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Original Article

Clinical Outcomes of Percutaneous Transhepatic Biliary Drainage in Pediatric Patients following Liver Transplantation

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ABSTRACT

Purpose: Cholestatic complications remain a primary cause of post-liver transplantation (LTX) morbidity in pediatric patients. Standard biliary access by endoscopic retrograde cholangioscopy may not be feasible due to modified biliary drainage. Percutaneous transhepatic biliary drainage (PTCD) may be performed alternatively. However, systematic data concerning safety and efficacy of PTCD in these patients are scarce.
Methods: In this retrospective study, procedural and safety characteristics of PTCD in pediatric patients following LTX were analyzed. We compared laboratory indicators of inflammation, cholestasis, and graft function before and at 6 and 12 months after the first PTCD insertion. Efficacy was analyzed by percentage of patients without cholangitis, need for surgical biliary re-intervention and re-transplantation during a follow-up period of 60 months.
Results: Over a decade, PTCD was attempted in a total of 15 patients, with technical success (93.3%) in 14 patients. Periprocedural complications, including bleeding (7.1%) and cholangitis (21.4%) were observed in patients. During follow-up, both MELD-score (baseline: 13 [8–15] vs. 12 months: 8 [7–8], $p<0.001$) and parameters of cholestasis (GGT: baseline: 286 [47–458] U/L vs. 12 months: 105 [26–147] U/L, $p=0.024$) decreased. Prior to PTCD, cholangitis (64.3%) and cholangiosepsis (21.4%) were common complications. In contrast, following PTCD, cholangitis occurred in only one patient (7.1%). Five patients (35.7%) needed surgical biliary re-intervention and two (14.3%) required re-transplantation.
Conclusion: PTCD in pediatric patients following LTX had an acceptable safety profile, demonstrating a biochemical improvement of both cholestasis and graft function and may prevent cholestatic complications, thus reducing the need for surgical re-intervention and re-transplantation.

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The authors have no financial conflicts of interest.

Keywords: Liver transplantation; Pediatrics; Percutaneous transhepatic biliary drainage; Cholestasis; Anastomotic stricture

INTRODUCTION

Cholestatic complications occur in approximately 11% of pediatric patients following liver transplantations (LTX) and remain a primary cause of post-LTX morbidity [1-6]. Biliary complications may be caused by stenosis of the bile duct anastomosis in surgically modified grafts (commonly known as biliodigestive anastomosis, BDA) or more diffuse strictures of the biliary tract such as ischemic type biliary lesions (ITBL) [3]. This may lead to cholangitis, cholangiosepsis, biliary fibrosis, and graft loss [1,2,4]. Notably, recent evidence suggests that subclinical biliary strictures are underdiagnosed and potentially associated with inferior graft survival in pediatric patients following LTX [7]. Thus, early intervention to enable improved biliary drainage is critical to prevent allograft dysfunction. However, biliary strictures can often not be resolved by standard biliary access using endoscopic retrograde cholangiography (ERC) due to modified biliary drainage using a Roux-en-Y intestinal loop during LTX [3,4,8]. Subsequently, dilating the stenosis via percutaneous transhepatic cholangiodrainage (PTCD) and accessing the small intestine is attempted to enable internal drainage. However, if the small intestine is inaccessible, an external PTCD may be performed instead; thereafter, bile is drained externally [4,8,9]. PTCD is a routine procedure in pediatric patients following LTX; however, studies on systematic data describing its usability and safety are limited [6,10-12].

Therefore, this retrospective single-center study aimed to describe the technique and clinical outcomes of PTCD on pediatric patients with cholestasis following LTX. Clinical data regarding preliminary efficiency (percentage of patients without cholangitis, need for surgical biliary re-intervention and re-transplantation during a follow-up period of 60 months), changes in laboratory indicators of inflammation, cholestasis, and graft function as well as safety and procedural characteristics of the intervention were analyzed.

MATERIALS AND METHODS

Screening and inclusion into the study

This retrospective single-center study investigated the clinical outcomes of PTCD (German OPS codes 5-514.G3 and 5-514.53) on 14 pediatric patients with cholestasis following LTX (International Classification of Disease 10th revision coding number 94.4). We included pediatric patients post-LTX receiving a PTCD at a tertiary care hospital between February 2013 and January 2023. A total of 1,158 patient cases were identified who underwent LTX. A PTCD was successfully placed in 14 out of 15 consecutive patients. A per-protocol analysis was performed. This study was performed in accordance with the principles of the Declaration of Helsinki 1964 and its later amendments. Informed consent was obtained from patients and/or legal representatives accordingly. The local institutional review board (Nr. 11131_BO_K_2023) approved the study protocol.

