Selective Indication of T-Tube in Liver Transplantation: Prospective Validation of the Results of a Randomized Controlled Trial

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ABSTRACT

Background and Aims. T-tube placement during choledochocholedochostomy (CCS) associated with liver transplantation (LT) remains controversial. This study was designed to validate the results of an earlier prospective randomized controlled trial (RCT) on use versus nonuse of the T-tube during CCS associated with LT.

Methods. Prospective cohort study. The primary outcome was the overall incidence of biliary complications (BCs).

Results. In total, 405 patients were included, and the median overall monitoring period was 29 months (interquartile range: 13–47 months). Selective use of the T-tube reduced BCs (23% vs 13%; $P = .003$), of which 75% were type IIIa or less in the Clavien-Dindo classification. The overall BC rate did not differ between patients with versus without T-tube placement.

Conclusions. We confirmed that selective use of a rubber T-tube during CCS associated with LT, following the principles established in our prospective RCT, reduced the rate of BC by 10% without detriment, even after enrolling patients at an a priori greater risk of BCs than were the RCT patients.

BOTH patient and graft survival after liver transplantation (LT) have improved in recent years, associated with better immunosuppression regimes, improved organ preservation, advances in perioperative patient management, and better surgical techniques. However, surgical biliary tract reconstruction remains challenging; biliary complications (BCs) continue to cause major morbidity in up to 30% of LT recipients [1,2].

Choledochocholedochostomy (CCS) reconstruction is the gold-standard treatment in most transplant centers, but in recent years the utility of T-tube placement has become controversial and remains unresolved [3–6]. In 2013, our group published the results of a single-center randomized controlled trial (RCT) that explored the utility of T-tube placement during CCS associated with LT; we then modified our routine clinical practice to include T-tube placement, on the basis of the conclusions drawn in the cited study [7].

Here, we describe the outcomes of a study in which we sought to prospectively confirm that T-tube placement, based on the conclusions we reached in our prior RCT, can reduce the incidence of BCs. The primary outcome was the overall incidence of BCs, and the secondary outcome was BC severity. We also compared the BCs of T-tube and non-T-tube groups.

MATERIALS AND METHODS

We designed a prospective single-center study to evaluate CCS outcomes in recipients of orthotopic livers; biliary complications were stratified by severity. We included all patients >18 years of age who received deceased liver grafts from January 2011 to December 2015. The exclusion criteria were living donation, age ≤18

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years, and a technical requirement for hepaticojejunostomy (HJ). Patients who underwent urgent retransplantation or died within 1 month of LT were excluded, as were those in whom BCs developed in conjunction with hepatic artery complications. Our protocol was approved by the Committee for Patient Protection in Biomedical Research of our hospital. All patients were informed in detail about their planned procedures and provided written consent in line with Spanish law.

Surgical Procedure

The surgical procedure was strictly standardized. The same team recovered all grafts using the standard technique of Starzl et al [8]. T-tubes were placed when either or both of the donor and recipient bile duct diameters were <7 mm or when a large difference (≥2-fold) was evident in the common bile duct diameters of the graft and the recipient. When retransplantation and split or reduced-size grafts were employed, the implanting surgeon always made the final decision, whatever the bile duct size.

The anastomosis method has been described previously, as have the details of T-tube placement and the follow-up protocol [7]; a 2.5-mm-diameter rubber tube (Teleflex R Medical, Willy Rüsch GmbH, Kernen, Germany) was always used.

Definitions

All types of complications were considered: primary, secondary, and inherent T-tube complications were prospectively recorded. These complications, and their diagnoses, have been described previously [7]. Only the most severe complication in each patient was considered when evaluating the severity of BCs, and all BCs were stratified using the Clavien-Dindo classification [9].

Statistical Analyses

Quantitative variables are expressed as means with standard deviations, medians with ranges, or interquartile ranges (IQRs). Categorical variables are expressed as frequencies with percentages. Comparisons were performed using Fisher's exact test, the χ^2 test, and the Mann-Whitney test, as appropriate. Patient and graft survival were estimated using the Kaplan-Meier method. Survival rates were compared using the log-rank test. A P value $< .05$ (2-sided) was considered to reflect statistical significance. MedCalc software (ver. 15.8; MedCalc Software bvba, Ostend, Belgium) was used for all statistical analyses.

RESULTS

Between January 2011 and December 2015, 480 LTs were performed at La Fe University Hospital. Seventy-five patients were excluded: pediatric LT patients (n = 35); those with a technical requirement for HJ due to technical problems/cirrhosis etiology or previous HJ (n = 28); those who died intraoperatively (n = 2); and those who underwent urgent retransplantation (n = 7). Three deaths occurred in the first month after transplantation, none of which were associated with BCs. Ultimately, we included 405 patients.

