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ORIGINAL ARTICLE

Retrospective Study

Endoscopic ultrasound-guided biliary drainage *vs* percutaneous transhepatic bile duct drainage in the management of malignant obstructive jaundice

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Abstract

BACKGROUND

Malignant obstructive jaundice (MOJ) is a condition characterized by varying degrees of bile duct stenosis and obstruction, accompanied by the progressive development of malignant tumors, leading to high morbidity and mortality rates. Currently, the two most commonly employed methods for its management are percutaneous transhepatic bile duct drainage (PTBD) and endoscopic ultrasound-guided biliary drainage (EUS-BD). While both methods have demonstrated favorable outcomes, additional research needs to be performed to determine their relative efficacy.

AIM

To compare the therapeutic effectiveness of EUS-BD and PTBD in treating MOJ.

METHODS

This retrospective analysis, conducted between September 2015 and April 2023 at The Third Affiliated Hospital of Soochow University (The First People's Hospital of Changzhou), involved 68 patients with MOJ. The patients were divided into two groups on the basis of surgical procedure received: EUS-BD subgroup (n = 33) and PTBD subgroup (n = 35). Variables such as general data, preoperative and postoperative indices, blood routine, liver function indices, myocardial function indices, operative success rate, clinical effectiveness, and complication rate were analyzed and compared between the subgroups.

RESULTS

In the EUS-BD subgroup, hospital stay duration, bile drainage volume, effective catheter time, and clinical effectiveness rate were superior to those in the PTBD subgroup, although the differences were not statistically significant ($P > 0.05$). The puncture time for the EUS-BD subgroup was shorter than that for the PTBD subgroup ($P < 0.05$). Postoperative blood routine, liver function index, and myocardial function index in the EUS-BD subgroup were significantly lower than those in the PTBD subgroup ($P < 0.05$). Additionally, the complication rate in the EUS-BD subgroup was lower than in the PTBD subgroup ($P < 0.05$).

CONCLUSION

EUS-BD may reduce the number of punctures, improve liver and myocardial functions, alleviate traumatic stress, and decrease complication rates in MOJ treatment.

Key Words: Percutaneous hepatic biliary drainage; Endoscopic ultrasound-guided biliary drainage; Malignant obstructive jaundice; Clinical effect; Liver function; Postoperative complications

Core Tip: Malignant obstructive jaundice (MOJ) primarily manifests in advanced tumors, posing significant risks to patient survival and necessitating prompt treatment. The principal treatment methods for MOJ are endoscopic ultrasound-guided biliary drainage and percutaneous transhepatic bile duct drainage. However, the efficacy of these two procedures varies, and their clinical value and postoperative effects require further analysis. This study, involving 68 patients, compares the therapeutic outcomes of these two surgical treatments for MOJ, aiming to identify the optimal treatment strategy.

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INTRODUCTION

Malignant obstructive jaundice (MOJ) is a type of jaundice disease arising from hepatic duct occlusion, which leads to impaired bile excretion and abnormal elevation of serum bilirubin[1]. MOJ commonly results in biliary tract infection or suppurative cholangitis. Without timely treatment, it can progress to abnormal coagulation function, impaired immune function, liver failure, and even death[2]. Currently, endoscopic retrograde cholangiopancreatography (ERCP) combined with biliary stent implantation is the primary standard treatment in clinical practice. However, intubation may pose a challenge in certain patients, with a failure rate reaching as high as 7%. Consequently, traditional percutaneous transhepatic biliary drainage (PTBD) is often employed for these patients, boasting a success rate of 87% to 100%. Yet, it is associated with risks such as bile duct injury, biliary fistula, drainage tube obstruction, dislocation, and other complications. Moreover, long-term external drainage can lead to bile loss, electrolyte disturbances, and infection, significantly impacting patients' quality of life and their functional recovery[3,4]. Endoscopic ultrasound-guided biliary drainage (EUS-BD), a newer internal drainage technique, is an alternative when ERCP treatment fails. It has a technical success rate of over 90% and an adverse event rate of less than 15%[5]. EUS-BD has shown promise in treating MOJ, particularly in terms of postoperative complications[6]. Therefore, this study aims to compare the effects of EUS-BD and PTBD in treating MOJ using a multi-variable and multi-sample approach. The specifics of this study are outlined below.

