3–11.7]	0.821
Diagnosis			0.272
PDAC	7 (15.2%)	9 (21.4%)	
AOV cancer	18 (39.1%)	10 (23.8%)	
CBD cancer	20 (43.5%)	20 (47.6%)	
Others**	1 (2.2%)	3 (7.2%)	
Operating time, median [range], min	440 [245–690]	402 [255–615]	0.135
Blood loss, median [range], mL	850 [100–4,000]	700 [200–2,500]	0.111
Transfusion, median [range], mL	285 [0–2,880]	0 [0–1,600]	0.277
Tumor size, median [range], cm	2.0 [0.5–7.0]	2.2 [0.2–5.0]	0.435
Margin status (R0:R1)	45 (97.8%):1	40 (100.0%):0	0.348

**, neuroendocrine tumor, duodenal cancer, intraductal papillary mucinous neoplasm. ENBD, endoscopic nasobiliary drainage; ERBD, endoscopic retrograde biliary drainage; BMI, body mass index; ASA, American society of anesthesiologists; PDAC, pancreatic ductal adenocarcinoma; AOV, ampulla of Vater; CBD, common bile duct.

Postoperative outcomes

The overall complication rates in the ENBD group were significantly lower than in the ERBD group (26.1% *vs.* 57.1%, P=0.003). POPF rates (11.1% *vs.* 38.1%, P=0.003) and PPH rates (2.2% *vs.* 14.3%, P=0.036) in the ENBD group were lower than in the ERBD group. The median postoperative hospital stay in the ENBD and ERBD groups were 20 and 24 days, respectively (P=0.198). The 30-day mortality rates (2.2% *vs.* 2.4%; P=0.948) and the 90-day mortality rates (2.2% *vs.* 7.1%; P=0.264) in the ENBD and ERBD groups were similar (*Table 2*).

Risk factors for POPF and PPH

There were significant differences in the incidence of POPF and PPH between the ERBD group and ENBD group.

Table 2 Postoperative outcomes of patients (n=88)

Variables	ENBD (n=46)	ERBD (n=42)	P value
All complications	12 (26.1%)	24 (57.1%)	0.003*
Pancreatic fistula	5 (11.1%)	16 (38.1%)	0.003*
Delayed gastric emptying	2 (4.3%)	3 (7.1%)	0.666
Hemorrhage	1 (2.2%)	6 (14.3%)	0.036*
Hospital stay, median [range], day	20 [3–113]	24 [8–90]	0.198
Re-admission	2 (4.3%)	4 (9.5%)	0.336
Re-operation	4 (8.7%)	5 (11.9%)	0.620
30 days mortality	1 (2.2%)	1 (2.4%)	0.948
90 days mortality	1 (2.2%)	3 (7.1%)	0.264

*, P<0.05 as statistically significant. ENBD, endoscopic nasobiliary drainage; ERBD, endoscopic retrograde biliary drainage.

Table 3 Univariate and multivariate analysis of the risk factors for pancreatic fistula (n=86)

Factor	Univariate analysis			Multivariate analysis		
	OR	95% CI	P value	OR	95% CI	P value
ERBD (compared to ENBD)	4.923	1.608–15.073	0.005*	6.599	1.825–23.859	0.004*
Old age (>60 years)	1.600	0.518–4.939	0.414			
Gender (male)	1.111	0.413–2.993	0.835			
High BMI (>23.2 kg/m^2)	0.900	0.305–2.659	0.849			
High preoperative bilirubin (3 mg/dL)	1.500	0.549–4.096	0.429			
Hypertension	0.797	0.296–2.144	0.653			
Diabetes mellitus	0.242	0.051–1.139	0.073	0.256	0.046–1.418	0.119
Abdominal surgical history	1.176	0.331–4.177	0.802			
Long operating time (>433 min)	1.234	0.460–3.306	0.676			
Large amount of blood loss (>1,000 mL)	1.700	0.580–4.979	0.333			
Large amount of transfusion (>500 mL)	2.357	0.866–6.413	0.093	4.567	1.336–15.614	0.015*
Large tumor size (>2.4 cm)	1.170	0.431–3.179	0.758			

*, P<0.05 as statistically significant. OR, odds ratio; CI, confidence intervals; ERBD, endoscopic retrograde biliary drainage; ENBD, endoscopic nasobiliary drainage; BMI, body mass index.

Specific risk factors for POPF and PPH were analyzed. The results of univariate and multivariate analyses for POPF are shown in *Table 3*. On univariate analysis, ERBD, diabetes mellitus and a large volume of blood transfusion (>500 mL) were associated with POPF. On multivariate analysis, ERBD (OR =6.599; 95% CI, 1.825–23.859; P=0.004) and a large volume of blood transfusion (>500 mL) (OR =4.567; 95% CI, 1.336–15.614; P=0.015) were independent risk factors for POPF. Similarly, the results of univariate and multivariate analyses for PPH are shown in *Table 4*. The univariate analysis showed that ERBD, long operating time (>433 min) and a large volume of blood loss (>1,000 mL) were associated with PPH. The independent risk factors for PPH identified by multivariate analysis were ERBD (OR =13.797; 95% CI, 1.458–130.568; P=0.022) and a long operating time (>433 min) (OR =16.161; 95% CI, 1.719–152.498; P=0.015).

