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Clinical Success and Safety of Percutaneous Transhepatic Biliary Drainage for Biliary Obstruction after Deceased Donor Liver Transplantation

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Abstract

Introduction: Endoscopic Retrograde Cholangiopancreatography (ERCP), EUS-guided Biliary Drainage (EUS-BD) or Double Balloon enteroscopy assisted-ERCP (DB-ERCP) are commonly used to manage biliary complications after Liver Transplant (LT). Percutaneous Transhepatic Biliary Drainage (PTBD) remains second-line treatment in patients after LT; however it has not been well studied, particularly in Deceased Donor Liver Transplantation (DDLT). We aimed to determine the efficacy and safety of PTBD in this setting.

Methods: This is a retrospective study of patients who underwent PTBD for biliary obstruction post DDLT at a quaternary referral centre between1st of January 2003 and 1st of September 2019. Technical success was defined as successful biliary cannulation and treatment. Clinical success was defined as a 50% reduction in serum bilirubin 7 days post-procedure and/or a 75% reduction at 4 weeks.

Results: 58 LT patients underwent 232 PTBDs (83% male, median age 55 [IQR 47 to 58] years). The most common underlying liver diseases were Primary Sclerosing Cholangitis (PSC) 16 (28%) and hepatitis C 15 (26%). Thirty (52%) patients had hilar and intra-hepatic strictures, 18 (31%) had surgical bilio-enteric anastomotic strictures and 10 (17%) patients had duct-to-duct anastomotic strictures. Clinical success was achieved in 27 (47%) patients and technical success in 53 (91%) patients. Complications occurred in 32 (55%) patients. Seven (12%) patients died within 90 days of PTBD.

Conclusion: Although technical success for PTBD post LT is high, clinical success is modest at 47% with complications occurring in the majority of patients. PTBD carries a significant risk of adverse events in this complex patient population.

Keywords: Biliary complications after liver transplantation; Deceased donor liver transplantation; Percutaneous transhepatic biliary drainage

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Abbreviations

ERCP: Endoscopic Retrograde Cholangiopancreatography; EUS-BD: Endoscopic Ultrasound-Guided Biliary Drainage; DB-ERCP: Double Balloon Enteroscopy Assisted-ERCP; PTBD: Percutaneous Transhepatic Biliary Drainage; LT: Liver Transplantation; DDLT: Deceased Donor Liver Transplantation; LDLT Living Donor Liver Transplantation; PSC: Primary Sclerosing Cholangitis; TPLT: Time Post Liver Transplantation

Introduction

Liver Transplantation (LT) is the definitive treatment for decompensated chronic liver failure, acute liver failure and selected cases of hepatocellular malignancy. Biliary complications post LT occur in approximately 22% to 30% of patients with higher rates seen in patients with Roux-en-Y choledochojejunostomy compared with conventional duct-to-duct anastomoses [1-3]. Strictures, bile leaks, biliary cast syndrome and choledocholithiasis are major causes of morbidity and mortality post-LT [3-5]. Endoscopic Retrograde Cholangiopancreatography (ERCP) with balloon dilatation

and/or stent placement is considered first-line management of post-LT biliary complications [6].

Percutaneous Transhepatic Biliary Drainage (PTBD) is an established second-line intervention in the management of biliary complications post-LT after failed ERCP [6]. However, PTBD used to treat biliary complications post-LT carries significant morbidity and has been associated with complications in 15% to 22% of patients [7,8]. Rates of clinical success vary for endoscopic, radiological and surgical approaches and 5% of patients with biliary strictures fail all attempted interventions and may even require re-transplantation [9].

Deceased Donor Liver Transplant (DDLT) patients have been previously shown to have lower rates of biliary complication compared to Living Donor Liver Transplantation (LDLT) [10,11]. Smaller diameter of intrahepatic bile ducts increases the surgical complexity with biliary injury and a higher incidence of strictures and bile leaks [12]. A higher rate of successful endoscopic treatment of biliary transplant complications is seen with DDLT *vs.* LDLT, 62% to 100% *vs.* 37% to 76% [13-20].

Previous studies describing clinical success and complication rates of PTBD in adult's post-LT have focused on LDLT and experience with DDLT in this situation is limited [8,21-23]. Therefore, we performed a large, single centre study at the Australian National Liver Transplant Unit, Royal Prince Alfred Hospital, to determine the clinical success rate and safety of PTBD in patients who received DDLT.

