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Staged Biliary Reconstruction After Orthotopic Liver Transplantation: A Practical Surgical Strategy for High-Acuity Adult Recipients

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Background. Biliary complications (BC) following orthotopic liver transplantation (OLT) is strongly associated with inferior patient outcomes and increased healthcare cost. BC in high-acuity patients can be lethal. While the utility of staged biliary reconstruction after liver transplantation (SBRALT) has been reported in adult and pediatric OLT, biliary outcome data are scarce. We sought to evaluate the clinical utility and outcomes of SBRALT in high-acuity transplant recipients. **Methods.** We conducted an analysis from our prospective database of 149 adult OLT between January 1, 2012, and September 30, 2017. Mean follow-up was 26 months. Variables were compared for Group I: one-stage OLT with biliary reconstruction (N = 58) versus Group II: SBRALT (N = 91). **Results.** Compared with Group I, patients in Group II had higher acuity of illness: median model for end-stage liver disease scores (19 vs 35 $P = 0.002$), requirement for pretransplant intensive care unit (29.3% vs 54.9%, $P = 0.022$), pretransplant renal replacement therapy (15.5% vs 48.4%), estimated blood loss (2000 vs 4750 mL, $P < 0.001$), and intraoperative packed red blood cells transfusion (4 vs 10 units, $P < 0.001$). For Group II, biliary reconstruction was performed between 1 and 6 days after OLT. Hepaticojejunostomy was performed in 8.6% (Group I) and 26.4% (Group II), $P = 0.010$. For Groups I and II, BC rates (8.6% vs 7.7%, $P = 0.955$) and 1-year graft failure-free survival rates (89.7% vs 88.2%, $P = 0.845$) were comparable. **Conclusions.** Graft failure-free survival and biliary outcomes of SBRALT in high-acuity recipients are excellent and comparable to one-stage OLT for low-risk patients. SBRALT is a practical surgical strategy in complex OLT.

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INTRODUCTION

Biliary complications (BC) following orthotopic liver transplantation (OLT), with an incidence of 10%–45%, is strongly associated with inferior patient outcomes and increased healthcare cost.[1-3] Even in the most ideal circumstances defined as benchmark OLT in low-risk patients (median model for end-stage liver disease [MELD] score of 12) utilizing excellent quality hepatic allografts, Clavien et al[4] reported a 6-month BC rate of 20%. For patients with the highest acuity, the risk of BC after OLT, such as leaks and strictures, is particularly significant due to their significantly reduced physiologic reserve. Such complications in these patient populations could be lethal.[5] As such, the surgical approach to OLT for high-acuity recipient patients warrants a strategy that would provide the optimal operative timing and condition to minimize the risk of BC.

A damage control strategy in critically ill surgical patients, as employed in trauma settings, has been adapted in complex OLT.[6] In contrast to the conventional single-stage OLT where the biliary reconstruction is performed at the time of OLT, the 2-stage OLT provides a period of resuscitation of the patient in

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the intensive care unit after liver graft revascularization prior to a second procedure of biliary reconstruction, staged biliary reconstruction after liver transplantation (SBRALT).[6,7] In high-acuity patients undergoing OLT, SBRALT offers the benefit of performing the biliary reconstruction under a more favorable hemodynamic state and operative milieu. While the utility of a 2-stage OLT with delayed biliary reconstruction has been reported in adult and pediatric OLT, biliary outcome data are scarce.[6,7] We sought to analyze the clinical utility and outcomes of SBRALT in high-acuity adult transplant recipients.

MATERIALS AND METHODS

Data Collection

Using a prospectively collected transplantation database, we conducted a retrospective review of all patients ≥18 years of age who underwent OLT at the Froedtert & The Medical College of Wisconsin Transplantation Center from January 1, 2012, to September 30, 2017. The median posttransplant follow-up duration was 26 months. The Medical College of Wisconsin Institutional Review Board approved the study.