Table 4 Univariate and multivariate analysis of the risk factors for postpancreatectomy hemorrhage (n=86)

Factor	Univariate analysis			Multivariate analysis		
	OR	95% CI	P value	OR	95% CI	P value
ERBD (compared to ENBD)	7.500	0.863–65.157	0.068	13.797	1.458–130.568	0.022*
Old age (>60 years)	0.561	0.117–2.701	0.471			
Gender (male)	5.571	0.642–48.378	0.119			
High BMI (>23.2 kg/m^2)	0.344	0.063–1.880	0.218			
High preoperative bilirubin (3 mg/dL)	1.420	0.297–6.793	0.661			
Hypertension	0.431	0.079–2.350	0.331			
Diabetes mellitus	0.447	0.051–3.926	0.468			
Abdominal surgical history	0.798	0.089–7.155	0.840			
Long operating time (>433 min)	9.188	1.056–79.935	0.045*	16.161	1.719–152.498	0.015*
Large amount of blood loss (>1,000 mL)	4.351	0.527–12.076	0.069	2.537	0.394–16.340	0.327
Large amount of transfusion (>500 mL)	2.524	0.527–12.076	0.246			
Large tumor size (>2.4 cm)	0.271	0.030–2.423	0.243			

*, P<0.05 as statistically significant. OR, odds ratio; CI, confidence intervals; ERBD, endoscopic retrograde biliary drainage; ENBD, endoscopic nasobiliary drainage; BMI, body mass index.

Discussion

Surgical outcomes following PD have largely improved due to advances in perioperative management and medical knowledge (14). Nevertheless, surgical outcomes are determined not only by tumor characteristics, but also by associated jaundice due to biliary obstruction, patient characteristics, and comorbidities. Consequently, efforts to optimize the perioperative management could translate into significant benefit for patients undergoing PD, whose frequency is increasing (15).

Although meta-analyses and randomized controlled trials failed to prove the effectiveness of routine preoperative biliary drainage, it is still performed widely. The rationale behind this is that if bile duct obstruction is not adequately resolved, patients may not be able to receive further treatment (16). To enhance the therapeutic efficacy of treating biliary obstruction, surgeons have been primarily concerned with identifying ways to achieve the most effective drainage. ERBD is an internal drainage that involves placement of a plastic stent. During EBD, ERBD is preferred over ENBD with regard to comfort (17). ENBD is an external procedure that decompresses the obstructed bile ducts by draining out the bile, cytological examination of which can be used to confirm malignancy, in addition to cholangiography to evaluate longitudinal tumor spreading (18).

After EBD, cholangitis is one of the most common complications (8). Some studies reported that ENBD decreased the incidence of cholangitis before surgery compared to ERBD (19,20), and this might be because ENBD is an external drainage procedure. In addition to this, ERBD has been associated with a higher rate of cholangitis also due to tube occlusion (19). Similarly, stent dysfunction has been reported to occur more frequently in the ERBD group than in the ENBD group as, in ERBD, there is a risk of clogging of the stent or dislodgement, which may result in cholangitis (21). Gastrointestinal bacteria pass from ERBD to the sphincter of Oddi and reflux into the bile duct, whereas ENBD contains external drainage with less bile or gastrointestinal reflux (22). Thus, the placement of a stent can cause inflammation, while the manipulation of the papillae and the duct can cause cholangitis (23). Cholangitis is one of the factors that make PD challenging. With severe cholangitis, dissection is difficult and the risk of unnecessary injury increases, which can lead to complications.

POPF is one of the most dreaded complications after PD (24). Several studies have shown that preoperative biliary drainage can increase the complications from PD, including POPFs, which result from procedure related cholangitis and biliary bacterial translocation after drainage (25,26). Pancreatic

secretions should be activated by bacterial phospholipase and lipopolysaccharide (27). Furthermore biliary tract infection is a significant risk factor for POPF (28). Our study illustrated that ERBD is a significant risk factor contributing to POPF development.

PPH is the most lethal complication of PD, related mortality being as high as 20% to 50% and its incidence ranging from 3% to 20% (29). In the present study, the incidence of PPH in the ENBD group was lower than in the ERBD group. ERBD may impact operative procedures during surgery, particularly during the dissection of the porta hepatis, because of periportal inflammation (15), which may explain the higher PPH rate in the ERBD group. Additionally, increased periportal inflammation corresponds to a higher risk of vascular wall damage during the dissection, which may increase the risk of PPH due to a pseudoaneurysm. Therefore, we find that ERBD does not appear to be the ideal choice in patients who are undergoing PD in terms of patient safety, due to a greater risk of complications.

This study has several limitations. First, this was a retrospective study and not a prospective randomized trial. There is significant potential for selection bias as there was no defined algorithm for selecting the biliary drainage method. Second, the scope of this study is limited due to disease heterogeneity. The degrees of combined inflammation vary with the specific diagnosis of disease. Third, because this is a multicenter study, technique and instrumentation varied from center to center.

In conclusion, our study provides further evidence that patients undergoing ERBD before PD are more likely to suffer POPF or PPH. Hence, ENBD may be preferred in order to minimize risk of POPF and PPH in patients with biliary obstruction, prior to PD. A well-designed randomized controlled trial is needed to produce more evidence of high quality.

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Footnote

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