MATERIALS AND METHODS

Patient characteristics

This retrospective analysis included 68 patients with MOJ who were admitted to The Third Affiliated Hospital of Soochow University (The First People's Hospital of Changzhou) between September 2015 and April 2023. On the basis of the treatment methods employed, these patients were divided into two groups: the EUS-BD subgroup ($n = 33$) and the PTBD subgroup ($n = 35$).

Inclusion criteria: MOJ diagnosis was confirmed through B-ultrasound, computed tomography (CT), or Magnetic resonance cholangiopancreatography prior to surgery; patients for whom conventional ERCP procedures had failed or were deemed unsuitable by endoscopists; availability of complete clinical data; absence of distant metastasis; normal coagulation function.

Exclusion criteria: Patients who had undergone radiotherapy or chemotherapy; those with hemophilia or other significant coagulation disorders; and patients suffering from severe infections.

Preoperative preparation

Prior to surgery, patients underwent routine blood tests, coagulation function assessment, liver function tests, and general blood biochemistry analysis. They were required to fast for 4 to 6 hours before the procedure. Additionally, medications that affect platelet aggregation and anticoagulation, such as clopidogrel, warfarin, aspirin, and low-molecular-weight heparin, were discontinued. Imaging data from the planned puncture site (abdominal CT or magnetic resonance imaging) were carefully reviewed to ascertain the presence of any large vessels crossing or adjacent to the site. The procedure was performed under general anesthesia or intravenous sedation, with assistance from an anesthesiologist.

Surgical methods

EUS-BD Subgroup: Using linear array endoscopic ultrasonography (UCT-260, Olympus Medical Systems, Tokyo, Japan), the appropriate puncture site was selected under guidance. Color Doppler was used to avoid blood flow signals in the puncture path. A 19G needle (ECHO-19, Cook Ireland Ltd, Limerick, Ireland) was inserted through the digestive tract into the intrahepatic bile duct. After confirming the aspiration fluid as bile, a contrast agent was injected to delineate the biliary system under X-ray guidance. A 0.035-inch guidewire was then introduced into the biliary system, exiting from the puncture needle. A cystotome along the guidewire was used to dilate the sinus tract, followed by the insertion of a nasobiliary tube or stent into the tract.

PTBD Subgroup: Under B-mode ultrasound guidance, bile duct dilatation was identified. The local skin was disinfected, and local infiltration anesthesia (2% lidocaine) was administered. To avoid blood vessels and intestinal structures, a 16G puncture needle was percutaneously inserted into the corresponding bile duct. Bile was withdrawn to confirm the needle's placement within the bile duct. A guidewire was then placed through the puncture needle, the puncture site expanded, and the tube inserted. Finally, an external drainage bag was connected, and the drainage device secured.

Observational indicators

General clinical data: This includes age, sex, body mass index (BMI), smoking history, cancer type, duration of the disease, duration of surgery, and length of hospital stay.

Surgery-related indicators: These encompass operation time, hospital stay duration, number of punctures, bile drainage flow rate, and effective duration of tube maintenance.

Blood routine before and 7 d after surgery: Measurements of red blood cells (RBC), white blood cells (WBC), and platelets (PLT).

Liver function indices before and 7 d after surgery: Levels of total protein (TP), albumin (ALB), serum alkaline phosphatase (ALP), alanine transaminase (ALT), aspartate transaminase (AST), gamma-glutamyl transferase (GGT), total bilirubin (TBIL), direct bilirubin (DBIL), and total bile acid are determined, along with hypersensitive C-reactive protein (hs-CRP), using an automatic biochemical analyzer (DNM-9602, Beijing Pulang New Technology Co., Ltd).

Myocardial function before and 7 d after surgery: Assessments of lactate dehydrogenase (LDH), creatine kinase (CK), and creatine kinase isoenzyme (CK-MB).

Surgical success rate and clinical efficiency: Successful surgery is defined as the correct placement of the stent or drain in the desired position. The clinical effectiveness rate is determined on the basis of the reduction in TBIL levels before and 7 d after surgery, as well as the absence of stent blockage or displacement one month post-surgery. A significant effective rate is characterized by a decrease in TBIL of > 30% post-surgery, with no stent blockage or displacement within one month. Effectiveness is defined as a 10%-30% decrease in TBIL post-surgery, without stent blockage or displacement within one month. Ineffectiveness is indicated by a less than 10% decrease in postoperative TBIL and stent blockage or displacement within one month.

