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Original Article

Comparison of efficiency and prognostic analysis in four biliary drainages for treatment of malignant obstructive jaundice

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Abstract: Objectives: This study was to evaluate different biliary drainage for the treatment of malignant obstructive jaundice. Methods: 152 patients suffering from malignant obstructive jaundice were divided into 4 groups, including percutaneous transhepatic biliary drainage (PTBD), endoscopic plastic biliary stent (EPBS), endoscopic metal biliary stent (EMBS), and endoscopic metal biliary stent combined with plastic stent (EPBS+EMBS). Results: The successful drainage rates of PTBD group, EPBS group, EMBS group, and EPBS+EMBS group were 54.2%, 59.1%, 70.8%, and 80.6%. The complication rates of PTBD group, EPBS group, EMBS group, and EPBS+EMBS group were 62.5%, 27.2%, 31.3%, and 16.7%. The mean length of drainage patency of PTBD group, EPBS group, EMBS group, and EPBS+EMBS group was 46 days, 82 days, 142 days, and 164 days. The mean survival time of patients was 191 days in PTBD group, 266 days in EPBS group, 284 days in EMBS group, and 436 days in EPBS+EMBS group. Through Cox proportional hazards regression, the Child-pugh class, age, infection, and TNM stage contributed to a higher probability of death, while the drainage method and gender contributed to a lower probability of death. Conclusion: The EPBS+EMBS drainage method may improve the successful biliary drainage, have lower complications, longer patency, and longer survival time than other drainage methods.

Keywords: Malignant obstructive jaundice, percutaneous transhepatic biliary drainage, endoscopic plastic biliary stent, endoscopic metal biliary stent, complications, drainage patency, survival

Introduction

Malignant obstructive jaundice is prevalent in cholangiocarcinoma, gallbladder carcinoma, periampullary carcinoma, and pancreatic carcinoma [1]. Fewer than 20% of patients with a malignant stricture of the common bile duct can be offered a cure by resection [2]. In patients with malignant obstructive jaundice, progressive jaundice is an immediate threat to survival in addition to a significant reduction of the quality of life secondary to the development of the associated pruritus, malaise and cholangitis [3]. There are two main options for palliative relief of biliary obstruction: surgical decompression by using biliary enteric anastomosis and nonsurgical methods, in which an internal-external catheter or, an endoprosthesis, is placed by way of either transhepatic or transduodenal routes [4]. In such cases, effective and lasting decompression of the biliary tree is priority, this consists of positioning of a biliary endoprosthesis by the endoscopic or percutaneous approach [5]. Percutaneous transhepatic biliary drainage (PTBD) and stent insertion are established methods used for the relief of malignant biliary obstruction. Although the effectiveness of PTBD has been reported, predictors able to differentiate between a good and poor prognosis have not been established [6, 7]. Endoscopic biliary stenting (EBS) is a well-established palliative treatment that can be used to relieve symptoms and improve quality of life with biliary tract cancer. However, the long-term placement of plastic biliary stents can itself become a cause of obstructive jaundice and/or reflux cholangitis [8]. Percutaneous transhepatic biliary drainage has a high rate complication, including bleeding, bile leakage, biliary fistula, peritonitis, hemobilia [9, 10]. Stent inserted by percutaneous transhepatic or endoscopic route has been proved disappointing with regard to recurrent jaundice because of the stent occlusion [11, 12]. Since plastic stents often become occluded with sludge, they usually must be changed every 3 to 4 months. Self-expandable metallic stents (SEMS) have been shown to be superior to plastic stents with respect to patency [13]. Moreover, SEMS are difficult to remove. When stent occlusion was diagnosed, a plastic stent was usually inserted into an occluded SEMS, and a plastic stent was usually changed to a metal stent [2]. In this study, the endoscopic metal biliary stent combined with plastic stent was defined as a plastic stent was inserted into an occluded SEMS, or a metal stent instead of an occluded plastic stent. Therefore, the present study aimed to evaluate the efficacy and prognostic analysis of percutaneous transhepatic biliary drainage, endoscopic plastic biliary stent, endoscopic metal biliary stent, and endoscopic metal biliary stent combined with plastic stent for the treatment of malignant obstructive jaundice.

