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ORIGINAL ARTICLE

Percutaneous radiological biliary interventions after failed endoscopic treatment in living liver donors: experience of a high-volume transplantation center

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SUMMARY

This study aimed to evaluate the role of percutaneous radiological treatments for biliary complications (BCs) in donors after living donor liver transplantation (LDLT). We retrospectively evaluated BCs in donors involved in 1839 LDLTs between May 2009 and January 2019 at our centre. BCs were classified according to the modified Clavien–Dindo classification (MCDC). Patients treated with percutaneous transhepatic biliary intervention (PTBI) were identified. Complications requiring endoscopic, interventional or surgical treatment (MCDC grades III–IV) involved 123 (6.6%) donors. Complications comprised leakage, $n = 73$ (60%); stricture, $n = 36$ (29%); and both leakage and stricture, $n = 14$ (11%). Percutaneous drainage of biloma formations under ultrasound guidance was performed in 57 donors, endoscopic treatment in 83 and PTBI in 14. Of 83 patients who received endoscopic treatment, 13 were referred for PTBI due to failure or uncannulation. Eight of 14 patients were successfully treated with PTBI. Six patients were treated with a rendezvous procedure combining percutaneous and surgical treatments. In 13 patients, no BCs were developed after catheter or stent removal. In donors with BCs, the treatment should progress from the least invasive method to surgery. In some patients, percutaneous radiological treatments eliminate the need for surgery or can guide surgical treatment.

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Introduction

The rate of living donor liver transplantation (LDLT) in the treatment of end-stage liver disease in both adults and children has greatly increased in response to low rates of deceased donations. With this increase in LDLT, morbidity and mortality in donors has become a significant problem.

Although LDLT is potentially lifesaving for the recipient, it exposes a healthy individual to a major surgical procedure and associated risks without any therapeutic benefit [1]. In the previous studies, the prevalence of

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donor morbidity associated with LDLT was found to range from 0% to 67% [2–6], with the most recent study reporting a rate of 23.9 ± 13.9% [6].

The most common complications are bile leakage, incisional hernia and wound infection [6]. One study reported rates of 0–12.6% for bile leakage and 0–5.8% for stricture [7]. Untreated biliary complications (BCs) can cause sepsis, multi-organ failure and even death.

Bile leakage usually originates from the cut surface of the liver but can also be due to bile ducts draining the caudate lobe. Less common BCs include cholestasis and intraoperative bile duct injury [8–10].

Percutaneous drainage of biloma under ultrasound (US) guidance, endoscopic retrograde cholangiopancreatography (ERCP), percutaneous transhepatic biliary interventions (PTBI) and surgery have been applied to treat BCs in donors. This study aimed to evaluate the role of percutaneous radiological treatments for BCs in donors after LDLT to determine whether these patients could be effectively treated without undergoing a surgical procedure.

Materials and methods

Approval for this study was granted by the Institutional Ethics Committee of Inonu University (2019/5-23). Between May 2009 and January 2019, a total of 2101 liver transplantations were performed at the Liver Transplantation Institute of Inonu University, in Turkey. Of these, 262 were deceased donor liver transplantations, and 1839 were LDLTs, comprising 1494 right lobes and 345 left lobes. A retrospective examination of donor BCs in LDLT was conducted using data retrieved from the hospital information and imaging system.

BCs in donors were evaluated according to the modified Clavien–Dindo classification (MCDC, Table 1) [11]. In total, 123 donors who developed complications that required endoscopic, interventional or surgical treatment (MCDC grades III–IV) were included in the study. Demographic characteristics, BC diagnoses and treatments were examined. Patients treated with PTBI were examined in detail. Donors with grade I–II complications were excluded. No donor mortality (grade V) was observed.

When BCs were suspected, the US was the first choice for imaging method to evaluate the bile ducts and determine the collection. Computerized tomography (CT) and magnetic resonance cholangiopancreatography (MRCP) were used to evaluate bile ducts.

Hepatectomy procedure

Graft choice was determined based on the metabolic needs of recipients and the risks to donors. To prevent the small-for-size syndrome, the minimum graft size should be 30–35% of the recipient's standard liver volume or 0.6–0.8% of graft-to-recipient body weight ratio [12]. If the left lobe grafts (including segments 2–4) could provide the recipients with needed donations, then the left lobe hepatectomy was performed. If not, the right lobe (including segments 5–8) was used. After hilar dissection, bile duct division was performed.