Postoperative complications: These include biliary fistula, cholangitis, bile duct bleeding, pneumoperitoneum, stent blockage, stent displacement, and mucosal laceration.

Statistical analysis

The measurement data, such as age, BMI, disease course, operation-related indicators, liver function indicators, and myocardial function indicators, are expressed as mean ± SD, and the *t*-test was used to analyze these data. Count data, such as sex, smoking history, cancer type, surgical success rate, clinical effective rate, and postoperative complications, are expressed as rates and were analyzed using the chi-square test. SPSS 27.0 software (IBM Corp.) was used to process the data. $P < 0.05$ was considered statistically significant.

RESULTS

General data comparison

The subgroups EUS-BD and PTBD were comparable in terms of age, sex, BMI, smoking history, cancer type, and duration of illness. No significant differences were observed between these groups (P > 0.05), as detailed in Table 1.

Comparison of surgery-related indicators

The EUS-BD subgroup exhibited shorter operative times and reduced lengths of hospital stay compared with the PTBD subgroup. Additionally, the EUS-BD subgroup demonstrated higher bile drainage volumes and longer effective tube times than the PTBD subgroup, though these differences were not statistically significant (P > 0.05). Notably, the number of punctures in the EUS-BD subgroup was fewer than in the PTBD subgroup (P < 0.05), as illustrated in Figure 1A.

Blood routine comparison

Prior to surgery, the blood routine parameters of the two subgroups EUS-BD and PTBD showed no significant differences (P > 0.05). However, 7 d post-surgery, the levels of RBC, WBC, and PLT in the EUS-BD subgroup were significantly lower than those in the PTBD subgroup (P < 0.05), as illustrated in Figure 1B.

Liver function comparison

Prior to surgery, the serum indices of both groups EUS-BD and PTBD were similar (P > 0.05). Postoperatively, the levels of TP, ALP, adenosine triphosphate, ALT, AST, GGT, TBIL, DBIL, and hs-CRP in the EUS-BD subgroup were lower than those in the PTBD subgroup (P < 0.05), as shown in Table 2.

Comparison of myocardial function indices

Postoperative myocardial function indices in the EUS-BD subgroup were significantly lower than those in the PTBD subgroup (P < 0.05), as illustrated in Figure 1C.

Comparing surgical success rate and clinical response rate

In the EUS-BD subgroup, 31 patients experienced successful biliary drainage, resulting in a success rate of 93.94%, which surpassed the 85.71% success rate observed in the PTBD subgroup. Among the EUS-BD subgroup, 16 patients (48.49%) demonstrated a postoperative decrease in TBIL of > 30%, a value of > 40.00% was observed in the PTBD subgroup. The proportion of patients whose TBIL decreased by 10%-30% post-surgery was 42.42% in the EUS-BD subgroup, comparable to that in the PTBD subgroup. Only 9.09% of the EUS-BD subgroup showed a TBIL decrease of < 10%, which was lower than the 17.14% in the PTBD subgroup. However, the differences in efficacy and clinical response between the two subgroups were not statistically significant (P > 0.05), as shown in Table 3.

Comparative analysis of postoperative complications

In the EUS-BD subgroup, complications were observed in 3 patients (9.09%), comprising 1 case of biliary fistula, 1 of stent blockage, and 1 of mucosal laceration. All these patients showed improvement following treatment. In the PTBD subgroup, 10 patients (28.57%) experienced complications, including 2 biliary fistulas, 2 instances of cholangitis, 1 bile duct hemorrhage, 1 pneumoperitoneum, 3 stent blockages, and 1 stent displacement, with all patients improving post-treatment. The EUS-BD subgroup had a significantly lower complication rate than the PTBD subgroup (P < 0.05), as shown in Table 4.