Patients and methods

Patients

Between December 2008 and October 2014, 152 patients received percutaneous transhepatic and endoscopic biliary drainage due to malignant obstructive jaundice in the Department of Gastroenterology, Shanghai Tenth Peoples' Hospital, Shanghai, China. The clinical data of all patients were retrospectively studied. The patients or their families provided written informed consent. The patients were divided into four groups: percutaneous transhepatic biliary drainage (PTBD), endoscopic plastic biliary stent (EPBS), endoscopic metal biliary stent (EMBS), and endoscopic metal biliary stent combined with plastic stent (EPBS+EMBS).

Data collection

The clinical records of all patients were reviewed. Age, gender, primary cause of obstruction, obstruction level, Bismuth type, hepatic functional reserve (Child-Pugh score), serum bilirubin levels prior to and following drainage, procedure-related complications, additional treatments, drainage patency and survival were analyzed. Successful drainage and drainage patency were recorded. Successful drainage was defined as either a decrease in bilirubin levels to less than 70% of the pretreatment value or near normalization (< 2 mg/dL) within 2 weeks after a procedure [14]. Drainage patency was measured by the elapsed days between the procedure and either the first occlusion requiring re-intervention or the date of death of the patient never experienced stent occlusion. For evaluation of the liver functional status, the Child-Pugh class was used for all patients [5]. The types of obstruction were confirmed by direct cholangiography or computed tomography (CT) or magnetic resonance imaging (MRI) as obstruction or stenosis of the biliary tree [15]. Obstruction level of bile duct included hilar region and non-hilar region. Non-hilar region included the middle and lower segment of common bile duct, upper middle segment of common bile duct and the pancreatic head region. The biliary obstruction of hilar region was classified according to Bismuth [16, 17]. The stage of tumor was according to TNM staging system. Procedure-related complications included cholangitis, bleeding, pancreatitis, mortality and so on. Cholangitis was defined to be related to abdominal pain and fever (temperature ≥ 38°C) without any other infectious focus outside the hepatobiliary system that required antibiotic treatment within 24 hours after a procedure [18]. Pancreatitis was diagnosed when serum amylase levels increased to more than three times the normal limit (60-180 U/L) with notable persistent abdominal pain for more than 24 hours after drainage [18]. Significant bleeding indicated a decrease in the serum hemoglobin level of ≥ 2 mg/dL with a requirement for blood transfusion or a hemostatic procedure (including surgery) after a drainage. The procedure-related mortality was defined as death directly related to a complication occurring immediately after the endoscopic or percutaneous procedure. Additional treatments included palliative surgery, systemic chemotherapy, interventional radiology, transarterial chemoinfusion and embolization.

Following intervention, the serum bilirubin levels of all patients were followed up at 2 weeks or later. For patients having received additional treatments, clinical records were tracked and telephone interviews were employed to check patient survival and performance. The survival was measured from the date of the intervention until the date of death or until the study time limit of October 2014.

Drainage procedure

Endoscopic retrograde cholangiopancreatography was performed by large or standard-channel duodenoscopes (TJF260V and JF260V; Olympus Optical Co., Ltd., Tokyo, Japan). Endoscopic sphincterotomy was performed in patients using pull-type sphincterotomy. Under radiographic guidance using contrast fluid bile duct strictures were localized. Dilation of the bile duct stricture was carried out using 8 F, 9 F, and 10 F bougies. Plastic or metal stents were placed above the stricture to obtain biliary drainage. The Caliber of plastic stents varied between 8 F and 10 F. The caliber of metal stents varied between 8 mm and 10 mm. In patients with percutaneous transhepatic drainage the biliary system was punctured with a steel needle, and a nitinol-coated guide wire (35'') was introduced into the bile duct after contrast visualization of the biliary system. After dilation of the parenchymal tract, an 8 F or 10 F external drainage catheter was inserted over the guidewire and positioned in the appropriate intrahepatic duct. Stent malfunction was suspected when a patient had signs of cholangitis or when the total serum bilirubin level increased ≥ 2 fold above the baseline level after the procedure [18]. When malfunction of biliary stent was suspected clinically, subsequent endoscopic or percutaneous cholangiography was performed to confirm the occlusion and for re-intervention, unless the patient's condition deteriorated rapidly. The procedure was explained to all patients and informed consent was obtained.

