The Impact of Preoperative Biliary Drainage on Postoperative Outcomes of Patients with Malignant Obstructive Jaundice: A Retrospective Analysis of 290 Consecutive Cases at a Single Medical Center

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Research

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Abstract

Background

The efficacy of preoperative biliary drainage (PBD) has been debated for several decades, and indications for PBD are still a controversial topic. The aim of this study was to compare the efficacy of PBD among patients with malignant obstructive jaundice in current clinical settings.

Methods

All consecutive patients with malignant obstructive jaundice who underwent radical resection from June 2017 to December 2019 at Zhongshan Hospital were analyzed retrospectively. The study population was divided into two groups: a PBD group (PG) and direct surgery group (DG). Subgroups were chosen by site of obstruction. Perioperative indicators and postoperative complications were compared and analyzed.

Results

A total of 290 patients were analyzed. Postoperative complications occurred in 134 patients (overall rate: 46.4%). Patients in group PG had a lower overall rate of postoperative complications as compared to group DG, with perioperative total bilirubin (TB) identified as an independent risk factor in multivariate analysis (hazard ratio = 1.004; 95% confidence interval 1.001–1.007; P = 0.017). Subgroup analysis showed that PBD reduced the complication rate in patients with proximal obstruction. In the proximal-obstruction subgroup, a preoperative TB level >162 μmol/L predicted postoperative complications.

Conclusions

PBD may reduce the overall rate of postoperative complications among patients with proximal malignant obstructive jaundice.

Trial registration

ClinicalTrials.gov, 2018ZSLC 24. Registered May 17, 2018, https://clinicaltrials.gov/.

Introduction

Biliary obstruction often presents as the first symptom in several cancers affecting the region from the perihilar bile duct to the pancreatic head, including perihilar cholangiocarcinoma (pCCA), distal cholangiocarcinoma (dCCA), ampullary carcinoma, and pancreatic ductal adenocarcinoma (PDAC)[1]. Patients with intrahepatic cholangiocarcinoma (iCCA), gallbladder carcinoma (GBC), or other tumors invading the extrahepatic bile duct may also present with biliary obstruction as the first symptom [2–4]. However, these types of tumors are distinct in their presentation and natural history, as well as the approach to diagnosis and management[5]. Surgical resection is the only well-established option which provides best possibility for long-term survival of these patients, and the procedure is very challenging[6, 7]. Prolonged and progressive obstructive jaundice induces fatigue, malnutrition, bile stasis, cholangitis, and endotoxemia and is associated with hepatic dysfunction, coagulopathy, infections, anastomotic leakage, and delayed recovery after the surgical operation [8–10]. Preoperative biliary drainage (PBD) procedures have been introduced to alleviate the negative effects of biliary obstruction. Nonetheless, PBD is an invasive treatment and carries a risk of procedure-related complications. Although it has theoretical value, routine PBD does not improve perioperative outcomes in jaundiced patients. Indications for PBD in malignant obstructive jaundice are still debated [11, 12].

In China, many high-volume medical centers have tried kinds of perioperative management to improve resectability and curability,and to reduce surgical mortality and morbidity rates for radical resections. Preoperative management protocols of PBD may have played a substantial role in these improvements. However, there is no firm standard. Nevertheless, in which cases PBD should be recommended is still a matter of debate, and indications for PBD remain a controversial issue.

Therefore, the present study was aimed at assessing the impact of PBD on postoperative outcomes and at investigating the effectiveness of the currently recommended PBD protocol.