Transhepatic biliary drainage (PTCD)

PTCD was indicated when persisting cholestasis was present based on biochemical parameters and imaging by transabdominal sonography or magnetic resonance imaging. All PTCD insertions were conducted under general anesthesia by the same physician

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(AS) following single-shot antibiotic prophylaxis. First, a prominent dilated intrahepatic biliary branch was located and punctured under sonographic guidance with a 22 G needle. Afterwards, bile was aspirated. Subsequently, initial biliary cannulation was performed using a 0.018-inch platin wire (Cook® Medical) and 4–6 F catheter sheath (Cook® Medical) following confirmation of the (dilated) bile ducts up to the anastomosis, via contrast visualization. Thereafter, the wire was changed to a 0.035-inch standard wire (Terumo) and intubation of the central biliary system and the BDA was attempted under fluoroscopic guidance. Contrast imaging further confirmed the proper placement within the small intestine. Further bougienage with different size bougies up to 9 F was performed over the guide wire. Eventually, a 6–8 F "Munich" biliary drainage (Peter Pflugbeil GmbH) was placed with the distal end reaching the small intestine. In cases where tube placement at the stricture site was not possible, and a small intestinal loop was not actualized, external drainage was the alternative approach.

In addition, PTCD was routinely replaced every 3 months over a guide wire and under fluoroscopic guidance. If the target biliary stricture persisted, PTCD size was increased up to 14 F. PTCD was removed if parameters of cholestasis regressed and no further signs of persistent biliary stenosis were observed on visual imaging. A more detailed description of PTCD placement is available in other studies [13].

If cholestasis worsened despite PTCD and biliary complications such as cholangitis or cholangiosepsis occurred, an interdisciplinary team comprised of pediatricians, transplant surgeons, and interventional gastroenterologists convened to discuss further management strategies involving surgical biliary revision or ultimate re-transplantation. Surgical biliary revision was performed in four of five cases with complete removal of the PTCD. In one case with extensive scarring of the BDA, an endless drain was placed intraoperatively to splint the stenosis (catheter advanced to the small bowel).

Outcome parameters

First, procedural characteristics, including technical success and safety of the intervention, were recorded. Changes in laboratory indicators of graft function represented by the "model for the end stage of liver disease" (MELD) score and laboratory indicators of inflammation (C-reactive protein, CRP) and cholestasis (that is, gamma-glutamyl transferase, GGT) and alkaline phosphatase, AP) were analyzed between first PTCD insertion and follow-up (6 and 12 months following PTCD insertion). Further, preliminary efficacy represented by the percentage of patients without cholangitis, need for surgical biliary re-intervention, and re-transplantation during a follow-up period of 60 months was analyzed.

Data collection

All personal patient data were pseudo-anonymized before further analysis. Data were collected using electronic medical records, including the patient data monitoring system (PDMS) SAP. MELD scores were calculated (including bilirubin, INR, and creatinine) according to the description by Kamath et al. [14].

Statistical analysis

GraphPad Prism (Version 9.0, GraphPad Software), IBM SPSS Statistics (Version 27.0, IBM Co.), and the R environment for statistical computing (Version 4.1.2, R Foundation for Statistical Computing) were used for data analysis. GraphPad Prism (Version 9.0, GraphPad Software) was used for graph generation. Categorical variables are expressed as numbers

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(n) and percentages (%). Continuous variables are expressed as median and 25–75% quartiles unless indicated otherwise. Variables were assessed for normal distribution using the D'Agostino–Pearson omnibus normality test and the Shapiro-Wilk normality test. For comparisons, the Mann–Whitney U-test, Wilcoxon matched-pairs signed rank test, two-sided paired *t*-test, one-way ANOVA, and Kruskal–Wallis test were used accordingly. Survival and preliminary efficiency (i.e., free of cholangitis) were visualized by Kaplan–Meier graphs and analyzed using the Log-rank test. All reported *p*-values are two-sided unless indicated otherwise; *p*-values<0.05 were considered statistically significant.