Characteristics of Donors and Recipients and Surgical Variables

CCS with and without T-tube placement was performed in 240 (59%) and 165 (41%) cases, respectively. The median overall monitoring period was 29 months (IQR: 13–47 months), 30 months (IQR: 12–47 months) in the T-tube group, and 29 months (IQR: 13–47 months) in the no-T-tube group.

Table 1 shows the baseline demographic characteristics and disease-related donor data, as well as recipient and surgical variables.

Table 1. Comparison of Donor, Recipient, and Surgical Variables

	T-Tube, n = 240	No T-Tube, n = 165
Donor Variables		
Sex (male/female)	139/101	89/76
Age (mean)	58 (SD 18)	63 (SD 14)
Exitus Etiology		
Cerebrovascular (%)	72.3	80
Trauma (%)	18	13.1
Others (%)	9.7	6.9
BMI (mean)	28 (SD 9)	27 (SD 8)
ICU (days) (mean)	6.3 (SD 8.3)	6.7 (SD 10.6)
Cardiac Arrest (%)	14.3	11.2
Na (mEq/L) (mean)	140 (SD 8.2)	135 (SD 5.5)
Hypotension Episodes (%)	38.8	44.4
Type of Donor		
Split (n)	5	1
DCD (n)	2	2
Domino (n)	1	1
Recipient Variables		
Sex (male/female) (n)	194/46	111/54
Age	54 (SD 11)	56 (SD 9)
Disease Etiology		
HCV (%)	47	42
Alcohol (%)	23	24
HCC (%)	42	39
Child Class (%)		
A/B/C/NA	56/78/98/8	35/50/71/9
Blood Type (%)		
O/A/B/AB	104/109/22/10	61/78/17/4
MELD Score	20.5 (SD 8.5)	19.7 (SD 7.8)
BMI	28.5 (SD 19.2)	32 (SD 55.2)
Retransplantation (n)	20	4
Surgical Variables		
Piggy-back Hepatectomy (%)	99	100
Cold Ischemia Time (min)	268 (SD 109)	265 (SD 105)
Warm Ischemia Time (min)	44 (SD 16)	41 (SD 12)
Operative Time (min)	292 (SD 66)	275 (SD 48)
Donor Bile Duct Size (mm)	6.4 (SD 2.4)	8.5 (SD 2.1)
Recipient Bile Duct Size (mm)	6.9 (SD 2.8)	9 (SD 1.9)
RBC Transfusion (units)	3.4 (SD 3)	3 (SD 2)
Blood Self-Transfusion (ml)	861.5 (SD 925.2)	717.6 (SD 489.2)

Abbreviations: BMI, body mass index; DCD, donation after cardiac death; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; ICU, intensive care unit; MELD, Model for End-Stage Liver Disease; Na, sodium; RBC, red blood cell; SD, standard deviation.

Patient and Graft Survival

The cumulative 1-, 2-, and 5-year patient survival rates were 87%, 80%, and 75%, respectively. The actuarial 1-, 2-, and 5-year graft survival rates were 86%, 78%, and 74%, respectively.

Biliary Complications

The number of patients with BCs was significantly lower in the current study than in the RCT [7] (13% vs 23%; $P = .003$). The 10% difference means that the number needed-to-treat (NNT) is 10. When the T-tube and non-T-tube group were compared, no significant difference in the overall complication rate was noted (13% [n = 31] and 12% [n = 20] in the T-tube and non-T-tube group, respectively; $P = .88$) (Table 2).

When BCs were graded by severity, of the 51 patients with BCs (12.6%), 16% were of type I, 4% of type II, 57% of type IIIa, and 20% of type IIIb; 1 patient (2%) had a type IV and another a type V (2%) BC. No significant between-group difference was evident.

Primary Complications

Anastomotic Stenosis. In terms of stenosis, 5.9% of the patients (24/405) were affected (RCT: 6.6% (15/187); $P = .46$) [7]. However, the percentage of patients with anastomotic stenosis was significantly lower in the T-tube group in the RCT [7] (2% vs 12%; $P = .002$).

Using our current criteria, there was no significant difference in the absolute number of stenoses in patients with versus without T-tubes (10 [4%] and 14 [8.5%], respectively; $P = .09$). Stenoses in the T-tube group were resolved via dilatation and placement of biliary prostheses (using endoscopic retrograde cholangiopancreatography [ERCP] in 5 cases and percutaneous transhepatic cholangiography in 5 cases). Two cases required conversion of the CCSs to HJs. In patients without T-tubes, 11 cases were resolved by dilatation and placement of biliary prostheses via ERCP; 4 cases underwent HJ conversion.