Patient, Donor, and Operative Variables

All patients with end-stage liver disease were evaluated for OLT by a multidisciplinary team. The current MELD system was utilized for patient waitlist prioritization and organ allocation.[8] Variables collected for analysis included for both patients and donors: age, ethnicity, gender, history of diabetes mellitus, and body mass index; for recipients, indication for OLT, number of prior OLT, MELD score or United Network for Organ Sharing status 1 category at time of OLT, presence of severe portal hypertension (defined as refractory ascites and variceal hemorrhage requiring placement of transjugular intrahepatic portosystemic shunt),[9,10] the need for pretransplant hospitalization, pretransplant intensive care unit (ICU) management including ventilator and vasopressor support, and pre and intraoperative continuous renal replacement therapy (CRRT); and for donors, length of hospitalization before donation, cause of death, need for vasopressors prior to donation, and deceased donor liver graft type (whole organ vs partial/split graft).

Operative variables included in the analysis were type and timing of biliary reconstruction (one stage vs SBRALT), graft cold and warm ischemia times, the intraoperative body temperature and acid-base status of the patient, presence of intraabdominal adhesions, visceral edema or bowel distention, the need for venovenous bypass, and requirement for blood transfusion, as well as the incidence of postperfusion syndrome. Posttransplant variables analyzed were post-OLT ICU and hospital length of stay, the need for CRRT, serum blood chemistry, and laboratory tests.

Timing and Technique of Biliary Reconstruction

The surgical procedure for OLT was performed in the standard manner, with replacement of the recipient inferior vena cava in most cases.[11] A one-stage OLT with biliary anastomosis at the same time of transplantation was initially intended for all patients. SBRALT was instituted for patients who exhibited the following after hepatic graft reperfusion prior to biliary reconstruction: hemodynamic instability requiring high doses of vasopressive agents, severe coagulopathy requiring massive transfusion of blood products, metabolic acidosis, hypothermia, the additional need for an extensive lysis of intraabdominal adhesions, and significant visceral edema and bowel distention.

Prior to abdominal wall closure, a hepatic graft cholecystectomy was performed and a biliary catheter was inserted into the hepatic graft bile duct and secured with 6–0 polypropylene (Prolene) suture. The biliary catheter was externalized and secured to the skin. The cut-end of the native (recipient) bile duct was ligated with a 2–0 silk suture.[7]

The second stage of biliary reconstruction, either choledochocholedochostomy (duct-to-duct) or hepaticojejunostomy, was performed between 1 and 6 days after OLT once the patient has achieved hemodynamic stability, improvement of hepatic graft function, and reduction or resolution of visceral edema or bowel distention. The choledochocholedochostomy was accomplished with interrupted stiches using monofilament absorbable sutures. In cases of size mismatch between the native and donor bile ducts, ductoplasty was performed. For the biliary anastomosis, the posterior bile duct wall stitches were placed prior to those for the anterior wall and all the sutured knots were tied extraluminally. T-tube was utilized selectively. For patients with T-tube, a T-tube cholangiography was performed 5 days after biliary reconstruction and capped if cholangiogram demonstrated normal findings and the serum total bilirubin level had decreased to <5 mg/dL. At 3 months after OLT, a follow-up T-tube cholangiography was performed at the radiology suite. If the cholangiogram showed normal findings, the T-tube was removed and an intraabdominal drain was placed via the same T-tube track. The tip of the intraabdominal drain was placed adjacent (extraluminal) to the exit site of the T-tube from the native bile duct. The intraabdominal drain was connected to an extracorporeal bag. The purpose of this intraabdominal drain was to remove any bile leak from the previous exit site of the T-tube immediately after T-tube removal. This drain is withdrawn at the bedside for an approximately 1–2 cm every 2 hours until it is completely removed.