Methods

All patients who underwent PTBD after DDLT between January 2003 and September 2019 at Royal Prince Alfred Hospital, a quaternary state-wide liver transplant referral centre, were retrospectively reviewed. PTBD procedures were identified by procedural billing codes from the medical record and -cross referenced with a prospectively kept liver transplant database. Clinical, laboratory, endoscopic and radiological data were obtained from paper and electronic medical records. Follow up in the cohort was a minimum of 90 days. Ethics approval was granted from the Sydney Local Health District Human Research Ethics Committee, protocol X16-0245 & LNR/16/RPAH/299.

Inclusion criteria

All patients with obstructive biliary disease who underwent PTBD post DDLT were included.

Exclusion criteria

LDLT recipients and PTBD performed for malignant indications were excluded. Check cholangiograms of t-tubes placed during LT were not included.

Study endpoints and definitions

The primary endpoint was clinical success defined as a 50% reduction in serum bilirubin 7 days post-procedure and/or a 75% reduction at 4 weeks. Secondary endpoints were technical success defined as successful biliary cannulation and treatment of obstruction. Additional endpoints include procedural complications, thirty- and ninety-day mortality. Hemobilia is an expected finding post PTBD and was only recorded as a complication if it was clinically significant and required transfusion.

Biliary obstructive lesions were categorized according to a classification for benign biliary strictures by location into: 1; distal common bile duct, 2; duct-to-duct anastomosis, 3; hilar and intrahepatic, 4; surgical and bilio-enteric anastomosis [24]. Recurrent primary sclerosing cholangitis was defined as non-anastomotic strictures occurring more than 90 days post LT with characteristic cholangiographic and/or histologic findings [25] in cases independently reviewed by an expert transplant hepatologist.

PTBD procedure

All PTBD procedures were performed by consultant interventional radiologists with experience in biliary intervention. All procedures were performed under general anesthesia with broad spectrum antibiotic cover. Initially ultrasound was used to identify bile ducts and combination ultrasound/fluoroscopy with contrast was used to opacify and cannulate bile ducts before stenoses were identified and crossed. A 10-Fr internal/external biliary drain (Cook Medical, Bloomington, IN, USA) was then placed across the stricture into the small bowel in most cases. The drainage tube was then left on free drainage. Tube checks were performed prior to the removal of tubes. PTBD was considered first-line treatment of biliary pathology for patients with Roux-en-Y hepaticojejunostomy prior to 2010 when DB-ERCP became available at this centre.

Statistical analysis

Statistical analysis was performed using SAS® Studio 3.71 (2019). Categorical data were analysed using Pearson X^2 test or Fisher's exact test where appropriate. Continuous data were analyzed with 2 sample t test where normally distributed and Mann Whitney U test or Kruskal-Wallis test for non-parametric variables. Univariate analysis was carried out to determine variables significantly correlated with the primary outcome. Significant variables on univariate analysis were added in a stepwise manner using a significance level of $p<0.10$ to perform a multivariate logistic regression model.

Results

Patient characteristics

Fifty-eight patients (83% male, median age 55 [IQR 47 to 58] years) underwent a total of 232 PTBDs (Table 1). Causes of liver disease included Primary Sclerosing Cholangitis (PSC) 16(28%), hepatitis C 15 (26%), hepatitis B 8 (14%), alcohol 6 (10%) and other 13 (22%). Seven (12%) LTs were retransplants following previous graft failure. Biliary anastomoses were duct-to-duct anastomoses in 25 (43%) and Roux-en-Y hepaticojejunostomy in 33 (57%). Thirty (52%) patients had hilar and intra-hepatic strictures, 18 (31%) had surgical bilio-enteric anastomotic strictures, 10 (17%) patients had duct-to-duct anastomotic strictures and no patients had distal CBD strictures. The median time to PTBD post liver transplant was 27 (IQR 4 to 69) months.

The majority of patients had prior ERCP (64%). Failed standard ERCP occurred in 23 (40%) and failed double balloon enteroscopy assisted-ERCP (DB-ERCP) in 14 (24%) patients. Twenty-one (36%) patients underwent PTBD as a primary procedure and 19 of those patients had a Roux-en-Y biliary anastomosis. Stratification of patients by anastomosis type, etiology of liver disease and prior procedure are displayed in Figure 1.