Statistical analysis

The data were analyzed with SPSS version 17.0 for Windows. The paired t-test was used for comparison of changes in bilirubin levels prior to and following drainage procedure. Pearson's chi-squared test and one-way analysis of variance were used, when appropriate, to calculate the statistical significance of different demographic and clinical variables. Drainage patency and survival data were evaluated by the Kaplan-Meier method and compared by the log-rank test. Multivariate analysis was undertaken using the Cox's proportional hazard model. $P < 0.05$ was considered to indicate a statistically significant difference.

Results

Patient characteristics

The distribution of clinic characteristic of 152 patients, including age, gender, cause of malignant obstructive jaundice, Child-Pugh class, TNM stage, Bile duct obstruction level and Procedure-related complications, has been summarized in **Table 1**. There is no significant difference among the four groups.

Effectiveness of biliary drainage

In the study group, 24 patients received percutaneous transhepatic biliary drainage (PTBD), 44 patients received endoscopic plastic biliary stent (EPBS), 48 patients received endoscopic metal biliary stent (EMBS), and 36 patients received endoscopic metal biliary stent combined with plastic stent (EPBS+EMBS). In PTBD group, 13 patients had successful biliary drainage. The successful drainage rate of PTBD group was 54.2%. In EPBS group, 26 patients had successful biliary drainage. The successful drainage rate of EPBS group was 59.1%. In EMBS group, 34 patients had successful biliary drainage. The successful drainage rate of EMBS group was 70.8%. In EPBS+EMBS group, 29 patients had successful biliary drainage. The successful drainage rate of EPBS+EMBS group was 80.6%. Serum bilirubin levels were recorded prior to and following intervention. The mean baseline total bilirubin levels was 201.8±134.7 umol/L, and mean baseline direct bilirubin levels was 165. 0±102.2 umol/L. Of these patients, the mean total bilirubin levels of PTBD group was 241.2±178.9 umol/L, EPBS group was 220.6±144.2 umol/L, EMBS group was 172.3±112.8 umol/L, and EPBS+EMBS group was 191.9±108.8 umol/L. The mean direct bilirubin levels of PTBD group was 183.7±129.1 umol/L, EPBS group was 181.4±107.7 umol/L, EMBS group was 142.9 ±89.5 umol/L, and EPBS+EMBS group was 162.0±88.4 umol/L. After two weeks of biliary drainage, mean total bilirubin levels fell to 115.7±102.3 umol/L, mean direct bilirubin levels fell to 88.3±79.5 umol/L. The mean total bilirubin levels of PTBD group fell to