For the hepaticojejunostomy, the biliary anastomosis was also accomplished with interrupted stitches using monofilament absorbable sutures. A short internal biliary anastomotic stent was placed and secured with a monofilament absorbable suture. After degradation and absorption of the absorbable anchor suture, the short internal biliary stent spontaneously dislodged and passed through the gastrointestinal tract.

Outcomes Measures

The primary end point was 1-year graft failure-free survival. Graft failure was defined as either the need for retransplantation or death due to primary graft nonfunction or biliary complication. Secondary outcome measures focused on BC after OLT, defined as either biliary anastomotic leak or stricture. In addition, the Clavien-Dindo Classification of Surgical Complication was utilized to grade the severity of BC.[12]

Statistical Analysis

Patient and graft failure-free survival curves were computed using Kaplan-Meier methods and compared using log rank tests. Medians with interquartile ranges of continuous variables and means were compared using the Wilcoxon tests and proportions using the chi-squared test. Cox proportional hazard was used for univariate and multivariate analyses. A *P*

value of <0.05 was considered significant in the multivariate analysis. Statistical analysis was performed using SAS software, version 9.1 (SAS Institute).

RESULTS

Transplant Recipient Characteristics

Among the 149 OLTs performed, 58 (39%) recipients underwent a single-stage OLT procedure (Group 1) and 91 (61%) underwent SBRALT (Group II). Table 1 compares the recipient characteristics between the 2 groups. Regarding indication for OLT, hepatic malignancy or chronic hepatitis C infection was more common in Group I (43.1%) compared with Group II (24.2%), $P = 0.016$. Compared with Group I, patients in Group II have a significantly higher acuity of illness (median laboratory MELD score of 19 vs 34.5, $P = 0.002$), required pretransplant hospitalization (37.9 vs 59.3%, $P = 0.001$), intensive care management (29.3 vs 54.9%, $P = 0.002$), and pre-OLT renal replacement therapy (15.5% vs 48.4%, $P < 0.001$). Moreover, a higher proportion of patients in Group II have pretransplant comorbidities, such as systemic hypertension (17.2% vs 36.3%, $P = 0.012$), chronic kidney disease (13.8% vs 37.4%, $P = 0.002$), and severe portal hypertension (1.7% vs 12.1%, $P < 0.001$).

Deceased Donor Characteristics

Table 2 shows the deceased donor characteristics. All patients received deceased donor hepatic grafts. For both groups, majority of the liver grafts utilized (95%) were from donation after brain dead donors. The proportion of liver grafts procured after circulatory death (donation after circulatory death) were also similar for Group I (5.2%) and Group II (4.4%), $P = 0.823$. While the median donor age in years (interquartile range, IQR) in Group I was significantly older than in Group II, 43 (24–54) versus 32 (23–44), $P = 0.015$, all other variables such as cause of donor death and preprocurement liver function were comparable (Table 2).

Operative Variables During OLT and Biliary Reconstruction Phases

A comparison of the operative variables during OLT and biliary reconstruction are shown in Tables 3 and 4, respectively. The median graft cold ischemia time (330 vs 340 min) and warm ischemia time (42 vs 41 min) in Groups I and II, respectively, were similar. A higher proportion of patients in Group II required intraoperative renal replacement therapy and venovenous bypass.

Table 4 compares the operative variables during biliary reconstruction. Compared with Group I, the patients in Group II had significantly better acid-base balance (base excess –0.1 vs –2.55, $P < 0.001$) and required less vasopressive agents during this operative phase. While Group II received a significantly higher volume of blood product transfusion during the OLT phase (Table 3), the amount of blood products required during biliary reconstruction was significantly less compared with those in Group I (Table 4).