The cumulative incidences of anastomotic biliary stenosis were 2% at 1 year, 6% at 3 years, and 14% at 5 years. Patients without T-tubes were at greater risk of stenosis. In those without T-tubes, the stenosis rates after 1, 3, and 5 years were 3%, 9%, and 20%, respectively; in those with T-tubes, the rates were 2%, 4%, and 10%, respectively (hazard ratio = 0.44; $P = .04$; Fig 1).

Anastomotic Fistulae. Anastomotic bile leakage was detected in 9 patients (2.2%) (RCT: 3.7% (7/187); $P = .44$) [7]: 4% (8 cases) of the T-tube group and 0.6% (1 case) of the non-T-tube group. The difference was not significant. In 6 cases, the fistulae resolved upon conservative treatment; 1 case required biliary drainage, performed with the aid of interventional radiology; another required fitting of a biliary prosthesis by ERCP; and another the conversion of the CCS to an HJ (Table 2).

Table 2. Comparison of Biliary Complications Between T-Tube and No T-Tube Groups

Biliary Complications	T-Tube (n = 240)	No T-Tube (n = 165)	*P*
Total Biliary Complications (Patients)	31 (13%)	20 (12%)	.88
Primary Complications (events)			
Anastomotic Bile Leak	8 (3.3%)	1 (0.6%)	.14
Anastomotic Stenosis	10 (4%)	14 (8.5%)	.09
Secondary Complications (events)			
Nonanastomotic Bile Leak	2 (0.8%)	1 (0.6%)	.85
Nonanastomotic Stenosis	1 (0.4%)	0 (0%)	.82
Choledocholithiasis	2 (1%)	5 (3%)	.27
T-Tube Inherent Complications (events)	12 (5%)	-	
Bile Leak After T-Tube Removal	4 (2%)	-	
Cholangitis	6 (2.5%)	-	
Bile Leak in T-Tube Insertion	2 (0.5%)	-	

Secondary Complications

We found no significant difference in the rate of secondary complications between patients with and without T-tubes (Table 2).

Inherent Complications Associated With the T-Tube

The number of complications associated with T-tube placement was 12 (5%) in the present study, which was clearly lower than the RCT [22 (23%); $P = .0001$] [7]. The frequency of cholangitis did not differ between those with and without T-tubes; all cases resolved upon antibiotic therapy. However, the number of choleperitoneums associated with T-tube removal fell from 13% in the RCT [7] to 2% (4 cases) in the present study ($P = .004$); 3 resolved upon percutaneous drainage and 1 after conservative treatment. The incidence of fistulae observed through the orifice of the T-tube fell from 3% in the RCT [7] to 0.5% (2 cases) in the present study ($P = .16$); 1 case resolved upon conservative treatment, and the other required conversion of the CCS to an HJ (Table 2).

DISCUSSION

We found that selective T-tube placement during CCS reduced BCs compared with the use of an all-or-none strategy. The reduction in BCs after LT to 13% is a valuable outcome, especially considering that 75% of all BCs resolved upon medical treatment or interventions using local anesthesia alone. Moreover, this percentage is under the benchmark cutoffs defined in liver transplantation ($\leq$12% at discharge and $\leq$28% at 1 year), even including high-risk patients [10].

Importantly, all complications were monitored prospectively for 29 months (IQR: 13–47 months), quite a long follow-up period because some complications (including anastomotic stenosis) take time to develop. In the RCT [7], the median monitoring period was 22.5 months (IQR: 6–35 months). Monitoring was longer in the present study by a mean of 8.5 months ($P = .0001$).

Donor age in the present series was greater than that of the RCT study [7]; the etiologies of death also differed. Donors in the present series had more cerebrovascular