Table 1. Patient characteristics

	PTBD (n=24)	EPBS (n=44)	EMBS (n=48)	EPBS+EMBS (n=36)	Overall (n=152)	*P* value
Age (n, %)						0.060
< 70 years	12 (50.0)	20 (45.5)	11 (22.9)	12 (33.3)	55 (36.2)	
≥ 70 years	12 (50.0)	24 (54.5)	37 (77.1)	24 (66.7)	97 (63.8)	
Gender (n, %)						0.937
Male	13 (54.2)	23 (52.3)	28 (58.3)	19 (52.8)	83 (54.6)	
Female	11 (45.8)	21 (47.7)	20 (41.7)	17 (47.2)	69 (45.4)	
Cause of disease (n, %)						0.187
Cholangiocarcinoma	10 (41.7)	23 (52.3)	19 (39.6)	12 (33.3)	64 (42.1)	
Ampullary carcinoma	0 (00.0)	3 (6.8)	2 (4.2)	5 (13.9)	10 (6.6)	
Gallbladdertumor	1 (4.2)	5 (11.4)	6 (12.5)	4 (11.1)	16 (10.5)	
Pancreatic cancer	10 (41.7)	5 (11.4)	18 (37.5)	9 (25.0)	42 (27.6)	
Hepatocellular carcinoma	3 (12.5)	6 (13.6)	2 (4.2)	5 (13.9)	16 (10.5)	
Other metastatic carcinoma	0 (00.0)	2 (4.5)	1 (2.1)	1 (2.8)	4 (2.6)	
Child-Pugh class (n, %)						0.760
A	1 (4.2)	4 (9.1)	5 (10.4)	2 (5.6)	12 (7.9)	
B	20 (83.3)	32 (72.7)	39 (81.3)	30 (83.3)	121 (79.6)	
C	3 (12.5)	8 (18.2)	4 (8.3)	4 (11.1)	19 (12.5)	
TNM stage (n, %)						0.298
I	0 (00.0)	5 (11.4)	2 (4.2)	3 (8.3)	10 (6.6)	
II	8 (33.3)	21 (47.7)	21 (43.8)	14 (38.9)	64 (42.1)	
III	4 (16.7)	9 (20.5)	9 (18.8)	10 (27.8)	32 (21.1)	
IV	12 (50.0)	9 (20.5)	16 (33.3)	9 (25.0)	46 (30.3)	
Bile duct obstruction level (n, %)						0.581
Bismuth II	1 (4.2)	4 (9.1)	4 (8.3)	1 (2.8)	10 (6.6)	
Bismuth III	6 (25.0)	10 (22.7)	8 (16.7)	9 (25.0)	33 (21.7)	
Bismuth IV	4 (16.7)	3 (6.8)	4 (8.3)	3 (8.3)	14 (9.2)	
Pancreas head	9 (37.5)	8 (18.2)	17 (38.6)	10 (27.8)	44 (28.9)	
Upper and middle section of common bile duct	3 (12.5)	1 4(31.8)	13 (29.5)	12 (33.3)	42 (27.6)	
Lower and middle section of hepatic duct	1 (4.2)	5 (11.4)	2 (4.2)	1 (2.8)	9 (5.9)	
Additional treatment (n, %)						0.475
Palliative surgery	11 (45.8)	13 (29.5)	11 (22.9)	12 (33.3)	47 (30.9)	
Chemotherapy	0 (00.0)	0 (00.0)	2 (4.2)	1 (2.8)	3 (2.0)	
Radiation therapy	2 (8.3)	0 (00.0)	0 (00.0)	1 (2.8)	3 (2.0)	
Transarterial chemo infusion	0 (00.0)	1 (2.3)	0 (00.0)	1 (2.8)	2 (1.3)	
Transarterial embolization	1 (4.2)	0 (00.0)	1 (2.1)	0 (00.0)	2 (1.3)	
Infection (n, %)						0.625
No infection	17 (70.8)	31 (70.5)	37 (77.1)	23 (63.9)	108 (71.1)	
Infection	7 (29.2)	13 (29.5)	11 (22.9)	13 (36.1)	44 (28.9)	
Laboratory data (mean ± SD)						
Total bilirubin (umol/L)	241.2±178.9	220.6±144.2	172.3±112.8	191.9±108.8	201.8±134.7	0.144
Direct bilirubin (umol/L)	183.7±129.1	181.4±107.7	142.9±89.5	162.0±88.4	165.0±102.2	0.241