The median days for SBRALT in Group II was 2 days (Table 4). Compared with Group I, hepaticojejunostomy was more frequently performed in Group II, 8.6% versus 26.4%, $P = 0.010$. Table 5 shows the indications for hepaticojejunostomy. While the needs for native bile duct resection at the time of OLT (for primary sclerosing cholangitis and hilar cholangiocarcinoma) and prior hepaticojejunostomy for other procedures (pancreaticoduodenectomy, choledochal cyst resection, hepatoportoenterostomy/Kasai procedure) were the common reasons for hepaticojejunostomy in Group I, native duct unsuitability due to prior OLT, bile duct stricture, or intraabdominal adhesions was the most common indication in Group II. No patient required hepaticojejunostomy due to retraction of native bile duct during the interval between OLT and SBRALT.

Posttransplant Outcomes

Compared with Group I, Group II had longer hospitalization after OLT (26.2 vs 45.7 days, $P < 0.001$), mean ICU

TABLE 1.

Pretransplant recipient characteristics

Characteristics	Group I (n = 58)	Group II (n = 91)	*P*
Age, median, y (IQR)	56 (50–61)	58 (49–63)	0.430
Gender, male, No. (%)	34 (58.6)	63 (69.2)	0.185
Diagnosis, No. (%)			
Malignancy/hepatitis C infection	25 (43.1)	22 (24.2)	0.016
Alcoholic liver disease	9 (15.5)	30 (32.9)	0.018
Nonalcoholic liver disease	4 (6.9)	4 (4.4)	0.511
PSC/PBC	5 (8.6)	10 (10.9)	0.226
Acute liver failure	8 (13.8)	5 (5.5)	0.081
Diabetes, No. (%)	19 (32.8)	38 (41.8)	0.270
Coronary artery disease, No. (%)	5 (8.6)	14 (15.4)	0.227
Systemic hypertension, No. (%)	10 (17.2)	33 (36.3)	0.012
Chronic kidney disease, No. (%)	8 (13.8)	34 (37.4)	0.002
Severe portal hypertension, No. (%)	1 (1.7)	11 (12.1)	<0.001
MELD Score (laboratory), Median (IQR)	19 (10–34)	35 (16–41)	0.002
Pre-OLT hospitalization, No. (%)	22 (37.9)	54 (59.3)	0.001
Pre-OLT ICU stay, No. (%)	17 (29.3)	50 (54.9)	0.002
Pre-OLT mechanical ventilation, No. (%)	8 (13.8)	24 (26.6)	0.065
Pre-OLT hemodialysis, No (%)	9 (15.5)	44 (48.4)	<0.001
Pre-OLT ≥ 2 vasopressors, No. (%)	2 (3.4)	6 (6.7)	0.392

ICU, intensive care unit; IQR, interquartile range; MELD, model for end-stage liver disease; OLT, orthotopic liver transplantation; PBC, primary biliary cirrhosis; PSC, primary sclerosing cholangitis.

TABLE 2.

Deceased donor characteristics

Characteristics	Group I (n = 58)	Group II (n = 91)	*P*
Age, median, y (IQR)	43 (24–54)	32 (23–44)	0.015
Gender, male, No. (%)	34 (58.6)	47 (51.6)	0.500
Donor type, DCD (%)	3 (5.2)	4 (4.4)	1.000
Cause of death (%)			
Cerebrovascular accident	21 (48.8)	24 (32.9)	0.091
Trauma	10 (23.2)	23 (31.5)	0.341
Anoxia/asphyxia	8 (18.6)	17 (23.4)	0.554
Preprocurement laboratory tests			
ALT, unit/L	78.6	46.3	0.061
AST, unit/L	53.5	35	0.071
Total bilirubin, mg/dL	1.5	0.8	0.252

ALT, alanine aminotransferase; AST, aspartate aminotransferase; DCD, donation after circulatory death; IQR, interquartile range.

TABLE 3.