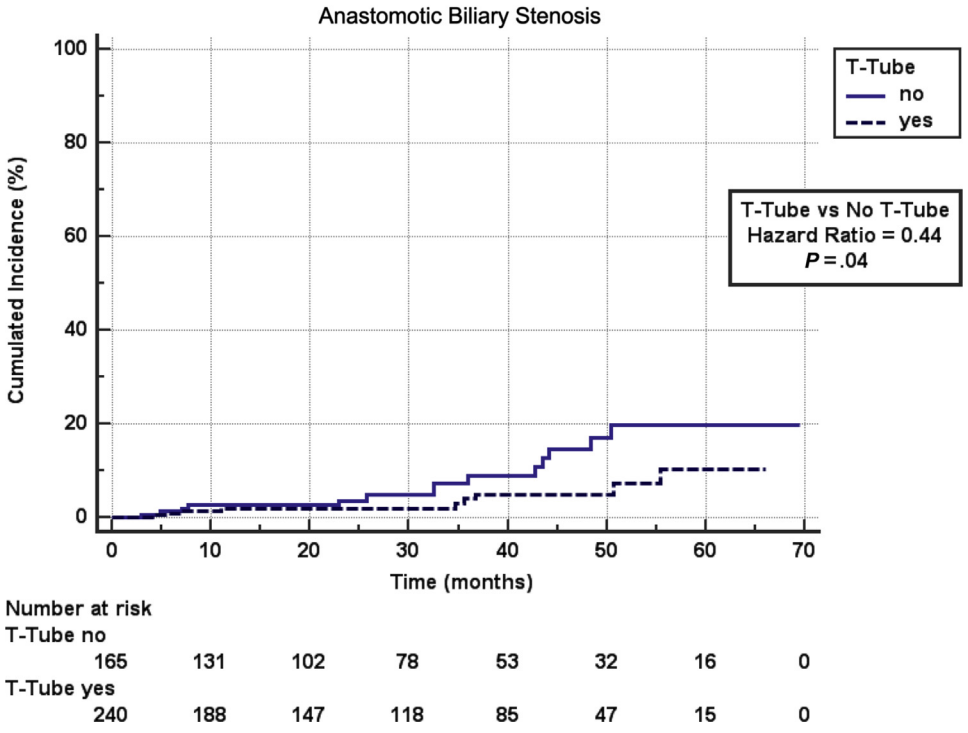

Fig 1. Cumulated incidence of anastomotic biliary stenosis.

accidents but fewer traumas than those of the RCT study. Otherwise, the baseline demographic characteristics and disease-related donor data were similar between the earlier and present groups.

The present recipients had higher Model for End-Stage Liver Disease scores and body mass indices than the RCT recipients.

In terms of the intraoperative details, the cold ischemia time was lower, but the surgical time slightly higher, than in the RCT, as was the need for hemoderivates and the blood levels in the cell salvage devices.

The number of patients with BCs was significantly lower in our current study than in the RCT [7] (13% vs 23%; $P = .003$). The 10% difference reflects a number needed-to-treat of 10. It would be necessary to operate on 10 patients, using our current criteria for selective use of the T-tube, to avoid complications in 1 patient that would have developed had we followed the RCT criteria.

BCs are the technical "Achilles heel" of LT, being common, requiring long-term repeat treatment, and exerting potentially detrimental effects on graft and patient survival. The choice of the biliary reconstruction mode during LT reflects several factors, including the basal disease triggering the need for transplantation, the diameters of the donor and recipient bile ducts, whether retransplantation is required, any prior surgery on the biliary duct, and the surgeon's preference. Many biliary reconstruction techniques have been described; these include end-to-end CCS, side-to-side CCS, and Roux-en-Y HJ, with or without placement of stents or a T-tube [1,11]. The type of biliary anastomosis used greatly influences the risk of BCs, which still develop in 10%–30% of patients undergoing whole-organ LT [2,12]. End-to-end CCS is used most commonly in patients with healthy bile ducts of calibers similar to those of the donors and has been our technique of choice since our LT program was initiated in 1991. One advantage of the technique is that it preserves the natural sphincter, which acts as a barrier to intestinal secretions and bacteria, thus facilitating future endoscopic therapy if required [13].

The use or non-use of a T-tube during LT CCS has been hotly debated; the literature on this area is vast. Several meta-analyses of both prospective and retrospective studies have appeared, and the issue remains contentious [3–6]. Only 6 prospective randomized trials [7,14–18] have explored the advantages and disadvantages of T-tube placement during CCS; the works differ in terms of both the results and conclusions. In these 6 studies [7,14–18], 27% of 826 patients had BCs. In our present series, the rate was 13%, thus 14 percentage points lower, although our median monitoring period was somewhat longer, allowing us to detect later BCs such as stenosis, lithiasis, and stenosis of the sphincter of Oddi [1,19]. This significant decrease in BCs to an average of 10% was achieved in a surgical environment similar to that in our previous RCT, using the same surgical technique but selectively placing rubber T-tubes following the principles learned during the RCT. Our results were good despite the fact that we monitored donors and recipients in poorer condition and for a longer time. Our present donors and recipients were older than those in the RCT, received more donations after cardiac death

[DCDs], more often required split transplantation, and had higher Model for End-Stage Liver Disease scores (recipients). Also, we did not exclude high-risk scenarios (retransplantation, primary sclerosing cholangitis, hepatic failure, or transplantation of more than 1 organ); all of these variables have been associated with greater numbers of BCs [1,2].