Table 1. Modified Clavien-Dindo classification.

Degree	Definitions
I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
III	Requiring surgical, endoscopic or radiological intervention.
IIIa	Intervention not under general anaesthesia.
IIIb	Intervention under general anaesthesia.
IV	Life-threatening complication (including CNS complications)* requiring IC/ICU-management.
IVa	Single organ dysfunction (including dialysis).
IVb	Multi organ dysfunction.
V	Death of a patient.

Reference [11].

IC, Intermediate care; ICU, Intensive care unit; CNS, Central Nervous System.

*Brain haemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks (TIA).

During hepatectomy, either a right or left bile duct cut too close to the bifurcation can increase the risk of stenosis or leakage in the donor due to suture or granulation. Leakage may also develop from the biliary stump [13]. Another mechanism of bile leakage involves isolated bile ducts that are not associated with common bile ducts, and which can cause bile leakage from the cut surface [14]. To avoid such complications, it is important to evaluate the biliary anatomy pre- or perioperatively using imaging methods and intraoperative cholangiography [15,16].

Management of BCs

Three types of BCs were examined, namely, leakage, stricture, and both leakage and stricture. A diagnosis of biliary leakage was made through draining 100 ml of fluid with a total bilirubin level of >5 mg/ml or three times the serum level per day from the surgical drainage catheter. Diagnosis could also be made by determining the bile content in aspirate taken from the intra-abdominal fluid. Patients treated with a percutaneous biloma drainage catheter placed under the US guidance were identified as having minor leakage. When percutaneous biloma drainage treatment was not sufficient (major leakage), ERCP was performed to confirm the diagnosis and treatment.

If ERCP failed or was insufficient, PTBI was performed, and biliary drainage was provided with a catheter and/or stent. If severe leakage could not be treated using these methods, then surgical treatment was applied.

A diagnosis of biliary stricture was made based on the determination of bile duct stenosis with CT or MRCP in addition to abnormal liver function tests. During the treatment, balloon dilatation with ERCP or PTBI and/or biliary drainage was performed.

Percutaneous transhepatic biliary intervention

Following antibiotic prophylaxis, PTBI was performed under general anaesthesia or sedation, using a diluted contrast agent targeting the peripheral bile ducts with a needle under the US and fluoroscopic guidance. The bile ducts were catheterized. An attempt was then made to pass through the stricture and/or leakage using guidewires and various diagnostic catheters. When a stricture required dilatation, this was performed for at least one minute, two or three times, using balloons of various dimensions. Biliary drainage was performed by placing an internal-external biliary drainage catheter (IEBD, Skater catheters, Argon Medical Devices, Frisco, USA) or using an external biliary drainage catheter (EBD). If the PTBI procedure was not successful (i.e. bile ducts could not be filled with contrast or could not be catheterized, the catheter could not be placed or sufficient drainage could not be obtained despite catheter placement), such patients were referred to surgery as the final treatment step.

Rendezvous procedure

The rendezvous procedure uses two access routes to reach a point in the body via a combination of at least two surgical, endoscopic and percutaneous approaches. This procedure is generally preferred in the treatment of hepatobiliary dysfunctions such as bile leakage, stricture, bile duct injury or stones when ERCP or PTBI alone is insufficient [17,18]. Only a limited number of cases have been reported involving main bile duct or right posterior sector bile duct injuries and severe hilar strictures having been treated using a rendezvous procedure [18]. In this study, the rendezvous procedure was combined with PTBI, and surgery was indicated for these patients when percutaneous treatment alone was insufficient.

Follow-up

The technical success of the PTBI procedure was defined as the successful placement of a drainage catheter into the bile ducts. Clinical success was defined as normalization of the liver function tests and clinical recovery.

After the PTBI procedure, the liver function tests were performed daily during the hospital stay. Following the hospital discharge, liver function tests were performed monthly during the first three months of follow-up. We routinely exchanged the catheters, if they had not been removed after a 6–8-week period, to avoid cholangitis or plugging.

After clinical recovery and with normal liver function tests following the balloon dilatation and biliary drainage, custom-made (C-M) plastic biliary stents obtained from IEBD catheters were placed so the distal end would extend from the papilla for stronger and persistent remodelling of the stricture. If a C-M stent was placed, the stent was removed or exchanged with ERCP after three months. If the C-M stent was not placed and the patient was not operated on, biliary catheters were removed after the clinical recovery.

