Transpl Int (1996) 9: 392–395


ORIGINAL ARTICLE

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# A prospective randomised trial of bile duct reconstruction at liver transplantation: T tube or no T tube?

Received: 7 July 1995
Received after revision: 17 November 1995
Accepted: 2 February 1996

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**Abstract** A prospective randomised study of end-to-end bile duct reconstruction with or without T-tube drainage during orthotopic liver transplantation (OLT) was undertaken in 60 patients well matched for age, sex, aetiology of liver disease, operative blood loss, cold ischaemic time, preoperative serum bilirubin level and Child-Pugh score. Significant biliary complications in the T tube group occurred in five patients and included bile duct stricture ($n = 2$), bile leak/peritonitis ($n = 1$) and cholangitis ($n = 2$). Bile duct strictures occurred in six patients in the no T tube group ($P > 0.05$, NS). Hepatic artery stenosis was identified in one patient from each group in association with a biliary stricture. Biliary complications in both groups were associated with a prolonged graft cold ischaemic time ($P < 0.01$). As no significant difference was noted in the number of early and late biliary complications between the two groups, the routine use of a T tube has been discontinued.

**Key words** Liver transplantation, bile duct reconstruction · T tube, liver transplantation · Bile duct reconstruction

## Introduction

Biliary complications following orthotopic liver transplantation (OLT) are a common cause of surgical morbidity with a reported incidence of 10%–50% [3, 13, 18]. Graft loss and mortality have been reported in up to 10% of cases [4, 8]. Biliary complications include leaks, anastomotic and non-anastomotic strictures and may be secondary to technical failure, ischaemic or preservation injury. Complications have also been reported due to the use of a T-tube stent including accidental dislodgement, cholangitis and bile leak [3, 5, 13]. In attempting to minimise these complications, a number of different techniques have been used for bile duct reconstruction during OLT and have included the gallbladder conduit, duct-to-duct (end-to-end or side-to-side) anastomosis with or without a T tube or internal stent and Roux-en-Y hepatico-jejunostomy [2, 5, 6, 13, 19].

A prospective randomised study of biliary anastomosis comparing the use of a T tube to no T tube has been performed in 60 consecutive patients undergoing OLT.

## Patients and methods

The 60 consecutive patients were entered into the trial between January and December 1992. Thirty patients (18 male, 12 female; median age 42 years, range 16–64 years) had an end-to-end bile duct anastomosis over an 8 FG latex T tube. The second group of 30 patients (17 male, 13 female; median age 45 years, range 19–65 years) had an end-to-end bile duct reconstruction without the use of a T tube or internal stent.

The indications for transplantation are shown in Table 1. Primary biliary cirrhosis and fulminant hepatic failure were the commonest indications. Factors that could contribute to biliary complications were noted and included aetiology of liver disease, graft cold ischaemic time, operative blood loss, recipient's serum bilirubin level prior to transplant and the Child-Pugh score. Both groups were well matched for these parameters (Table 2). All patients re-

**Table 1** Aetiology of liver disease

| | T tube | No T tube |
|---|---|---|
| Primary biliary cirrhosis | 7 | 8 |
| Fulminant liver failure | 6 | 4 |
| Cryptogenic cirrhosis | 2 | 3 |
| Chronic active hepatitis | 2 | 2 |
| Hepatoma | 2 | 1 |
| Carcinoid | – | 1 |
| HBV cirrhosis | 3 | 4 |
| HCV cirrhosis | 3 | 1 |
| Alcoholic cirrhosis | 3 | 3 |
| α1 Antitrypsin deficiency | – | 1 |
| Polycystic liver | – | 1 |
| Epithelioid haemangioendothelioma | 1 | – |
| Hepatic fibrosis | 1 | – |
| Primary hyperoxaluria | – | 1 |
| | 30 | 30 |

**Table 2** Details of patients in the study. Valves given indicate median (range) (*FHF*, fulminant hepatic failure; *CLD*, chronic liver disease)

| | T tube ($n = 30$) | No T tube ($n = 30$) |
|---|---|---|
| Age (years) | 42 (16–64) | 45 (19–65) |
| Aetiology | FHF 6, CLD 24 | FHF 4, CLD 26 |
| Blood loss (liters) | 5.2 (0.99–18) | 5.6 (1–16) |
| Cold ischaemia (hours) | 11.3 (7–15) | 11.6 (4–20) |
| Bilirubin (mmol/l) | 229 (6–1121) | 232 (6–842) |
| Child-Pugh score | 9.6 (5–13) | 10.3 (6–14) |

ceived ABO blood group-compatible grafts. Compatible, but non-identical, ABO blood group grafts were transplanted in eight patients.

All donor livers were perfused with cold University of Wisconsin (UW) solution via the portal vein and Marshall's solution was used via the aorta for kidney preservation. The gallbladder was drained and flushed with 40–60 ml of normal saline solution and the biliary tree was flushed with 150 ml of UW solution following donor hepatectomy.