Procedural characteristics

There was a median of 3 (IQR 2 to 5) procedures per patient (Table 2). Interventions performed at PTBD included balloon dilatation in 39 (67%), metal stenting in 5 (9%) and plastic stenting in 14 (24%). Biliary drainage was internal/external in 34 (59%), external only in

Table 1: Patient characteristics.

	All
n	58
Age (years)	55 (47 to 58)
Male	48 (83)
Causes of liver disease	
PSC	16 (28)
Hepatitis C	15 (26)
Hepatitis B	8 (14)
Alcohol	6 (10)
Other	13 (22)
Type of donor	
DBD	56 (97)
DCD	2 (3)
Retransplant	7 (12)
Anastomosis	
RouxtoentoY	33 (57)
Ductto duct	25 (43)
Level of lesion	
Hilar and intratohepatic	30 (52)
Surgical biliotoenteric anastomosis	18 (31)
Ducttototoduct anastomosis	10 (17)
Distal CBD	0 (0)
Prior procedure	
ERCP	23 (40)
Primary PTBD	21 (36)
DBtoERCP	14 (24)
Time post liver transplant (months)	27 (4to 69)
Pathology tests prior to procedure	
Bilirubin (µmol/L)	48 (21 to 180)
Albumin (g/L)	35 (29 to 41)
ALP (U/L)	320 (204 to 466)
GGT (U/L)	395 (156 to 705)
ALT (U/L)	90 (35 to 199)
AST (U/L)	60 (37 to 119)
WCC (10^9/L)	6.6 (4.4 to 8.7)
Hb (g/L)	109 (97 to 133)
Plts (10^9/L)	142 (103 to 202)
INR	1.1 (1.0 to 1.3)

The data are shown in n(%) and median(interquartile range)
Abbreviations: PSC: Primary Sclerosing Cholangitis; DBD: Donation after Brain Death; DCD: Donation after Cardiac Death; Roux toen toY; Roux toen toY hepaticojejunos tomy; Duct to duct: duct to duct anas tomosis; CBD: Common Bile Duct; ERCP: Endoscopic Retrograde Cholangiopancrea Tography, Primary; PTBD: Percutaneous Transhepatic Biliary Drainage; DB to ERCP: Double Balloon enteroscopy assisted to ERCP; ALP: Alkaline Phosphatase; GGT: Gamma Glutamyl Transferase; ALT: Alanine Transaminase; AST: Aspartate Transaminase; WCC: White Cell Count; Hb: Haemoglobin; Plts: Platelets; INR: International Normalised Ratio

17 (29%) and internal only in 6 (10%). In 1 patient (2%) no biliary drainage was performed.

Cause of obstruction identified included anastomotic stricture 25 (43%), recurrent PSC 10 (17%), non-anastomotic stricture 10 (17%), ischemic stricture 8 (14%) choledocholithiasis 4 (7%) and biliary cast syndrome 1 (2%). Baseline characteristics including pathology test results prior to PTBD are detailed in Table 2.

Table 2: Procedural characteristics.

	All
n	58
Number of procedures	3 (2 to 5)
Balloon dilatation	
Yes	39 (67)
No	19 (33)
Stenting	
Metal	5 (9)
Plastic	14 (24)
No stenting	39 (67)
Drainage	
Internal	6 (10)
External	17 (29)
Internal-external	34 (59)
No drainage performed	1 (2)
Cause of biliary obstruction identified	
Anastomotic stricture	25 (43)
Recurrent PSC	10 (17)
Non-anastomotic stricture	10 (17)
Ischaemic stricture	8 (14)
Choledocholithiasis	4 (7)
Biliary cast syndrome	1 (2)
Length of stay post procedure(days)	20 (10 to 29)
External drain removed prior to discharge	
Yes	31 (61)
No	20 (39)
Clinical success	27 (47)
Technical success	53 (91)

The data are shown in n(%) and median(interquartile range)
Abbreviations: PSC: Primary Sclerosing Cholangitis

Procedural efficacy and outcomes

Technical and clinical success was seen in 91% and 47% of patients respectively (Table 2). The median length of stay post procedure was 20 (IQR 10 to 29) days. External drainage was removed prior to discharge in 31 (61%) of patients. On univariate analysis, predictors of clinical success included cause of liver disease (p=0.03), with a lower proportion of clinical success (4/16 (25%)) in patients with PSC and a higher proportion of clinical success (12/15 (80%)) in patients with hepatitis C. Other predictors of clinical success included: shorter median Time Post Liver Transplantation (TPLT) (19.2 *vs.* 52.9 months, p=0.03) and lower median bilirubin pre-procedure (27 *vs.* 60 µmol/L, p=0.03) (Supplemental Table 1). There were no procedural characteristics associated with clinical success (Supplemental Table 2).