Methods

Patients and study design

Data on the patients that were consecutively referred for radical resection because of malignant biliary obstruction at Zhongshan Hospital Fudan University, Shanghai, China, from June 2017 to December 2019 were retrieved from the Hospital Information System and retrospectively analyzed. Only patients who achieved preoperative total bilirubin >51 μmol/L were included. They either underwent a radical resection or received PBD before this surgical operation after admission. Only cases where PBD was carried out at our institution with full medical records were included. Full medical records included: initial imaging data, PBD and surgical operation records, hospitalization records, perioperative laboratory testing results (within three days before operation, on the first, third and seventh days after PBD or operation, and then once a week after operation). Demographic and clinical data were collected, including age, sex, the American Society of Anesthesiologists (ASA) score, body–mass index (BMI), medical history, histopathological diagnosis, preoperative physical examinations, laboratory tests, chest X-ray imaging, and computed tomography or magnetic resonance imaging of the abdomen. Informed written consent was obtained from each participating patient. A radical resection was considered complete if the entire gross tumor volume was removed with negative resection margins (R0 resection), whereas an incomplete resection was defined as the presence of a microscopic tumor in the surgical resection margin (R1 resection). Palliative resection was defined as the presence of any gross residual tumors (R2 resection), and such cases were excluded from the study. Antibiotic prophylaxis was administered and continued until at least postoperative day 5. All patients were treated with the second-generation cephalosporin intravenously ½ hour to 1 hour prior to start of surgery. For lengthy operative procedures (e.g., 3 hours or more) or that the amount of bleeding exceeds 1500 ml, additional dose will be given intravenously during surgery (administration modified depending on the duration of the operative procedure). Finally, 290 patients were enrolled in the study, of whom 159 had PBD before the resection ("PBD group"; PG) and 131 had underwent an early surgical resection without PBD ("direct surgery group"; DG). The study protocol was approved by the ethics committees of Zhongshan Hospital and Fudan University. The methods were used in accordance with the approved guidelines. All postoperative complications were scored and classified using Common Terminology Criteria for Adverse Events 5.0.

The Pbd Procedure

According to the clinical practice guidelines of Zhongshan Hospital, jaundiced patients with a total bilirubin level >200 μmol/L or with malnutrition and cholangitis were treated with PBD as a "bridge therapy" before a radical surgical resection was attempted. PBD types included percutaneous transhepatic biliary drainage (PTBD), endoscopic nasobiliary drainage (ENBD), and endoscopic biliary stenting (EBS). In cases of failure, PTBD is usually carried out as a remedial treatment. Some patients treated were referred from low-volume centers or other hospitals where PBD had already been carried out as the first intervention. For these reasons, during the study period, there were no standardized indications for jaundice palliation.

The definitions of radical resections are given above. Radical resections for proximal obstruction, mainly in pCCA and gallbladder carcinoma, were normally hepatectomies, whereas for distal obstruction, mainly in biliary carcinoma, ampullary carcinoma, and PDAC, the radical resections were normally pancreatoduodenectomies. Standard lymph node dissection was performed too.

All the patients received intraoperative antibiotic prophylaxis.

Statistics

The data were analyzed in the SPSS software version 25.0 (IBM Corp., Armonk, NY, USA). Categorical data are presented as percentages and frequencies and were compared by the χ^2 test or McNemar's test, as appropriate. Continuous variables are analyzed for normality using Kolmogorov-Smirnov Test first. Normally distributed continuous variables are presented as means and standard deviations (SD), and the significance of pairwise differences was assessed by the independent-sample or dependent-sample *t* test where appropriate. Non-normally distributed continuous variables are presented as medians and interquartile ranges, and the significance of their differences was evaluated by the Mann–Whitney *U* test or Wilcoxon signed-rank test as appropriate. To identify the best cutoff of preoperative total bilirubin (TB) for distinguishing patients with postoperative complication(s) from those without, a receiver-operating characteristic (ROC) curve analysis was conducted. Data with a P value <0.05 were considered statistically significant.

Results

A total of 290 consecutive patients with malignant obstructive jaundice who underwent a radical resection at Zhongshan Hospital between June 2017 and December 2019 were included in the study. One hundred fifty-nine (54.8%) patients received PBD (group PG) before the resection, and 131 (45.2%) patients underwent a radical resection directly after admission (group DG). In group PG, for 5 (3.1%), 5 (3.1%), and 149 (93.7%) out of 159 patients, EBS, ENBD, and PTBD were chosen as initial PBD, respectively. Eight patients (5.0% of the 159) needed a second PBD, which was PTBD in all cases. The frequency of the second PBD was not significantly different among the 3 subgroups ($P = 0.082$; Table 1). Radical resections included pancreaticoduodenectomy, radical resection for pCCA, and other procedures according to the tumor site.