Comparison of operative variables during OLT by group

Factors	Group I (n = 58)	Group II (n = 91)	*P*
Graft cold ischemia time, min, median (IQR)	330 (278–382)	340 (295–418)	0.234
Graft warm ischemia time, min, median (IQR)	42 (36–44)	41 (37–47)	0.952
Venovenous bypass, No. (%)	21 (36.2)	60 (65.9)	<0.001
Intraoperative CRRT, No. (%)	9 (15.9)	44 (48.4)	<0.001
Estimated blood loss, mL, median (IQR)	2000 (1000–3250)	4750 (2250–6500)	<0.001
Blood transfusion requirement during OLT			
pRBC, units, median (IQR)	4 (2–9)	10 (5–23)	<0.001
FFP, units, median (IQR)	6 (2–9)	8 (2–18)	0.069
Cryoprecipitate, units, median (IQR)	0 (0–2)	4 (0–10)	0.006
Operative time, min, median (IQR)	347 (302–420)	372 (290–485)	0.329

CRRT, continuous renal replacement therapy; FFP, fresh frozen plasma; IQR, interquartile range; OLT, orthotopic liver transplantation; pRBC, packed red blood cells.

TABLE 4.

Comparison of operative variables during biliary reconstruction by group

Factors	Group I (n = 58)	Group II (n = 91)	*P*
Interval between OLT and BR, median (IQR), days	0 (0)	2 (2–3)	<0.001
Type of biliary reconstruction, No. (%)			
CC	53 (91.4)	68 (74.7)	0.011
RYHJ	5 (8.6)	24 (26.4)	0.010
Blood Base excess, median (IQR)	−2.55 (−3.82 to 0.45)	−0.1 (−1.77 to 1.27)	<0.001
Pts requiring vasopressors at time of BR, No. (%)	18 (36)	25 (28)	0.305
Pts requiring ≥2 vasopressors, No. (%)	11 (21.1)	7 (8)	0.026
Estimated blood loss, median (IQR), mL	750 (250–1500)	200 (150–475)	<0.001
Blood transfusion requirement during BR			
pRBC, units, median (IQR)	2 (0–4)	0 (0–1)	<0.001
FFP, units, median (IQR)	2 (0–4)	0 (0–0)	<0.001
Cryoprecipitate, units, median (IQR)	0 (0–0)	0 (0–0)	0.05
Platelets, units, median (IQR)	0 (0–11)	0 (0–1)	<0.001

BR, biliary reconstruction; CC, choledochocholedochostomy; FFP, fresh frozen plasma; IQR, interquartile range; OLT, orthotopic liver transplantation; pRBC, packed red blood cells; RYHJ, roux-en-y hepaticojejunostomy.

TABLE 5.

Indications for hepaticojejunostomy

Indications	Group I (n = 5)	Group II (n = 24)	*P*
Native bile duct unsuitability (%)	1 (20)	13 (54.2)	0.330
Need for bile duct resection at OLT	2 (40)	5 (20.8)	0.569
Prior hepaticojejunostomy	2 (40)	1 (4.2)	0.068
Conversion from choledochocholedochostomy	0	5 (20.8)	0.553

OLT, orthotopic liver transplantation.

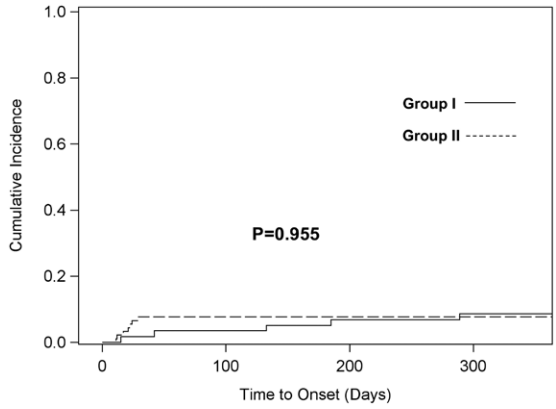

FIGURE 1. One-y cumulative incidence of biliary complications by group.