DISCUSSION

MOJ is a common surgical condition characterized by symptoms of bile duct obstruction, including yellowing of the skin, sclera, and other tissues. The pathogenesis of the disease mainly consists of compromised bile excretion and subsequent sepsis, causing infiltration of cytokines, oxidative stress, and disruption of physiological functions, resulting in hepatic cell injury and apoptosis[7-9]. The predominant clinical approach to MOJ is surgical intervention, yet the efficacy of various surgical techniques varies. ERCP is frequently used but can be technically challenging and carries a risk of postoperative biliary tract infection, thus affecting the surgical success rate. Recently, PTBD and EUS-BD have gained prominence in MOJ treatment owing to their minimal invasiveness. While both methods have shown effective outcomes and serve as alternatives for ERCP failures, determining which procedure holds greater clinical value remains a subject of ongoing exploration[10,11]. This study aims to compare and analyze the clinical effects of PTBD and EUS-BD in treating MOJ by examining surgery-related metrics, blood routine, liver and myocardial function indices, surgical success rate, clinical effectiveness, and complication rate, to identify a superior treatment approach.

PTBD and EUS-BD are comparable in terms of operation duration, hospital stay, bile flow, and effective drainage time. However, EUS-BD is characterized by a lower puncture frequency compared with PTBD. This may be attributed to the shorter puncture path in EUS-BD, its traversal through fewer organs, and its relatively higher accuracy. Additionally, EUS-BD offers a broader range of puncture sites. The stent can be positioned in the common bile duct under X-ray guidance, and its design often includes multiple side holes or a nasal cyst, enhancing the drainage effectiveness. In contrast, PTBD is more susceptible to complications like secondary biliary peritonitis and is limited by the extent of intrahepatic bile duct dilation, which can result in a lower puncture success rate[12,13].

Table 1 Comparison of general data between the two subgroups

	EUS-BD (*n* = 33)	PTBD (*n* = 35)	t/χ^2	*P* value
Age (mean SD, yr)	66.13 ± 10.04	64.36 ± 9.28	0.755	0.453
Sex, *n* (%)			0.391	0.532
Male	24 (72.73)	23 (65.71)		
Female	9 (27.27)	12 (34.29)		
BMI (mean SD, kg/m^2)	23.10 ± 3.18	23.25 ± 3.23	0.195	0.846
History of smoking, *n* (%)			0.000	0.994
Yes	17 (51.52)	18 (51.43)		
No	16 (48.48)	17 (48.57)		
Cancer type, *n* (%)			0.066	0.967
Carcinoma of head of pancreas	15 (45.46)	17 (48.57)		
Cholangiocarcinoma	10 (30.30)	10 (28.57)		
Other	8 (24.24)	8 (22.86)		
Disease course (mean SD, months)	6.30 ± 3.04	6.31 ± 3.17	0.015	0.988

BMI: Body mass index; EUS-BD: Endoscopic ultrasound-guided biliary drainage; PTBD: Percutaneous transhepatic puncture biliary drainage.

In the context of blood routine, liver function, and myocardial function indices, the postoperative metrics for these parameters in the EUS-BD subgroup were lower than those in the PTBD subgroup. This suggests that EUS-BD causes less trauma to the body, can effectively improve serum levels, liver function, and myocardial function in patients, and inflicts minimal damage to the liver. Firstly, routine blood tests are fundamental in clinical diagnostics, encompassing a range of commonly used sensitive indicators that are responsive to various bodily disease changes and assist in disease assessment. WBCs are a crucial type of blood cell, capable of phagocytizing foreign bodies and producing antibodies. RBCs play a role in clearing immune complexes and participating in immune regulation. PLTs are indicators reflecting the formation and reduction of platelets; changes in PLT levels can indicate alterations or damage within the blood system[14-16].

Secondly, MOJ frequently leads to abnormal coagulation function, as well as impairment of liver and kidney functions, often resulting in secondary infections. TBIL serves as a crucial liver function marker and a primary indicator for diagnosing jaundice. Elevated TBIL levels, particularly high DBIL, suggest potential liver lesions or bile duct obstruction. In this study, preoperative TBIL levels in patients with MOJ were high, but post-treatment levels significantly decreased, with a more pronounced reduction observed in the EUS-BD group. This suggests that EUS-BD treatment for MOJ can alleviate biliary obstruction, lower biliary pressure, reduce infection rates, and consequently enhance liver function in patients[17,18]. Additionally, some patients with MOJ experience abnormal metabolism, potentially affecting the energy metabolism of cardiomyocytes and leading to myocardial damage. Commonly assessed myocardial damage markers include LDH, CK, and CK-MB[19,20]. LDH and CK are enzymes widely distributed in body tissues such as the heart, liver, and kidneys, and are closely linked to myocardial function. CK-MB is predominantly found in the myocardium, and an increase in its blood levels, due to increased cell permeability following myocardial injury, is indicative of such damage[21,22].