Table 1
The frequency of a second PBD in group PG

	Total	EBS	ENBD	PTBD	Statistic	*P* value
First PBD	159 (100%)	5 (3.1%)	5 (3.1%)	149 (93.7%)	$\chi^2 = 5.665$	0.082*
Second PBD	8 (5.0%)	1 (20.0%)	1 (20.0%)	6 (4.0%)		

*Fisher's exact test in Monte Carlo mode.

Patient Characteristics

Baseline characteristics of the patients with malignant obstructive jaundice in groups DG and PG are described in Table 2. The baseline characteristics (on admission) including age, sex, and BMI were not significantly different between the two groups. ASA scores were significantly different between the two groups: the PG group contained more patients with ASA score III–IV ($P < 0.001$). One hundred seventy-two (59.1%) patients had proximal biliary obstruction, and 119 (40.9%) distal biliary obstruction. The site of obstruction did not significantly affect the choice of PBD ($P = 0.301$). Final histopathological diagnoses were as follows: 4 iCCAs and 14 GBCs with invasion of an extrahepatic bile duct, 153 pCCAs, 51 distal biliary carcinomas, 47 ampullary carcinomas, 20 PDACs, and 1 hepatocellular carcinoma with invasion of an extrahepatic bile duct; prevalence rates of these diagnoses were not significantly different between groups DG and PG ($P = 0.301$).

Table 2
Demographic data on the patients under study

Characteristics		**Total (n=290)**	**DG (n=131)**	**PG (n=159)**	**statistic**	***P* value**
Age (years)	Mean±SD (range)	62.21±9.41 (24-80)	62.21±9.60 (24-80)	62.2±9.30 (28-80)	t=0.007	0.994
	≥70, n (%)	63 (21.72%)	29 (22.14%)	34 (21.38%)	χ^2= 0.024	0.877
	<70, n (%)	227 (78.28%)	102 (77.86%)	125 (78.62%)		
Sex	Male, n (%)	185 (63.79%)	82 (62.60%)	103 (64.78%)	χ^2= 0.148	0.700
	Female, n (%)	105 (36.21%)	49 (37.40%)	56 (35.22%)		
BMI (kg/m^2)	Mean±SD	22.72±3.02	22.52±2.65	22.86±3.25	t=0.862	0.389
ASA score	I	22 (7.59%)	10 (7.63%)	12 (7.55%)	χ^2= 17.810	**<0.001**
	II	237 (81.72%)	118 (90.08%)	119 (74.84%)		
	III-IV	31 (10.69%)	3 (2.29%)	28 (17.61%)		
Medical history	hepatolithiasis	12	2	10	χ^2= 1.752	0.636*
	cholecystolithiasis	29	11	18		
	HBP	50	17	33		
	Diabetes	26	8	18		
Obstruc-Tion site	Proximal	172	82	90	χ^2= 1.068	0.301
	Distal	118	49	69		
Histopa-thological diagnosis	iCCA	4	3	1	χ^2= 4.187	0.664*
	GBC	14	8	6		
	pCCA	153	71	82		
	biliary carcinoma	51	21	30		
	ampullary carcinoma	47	21	26		
	PDAC	20	7	13		
	hepatocellular carcinoma	1	0	1		

*Fisher’s exact test in Monte Carlo mode.

HBP: high blood pressure.

Laboratory Testing Results

A comparison of these data between the time of initial diagnosis and the time point of perioperative testing is presented in Table 3. Within the DG group, initial laboratory test results including hemoglobin (Hb) and ALB (albumin) were significantly higher as compared with the perioperative test ($P < 0.001$ and $P = 0.016$). ALT and AST levels also decreased significantly ($P < 0.001$ and $P = 0.005$, respectively). TB and direct bilirubin (DB) levels increased obviously (both $P < 0.001$). PBD was found to prevent the deterioration of liver function. Within the PG group, Hb levels improved significantly ($P < 0.001$). ALT, AST, TB, and DB decreased significantly ($P < 0.001$, $P < 0.001$, $P < 0.001$, and $P < 0.001$, respectively).