A standard OLT was performed using veno-venous bypass in 58 out of 60 patients. Bypass was not used in two patients because of their young age and haemodynamic stability during a trial of inferior vena cava clamping. Randomisation of each patient was performed after vascular anastomoses were completed and following inspection of donor and recipient bile ducts. Inspection of bile ducts identified any major size discrepancy that would exclude a patient from randomisation. Every patient was eligible for randomisation unless he was excluded according to exclusion criteria followed in this trial. Randomisation was by drawing a card (previously marked either as "T tube" or "no T tube") from a ballot-box. A uniform technique of bile duct reconstruction was used by all surgeons involved in this study. Five surgeons (two consultants and three trainees) were involved in this study and the distribution of cases for both groups was similar for each surgeon. The bile duct anastomosis was performed using an interrupted layer of 5.0 or 6.0 polydioxanone suture, placing the back row knots on the inside. After completion of the posterior wall, a T tube was inserted into the supraduodenal portion of the recipient's common bile duct and the front row of biliary anastomosis was completed with the same interrupted suture but with the knots placed on the outside.

Exclusions from the study included patients less than 16 years of age, patients with primary sclerosing cholangitis requiring choledocho-jejunostomy or undergoing retransplantation and cases of major discrepancy in duct size between donor and recipient. Duration of T-tube gravity drainage during the post-transplant period was 10 days before progressive daily clamping of the T tube (4 hourly and 12 hourly) until it was fully clamped. The T tube was removed 12 weeks after surgery. All patients from both groups were followed regularly with liver function tests and clinical examination. T-tube cholangiography was performed only if clinically indicated in the post-transplant period. An ultrasound scan was performed at 1 week and at 3 months post-transplant for evidence of intrahepatic bile duct dilatation. Endoscopic retrograde cholangiopancreatography (ERCP) was performed in patients from the no T tube group to assess liver dysfunction if liver function tests, ultrasound and liver biopsy were not conclusive of features suggesting biliary obstruction. Patients in the T tube group had ERCP only to assess or treat biliary problems previously diagnosed with ultrasound and T-tube cholangiography. A Doppler ultrasound of the portal vein and hepatic artery was also performed at these times. A (HIDA) scan was not performed in the patients in this series.

"Early" biliary complications were defined as those occurring during the first 3 months post-transplant and "late" were those occurring beyond this period. The standard postoperative immunosuppressive regimen was a triple drug protocol including cyclosporin A (CyA; 3–5 mg/kg per day), azathioprine (1–1.5 mg/kg per day) and prednisolone (40 mg/day) to both groups. According to the protocol, CyA was given intravenously (i.v.) to the T tube group for 10 days and then orally after the T tube was fully clamped.

Patients in the no T tube group would start on i.v. CyA and convert to oral CyA 5 days post-transplant provided they had established oral feeding.

Acute rejection episodes were treated with methylprednisolone i.v. infusions (1 g) for 3 consecutive days. Patients with acute ongoing rejection episodes or chronic rejection were converted to FK 506 (0.05–0.1 mg/kg per day).

## Results

Seventeen patients were excluded from the trial because a Roux-en-Y hepatico-jejunostomy was used for biliary reconstruction (eight had retransplants and five primary sclerosing cholangitis). One patient undergoing a combined heart-liver transplant and two patients with a significant donor:recipient duct size discrepancy had T-tube stents and were excluded from the trial.

Significant biliary complications occurred in five patients (16.6 %) in the T tube group. These included one patient in whom a bile leak and generalised peritonitis occurred due to accidental dislodgement of the T tube 2 weeks post-transplant. Following laparotomy, peritoneal lavage and drainage he underwent endoscopic stent placement and made an uncomplicated recovery. A late bile duct stricture occurred in one patient at 5 months and was treated successfully with balloon dilatation and stenting. Two patients had severe cholangitis at

3 months that settled following T-tube removal. One patient developed a biliary stricture secondary to hepatic artery thrombosis 4 months post-transplant and was successfully retransplanted.

In the no T tube group, six patients (20 %) developed biliary stricture; of these, five presented later than 3 months. One bile duct stricture occurred secondary to hepatic artery stenosis and was managed successfully by balloon angioplasty and endoscopic bile duct balloon dilatation. The other five patients were treated with endoscopic balloon dilatation and stenting. Of these, two resolved without further treatment; however, the remaining three underwent Roux-en-Y hepatico-jejunostomy for recurrent stricture.

Two (one from each group) out of eight patients who received compatible, but non-identical, ABO blood group grafts developed biliary complications. A patient from the T tube group developed prolonged cholestasis with cholangitis and another from the no T tube group developed a bile duct stricture.

A number of minor complications in the T tube group included three patients with ascitic leak around the T tube and two patients with local pain and low-grade fever after T-tube removal. In the no T tube group minor complications included two patients with prolonged mild cholestasis in the early postoperative period. Both underwent ERCP and liver biopsy, which were normal. No treatment was needed in either group for these minor complications.