RESULTS

Cohort characterization

Between February 2013 and January 2023, a total of 1158 LTX were performed on pediatric patients at our center. Among the patients, 264 (22.8%) developed biliary strictures. PTCD was attempted in a total of 15 pediatric patients following LTX (incidence among all patients following LTX: 1.3%; incidence of biliary strictures among patients following LTX: 5.7%) and was successful in 14 patients (93%) (**Fig. 1**). However, in other patients with biliary strictures, ERC or conservative care was successful.

Demographic and clinical characteristics at the time of PTCD admission are presented in **Table 1**. Median (interquartile range [IQR]) age was 9 (4–13) years with 9 (64.3%) male patients. Biliary atresia was the main indication for LTX (50.0%), followed by acute liver failure (28.6%) with different etiology (death cap poisoning, association with acetaminophen intake or unknown), hepatoblastoma (14.3%), and alpha-1 antitrypsin deficiency (7.1%). Most pediatric patients (92.9%) received a split liver transplant from a deceased organ donor (78.6%), which were all donations after brain death (DBD). There is no further information on donors or donor organs due to donor anonymization required by federal law. A BDA was established in all 14 patients.

Procedural characteristics and safety of PTCD admission

A PTCD was inserted after a median of 41 (17–124) months following LTX. The major indication for a PTCD admission was a stenosis of the BDA (92.9%). Notably, all patients received a single bile duct anastomosis. In this study, one of every five patients had ITBL,

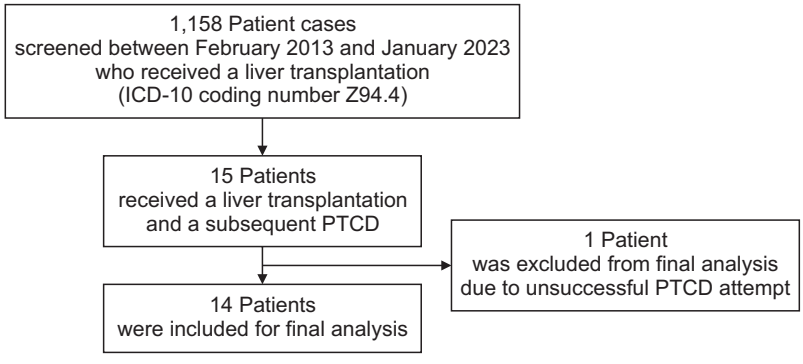

Fig. 1. Study inclusion. PTCD was performed in 15 pediatric patients following LTX between February 2013 and January 2023. Fourteen successful PTCD admissions were included in the study (per protocol analysis).
ICD-10: International Classification of Disease 10th revision, PTCD: percutaneous transhepatic cholangiodrainage, LTX: liver transplantation.

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Table 1. Demographic and clinical characteristics at first PTCD insertion

Category	Value (n=14)
Age (yr)	9 (4–13)
Sex	
Male	9 (64.3)
Female	5 (35.7)
Height (m)	1.35 (0.97–1.59)
Weight (kg)	26.0 (15.3–41.9)
BMI (kg/m^2)	16.1 (15.4–17.7)
Indication for LTX	
Biliary Atresia	7 (50.0)
Acute liver failure	4 (28.6)
Hepatoblastoma	2 (14.3)
Alpha-1 antitrypsin deficiency	1 (7.1)
Living liver donor	3 (21.4)
Deceased living donor	11 (78.6)
Split-LTX	13 (92.9)
BDA	14 (100)
LTX to PTCD (mo)	41 (17–124)
Biliary dilatation in imaging prior to PTCD	13 (92.9)
PTCD primary	12 (85.7)
Reason for PTCD insertion	
Biliary Insufficiency	1 (7.1)
Biliary abscess	1 (7.1)
ITBL	3 (21.4)
Stenosis of anastomosis	13 (92.9)
Biliary leakage	0 (0.0)
Complications prior to PTCD	
Cholangitis	9 (64.3)
Cholangiosepsis	3 (21.4)
Cholangioabscess	3 (21.4)
Re-BDA	5 (35.7)
Biochemical data prior to PTCD	
AP (U/L)	550 (395–787)
GGT (U/L)	286 (47–458)
Bilirubin total (μmol/L)	38 (12–110)
MELD score	13 (8–15)
CRP (mg/L)	9.1 (2.6–15.1)