On multivariate analysis there was no significant difference in clinical success for any of the above factors, however, there was a trend toward significance for decreasing clinical success with longer

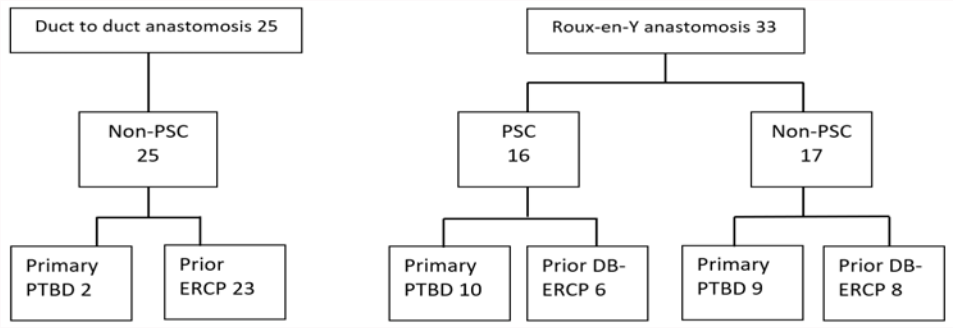

Figure 1: Flow diagram: Anastomosis, aetiology and prior procedure.

Table 3: Multivariate analysis for clinical success.

	Odds ratio (95% CI)	P value
Time post liver transplant (years)	0.85 (0.73 to 0.998)	**0.05**
Cause of liver disease (reference: PSC)		
Alcohol	2.72 (0.33 to 22.41)	0.81
Hepatitis B	0.74 (0.11 to 5.08)	0.13
Hepatitis C	6.70 (1.09 to 41.18)	0.09
Other	4.38 (0.75 to 25.43)	0.3
Bilirubin (μmol/L)	0.996 (0.99 to 1.0)	0.14
INR	0.21 (0.01 to 7.66)	0.4
AST(U/L)	1 (0.999 to 1.001)	0.76
Hb(g/L)	1.02 (0.99 to 1.05)	0.22

Abbreviations: PSC: Primary Sclerosing Cholangitis; INR: International Normalised Ratio; AST: Aspartate Transaminase; Hb: Haemoglobin

TPLT (years) OR=0.85 (95% CI 0.73 to 0.998, p=0.05) (Table 3).

Adverse outcomes

Thirty-two (55%) patients experienced at least one adverse event with 17% of patients requiring ICU admission post-procedure. Adverse events included cholangitis 23 (40%), bile leak 7 (12%), bleeding outside the biliary tree 6 (10%), pleural effusion 3 (5%) and hemobilia 2 (3%) (Table 4). Eight (14%) patients had more than 1 complication.

Five (9%) patients died within 30 days of PTBD and 7 (12%) patients died within 90 days of PTBD. Causes of death included biliary sepsis 3 (5%) liver failure 2 (3%) aspiration 1 (2%) and intrahepatic abscess 1 (2%) (Table 4). Five of the seven patients with ninety-day post procedure mortality experienced one or more complication including bile leak, hemobilia, and cholangitis or bleeding outside the biliary tree. No baseline patient or procedural characteristics were significantly associated with ninety-day mortality.

Discussion

Biliary complications of LT are common, and most can be effectively treated with ERCP as first line therapy. Few studies have evaluated PTBD which remains the standard of care as second line therapy in this context. To our knowledge, this study describes the largest cohort of patients undergoing PTBD after DDLT. This is important because the complexity of biliary intervention varies based on the type of graft and DDLT recipients have previously been shown to have lower rates of biliary pathology post LT and higher rates of successful endoscopic intervention in comparison to LDLT [6,10,14-20].

Table 4: Adverse events.