160.7±140.8 umol/L, EPBS group fell to 127.0±121.8 umol/L, EMBS group fell to 97.7±69.8 umol/L, and EPBS+EMBS group fell to 95.8±70.5 umol/L. The mean direct bilirubin levels of PTBD group fell to 123.4±109.9 umol/L, EPBS group fell to 97.1±93.3 umol/L, EMBS group fell to 74.8±56.8 umol/L, and EPBS+EMBS group fell to 72.2±53.4 umol/L. The decrease in total bilirubin levels pre- and post-procedure of every group was statistically significant (PTBD group, P=0.000; EPBS group, P=0.000; EMBS group, P=0.000; EPBS+EMBS group, P=0.000). The decrease in direct bilirubin levels pre- and post-procedure of every group was statistically significant (PTBD group, P=0.000; EPBS group, P=0.000; EMBS group, P=0.000; EPBS+EMBS group, P=0.000). The decrease extent in total bilirubin levels among four groups was no statistically significant (P=0.508). The decrease extent in direct biliru-

Table 2. The total and direct bilirubin levels pre- and post-procedure of four groups

Group	Number	TBIL (umol/L)		DBIL (umol/L)		Decrease extent (%)	
		Pre-procedure	Post-procedure	Pre-procedure	Post-procedure	TBIL	DBIL
PTBD	24	241.2±178.9	160.7±140.8	183.7±129.1	123.4±109.9	37.9	40.0
EPBS	44	220.6±144.2	127.0±121.8	181.4±107.7	97.1±93.3	43.7	48.6
EMBS	48	172.3±112.8	97.7±69.8	142.9±89.5	74.8±56.8	42.0	48.2
EPBS+EMBS	36	191.9±108.8	95.8±70.5	162.0±88.4	72.2±53.4	47.6	52.6

Table 3. Procedure-related complications

Complications (n, %)	PTBD (n=24)	EPBS (n=44)	EMBS (n=48)	EPBS+EMBS (n=36)	Overall (n=152)	*P* value
Cholangitis	9 (37.5)	7 (15.9)	6 (12.5)	2 (5.6)	24 (15.8)	0.008
Bleeding	5 (20.8)	2 (4.5)	2 (4.2)	1 (2.8)	10 (6.6)	0.023
Pancreatitis	1 (4.2)	3 (6.8)	7 (14.6)	3 (8.3)	14 (9.2)	0.437

Table 4. Drainage patency of four groups

Drainage patency	PTBD	EPBS	EMBS	EPBS+EMBS	Overall	*P* value
Mean patency	46	82	142	164	115	0.000

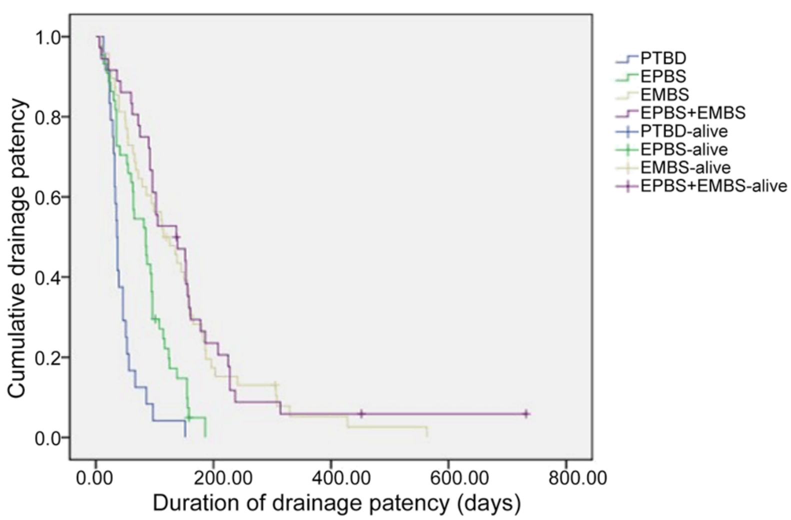

Figure 1. Cumulative drainage patency. Kaplan-Meier estimation of cumulative drainage patency according to biliary drainage method. Cumulative drainage patency from high to low was: EPBS+EMBS group > EMBS group > EPBS group > PTBD group (P=0.000).

bin levels among four groups was no statistically significant (P=0.348) (**Table 2**).