Values are presented as median (interquartile range) or number (%).
AP: alkaline phosphatase, BDA: biliodigestive anastomosis, BMI: body mass index, CRP: C-reactive protein, GGT: gamma glutamyl transferase, ITBL: ischemic type biliary lesions, LTX: liver transplantation, MELD: model of end stage liver disease, PTCD: percutaneous transhepatic cholangio-drainage.

implying multiple strictures (**Table 1**). In 43% of cases, the drainage was placed into the small intestine at the first attempt (internal). In the remaining cases, external drainage needed to be placed initially and was either redirected to the small intestine throughout the following interventions (external-internal) (35.7%) or kept as an exclusive external drainage (21.4%). For the exclusive external drainages, internal drainage was challenging due to complete bile duct occlusion (no contrast visualization into the small bowl). This implied improper tube placement in the stricture site. In 79% of the cases, internal drainage was achieved initially or at some point during treatment (**Table 2**). The initial PTCD had a median size of 8 (6–8) French. A dilatation (Bougie procedure) was performed in nine patients (64.3%). Subsequently, strictures were resolved in 79% overall. In cases where exclusive external drainage was achieved (no passing through the anastomosis), strictures were not resolved, and surgical revision was needed during follow-up.

Furthermore, a total of four procedural-associated complications were noted (28.6%), including post-interventional cholangitis in three patients (21.4%) and bleeding in one

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Table 2. Procedural characteristics and complications

Category	Value (n=14)
Location of PTCD	
PTCD right liver lobe	5 (35.7)
PTCD left liver lobe	9 (64.3)
PTCD both liver lobes	0 (0)
Drainage strategy	
External drainage only	3 (21.4)
Initial External drainage only, internal drainage later achieved	5 (35.7)
Internal drainage at first attempt	6 (42.9)
Number of total PTCD changes	3 (1–4)
Size of first PTCD (Fr)	8 (6–8)
Maximum size of PTCD (Fr)	11.0 (8.0–13.5)
Cholangioscopy	1 (7.1)
Dilatation	9 (64.3)
Bougie	9 (64.3)
Balloon	0 (0)
Strictures resolved	11 (78.6)
PTCD dislocated	2 (14.3)
PTCD demission	13 (92.9)
PTCD reinsertion	2 (14.3)
Complications after procedure	4 (28.6)
Bleeding complications	1 (7.1)
Cholangitis complications	3 (21.4)

Values are presented as number (%) or median (interquartile range).
PTCD: percutaneous transhepatic cholangio-drainage.

patient (7.1%) (**Table 2**). In the one patient with a bleeding complication, bleeding was immediately noticed when fresh blood was discharged after opening the PTCD; a subsequent emergency CT scan revealed a portal venous fistula. However, successful embolization of the puncture tract using gel foam stopped the bleeding, and the PTCD was maintained.

After a median of 3 (1–4) changes, PTCD could be removed in 93% of patients after a median time of 8 (1–14) months (**Fig. 2B**) and only needed to be reinserted in two patients (**Table 2**). No significant differences in tube removal time were observed between internal and external-internal drainage techniques, which was achieved after a median of 11 (5–15) months. However, if only external drainage was achieved, an early surgical revision of the BDA (including tube removal) was necessary within a median of 1 (0–1) month.

Changes in laboratory indicators of graft function, inflammation, and cholestasis

Liver synthesis performance represented by albumin serum concentration (baseline: 36 [31–39] g/L vs. 12 months: 40 [38–41] g/L, p=0.062) (**Fig. 3A**) increased. The median (IQR) MELD score as a surrogate of liver graft dysfunction was significantly reduced 6 and 12 months after PTCD insertion (baseline: 13 [8–15] vs. 12 months: 8 [7–8], p<0.001) (**Fig. 3B**).

At baseline, cholestasis parameters (GGT and AP), as well as the CRP, were elevated, representing cholestasis and recurrent cholangitis. Inflammation represented by CRP significantly decreased after PTCD insertion (baseline: 9.1 [2.6–15.1] mg/L vs. 12 months: 2.1 [0.0–4.8] mg/L, p=0.037) (**Fig. 3C**) Notably, GGT decreased significantly during the follow-up (GGT: baseline: 286 [47–458] U/L vs. 12 months: 105 [26–147] U/L, p=0.024) (**Fig. 3D**), while AP only decreased significantly at 6 months (AP: baseline: 439 [337–864] U/L vs. 6 months: 346 [222–581] U/L, p=0.048) (**Fig. 3E**). Liver injury represented by the concentration of aspartate aminotransferase (AST) (baseline: 79 [38–101] U/L vs. 12 months: 53 [48–75] U/L, p=0.053) (**Fig. 3F**) decreased following PTCD. Further data is shown in **Supplementary Table 1**.