The frequency of follow-up visits was adjusted according to the patient's symptoms such as jaundice,

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itching or nausea on completion of all treatment. We followed all patients from the first PTBI to January 2020 at our liver transplantation outpatient clinic.

Descriptive statistics related to age, sex, BC type, and treatment methods were collected and are presented as numbers (n) and percentages.

Results

In the evaluation of 1839 LDLT cases, the rate of BCs requiring endoscopic, interventional or surgical treatment was 6.6% (n = 123). These 123 patients comprised of 81 (66%) men and 42 (34%) women (mean age, 30.3 [range, 18–62] years). Leakage was determined in 73 (60%) donors, stricture in 36 (29%) and leakage and stricture in 14 (11%, Fig. 1), comprising 104 patients who donated right lobes and 19 patients who donated left lobes.

Percutaneous biloma drainage under US guidance was performed for 57 patients. No additional therapy was required for 39 donors who were considered to have only minor bile leakage. Eighteen patients who did not respond to drainage treatment were considered to have major bile leakage and were referred for ERCP, which was performed in 83 patients, of whom 70 (84%) were treated endoscopically.

Fourteen patients received PTBI (12 donors and two aborted donors). Eleven patients were referred for PTBI due to failure or insufficient biliary drainage during the ERCP procedure. Two patients underwent PTBI because the common bile duct could not be cannulated during ERCP. PTBI was applied to the remaining patient without ERCP, who had undergone hepaticojejunostomy (H-J) anastomosis because of peritonitis. The mean age of these 14 patients was 28 years (women, 50%). The median time to diagnosis of a BC after hepatectomy