Procedure-related complications

The overall incidence of procedure-related complications was 31.6% (48 patients). The incidence of cholangitis was 37.5% (9 patients) in PTBD group, 15.9% (7 patients) in EPBS group, 12.5% (6 patients) in EMBS group, and 5.6% (2 patients) in EPBS+EMBS group (P=0.008). Bleeding occurred in 5 patients (20.8%) in PTBD group, 2 patients (4.5%) in EPBS group, 2 patients (4.2%) in EMBS group, and 1 patient (2.8%) in EPBS+EMBS group (P=0.023). The incidence of pancreatitis was 4.2% (1 patients) in PTBD group, 6.8% (3 patients) in EPBS group, 14.6% (7 patients) in EMBS group, and 8.3% (3 patients) in EPBS +EMBS group (P=0.437) (**Table 3**).

Drainage patency

The total mean drainage patency was 115 days. The mean drainage patency was 46 days in PTBD group, 82 days in EPBS group, 142 days in EMBS group, and 164 days in EPBS+ EMBS group. There was statistically significant difference among four groups (P=0.000) (**Table 4** and **Figure 1**). The mean drainage patency from high to low was EPBS+EMBS group > EMBS group > EPBS group > PTBD group.

Survival and prognostic analysis

By the cut-off date, 145 patients died and 7 patients were alive (2 patients in EPBS group, 2 patients in EMBS group, and 3 patients in EPBS+EMBS group). The overall mean survival

Table 5. Survival time of four groups

	PTBD	EPBS	EMBS	EPBS+EMBS	Overall	*P* value
Mean survival	191	266	284	436	306	0.002

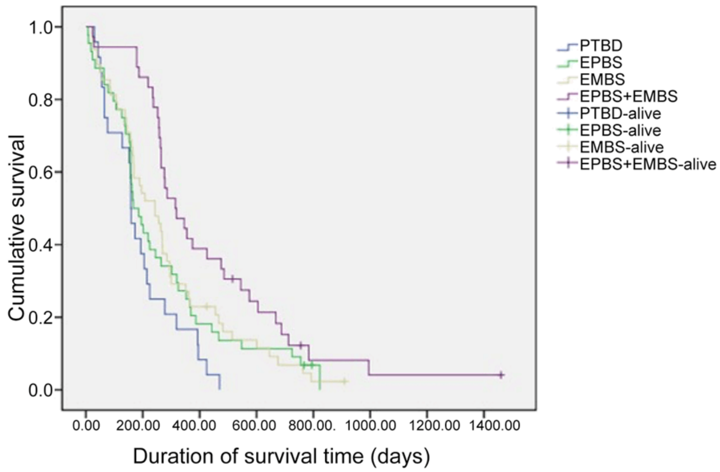

Figure 2. Cumulative survival. Kaplan-Meier estimation of cumulative survival according to biliary drainage method. Cumulative survival from high to low was: EPBS+EMBS group > EMBS group > EPBS group > PTBD group (P=0.002).

time was 306 days. The mean survival time was 191 days in PTBD group, 266 days in EPBS group, 284 days in EMBS group, and 436 days in EPBS+EMBS group. There was statistically significant difference among four groups (P=0.002) (**Table 5** and **Figure 2**). The mean survival time from high to low was EPBS+EMBS group > EMBS group > EPBS group > PTBD group.

Multivariate analysis using cox proportional hazards regression showed that the child-pugh class (RR=2.604; 95% CI: 1.759-3.855; P=0.000), age (RR=2.101; 95% CI: 1.399-3.156; P=0.000), infection (RR=1.771; 95% CI: 1.215-2.581; P=0.003), and TNM stage (RR=1.305; 95% CI: 1. 086-1.569; P=0.005) contributed to a higher probability of death, while the drainage method (RR=0.606; 95% CI: 0.507-0.725; P=0.000) and gender (RR=0.650; 95% CI: 0.453-0.933; P=0.019) contributed to a lower probability of death. According to the extent of impact factors for poorer survival, the orders from high to low are as follows: Child-pugh class: C > B > A; age: elder (≥ 70 years) > young (< 70 years); infection: infection > no infection; TNM stage: IV > III > II > I; drainage method: PTBD > EPBS > EMBS > EPBS+EMBS; gender: female > male (**Table 6**).