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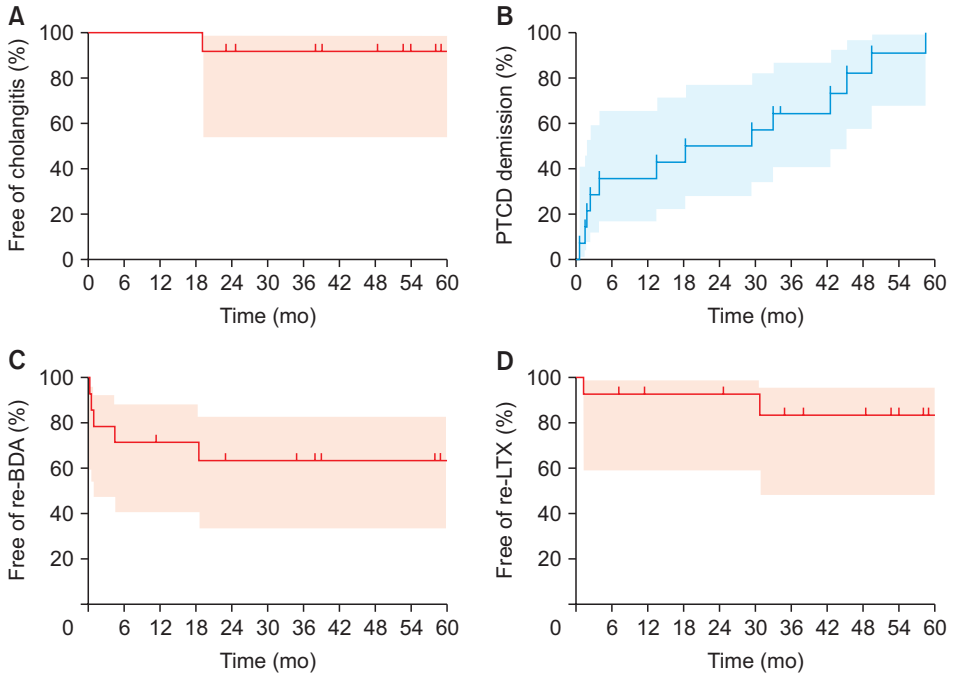

Fig. 2. Preliminary efficacy of PTCD. Percentage of patients without cholangitis (A), with PTCD demission (B), without need for surgical biliary re-intervention (C) and without re-transplantation (D), are shown as Kaplan–Meier graphs for a 5-year follow-up. *p*-values<0.05 are considered significant.
PTCD: percutaneous transhepatic cholangiodrainage, BDA: body mass index, LTX: liver transplantation.

Preliminary efficacy of PTCD

Prior to PTCD admission, cholangitis (64.3%) and cholangiosepsis (21.4%) were common complications (**Table 1**). A surgical re-intervention to the BDA prior to PTCD was necessary in five patients (35.7%).

During a maximum follow-up period of 5 years, only one patient had cholangitis approximately 19 months after PTCD admission (if direct procedural-related cholangitis was not considered) (**Fig. 2A**). A surgical biliary revision after PTCD treatment was still necessary in five patients, on average within 6 months after PTCD intervention (**Fig. 2C**, **Supplementary Table 2**). Patients who initially required exclusively external drainage via PTCD may have a higher tendency for surgical revision, although not statistically significant (p=0.145) (**Supplementary Fig. 1**). However, in the subgroups, all patients with exclusively external drainage needed a surgical biliary revision (100%), whereas in cases where internal drainage was achieved initially (internal) or over time (external-internal) only three patients (17.6%) needed a surgical biliary revision (p=0.009). No significant differences in outcomes were observed in patients with successful internal PTCD at the first attempt and those after multiple attempts during the procedures. As a surgical biliary revision, a hepaticojejunostomy was performed only in three patients with prior removal of the PTCD. In one case, the BDA was twisted, necessitating derotation and subsequent fixation. In one case of subtotal scarred stenosis of the BDA, an endless drain was placed intraoperatively to splint the stenosis. The outcome in terms of restenosis and reinsertion of PTCD did not differ in these small subgroups. LTX as ultima ratio was necessary for two patients within 5 years following PTCD insertion with no significant differences between the small subgroups (**Fig. 2D**, **Supplementary Table 2**). Seven patients (50.0%) did not need any surgical revision or a re-transplantation following PTCD treatment.