This and other studies indicate that the success rate and clinical effectiveness of the EUS-BD subgroup were lower than those of the PTBD subgroup, although the difference was not statistically significant[23,24]. Regarding complication rates, the PTBD subgroup exhibited a higher incidence compared with the EUS-BD subgroup. While the PTBD procedure is straightforward with a high success rate, it often leads to complications, resulting in a poorer prognosis for some patients. In this study, the complication rate for patients with PTBD was as high as 28.57%, with common issues including cholangitis, stent blockage, and biliary fistula. In contrast, the complication rate in the EUS-BD subgroup was 9.09%, which could be managed with conservative treatment, effectively reducing patient discomfort[8,25]. Complications typically arise due to the following: (1) Mucosal tear and injury to peripheral blood vessels during endoscopic procedures; (2) Bile retrograding into blood, leading to infection; (3) Cholestasis causing biliary sludge formation, either from longitudinal tissue development or tumor growth causing stent obstruction; and (4) Injury to the pancreas, gallbladder, and bile duct during surgery. EUS-BD, conducted under endoscopic ultrasound and X-ray guidance, can enhance operational accuracy and reduce postoperative complications like infection and bleeding.

This study has the following limitations: (1) This study employed a retrospective research design, which retrospectively examined past data to determine present outcomes. The collected data may be subject to interference from various factors, potentially affecting the results; (2) Owing to the limited number of patients meeting the inclusion criteria at our hospital, only 68 patients were included, leading to potential bias and compromising the accuracy of our study's conclusions; and (3) Given the restricted sample size, this study did not assess the advantages and disadvantages of different types of stents and malignant tumors in relation to both treatment methods; thus, further research is needed to

Table 2 Comparison of preoperative and postoperative serum indices between the two subgroups, mean ± SD

Index	Time	EUS-BD (*n* = 33)	PTBD (*n* = 35)	*t*	*P* value
TP (g/L)	Before surgery	61.85 ± 7.14	59.25 ± 7.12	-1.498	0.139
	7 d after surgery	41.75 ± 5.80[a,b]	55.13±6.82[a]	8.687	< 0.001
ALB (g/L)	Before surgery	44.04 ± 6.98	40.97 ± 6.70	-1.846	0.069
	7 d after surgery	31.20 ± 4.45[a,b]	39.55 ± 6.07[a]	6.439	< 0.001
ALP (U/L)	Before surgery	529.68 ± 182.52	505.45 ± 176.87	-0.559	0.578
	7 d after surgery	285.39 ± 97.22[a,b]	360.65 ± 150.02[a]	2.439	0.017
ALT (U/L)	Before surgery	148.76 ± 52.55	146.58 ± 53.35	-0.169	0.866
	7 d after surgery	51.33 ± 6.61[a,b]	73.58 ± 7.03[a]	13.424	< 0.001
AST (U/L)	Before surgery	121.29 ± 37.58	107.62 ± 28.98	-1.685	0.097
	7 d after surgery	42.02 ± 13.95[a,b]	75.03 ± 16.25[a]	8.969	< 0.001
GGT (U/L)	Before surgery	612.05 ± 179.24	575.13 ± 174.30	-0.861	0.391
	7 d after surgery	213.67 ± 61.37[a,b]	299.65 ± 65.12[a]	5.595	< 0.001
TBIL (mmol/L)	Before surgery	228.02 ± 66.39	205.23 ± 76.28	-1.311	0.194
	7 d after surgery	107.93 ± 52.43[a,b]	144.79 ± 59.10[a]	2.714	0.008
DBIL (mmol/L)	Before surgery	204.18 ± 52.86	192.13 ± 49.66	-0.969	0.336
	7 d after surgery	70.19 ± 17.16[a,b]	84.48 ± 19.41[a]	3.208	0.002
TBA (mmol/L)	Before surgery	228.62 ± 55.45	208.90 ± 63.35	-1.362	0.178
	7 d after surgery	66.31 ± 18.61[a,b]	90.55 ± 20.11[a]	5.152	< 0.001
hs-CRP (mg/L)	Before surgery	13.22 ± 3.29	11.60 ± 3.90	-1.843	0.070
	7 d after surgery	4.58 ± 1.33[a,b]	7.66 ± 2.36[a]	6.576	< 0.001