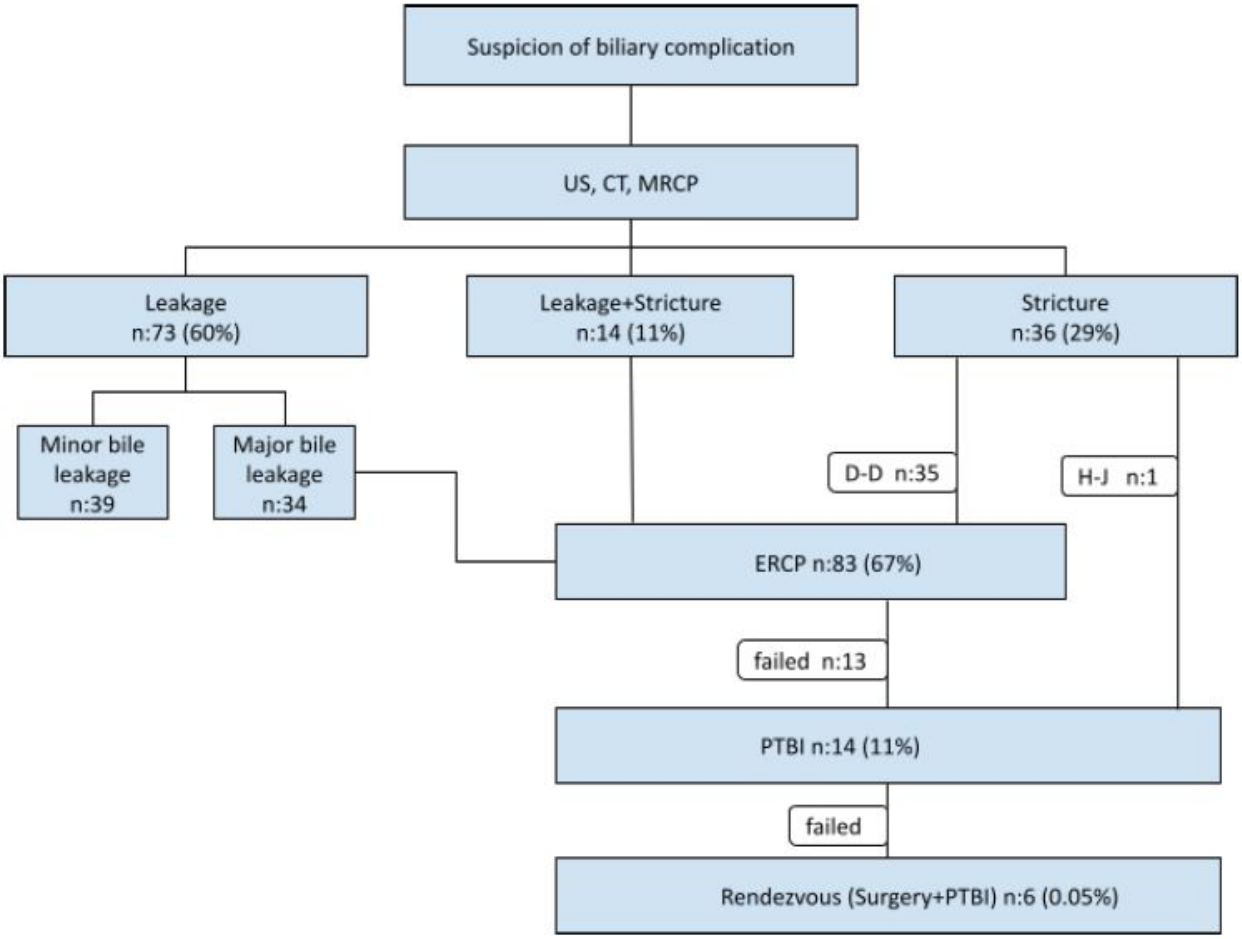

Figure 1 Algorithm of management of biliary complications in living liver donors in our centre. US, ultrasound; CT, computed tomography; MRCP, magnetic resonance cholangiopancreatography; D-D, duct-to-duct anastomosis; H-J, hepaticojejunostomy; ERCP, endoscopic retrograde cholangiopancreatography; PTBI, percutaneous biliary interventions.

was 12.5 (range, 1–30) days. Prior to the PTBI procedures, the mean alkaline phosphatase level in these 14 patients was 216 (range, 58–432) U/L, the gamma-glutamyl transferase level was 271 (range, 23–595) U/L and the total bilirubin level was 2.5 (range, 0.38–7.31) mg/dl. ERCP and PTBI were performed for a median of 17 (range, 2–45) days and 33 (range, 10–78) days post-hepatectomy, respectively. Stricture, leakage and both leakage and stricture were determined in eight, three and three patients, respectively. Balloon dilatation was performed in six patients whose strictures could be passed through (Fig. 2). Biliary drainage with IEBD or EBD catheters was provided for all patients (Fig. 3). The technical success rate of PTBI was 100%. The clinical success rate of PTBI alone was 57%, which increased to 93% when combined with the rendezvous procedure. The median follow-up time with the catheter after PTBI was 22 (range, 5–94) days.

C-M plastic biliary stents were placed in three patients, who were followed for three months for stronger and persistent remodelling of the stricture. All the C-M stent removals were performed endoscopically.

The rendezvous procedure combining percutaneous and surgical treatments was applied in six patients. Of these, two patients underwent H-J anastomosis with the guidance of a previously placed percutaneous EBD catheter. In four patients, H-J anastomosis was performed by interventional radiologists intraoperatively passing through the occluded bile duct with the back end of the guidewire within the existing EBD catheter (Fig. 4).

All 14 patients were followed up without any catheter or stent for a median of 41 (range, 5–123) months. In 13 patients, no BCs developed after catheter or stent removal. In only one patient with H-J anastomosis, and after 45 months of clinical recovery, anastomotic stricture and bile duct dilatation were detected and this patient was referred to the PTBI. After balloon dilatation and IEBD catheter insertion, the patient was followed up for eight months without a catheter.