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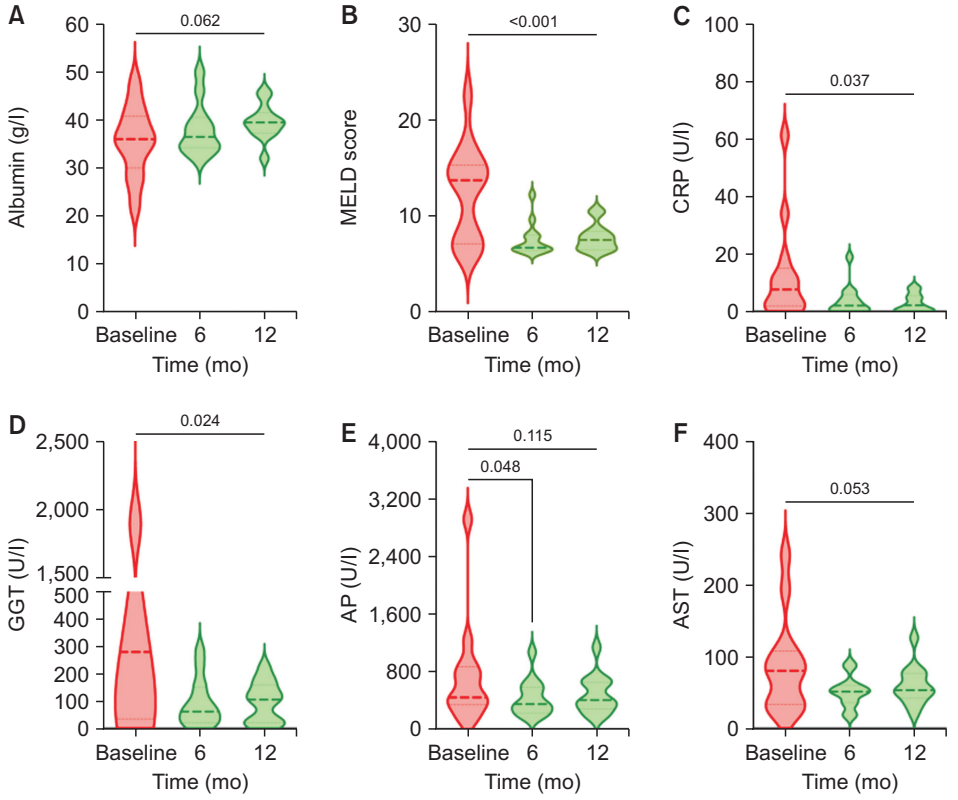

Fig. 3. Changes in laboratory indicators of graft function, inflammation, and cholestasis. Laboratory indicators of graft function (A, B), inflammation (C), cholestasis (D, E), and liver injury (F) are shown as violin plots for baseline (before PTCD insertion) and follow-up (6 and 12 months following PTCD insertion). Values are presented as median (25% to 75% interquartile range). *p*-values<0.05 are considered significant.
MELD: model for the end stage of liver disease, CRP: C-reactive protein, GGT: Gamma glutamyl transferase, AP: Alkaline phosphatase, AST: Aspartate aminotransferase, PTCD: percutaneous transhepatic cholangiodrainage.

DISCUSSION

In this retrospective single-center study, 14 liver-transplanted children without alternative biliary access received at least one PTCD procedure, with a high initial technical success rate and a tolerable safety profile. Laboratory indicators of inflammation, cholestasis, and graft function (that is, MELD) improved following PTCD. PTCD may have prevented cholestatic complications, thereby reducing the need for surgical biliary re-intervention and, ultimately, re-transplantation.