[a]$P < 0.05$, compared to the preoperative subgroup.
[b]$P < 0.05$ compared to the percutaneous transhepatic puncture biliary drainage subgroup.
TP: Total protein; ALB: Albumin; ALP: Serum alkaline phosphatase; ALT: Alanine aminotransferase; AST: Aspartate transaminase; GGT: Gamma-glutamyl transferase; TBIL: Total bilirubin; DBIL: Direct bilirubin; TBA: Total bile acid; hs-CRP: Hypersensitive C-reactive protein; EUS-BD: Endoscopic ultrasound-guided biliary drainage; PTBD: Percutaneous transhepatic puncture biliary drainage.

Table 3 Comparison of surgical success rates and clinical response rates between the two subgroups, *n* (%)

	EUS-BD (*n* = 33)	PTBD (*n* = 35)	χ^2	*P* value
Successful operation	31 (93.94)	30 (85.71)	1.244	0.265
Excellent	16 (48.49)	14 (40.00)		
Effective	14 (42.42)	15 (42.86)		
Ineffective	3 (9.09)	6 (17.14)		
Total effective	30 (90.91)	29 (82.86)	0.959	0.327

EUS-BD: Endoscopic ultrasound-guided biliary drainage; PTBD: Percutaneous transhepatic puncture biliary drainage.

strengthen our findings. In future clinical practice, we aim to expand our sample size, conduct prospective controlled studies, and incorporate multiple influencing factors to enhance the clinical application of EUS-BD.

CONCLUSIONS

When comparing the EUS-BD subgroup with the PTBD subgroup, the differences in surgical success rates and clinical efficiency were not significant. However, the EUS-BD subgroup showed superiority in several aspects, including the number of punctures, blood routine, liver function, myocardial function, and complications, when compared with the