Discussion

Malignant biliary obstruction is a condition commonly seen in Asians [13]. Because many of these tumors are discovered at a late stage, curative treatment may not be feasible. Malignant obstructive jaundice is a poor prognostic disease with important consequences for patients' lifestyle and survival [19]. Most of these patients have associated symptoms of pruritus, malaise, nausea of cholestasis or pain [20]. Percutaneous transhepatic biliary drainage (PTBD) and endoscopic biliary stenting are palliative treatment to relieve jaundice and symptoms of malignant biliary obstruction [5]. However, percutaneous transhepatic biliary drainage has a high rate complication, and endoscopic biliary stent has a relatively short period of stent patency. Although the application of self-expandable metal stents may prolong stent patency, the self-expandable metal stents are difficult to remove. Many Asian patients still choose plastic stents over the metal stents because of the cost [21]. Therefore, combined with clinical data, the application of metallic stent combined with plastic stent after stent occlusion may prolong stent patency. This study retrospectively analyzed the efficacy and prognostic analysis of percutaneous transhepatic biliary drainage, endoscopic plastic biliary stent, endoscopic metal biliary stent, and endoscopic metal biliary stent combined with plastic stent for the treatment of malignant obstructive jaundice.

Effectiveness of biliary drainage

In patients with malignant obstructive jaundice, some studies reported rates of successful endoscopic biliary drainage and percutaneous transhepatic biliary drainage were 54.5-72% [22] and 18.2-59.1% [23]. In this study, the successful drainage rate of PTBD group was 54.2%, EPBS group was 59.1%, EMBS group was 70.8%, and EPBS+EMBS group was 80.6%. The successful drainage rate of PTBD group, EPBS group, and EMBS group were consistent with previous reports. The successful drainage

Table 6. Prognostic factors associated with survival in all patients shown by Cox proportional hazards regression

	n	Mean survival-days	Cox regression *P* value (RR: 95% CI)
Age (years)			0.000 (2.101: 1.399-3.156)
< 70	55	390	
≥ 70	97	266	
Gender			0.019 (0.650: 0.453-0.933)
Female	69	309	
Male	83	300	
Cause of disease			0.258 (1.068: 0.953-1.198)
Cholangiocarcinoma	64	347	
Ampullary carcinoma	10	396	
Gallbladder tumor	16	233	
Pancreatic cancer	42	235	
Hepatocellular carcinoma	16	288	
Other metastatic carcinoma	4	308	
Drainage method			0.000 (0.606: 0.507-0.725)
PTBD	24	191	
EPBS	44	266	
EMBS	48	284	
EPBS+EMBS	36	436	
Child-Pugh class			0.000 (2.604: 1.759-3.855)
A	12	517	
B	121	306	
C	19	142	
TNM stage			0.005 (1.305: 1.086-1.569)
I	10	504	
II	64	337	
III	32	219	
IV	46	269	
Bile duct obstruction level			0.299 (0.933: 0.820-1.063)
Bismuth II	10	261	
Bismuth III	33	366	
Bismuth IV	14	228	
Pancreas head	44	230	
Upper and middle section of common bile duct	42	372	
Lower and middle section of hepatic duct	9	248	
Additional treatment			0.399 (1.035: 0.956-1.120)
Palliative surgery	47	280	
Chemotherapy	3	439	
Radiation therapy	3	316	
Transarterial chemoinfusion	2	1108	
Transarterial embolization	2	348	
Infection			0.003 (1.771: 1.215-2.581)
No infection	108	324	
Infection	44	262	

rate of EPBS+EMBS group was higher than previous reports. It is indicated that the EPBS+EMBS group may improve the successful drainage. The decrease in total and direct bilirubin levels pre- and post-procedure of every group was statistically significant. The decrease extent in total and direct bilirubin levels among four groups was no statistically significant. This means that these biliary drainage methods had obvious effect to reduce jaundice, but there was no significant difference among various biliary drainage methods.