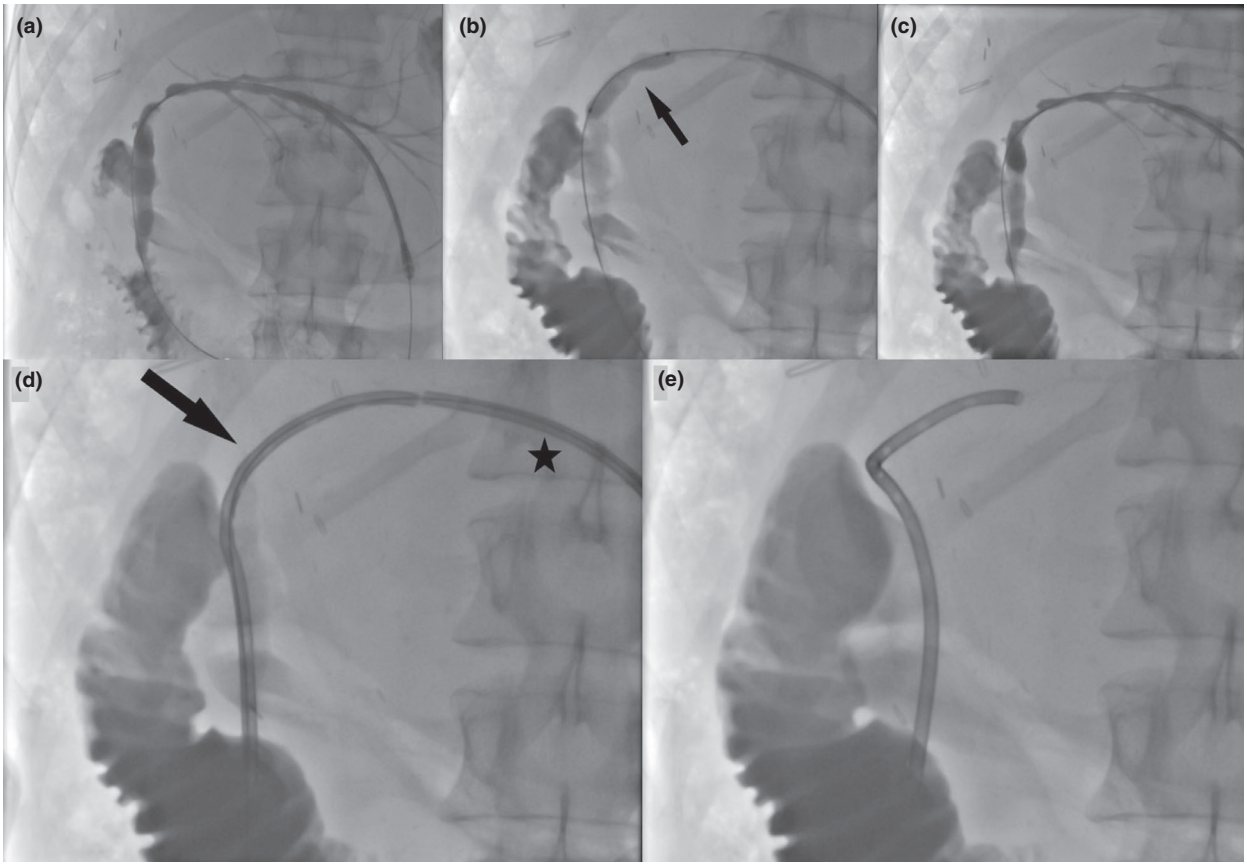

Figure 2 (a) A cholangiogram of a 32-year-old male donor shows stricture of the common bile duct. (b) The stricture was passed through and balloon dilatation (arrow) was applied. (c) Despite to the repeated balloon dilatations, tight stricture persisted. (d, e) A custom-made plastic biliary stent (arrow), obtained from an 8F IEBD catheter, was placed using a pusher (star) for stronger remodelling.

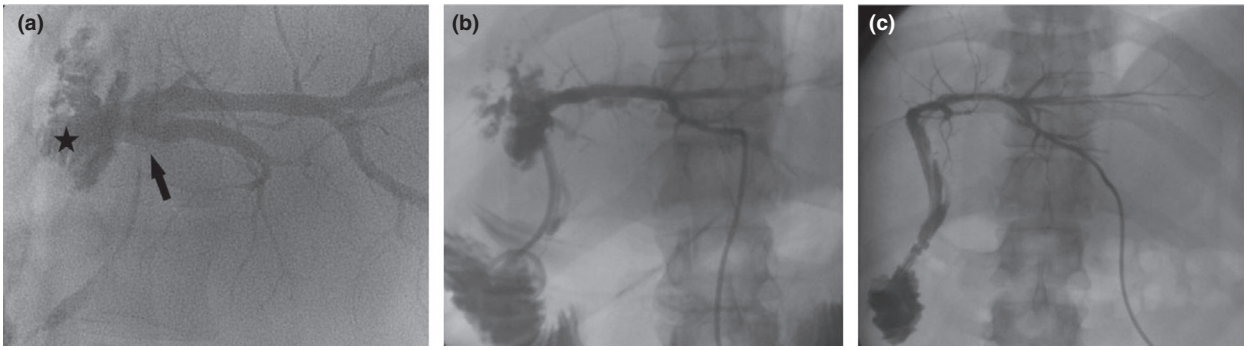

Figure 3 (a) Cholangiogram of 26 years old male donor shows dilatation of intrahepatic bile ducts due to the stricture in common bile duct (arrow) and bile leakage to the cut surface of liver (star). (b) An IEBD catheter was placed extending from peripheral bile ducts to the common bile duct and duodenum. (c) In control cholangiogram after 2 months, no biliary leakage is seen.