Table 3
A comparison of laboratory testing results between two time points (initial diagnosis and perioperative testing) within each group

Parameters	DG		Within DG			PG		Within PG		
	initial	perioperative	cases with paired data available	statistic	*P* value	initial	perioperative	cases with paired data available	statistic	*P* value
Hb (g/L)	126.13±14.34	122.97±14.71	124	t=5.400	<0.001	121.47±17.51	114.70±15.78	147	t=6.352	<0.001
WBC (10^9/L)	6.12±1.84	5.98±1.75	124	t=1.463	0.146	6.45±2.10	6.34±2.00	147	t=0.639	0.524
NEUT (%)	63.10±9.36	64.23±9.31	124	t=-1.789	0.076	66.94±9.27	62.30±9.37	146	t=4,705	0.028
Plt (10^9/L)	252.23±83.36	254.86±85.68	124	t=-0.751	0.454	253.24±87.03	243.80±83.14	147	t=1.764	<0.001
ALB (g/L)	38.82±4.09	38.17±4.05	121	t=2.435	0.016	37.43±4.99	40.70±5.22	147	t=-5.914	0.100
ALT (U/L)	200.21±151.89	165.80±140.32	122	t=4.517	<0.001	166.09±152.17	78.52±59.40	147	t=7.656	<0.001
AST (U/L)	133.94±99.47	115.38±93.63	122	t=2.887	0.005	131.58±122.80	54.60±43.18	146	t=7.882	0.001
TB (μmol/L)	140.99±83.27	158.12±95.11	122	t=-4.572	<0.001	227.38±126.49	83.03±57.59	147	t=14.399	<0.001
DB (μmol/L)	116.11±70.21	133.40±79.21	121	t=-5.402	<0.001	186.06±103.03	71.49±49.17	147	t=13.904	<0.001
GGT (U/L)	798.17±602.69	739.93±593.06	119	t=3.228	0.002	586.88±436.73	228.60±181.69	145	t=11.031	<0.001
ALP (U/L)	434.24±268.60	423.75±262.36	122	t=1.031	0.305	465.28±363.83	230.40±158.91	145	t=9.484	<0.001
Na (mmol/L)	139.83±3.01	139.74±3.16	119	t=0.460	0.646	138.87±3.16	139.78±2.96	146	t=-3.279	<0.001
PT (s)	11.35±1.42	11.20±1.22	117	t=0.843	0.401	11.59±1.51	11.65±1.08	146	t=-0.402	0.682

Hb: hemoglobin; WBC: white blood cell; NEUT: neutrophils; Plt: platelet; ALB: albumin; ALT: alanine transminase-glutamic pyruvic transaminase; AST: aspartate transminase-glutamic oxalo-acetic transaminase; TB: total bilirubin; DB: direct bilirubin; GGT: γ-glutamyltransferase; ALP: alkaline phosphatase; Na; natrium; PT: prothrombin time

A comparison of the laboratory test results between the two groups is presented in Table 4. At the time of initial diagnosis, the PG patients had severer anemia, higher percentage of neutrophils (NEUT %), hypoalbuminemia, and jaundice (P = 0.015, P = 0.001, P = 0.038, and P < 0.001, respectively). As to perioperative laboratory findings, the PG patients' condition reversed in terms of neutrophils, hypoalbuminemia and jaundice (P = 0.050, < 0.001, and < 0.001, respectively), but their anemia did not improve (P < 0.001).

