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Biliary reconstruction with or without an internal biliary stent in orthotopic liver transplantation: a prospective randomised trial

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Abstract Choledochocholedochostomy (CCD) with a 7 fr/8 fr Cotton Leung internal biliary stent removed at endoscopic retrograde cholangiography (ERC) 3 months following orthotopic liver transplantation (OLT) was the technique used on our unit for biliary reconstruction. From June 1995 to July 1996, we randomised 37 OLT patients with CCDs to receive either an internal stent (group I, *n*d= 18) or no stent (group II, $n = 19$). Patients in group I had an ERC at 3 months for stent removal whereas patients in group II had an ERC if indicated. The mean follow up was 19 (13–26) months. Biliary complications occurred in 9 out of 18 patients in group I compared to 1 out of 19 patients in group II ($P = 0.007$). In group I, ERC was required for complications in 8 patients and early surgery in 2, compared to 1 ERC for abnormal liver function tests in group II. Five of the early complications in group I were stent related. Late biliary stenosis occurred in 1 patient at 9 months. There was one stent-related death. The use of stents contributes to biliary complications and CCD without stenting is safe after OLT.

Key words Biliary complications · Liver transplant · Biliary stent

Introduction

At orthotopic liver transplantation (OLT) most patients undergo primary choledochocholedochostomy (CCD) as the method of primary biliary reconstruction [1]. The place of indwelling biliary stents following completion of the anastomosis has in recent times been debated, although most centres used to splint the CCD [1, 2]. T tubes have been associated with a significant rate of biliary leaks following their removal and although there are no large randomised controlled trials, recent published literature suggests that biliary complications following OLT remain the most significant source of patient morbidity and mortality [1].

When our liver transplant programme started, all patients undergoing primary CCD had a 7 fr/8 fr Cotton Leung polyvinyl internal biliary stent inserted. At 3 months the stents are removed using a side-viewing duodenoscope and diagnostic endoscopic retrograde cholangiography (ERC) was performed. A retrospective review of the first 71 patients in 1995 revealed an acceptable overall biliary complication rate of 17%, but an unacceptably high rate of septic complications related to removing the stent [3]. This prompted us to embark on a randomised controlled trial comparing a stented group of patients to a group who had a non-stented end-to-end CCD.

Patients and methods

From June 1995 to July 1996, we randomised 37 consecutive transplant patients who had OLT with CCD to receive either an internal stent (group I, $n = 18$) or no stent (group II, $n = 19$). All patients in group I had ERC at 3 months with a view to stent removal. Patients in group II had ERC if clinically indicated. All biliary anastomoses were sutured with interrupted 5/0 polydioxanon (PDS; Ethicon) suture.

The two groups were comparable for age, sex, donor age, indication, immunosuppression, antimicrobial prophylaxis, cold is-

Table 1 Indications for liver transplantation

Indication	Stented	Non-stented
Alcoholic liver disease	4	6
Viral hepatitis	4	3
Primary biliary cirrhosis	3	4
Seronegative hepatitis	2	1
Others	3	4
Cryptogenic cirrhosis	2	1
Total	18	19

Table 2 Methods: donor and liver characteristics. Results expressed as median and range

	Stented	Non-stented	Significance
Cold ischaemia time (min)	702 (371–994)	732 (362–1050)	n.s.
Warm ischaemia time (min)	49 (20–86)	51 (30–114)	n.s.
Arterial ischaemia time (min)	45 (26–209)	37 (19–60)	n.s.
Donor age (years)	39 (17–59)	47 (23–59)	n.s.
Recipient age (years)	53 (13–66)	49 (19–69)	n.s.
Donor arterial anatomy (% normal)	13 (72%)	16 (84%)	n.s.

Table 3 Complications

Complication	Stented	Non-stented
Bile leak	2	–
Cholangitis	2	1
Cholangitis + blocked stent	2	–
Blocked stent	2	–
Stricture	1	–
Duodenal perforation	1	–

Table 4 Indications for endoscopic retrograde cholangiography

Indications	Stented	Non-stented
Routine stent removal	7	–
Cholestasis	2	–
Bile leak	2	–
Cholangitis	4	1
Other	–	3

chaemia time and early graft function parameters (Tables 1, 2). Statistical analysis was by the chi-squared test and results were considered significant at $P < 0.05$.

Results

Mean follow up overall was 19 months (13–26). Biliary complications occurred in 9 out of 18 patients in group I compared to 1 of 19 patients in group II ($P = 0.007$) (see Table 3). In group I, endoscopic intervention was required in 5 patients to remove blocked stents (and associated clinically significant cholangitis). Two patients in group I experienced bile leakage requiring early surgery (Roux en y in both including drainage of an intraabdominal abscess in 1 patient with a perforated duodenum) compared to one endoscopic intervention for abnormal liver function tests in group II. Five of the early complications were related to the stent (four blocked stents, one duodenal perforation). Late biliary anastomotic stenosis requiring reconstruction occurred in 1 patient at 9 months (see Table 3). There were no late strictures in group II, however, our mean follow up is only 19 months. There was one stent-related death in the patient with duodenal perforation due to septicaemia. As a result of this we have now discontinued the use of stents in our practice, preferring end-to-end CCD for biliary reconstruction without stents with a subsequent decrease in biliary complications.

Discussion

Biliary complications after liver transplantation continue to be reported in 8–25% of patients [4–6]. The rationale for biliary stenting after biliary reconstruction was to facilitate precise completion of the anterior wall, to permit easy cholangiography, to provide postoperative decompression of the biliary tree and to estimate quality and quantity of bile production [1]. With improvements in surgical techniques, better organ preservation, the realisation that ERC posttransplant can be performed safely and the high incidence of stent-related biliary complications, the use of a biliary stent has been questioned.

The use of the endobiliary stent has the advantage of easy endoscopic removal without the risk of an exit site bile leak, as seen with the use of T tubes. An earlier retrospective analysis on our unit revealed that this method was safe and effective although there was a high incidence of sepsis related to stent removal at ERC [3]. Other groups have reported a higher incidence of T tube-related problems following CCD compared to patients without T tubes [7, 8].

In this small randomised trial we have seen a high incidence of biliary complications, particularly related to the use of the endobiliary stent. A blocked stent with or without cholangitis was the commonest indication for intervention with ERC (Table 4) and subsequent stent removal. Endoprosthetic stenting may alter the endobiliary microflora and this could predispose to cholangitis and more generalised septic complications [9]. Recent data published in abstract form at the recent ASTS suggest that endoprosthetic stents are more suitable than T tubes with a reduction in biliary complications from 26% to 7% [10]. Although the numbers in-

volved are not large, only 1 of 19 non-stented patients in our study developed biliary complications. In view of the one stent-related death in a patient with a duodenal perforation and the high incidence of blocked stents, we have discontinued the use of stents during CCD at OLT.

We have shown in this small prospective randomised study that the use of biliary stents may even contribute to some of the complications after OLT, and that CCD without stenting is a safe and efficient technique for biliary reconstruction after OLT. We do, however, recognise the need for continuing long-term follow up to document the incidence of late stenosis.

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