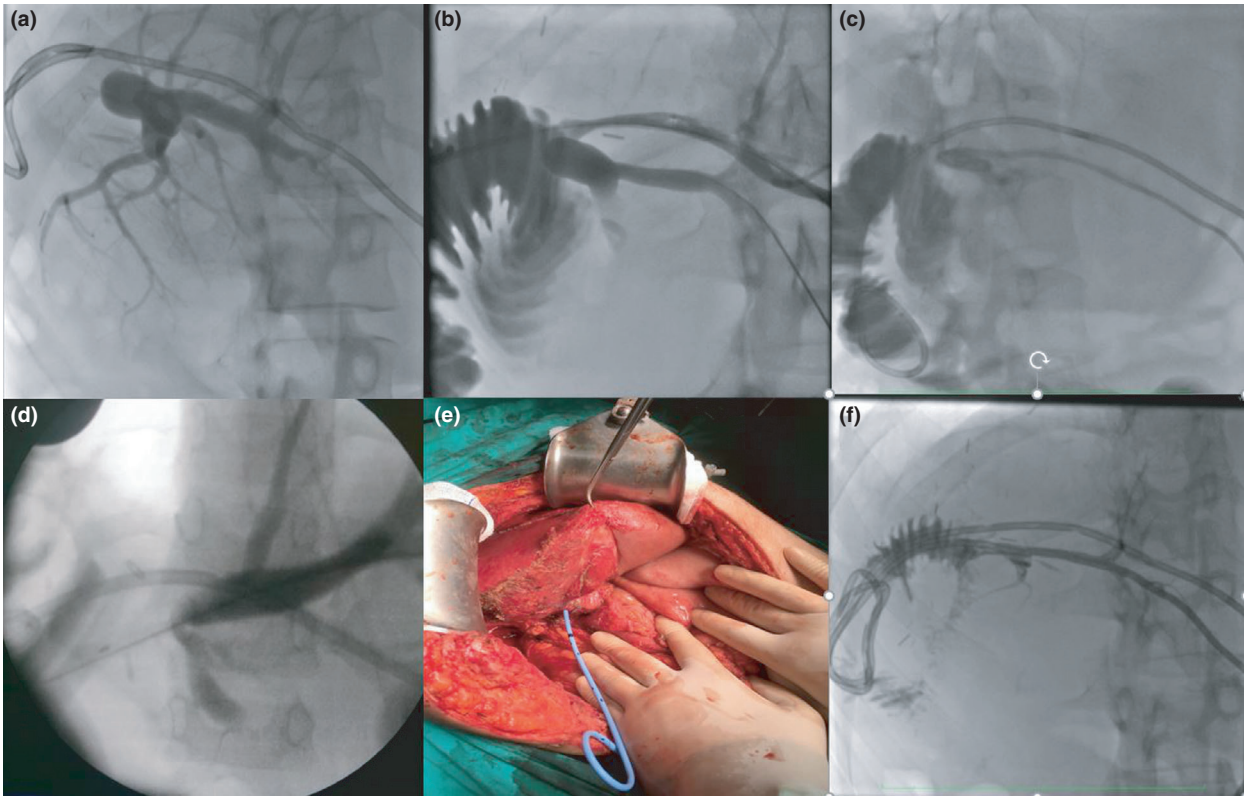

Figure 4 (a, b) A cholangiogram of a 28-year-old female donor shows an IEBD catheter extending from segment 2 bile ducts to the jejunum, which had been placed previously, and dilatation of segment 3 bile ducts with no passage to the intestines. (c) An EBD catheter was placed into segment 3 bile ducts proximal to the occlusion. (d) The occluded segment was passed intraoperatively after passing the occlusion with the back end of the guidewire through a previously placed EBD catheter. (d, e) The catheter was exchanged with an IEBD catheter. (f) H-J anastomosis was then performed. The control cholangiogram shows an intraoperatively placed IEBD catheter, resolution of the biliary dilatation and patency of the H-J anastomosis.

The demographic characteristics and BC types of the patients that could not be managed endoscopically are shown in Table 2. Reasons for the failure of endoscopic treatments and the percutaneous radiological procedures applied to these donors to avoid or guide the surgery and follow-up time with and without any catheters or stents are also shown in Table 2.