Table 4
A comparison of laboratory testing results at two time points (initial diagnosis and perioperative testing) between the two groups

Characteristics	DG		PG		Initial data compared between groups		Perioperative data compared between groups	
	initial	perioperative	initial	perioperative	statistic	*P* value	statistic	*P* value
Hb (g/L)	125.85±14.41	123.11±14.74	121.17±17.58	115.35±15.93	t=2.441	0.015	t=4.193	<0.001
WBC (10^9/L)	6.11±1.82	6.00±1.76	6.55±2.26	6.37±2.04	t=-1.754	0.081	t=-1.670	0.096
NEUT (%)	63.15±9.44	64.16±9.31	67.11±9.40	61.9±9.51	t=-3.504	0.001	t=1.972	0.050
Plt (10^9/L)	250.5±82.90	255.24±85.44	255.6±88.94	248.31±84.76	t=-0.494	0.662	t=0.679	0.498
ALB (g/L)	38.57±4.16	38.21±4.06	37.42±4.96	40.75±5.23	t=2.085	0.038	t=-4.552	<0.001
ALT (U/L)	198.78±153.36	165.80±140.32	166.10±150.58	79.19±62.58	t=1.799	0.073	t=6.340	<0.001
AST (U/L)	134.50±99.18	115.38±93.63	131.63±121.91	55.24±44.08	t=0.140	0.889	t=6.530	<0.001
TB (μmol/L)	140.84±82.94	158.12±95.11	225.1±126.27	81.76±56.74	t=-6.695	<0.001	t=7.837	<0.001
DB (μmol/L)	115.70±69.55	132.52±79.48	184.20±102.96	70.36±48.47	t=-6.601	<0.001	t=7.598	<0.001
GGT (U/L)	812.81±627.21	736.18±592.00	582.53±434.59	224.00±178.62	t=3.501	0.001	t=9.160	<0.001
ALP (U/L)	430.06±265.00	423.75±262.36	465.36±362.82	230.09±157.57	t=-0.936	0.350	t=7.195	<0.001
Na (mmol/L)	139.74±3.03	139.75±3.15	138.88±3.18	139.87±2.96	t=2.303	0.022	t=-0.327	0.728
PT (s)	11.53±2.12	11.16±1.21	11.569±1.50	11.69±1.09	t=-0.171	0.864	t=-3.824	<0.001

All Postoperative Outcomes And Risk Factors For Postoperative Complications

The postoperative outcomes are shown in Table 5. The overall rate of postoperative complications was 46.4% (134 patients out of 290), and complications occurred more frequently in group DG (P = 0.029). The postoperative hemorrhage rate was significantly higher in group DG (P = 0.038), whereas postoperative delayed gastric emptying was significantly more frequent in group PG (P = 0.065). The rates of mortality and of other complications were similar between the two groups. The location of obstruction was used to decide on the main routine surgical procedure, and each group was divided into a proximal-obstruction subgroup and distal-obstruction subgroup. The overall rate of postoperative complications in the combined proximal-obstruction group was 77.9% (Table 6), and complications occurred more frequently in the proximal-obstruction DG subgroup (P = 0.038; Table 7). In the combined distal-obstruction group, the overall rate of postoperative complications was 50.8% (Table 6), and PBD did not affect this rate (P = 0.249, Table 7).

Table 5
All postoperative complications in the study population

	Total (n=290)	**DG (n=131)**	**PG (n=159)**	**statistic**	***P* value**
All complications	134	70	64	χ^2 = 5.002	0.025
Intestinal fistula	23	10	13	χ^2 = 0.029	0.865
Pancreatic fistula	20	10	10	χ^2 = 0.202	0.653
Biliary fistula	1	0	1	-	-
Gastrointestinal anastomotic fistula	2	0	2	-	-
Abdominal liquid accumulation	31	16	15	χ^2 = 0.581	0.446
Delayed gastric emptying	17	4	13	χ^2 = 3.415	0.065
Hemorrhage	21	14	7	χ^2 = 4.223	0.040
Hepatic failure	6	3	3	-	1.000
Reoperation	11	6	5	χ^2 = 0.406	0.552
Incision complication	8	3	5	χ^2 = 0.196	0.733
Mortality	6	3	3	-	1.000
Sepsis	78	41	37	χ^2 = 2.354	0.125

Table 6
Postoperative outcomes in proximal- and distal-obstruction groups

	Proximal obstruction	**Distal obstruction**	**statistic**	***P* value**
Total	172	118	χ^2 = 23.141	<0.001
All complications (%)	134 (77.9%)	60 (50.8%)		