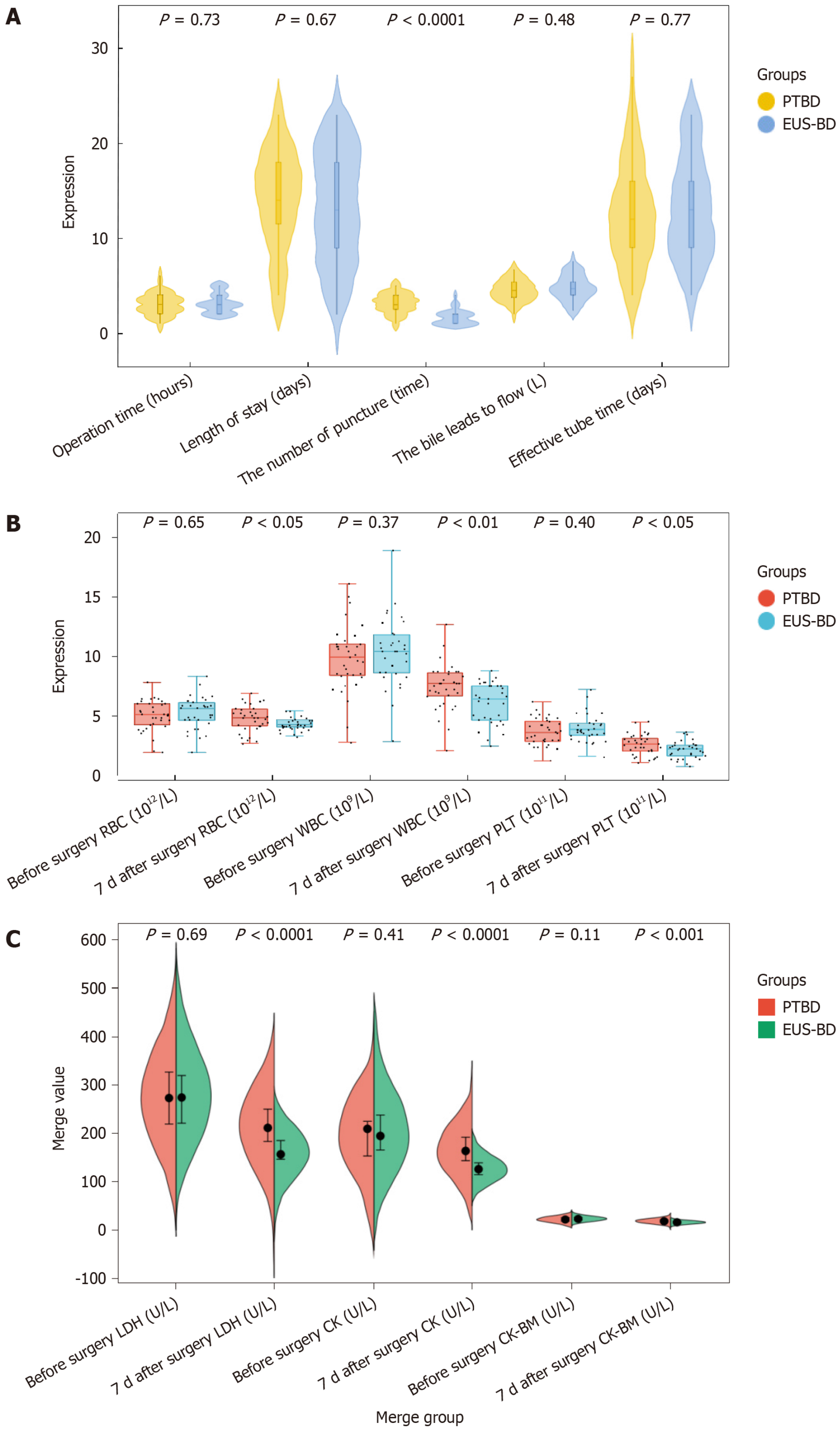

Figure 1 Comparison of procedure-related measures, routine blood parameters, and myocardial function measures between the endoscopic ultrasound-guided biliary drainage and percutaneous transhepatic puncture biliary drainage groups. A: Comparison of procedure-related measures between the endoscopic ultrasound-guided biliary drainage (EUS-BD) and percutaneous transhepatic puncture biliary drainage (PTBD) groups; B: Comparison of routine blood parameters between the EUS-BD and PTDB groups; C: Comparison of myocardial function measures between the EUS-BD and PTDB groups. EUS-BD: Endoscopic ultrasound-guided biliary drainage; PTBD: Percutaneous transhepatic puncture biliary drainage; RBC: Red blood cells; WBC: White blood cells; PLT: Platelets; LDH: Lactate dehydrogenase; CK: Creatine kinase; CK-MB: Creatine kinase isoenzyme.

Table 4 Comparison of postoperative complications between the two subgroups, *n* (%)

Complication	EUS-BD (*n* = 33)	PTBD (*n* = 35)	χ^2	*P* value
Biliary fistula	1 (3.03)	2 (5.71)		
Cholangitis	0 (0.00)	2 (5.71)		
Bile tube bleeding	0 (0.00)	1 (2.86)		
Pneumoperitoneum	0 (0.00)	1 (2.86)		
Stent blockage	1 (3.03)	3 (8.57)		
Stent displacement	0 (0.00)	1 (2.86)		
Mucosal laceration	1 (3.03)	0 (0.00)		
Total	3 (9.09)	10 (28.57)	4.169	0.041

EUS-BD: Endoscopic ultrasound-guided biliary drainage; PTBD: Percutaneous transhepatic puncture biliary drainage.

PTBD subgroup. Consequently, it can be concluded that EUS-BD offers an effective therapeutic approach for patients with MOJ. Compared with PTBD, EUS-BD presents advantages such as reduced puncture frequency, improved liver and myocardial functions, alleviated traumatic stress, and fewer complications.

FOOTNOTES

Author contributions: Zhu QQ conceptualized and conducted the research, authored the manuscript, and performed data analysis; Chen BF and Yang Y conducted literature review and provided research guidance; Zuo XY and Liu WH were responsible for data collection; Wang TT contributed to formal analysis and data visualization; Zhang Y offered research advice and oversaw the report preparation.

Institutional review board statement: This study was reviewed and approved by the Ethics Committee of The Third Affiliated Hospital of Soochow University (The First People's Hospital of Changzhou).

Informed consent statement: An exemption from informed consent was requested and obtained from the Ethics Committee.

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