Table 2. Descriptive characteristics of patients who were applied PTBI.

	Age/ gender	Hepatectomy lobe	Time to Diagnosis of BC (day)	Time to ERCP (day)	Time to PTBI (day)	Indication of PTBI	Diagnosis	Procedure applied in PTBI	Follow up with catheter (day)	Follow up with no catheter or stent (month)
1	32/M	Right	30	45	47	Leakage region could not be passed in ERCP	L	EBD Catheter + Rendezvous	20	12
2	36/M	Left	10	12	42	Stricture could not be passed in ERCP	L + S	IEBD Catheter + C-M Stent	24	6
3	35/F	Right	13	19	27	Stricture could not be passed in ERCP	S	BD+ IEBD Catheter + C-M Stent	12	5
4	27/F	Abort	12	14	74	Right lobe intrahepatic bile ducts could not be catheterized	L	EBD Catheter + Rendezvous	6	24
5	28/F	Right	13	16	25	Common bile duct could not be cannulated	S	EBD Catheter + Rendezvous	5	36
6	22/M	Left	10	-	78	H-J anastomosis stricture which was performed due to peritonitis before	S	BD + IEBD Catheter	60	32
7	32/F	Abort	12	23	29	Leakage region could not be passed in ERCP	L	IEBD CATHETER + C-M Stent	9	37
8	29/F	Right	1	2	10	Insufficient biliary drainage in ERCP	S	BD+ EBD Catheter + Rendezvous	17	45
9	26/M	Right	9	17	21	Stricture could not be passed in ERCP	L + S	IEBD Catheter	58	90
10	28/M	Right	13	15	25	Stricture could not be passed in ERCP	S	BD + IEBD Catheter	15	91
11	23/M	Right	12	17	46	Insufficient biliary drainage in ERCP	L + S	EBD Catheter + Rendezvous	94	103
12	18/F	Right	20	22	24	Stricture could not be passed in ERCP	S	BD + IEBD Catheter	29	98
13	35/M	Right	20	27	33	Common bile duct could not be cannulated	S	EBD Catheter + Rendezvous	44	110
14	51/F	Left	27	31	34	Stricture could not be passed in ERCP	S	BD + IEBD Catheter	62	123

M, male; F, female; BC, biliary complications; L, leakage; S, stricture; L + S, leakage + stricture; BD, balloon dilatation; C-M, custom-made; IEBD, internal-external biliary drainage; EBD, external biliary drainage; ERCP, endoscopic retrograde cholangiopancreatography; PTBI, percutaneous transhepatic biliary interventions; H-J, hepaticojejunostomy.

Discussion

While the number of patients with end-stage liver disease who are candidates for organ transplantation has increased, there has not been a corresponding increase in deceased organ donation to meet this need. Therefore, LDLT has become the primary method of liver donation at our institution. However, LDLT exposes a healthy individual to a wide range of potential mild to severe complications, including death. This study aimed to evaluate percutaneous biliary interventions, the results of such interventions, and the contributions of other treatment procedures applied to donors with BCs of MCDC grades III–IV following LDLT.

During the study period, 123 of 1839 LDLT donors developed grade III–IV BCs and were treated with percutaneous biloma drainage under US guidance, ERCP, PTBI and surgery.

While the living donor BC rate has been reported to range from 8% to 38% in recent studies [6,19–21], the complication rate in our study was found to be 6.6%. Data on PTBI after LDLT are limited. We applied PTBI in 14 patients. Our aim was to highlight that this less invasive treatment method could be used in preference to surgery and can be applied after ERCP failure.

To provide biliary drainage in patients who have received PTBI, we first placed an IEBD catheter to enable external flow (reducing both bile duct pressure and volume) and internal flow to the intestines through passing through the common bile duct and duodenum. In patients where the passage to the common bile duct and duodenum could not be provided secondary to the stricture, the placement of an EBD catheter was used to provide external flow only.