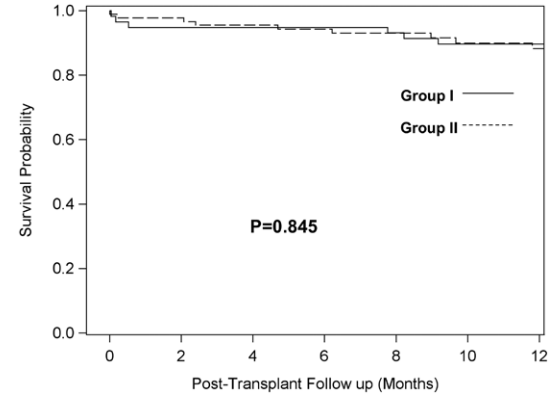

FIGURE 2. One-y patient graft failure-free survival after liver transplantation by group.

length of stay (7.5 vs 18.6 days, $P < 0.001$), mean number of days on the ventilator (3.3 vs 10.9, $P < 0.001$), and CRRT (1.07 vs 3.68, $P = 0.021$).

The overall incidence rate for BC was 8.1%. There was no difference in the incidence rate of BC between Group I (8.6%) and Group II (7.7%), $P = 0.955$. Figure 1 shows the 1-year cumulative incidence of BC by group. Table 6 compares the types of BC, times of onset of BC after biliary reconstruction, Clavien-Dindo Classification of Surgical Complications, and management of BC. Surgical intervention for BC was required in only 1 patient in Group I while it was necessary for all patients in Group II. Among these patients in Group II, 5 of 24 (20.8%) patients required conversion from choledocho-choledochostomy to hepaticojejunostomy (Table 5). For both groups, there was no graft failure or patient death due to BC.

The vascular complication rate was 3.4% (Group I) and 3.3% (Group II). The incidence of hepatic artery thrombosis was 3.4% in Group I and 1.1% in Group II. Although the acuity of illness was significantly higher in Group II, the 1-year graft failure-free survival rates were comparable for Group I (89.7%) and Group II (88.2%), $P = 0.845$ (Figure 2).

For Group II, 17 of 91 patients (18.7%) required additional planned re-laparotomy procedures for staged abdominal closure due to loss of abdominal domain secondary to visceral edema and bowel distention. Incidental unexpected intraoperative findings were noted in 30.8% of the cases: 23 (25.3%) patients were found to have intraabdominal blood clots and required evacuation, 4 (4.4%) with suboptimal hepatic arterial blood flow and underwent hepatic arterial modulation procedures (splenic artery ligation and release of median arcuate ligament), and 1 (1.1%) with segmental ischemic colon requiring partial colectomy.[13]

DISCUSSION

BC after OLT remain causes of significant patient morbidity and mortality, particularly in patients with the highest acuity of illness. While surgical refinements have resulted in improvement of outcomes, nontechnical risk factors also contribute substantially to the development of BC following OLT. These factors include compromised hepatic arterial flow, severe malnutrition, coagulopathy, use of high doses of steroids for immunosuppression, prolonged cold organ preservation duration, and immunological factors.[14-17] Furthermore, critically ill patients frequently exhibit hemodynamic instability, severe metabolic derangement, hypothermia, visceral edema, and bowel distention during OLT, rendering them at increased the risk for BC when biliary reconstruction is performed under these conditions.[6,18,19]

TABLE 6.

Comparison of biliary complication type, classification, and management

Patients	BC type	Time to BC (days)	Clavien-Dindo Classification	Management
Group I				
1	Leak	15	IIIa	ERCP/Stent
2	Stricture	42	IIIa	ERCP/Stent
3	Stricture	289	IIIa	ERCP/Stent
4	Leak	185	IIIa	ERCP/Stent
5	Leak	2	IIIb	Revision of CC with T-tube
Group II				
1	Leak	22	IIIb	Conversion to RYHJ
2	Leak	11	IIIb	Revision of CC with T-tube
3	Leak	24	IIIb	Conversion to RYHJ
4	Leak	21	IIIb	Conversion to RYHJ
5	Leak	12	IIIb	Revision of CC with T-tube
6	Leak	17	IIIb	Conversion to RYHJ
7	Leak	29	IIIb	Revision of RYHJ

BC, biliary complication; CC, choledochocholedochostomy; ERCP, endoscopic retrograde cholangio-pancreatography; RYHJ, roux-en-y hepaticojejunostomy.