In our study, initial biliary access was achieved in 93% of PTCD procedures (technical success). This result is similar to the success rates of other studies, mainly using sonographic guidance for the initial puncture of dilated bile ducts [6,10,11,15]. Nevertheless, different procedural standards exist. Lorenz et al. [10] mainly describe puncture of the bile ducts for visualizing stenosis of the biliary tract rather than using it as a primarily therapeutic tool, as we described here. In more recent studies, the focus shifted to potential therapeutic efforts, including dilatation of the biliary stenosis [16,17]. However, different long-term success rates and follow-up strategies have been described. Moreira et al. [11] reported a resolution of biliary stenosis in 66% of patients with single balloon dilatation and PTCD over a median time of 10 months. In another study, only 34% of strictures were resolved by balloon dilatation and stents during a median follow-up time of 4.5 years when the PTCD

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was kept for 3 months [12]. Another study found that in 40% of patients initially treated with balloon dilatation and PTCD, re-intervention, re-transplantation, or stent placement was necessary [18]. Balloon dilatation may have the significant advantage of being able to adjust the pressure according to the length of the targeted segment. Other options to resolve biliary stenosis that remain debatable in the literature are cutting balloons and stents [16,17]. Similar to Uller et al. [6], we changed PTCD catheters on a regular basis and dilated the stenosis by bougienage (as a standard procedure at our center) only if bypass by the catheter itself was not achievable. The success rate of resolving strictures was slightly high compared to other studies. Moreover, identifying the type of organs related to strictures and requiring PTCD remains challenging, mainly due to the small and heterogenous group as well as donor anonymization requirements by federal laws.

In addition, PTCD insertion has procedural risks. We experienced four peri-interventional complications (three patients experienced episodes of postinterventional cholangitis and one bleeding event); however, all of these complications were non-fatal and well manageable. Compared to previous reports with high major complication rates, the rate of procedural safety has improved in more recent times through the standardized use of sonographic guidance [6,10,11,19]. Minor complications, such as infections, can occur; however, regular treatment, without causing any negative long-term consequences, can be employed.

Although elevated laboratory markers of cholestasis (including GGT and AP or bilirubin) and inflammation (including CRP and leucocytes) are often used as an indication for PTCD. Studies suggest that only bilirubin is significantly reduced after PTCD insertion [6,10]. In contrast, our results show a significant reduction of diverse laboratory indicators of inflammation and cholestasis, suggesting that PTCD reduces both cholestasis and cholestatic complications in pediatric patients following LTX. Furthermore, this effect seems to be more pronounced after 6 months, with slightly increasing (but still low compared to baseline) cholestatic parameters after 12 months. PTCD removal might be responsible for this slight increase. Uller et al. [6] reported that four of 23 patients were successfully bridged to surgical revision or re-transplantation and that cholangitis was resolved in 13 patients who received a long-term dilatation and a PTCD catheter for a median time of 260 days during a follow-up of 295 days. Bilirubin serum levels also decreased in these 13 patients [6]. This suggests that PTCD might be a strategy to facilitate surgical re-intervention or re-transplantation. Notably, fewer cholestatic complications (including cholangitis) after PTCD insertion were observed in this study, and the MELD score representing graft dysfunction was reduced. This suggests that PTCD, in addition to facilitating surgical re-intervention or re-transplantation, can also prevent such interventions in a subset of patients. Further research is required to validate these findings. Further, If a surgical revision is needed, a hepaticojejunostomy may be considered, with the placement of an additional PTCD and advancing an external drain to the small intestine, if feasible, during surgery.

This study has a few limitations. First, the limited sample size, as this is a retrospective, single-center study with a relatively small number of patients included. Furthermore, this study is mostly descriptive, allowing only assumptions regarding the value of PTCD on the outcome and possible prevention of surgical revision and re-transplant. Nevertheless, this systematic data from a large pediatric transplant center over a decade suggests that PTCDs may improve the outcome of patients by directly improving cholestasis and its complications (including cholangitis).

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Recent studies are focusing on the performance of the PTCD procedure itself rather than reporting the follow-up period and clinical outcomes. Further larger prospective interventional studies are certainly needed to investigate the value of PTCD in pediatric patients following LTX without alternative biliary access.

In conclusions, PTCD in pediatric patients following LTX without alternative biliary access had an acceptable safety profile and was associated with biochemical improvement of cholestasis and graft function. PTCD may prevent cholestatic complications, thus reducing the need for surgical biliary re-intervention and, ultimately, re-transplantation, especially if internal drainage is achieved. To further elucidate the value of PTCD in pediatric patients with biliary complications following LTX, larger prospective multi-center studies are needed.

SUPPLEMENTARY MATERIALS

Supplementary Table 1

Laboratory indicators of graft function, inflammation and cholestasis

Supplementary Table 2

Follow up data after first PTCD insertion

Supplementary Fig. 1

Free of surgical biliary re-intervention after PTCD admission for initial internal vs. internal-external/external admission.

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