In a study of 337 right lobe donors, Woo *et al.* [19] reported that the rate of BCs was 15%. They applied percutaneous biloma drainage under US guidance for minor bile leakage. Sixteen patients (5 major leakages and 11 strictures) were referred for ERCP. Of these, two patients were treated with PTBI (failure of common bile duct cannulation, $n = 1$; insufficient biliary drainage, $n = 1$). Likewise, we first applied biloma drainage under the US guidance in 57 of 123 patients. For 39 (32%) patients, no additional treatment was required (minor bile leakage). Two patients with a drainage catheter who developed peritonitis and one patient with a diaphragm and jejunum injury due to the catheter were removed from the algorithm and treated surgically. ERCP was performed together with stent placement in addition to the drainage treatment in 17 patients. Like Woo *et al.*, we recommend percutaneous biloma drainage for patients with bile leakage as a first-step treatment. If there is no response to drainage (major bile leakage), more invasive methods can then be applied.

Shio *et al.* [20] examined 731 donors, 55 (8%) of whom experienced BCs, 24 were followed up conservatively, and 24 were treated endoscopically. The remaining 7 (13%) patients underwent surgery without PTBI. In contrast to Shio *et al.*'s study, 13 (10%) patients (failure or insufficient drainage, n = 11; uncannulation in ERCP, $n = 2$) were referred for less invasive PTBI instead of surgery in our study. Eight patients were treated with non-surgical methods. Surgical treatment was required for 6 (5%) patients. Furthermore, PTBI was used as a guide for surgery in combination with the rendezvous procedure. Shio *et al.* recommended the endoscopic approach as first-line therapy before surgery. However, as shown in our study, PTBI should be the next step following the failure of the endoscopic method. PTBI eliminates the need for surgery or can be used to guide the treatment in patients undergoing surgery.

In a study of 75 donors conducted by Gruttadauria *et al.* [21], bile leakage developed in 7 (9%) patients, all of whom were treated with interventional methods. Endoscopic treatment was successful in five patients. In the remaining two patients, the rendezvous procedure was performed with a combination of endoscopic and percutaneous biliary drainage. The rendezvous procedure has been defined as the combined application of surgical and interventional radiological treatments [22,23]. In our study, this method was applied in patients with severe stricture where bilioenteric anastomoses (such as H-J), endoscopic treatment at the anastomosis level, and the percutaneous transhepatic approach alone was insufficient. In the current study, four patients for whom the occluded segment could not be passed through were referred for PTBI. As the first stage of treatment, an EBD catheter was placed to provide biliary drainage, and the rendezvous procedure was then applied using a combination of percutaneous and surgical treatment. During the operation, the back end of the guidewire was advanced from within the previously placed EBD catheter, and after having determined the occluded bile duct, it was removed from the cut surface. By placing an IEBD catheter, a tract was formed to allow an H-J anastomosis to be performed. Although percutaneous radiological treatment alone was not sufficient in these patients, it played an important role in the treatment of BCs by guiding the surgeon. To our knowledge, no previous studies have reported using a

rendezvous procedure applied as a combined percutaneous radiological treatment and a surgical treatment in donors without previous bilioenteric anastomosis. Therefore, this is the first study to report this method, along with the successful outcomes for this patient population.

Cheah *et al.* [6] reported a 1.2% rate of aborted donors (where the donor candidate was admitted to the operating room but hepatectomy could not be completed). Hepatectomy could not be completed in these patients mainly due to unexpected vascular and biliary tree anomalies. In our study, one patient was identified as an aborted donor because the biliary anatomy was not suitable following the intraoperative cholangiography performed after cholecystectomy. However, as cholecystectomy had been completed, resulting in bile leakage from the cystic duct stump, this patient was treated with PTBI. In another patient, transplantation indications for the recipient changed during the operation; therefore, hepatectomy of the donor was not completed. However, dissection of the parenchyma and bile duct had been initiated and bile duct complications subsequently developed. As these examples show, in LDLT with correct indications, undesired complications can occur in healthy donors without the trade-off of any medical benefit.

Our study had some limitations. This study was retrospectively designed. The frequency of follow-up visits was adjusted according to the patient symptoms. Finally, single-centre data were used; therefore, the number of patients might be too low, and further analysis is recommended.

Conclusion

Although BCs in liver donors are uncommon, they have been reported following hepatectomy surgeries. Percutaneous drainage is an invasive first-step treatment for minor bile leakage. Due to the less-invasive nature of the procedure, ERCP is usually the first option for major bile leakage and stricture. However, especially in cases of ERCP failure, percutaneous biliary interventions are still required and are important treatment options available to help resolve pre- or perioperative issues. Close cooperation between related disciplines is essential for optimal treatment of BCs in otherwise healthy liver donors.

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Conflicts of interest

The authors declare that they have no conflict of interests.

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