The surgical approach to biliary reconstruction following OLT has evolved with regard to optimal timing and anatomic preference.[20] Despite a significant rise in patient acuity, comparable survival rates can be achieved.[21,22] Surgical strategies which may positively impact both short- and long-term outcomes include a damage control approach following hepatic graft reperfusion. Perihepatic packing and temporary abdominal closure with delayed biliary reconstruction have been employed with reasonable success during massive intraoperative bleeding.[6,23] Busuttil et al[6] from the University of California, LA, recently reported their experience with damage control in the setting of OLT. Interestingly, despite hemodynamic instability and ongoing hemorrhage, outcomes were comparable comparing the damage control recipients and those undergoing primary biliary reconstruction.

In the present study, recipients who underwent SBRALT had a significantly higher MELD score, concomitant coronary artery disease, severe portal hypertension, required a pretransplant ICU stay, and intraoperative renal replacement therapy. As such, it is not surprising that the SBRALT group required more blood products during the initial procedure. Cumulatively, these data suggest a benefit to delaying the biliary reconstruction as the need for vasopressors and blood products, as well as the degree of metabolic acidosis, were significantly reduced in the SBRALT cohort during the biliary reconstruction phase. Noteworthy is the relatively low rate of BC (7.7%) in our cohort despite high patient acuity (median MELD score of 35). While all BC in Group II required surgical intervention, 4 out of 7 cases (57%) were incidental subclinical findings during a planned re-laparotomy for staged abdominal closure. These subclinical bile leaks were most likely due to sequela of critical illness, such as persistent tissue edema, malnutrition, delayed wound healing, and hemodynamic swings during the immediate posttransplantation period. The classification of all BC was grade IIIa or IIIb and none of the graft failure or patient death was due to BC.

While these findings are encouraging, we acknowledge several limitations of this study. In general, the retrospective design and modest number of patients render drawing firm conclusions difficult. Furthermore, we recognize that the care for high-acuity patients with end-stage liver disease and those receiving OLT requires a multidisciplinary critical care management and that SBRALT as well as intraoperative renal replacement therapy during OLT are part of the surgical strategy to optimize outcomes in high-acuity liver transplant recipients.[18,24] As such, this specialized approach may contribute to, at least in part, the observed outcomes.

Based upon the findings in the present study, the risk of BC in complex OLT could be further reduced by utilizing a staged operative approach, SBRALT. We recommend an assessment of the patient's suitability to proceed with the traditional one-stage OLT after hepatic graft reperfusion. SBRALT should be considered for patients meeting the following criteria after hepatic graft reperfusion: hemodynamic instability requiring high doses of vasopressive agents, severe coagulopathy requiring massive transfusion of blood products, metabolic acidosis, hypothermia, need for additional lysis of intraabdominal adhesions, and significant visceral edema and bowel distention. Deferring the second operative stage (biliary reconstruction) allows for a brief period of patient resuscitation and stabilization as well as hepatic graft recovery from the inherent ischemia-reperfusion injury. This 2-stage OLT surgical approach provides an optimal milieu for biliary reconstruction, reducing the need for transfusion of blood products and hemodynamic support as well as minimizing the risk of BC in high-acuity transplant recipients.

In conclusion, biliary strictures and leaks are serious complications after OLT that decrease patient and graft survival. Avoidance of these complications is critical to the success of OLT and patient survival. Our study shows excellent outcomes of SBRALT in high-acuity transplant recipients and is an important surgical strategy in complex OLT.

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