The median i.v. CyA administration was 10.5 days (range 9–12 days) for the T tube group and 6 days (range 4–7 days) for the no T tube group. Six patients in the no T tube group had seven episodes of acute rejection that were treated with methylprednisolone. One patient developed chronic rejection and was converted to FK 506 and finally retransplanted. Seven patients in the T tube group had nine episodes of acute rejection that were treated with methylprednisolone. Three patients developed chronic rejection and were converted to FK 506. Two responded successfully and one was retransplanted. Severe gastrointestinal problems such as diarrhoea were present in four patients in the no T tube group and three in the T tube group in the early post-transplant period but did not affect the levels of immunosuppressive drugs.

The median patient follow-up for both groups was 30 months and no statistically significant difference was found between the two groups with respect to biliary tract complications ($P > 0.05$). A comparison of the 10 patients with significant biliary tract complications to the 50 without showed no significant difference for median operative blood loss (7.5 l vs 5.3 l). There was a significant difference in the median cold ischaemic time (14.5 h for the biliary complication group vs 11 h for the group without complications; $P < 0.01$, Mann-Whitney U-test).

The overall mortality was 16.6 %, which included five patients (16.6 %) in the T tube group and five (16.6 %) in the no T tube group. Eight patients died as a result of multi-organ failure or cerebral oedema; of these, four had been transplanted for fulminant hepatic failure. One patient with hepatoma died due to cardiac failure and one patient with epithelioid haemangio-endothelioma died from metastatic disease. Mortality was unrelated to biliary complications or biliary sepsis.

## Discussion

Despite improvements in organ preservation, surgical techniques and immunosuppressive therapy, biliary complications remain a significant cause of morbidity following liver transplantation [2, 3, 8, 13, 18, 19]. These complications have been associated with the techniques of surgical anastomosis, graft ischaemia, suture material, cold ischaemic time, ABO incompatibility, chronic rejection, cytomegalovirus infection and recurrence of primary ductal disease [5–7, 9, 11, 14–16].

The method most widely used for biliary reconstruction is end-to-end choledocho-choledochostomy over a T tube because it avoids intestinal surgery, preserves the sphincter of Oddi, decompresses the biliary tree in the early postoperative period and allows monitoring of bile production and radiological access to the biliary tree. However, the use of a T tube is associated with complications in up to 35 % of transplants including bile leak from the site of T-tube insertion, accidental dislodgement, obstruction, cholangitis and local or diffuse peritonitis after removal, even several months after surgery. An end-to-end bile duct anastomosis without the use of a T tube or an internal stent offers the advantage of avoiding these complications [1, 6, 14, 17, 19]. In the present series, five patients in the T tube group experienced minor but significant complications in addition to major complications, which would further support the discontinuation of the routine use of T tubes.

Two patients presented with late biliary strictures due to hepatic artery stenosis in one group and hepatic artery thrombosis in the other. The patient from the no T tube group with hepatic artery stenosis underwent a successful angioplasty and biliary dilatation as previously described [11]. Hepatic artery stenosis or thrombosis should be excluded in patients with anastomotic and non-anastomotic biliary strictures with the use of Doppler ultrasonography, and abnormal or absent signals should be investigated by visceral angiography [4, 12, 19].

The overall incidence of biliary strictures was 13.3 % (eight patients) and compares with the experience reported by others [4, 8, 18, 19]. An association of prolonged cold ischaemic time with UW solution-perfused livers and the subsequent development of biliary stric-

tures has previously been reported [7, 10, 15]. Prolonged storage of grafts may cause biliary complications by direct injury to bile duct epithelium or by reperfusion injury to the microvasculature of the bile duct arteriolar plexus.

Biliary strictures were more common in the no T tube group than in the T tube group (6 vs 2). This could have been due to these patients having had a small bile leak that was not clinically detected and that resulted in a localised stricture, whilst patients with a T tube were protected. Since the completion of the trial, the incidence of biliary strictures after duct-to-duct anastomosis without a T tube in 100 consecutive liver transplant patients has been less than 10%. The higher biliary stricture rate reported in this series may have been related to a "learning curve" following the introduction of this method of bile duct anastomosis in our unit.

The place of endoscopic balloon dilatation and stenting in the management of biliary strictures has still to be defined [9, 11, 17, 19]. In patients with early strictures (less than 3 months), dilatation and stenting of the stricture was more likely to result in successful outcome without the need for surgical reconstruction. Late strictures tended to recur and usually came to surgical revision by conversion to Roux-en-Y hepatico-jejunostomy.

In conclusion, biliary complications were not a cause of death or graft loss in this series. Hepatic artery stenosis or thrombosis should be excluded by Doppler ultrasound and, if indicated, by angiography if biliary complications occur. An association between the development of biliary complications and prolonged graft cold ischaemic time was noted. There was no difference between the groups in the overall incidence of biliary complications and the routine use of T tubes has been discontinued.

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