Table 7
Postoperative outcomes by subgroups

	Total	**DG**	**PG**	**statistic**	***P* value**
Proximal obstruction (number of patients)	172	82	90	χ^2 = 4.295	0.038
Complication(s) (number of patients)	134	70	64		
Distal obstruction	118	49	69	χ^2 = 1.329	0.249
Complication(s)	60	28	32		

In univariate analysis, PBD proved to be associated with better postoperative outcomes (P = 0.025; Table 8). Perioperative Hb and perioperative TB were associated with postoperative complications (P = 0.027 and P = 0.016, respectively). Multivariate analysis indicated that perioperative TB is an independent risk factor for postoperative complications (Table 8).

Table 8
Univariate and multivariate analyses of factors possibly associated with postoperative outcomes in the study population (290 patients)

	Univariate analysis			Multivariate analysis		
	HR	95% CI	P value	HR	95% CI	P value
Age>70	0.831	0.456-1.515	0.545			
Gender	0.971	0.601-1.570	0.906			
Tumor site	0.970	0.606-1.553	0.900			
PBD	0.587	0.368-0.937	**0.025**			0.163
Initial Hb	1.012	0.997-1.027	0.111			
Perioperative Hb	1.017	1.002-1.033	**0.027**			0.059
Initial WBC	0.953	0.849-1.068	0.407			
Perioperative WBC	1.006	0.891-1.137	0.922			
Initial TB	0.999	0.997-1.001	0.516			
Perioperative TB	1.004	1.001-1.007	**0.016**	1.004	1.001-1.007	0.017
Initial GGT	1.000	1.000-1.000	0.860			
Perioperative GGT	1.000	1.000-1.001	0.893			
Initial Na	0.936	0.867-1.011	**0.091**			0.184
Perioperative Na	0.990	0.916-1.071	0.806			
Initial PT	0.962	0.841-1.100	0.567			
Perioperative PT	0.915	0.746-1.123	0.395			
HR: hazard ratio, CI: confidence interval, GGT: gamma-glutamyl transferase.						

Preoperative TB concentration greater than 162 μmol/L distinguished patients with postoperative complication(s) from those without (Fig. 1, ROC curve analysis). For this cutoff, the area under the ROC curve was 0.7024 (95% confidence interval 0.588–0.816) ($P = 0.002$, sensitivity 62.8%, specificity 74.4%).

Discussion

In this retrospective study, we analyzed the efficacy of PBD in patients with malignant obstructive jaundice in current clinical settings. It sounded confusing to see patients with a number of different malignancies. However, we want to emphasize that patients often do not have full medical examination at their first visit but require receiving preliminary treatment with limited data. So, we want to find some easily accessible indicators to help patients receive treatments as early as possible.

Obstructive jaundice is a life-threatening problem in patients with malignant tumors. Although the degree of hyperbilirubinemia is not necessarily related to a tumor stage, hyperbilirubinemia interferes with many organ functions and limits treatment choices. Bilirubin, as a product of heme metabolism, is nearly nontoxic in its normal physiological range of concentrations, whereas hyperbilirubinemia is toxic and should be taken seriously. In particular, it has been associated with an increased risk of postoperative complications. PBD is a kind of "bridge therapy" before a radical surgical resection is attempted for malignant obstructive jaundice. There is no consensus on indications for PBD so far.

The retrospective data showed that PBD may reduce the overall rate of postoperative complications among patients with proximal obstructive jaundice. Perioperative TB turned out to be an independent risk factor for postoperative complications. Preoperative TB greater than 162 μmol/L distinguished patients with postoperative complications from those without.