Procedure-related complications

The incidence of PTBD complications of from previous studies ranges between 8 and 42% [24]. In this study, the incidence of complication s of PTBD group was 62.5%, including cholangitis (37.5%), bleeding (20.8%), and pancreatitis (4.2%). The incidence of PTBD complication was higher than previous reports, the causes of which may be associated with fewer patients and technical difference in PTBD group. It was reported that the incidence of complication of endoscopic biliary self-expandable metal stent drainage was 25.9%, including cholangitis (14.8%), pancreatitis (14.8%), and bleeding (0). That the incidence of complication of endoscopic biliary plastic stent drainage was 40.7%, including cholangitis (24%), pancreatitis (14.8%), and bleeding (1.9%) [25]. In this study, the incidence of complication of EPBS group was 27.2%, including cholangitis (15.9%), bleeding (4.5%), and pancreatitis (6.8%). The incidence of complication of EMBS group was 31.3%, including cholangitis (12.5%), bleeding (4.2%), and pancreatitis (14.6%). The incidence of complication of EPBS+EMBS group was 16.7%, including cholangitis (5.6%), bleeding (2.8%), and pancreatitis (8.3%). Therefore, the EPBS+EMBS drainage method has lower complications than other drainage methods.

Drainage patency

Partial or total occlusion of the plastic stent usually occurs 3 to 4 months after the insertion of plastic stent [26]. A randomized controlled study reported that wide-bore self-expanding metal stents (SEMS) remained patent up to a median of 9 months [27]. Recently, it was reported that median stent patency time of percutaneous unilateral biliary metallic stent placement in patients with malignant obstruction was 133 days (95% CI, 94-171 days) [28]. In this study, the mean drainage patency of PTBD group, EPBS group, EMBS group, and EPBS+EMBS group were shorter than previous reports. This may be explained partly by the short mean drainage patency in our series. Through the comparison of four groups, the mean drainage patency from high to low was EPBS+EMBS group > EMBS group > EPBS group > PTBD group. It is indicated that the EPBS+EMBS drainage method may have longer patency than other drainage methods.

Survival and prognostic analysis

Studies have reported that mean survival time of percutaneous transhepatic biliary drainage ranges between 79-210 days [28-31]. Some studies have reported that the mean survival time of self-expanding metal stents (SEMS) ranges between 126-159 days, and plastic stents (PS) ranges between 49-117 days [2, 25]. In this study, the mean survival time of PTBD group was 191 days, which was consistent with previous reports. The mean survival time of EPBS+EMBS group was 436 days, which was longer than other groups. This indicates that the EPBS+EMBS drainage method may have longer survival time than other drainage methods. In recent years, some studies have reported that many factors such as patient age, bilirubin levels, additional treatment, and successful drainage were associated with survival [1, 5]. In our study, multivariate analysis using cox proportional hazards regression showed that the Child-Pugh class, age, infection, and TNM stage contributed to a higher probability of death, while the drainage method and gender contributed to a lower probability of death. Through Cox proportional hazards regression analysis, it indicates that the child C, elder (≥ 70 years), infection, and stage IV are risk factors for poorer survival, while the EPBS+EMBS drainage method and male may be protective factors for better survival.

In conclusion, the EPBS+EMBS drainage method may improve the successful biliary drainage, with lower complications, longer patency, and longer survival time than other drainage methods. Impact factors such as Child-Pugh class, age, infection, and TNM stage contributed to a higher probability of death, while the drainage method and gender contributed to a lower probability of death.

Disclosure of conflict of interest

None.

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