Complication	
Cholangitis	23 (40)
Hemobilia	2 (3)
Bile leak	7 (12)
Bleeding outside the biliary tree	6 (10)
Pleural effusion	3 (5)
One or more complication	32 (55)
ICU admission post procedure	10 (17)
Thirty-day mortality	5 (9)
Ninety-day mortality	7 (12)
Causes of death	
Biliary sepsis	3 (5)
Liver failure	2 (3)
Aspiration	1 (2)
Intrahepatic abscess	1 (2)

Adverse outcomes are reported per patient.
Abbreviations: ICU: Intensive Care Unit. The data are shown in n (%)

The outcomes of this study are comparable with previously reported data. Technical success was achieved in 91% of patients which is higher than most reported cohorts [7,8, 26,27]. However, we found clinical success was suboptimal and achieved in 27 of 58 (47%) patients. This is similar to previous retrospective cohorts of PTBD post liver transplant with clinical success rates of 51% to 78% [7,8,26,27]. We found that no factors were significantly associated with clinical success on multivariate analysis. However, there was a trend toward significance for longer TPLT being associated with lower rates of clinical success. This may be because of potential differences in indication for PTBD for early *vs.* late procedures although indication for PTBD was not a significant predictive factor on univariate analysis. Previous cohorts have shown similar success rates for PTBD treatment of biliary obstruction post LT in Roux-en-Y compared with duct-to-duct biliary anastomosis [26]. In this cohort, we also observed no difference in PTBD clinical success based on the type of surgical anastomosis.

Complications occurred in a very high proportion of patients (55%) which is higher than the 15% to 22% previously reported in the literature [7,8,27]. However, as previously noted, this cohort is unique in the literature in describing PTBD post DDLT. Our cohort represents a particularly complex group of patients with a high incidence of altered anatomy and previously failed endoscopic management. The majority (67%) of PTBDs performed were rescue

procedures following failed ERCP or DB-ERCP which may suggest increased complexity of cases in this population contributed to higher complication rates. We have not included patients who were successfully managed with first line ERCP including patients with altered anatomy who were managed with DB-ERCP. Recent advances in endoscopic techniques has allowed for patients with altered anatomy to undergo attempted DB-ERCP instead of PTBD. This endoscopic approach is well described with few complications and has been used successfully in patients post-LT [28,29]. The drainage success rate varies depending on the pathology encountered but is likely to improve as devices and techniques improve. There was also a significant number of procedures required in our cohort with a median of 3 procedures per patient and a median of 20 days hospital stay post PTBD. The most common complication was cholangitis at 40%; this reflects the complexity and often the indication for the procedure.

Another potential alternative in these patients is Endoscopic Ultrasound guided Biliary Drainage (EUS-BD). Over the last 7 years its utility has risen significantly for the treatment of biliary obstruction after liver transplantation or post-surgical anatomy [30,31]. A recent large meta-analysis demonstrated the superiority of EUS-BD over PTBD in failed ERCP [32]. It has significantly better clinical success (OR=0.45; 95% CI, 0.23 to 0.89; I2=0%), fewer reinterventions (OR=0.13; 95% CI, 0.07 to 0.24; I2=0%) and a lower rate of post-procedural adverse events (OR=0.13; 95% CI, 0.07 to 0.24; I2=0%). However, this meta-analysis consisted of predominantly patients with malignant biliary obstruction and these findings have yet to be replicated for the treatment of biliary obstruction post LT. EUS-BD has also been assessed as equivalent to ERCP for first-line palliation of malignant distal biliary obstruction [33]. As a safe and effective method in patients with failed ERCP or who cannot undergo ERCP due to surgically altered anatomy, EUS-BD will probably become even more important in the future.

We report a thirty-day post procedural mortality rate of 9%. A previous study has noted a post procedural mortality rate of 6% unrelated to the procedure and other studies excluded patients who died post procedurally [7,8,27]. By reporting the significant short-term mortality in this cohort, this study highlights the severity and complexity of biliary disease in this population and the need for improved techniques and outcomes.

Limitations of this study include that it is single-centre and retrospective which limits the generalizability of results. This study primarily examines procedural efficacy and safety and does not assess longer- term outcomes including patient and graft survival. Previous retrospective data of patients undergoing radiological and endoscopic interventions in this context found long term success rates to be low at 51% to 52% which further highlights the need to improve outcomes in this area [19,34]. As units have increasing options to manage these patients a multidisciplinary discussion to guide management and allocate patients appropriately should be routine.

In summary, this is the largest studied cohort of patients undergoing PTBD for the management of biliary complications post DDLT. In this cohort clinical success was modest at 47% and the complication rate was high at 55%. If available, alternative techniques like DB-ERCP or EUS-BD should probably be considered prior to PTBD. The high complexity of these cases should be considered when referring patients for biliary drainage.

Human/Animal Rights

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013 [35].

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