PBD has had varied effects in different studies. To be exact, different PBD options have manifested various effects in different cancers. It must be emphasized that the data published so far came from diverse studies, where the patients had a small number of cancer types affecting the biliary tree. In 2010, van der Gaag N.A. et al. conducted a multicenter randomized controlled trial regarding the cancer of the pancreatic head and demonstrated that routine PBD increases the rate of complications. This conclusion was based on the bilirubin range 40 to 250 μmol/L and was made about the cancer of the pancreatic head [13]. In 2016, a meta-analysis suggested that the PBD group has significantly fewer major adverse effects than the direct surgery group [14]. This conclusion was made about a series of tumors, e.g., cancers of the biliary tract, cancers of the head and neck, and cancers of the duodenum. On the other hand, the studies included in this meta-analysis took place between 1981 and 2011. Nearly at the same time, another meta-analysis suggested that PBD worsens postoperative outcomes, increasing the prevalence rate of infectious complications, surgical site infections, and delayed gastric emptying [15]. Few studies have been conducted on multicenter randomized controlled trials for malignant obstructive jaundice[16]. Actually, in recent years, several PBD methods were simultaneously employed, and new drainage brackets are coming onto the scene [17, 18]. The management of obstructive jaundice is complicated and involves not only surgeons and medical centers but also the entire healthcare system [19]. Hegel's principle "what exists is reasonable" is thought to be applicable worldwide, but we found a more accurate observation by examining the current methods in some clinical settings. For example, a

Japanese retrospective study covered 10-year clinical experience and revealed that PBD reduces postoperative morbidity and mortality in the whole country regardless of the PBD type [20]. This finding makes us think that we can also find a beneficial modality at our medical center. In the 2 years under study, we applied a mature surgical technology and advanced equipment, and the observed prevalence of postoperative complications is not consistent with other hospitals and countries.

Our results show a clear difference made by PBD among patients with malignant obstructive jaundice. This report is the first retrospective study at the latest level of technology to show benefits of PBD for patients with malignant obstructive jaundice in China. Accurate preoperative diagnosis of biliary tract tumors is difficult, but the estimation of an obstruction site is easier. On the basis of our study, we believe that patients with proximal obstruction should consider PBD more often. Due to the limited number of cases in the 2 recent years under study, we did not obtain strong evidence that PBD affects postoperative complications of patients with distal obstruction.

Concerning limitations of this study, first, this study was retrospective, so selection bias potentially occurred. Although the best way to reduce or eliminate the selection bias is a randomized controlled trial, such a trial is not feasible for patients with malignant obstructive jaundice. Second, the study involved a small sample at only one hospital in China with predominantly Chinese patients. Medical treatment level differs widely among regions of China, so data in this study could not be widely representative.

Conclusion

Our study indicates that PBD may reduce the overall rate of postoperative complications in patients with proximal malignant obstructive jaundice. Perioperative TB is an independent risk factor for postoperative complications and supports the decision to recommend preoperative PBD when preoperative TB is >162 μmol/L.

Declarations

Authors' contributions

Houbao Liu and Sheng Shen conceived the study. Zhihui Gao and Huang Lihong analyzed and interpreted the data. Zhihui Gao performed the writing of the manuscript. Wang Jie, Bo Xiaobo, Suo Tao, Ni Xiaoling, Liu Han and Wang Yueqi collected and assembled the data. Houbao Liu submitted the manuscript and is the corresponding author. All authors read and approved the final manuscript.

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Availability of data and materials

The data used to support the findings of this study are available from the corresponding author upon request.

Ethics approval and consent to participate

This study was approved by the ethics committees of Zhongshan Hospital and Fudan University. All patients signed informed consent.

Consent for publication

The patient was given his consent for information about himself to be published in World Journal of Surgical Oncology.

Competing interests

The authors declare that they have no competing interests.

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Figures

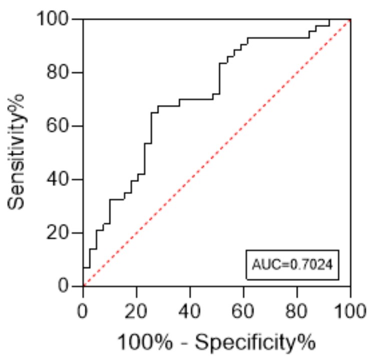

Figure 1

The ROC curve. This analysis shows that the best cutoff of preoperative TB for discriminating patients with complications from those without complications is 162 μmol/L (P = 0.002, sensitivity 62.8%, specificity 74.4%), with an area under the ROC curve (AUC) = 0.7024 [95% CI 0.588–0.816].