We concede that use of a T-tube prolongs the duration of surgery and causes patient discomfort; the incidence of biliary drain-related BCs ranges from 10%–22%, leakage after bile drain removal occurs in 5%–15% of patients, and a T-tube can trigger cholangitis after cholangiography. Also, there is a risk of T-tube displacement and other complications [15,19–22].

However, a T-tube prevents anastomotic stenosis [3–7,13,15–17]. In the RCT [7], we identified situations in which use of a T-tube afforded a clear benefit by reducing the number of stenoses. For this reason, we performed the present prospective study to validate our previous results and to demonstrate the utility of selective T-tube placement. A T-tube should be placed only when a clear benefit is expected to avoid the complications inherent to such placement. It was essential to study donors and recipients of all types; thus, we included retransplantations, asystolic donors, and split transplantations. Based on our earlier results [7], we decided to place T-tubes when either the donor or recipient bile duct diameter, or both, was <7 mm, when a large difference ($\geq$2-fold) was evident between the donor and recipient common bile duct diameters, and during retransplantation and transplantation of split or reduced-size grafts (all of which are associated with a high level of BCs) [1,2].

In our present study, the number of stenoses in the T-tube and no-T-tube group did not differ significantly, unlike what was noted in the RCT. Thus, despite the fact that T-tubes were not placed in 41% of cases, the frequency of anastomotic stenosis fell somewhat, from 6.6% in the RCT to 5.9% in our current series. It seems clear that this was influenced by the fact that the bile duct diameter was greater in the group of patients in whom T-tubes were not placed.

When we compared the cumulative incidence of BCs between patients with and without T-tubes, the risk of stenosis was greater in those without T-tubes, being 3%, 9%, and 20% in patients with T-tubes and 2%, 4%, and 10% in those without after 1, 3, and 5 years, respectively. This emphasizes that use of a T-tube reduces the risk of anastomotic stenosis and confirms the results of earlier studies showing that the T-tube is protective in this context [3–7,15–17,20].

In the RCT, we noted that the T-tube type plays an important role in the development of BCs [7]; use of latex was associated with more BCs. Thus, we used a 2.5-mm-diameter rubber T-tube in this study and recorded a 19% improvement in the incidence of BCs, with 4% of complications inherent in T-tube use, a level well below the 10%–22% BC rates reported previously [15,19–22]. This was attributable to the reduction in choleperitoneums on T-tube removal (from 13% in the RCT to 2% in the present study; $P = .004$). The frequency of clinically significant bile leakage after T-tube removal ranges from 0.84%–4% after standard biliary surgery [23] but is higher among LT patients (5%–15%) [15,20,22,24]. The pathogenesis of this complication has been explored. Biliary leakage is usually attributable to the lack of complete, fibrous, T-tube-mediated fistula formation or to proximal fistula disruption during tube removal [25]. In LT patients, immunosuppression and corticosteroid use may render the development of a fibrous fistulous tract inadequate along the course of the drain because fibrogenesis is impaired [26]. The T-tube material used affects the quality of the fibrous fistula formed [27,28]. T-tubes made from polyvinyl chloride or hypoallergenic latex (such as those coated with silicon) increase the rate of biliary peritonitis compared with that associated with the use of T-tubes made from red rubber [7,29,30].

Selective T-tube placement can balance the risks and benefits of T-tube use. We place T-tubes only when a high risk of stenosis is evident (bile duct diameters <7 mm in either or both the recipient and/or donor), when the diameters differ greatly, or when the risk of BCs is high (retransplantation, split transplantation, or an asystolic donor). Use of the rubber T-tube was associated with BCs in 13% of patients, but 75% of the BCs were of Clavien-Dindo type I, II, or IIIa (most of which can be resolved without any need for general anesthesia). When we compared the severity of BCs between the RCT and the current study, we found that the level of type II BCs was clearly lower in our current series, attributable to fewer BCs in patients in whom T-tubes were placed. In those without T-tubes, the incidence of group IIIb BCs fell significantly, attributable to a reduction in the number of repeat interventions required to convert CCSs to HJs.

In conclusion, we confirmed that selective use of a rubber T-tube during CCS associated with LT, following the principles learned in our earlier RCT, reduced the rate of BCs by 10% without increasing their severity. We prospectively studied a series of patients at a greater a priori risk of suffering BCs versus the RCT patients and monitored our present patients more intensively.

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