Use of a stepwise versus straightforward clamping biliary drainage tube after living donor liver transplantation: A prospective, randomized trial.

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A short running head: Clamping method for biliary splint closure after LDLT

Abstract

Background/Purpose. There has been no report describing the optimal clamping method for biliary drainage tubes, although biliary splinting and drainage plays an important role in living donor liver transplantation (LDLT).

Methods: We generally use a 2 mm tube for the splint at the biliary anastomosis, and externalize it through the lower common bile duct. When the serum levels of total bilirubin were lower than 5 mg/dl, and negativity for biliary complications and a good passage of contrast media to duodenum was confirmed, then the drainage tubes were clamped. To determine the optimal clamping method, patients were randomly divided into two groups; those whose stents were subjected to stepwise clamping for 3, 6, 12 and 24 hours per day (n=20), or those subjected to straightforward clamping (n=20).

Results: The results of liver function tests and rate of clamping failure were not different between the two groups after the different clamping methods were used.

Conclusions: The straightforward clamping could be a simple and reasonable method to close a biliary drainage tube after LDLT.

Key words clamp, liver transplantation, biliary drainage, tube

Introduction

Biliary drainage and splinting plays an important role in living donor liver transplantation (LDLT) since the rate of biliary complications is higher in LDLT than in deceased donor whole LT[1,2]. Therefore, we generally use an external biliary splint and have previously reported the two-step method used for removal of the splint.[3] Anecdotally, the stepwise clamping method has been sometimes preferred and has been adopted to train the sphincter of Oddi in the papilla Vater after decompression through the drainage tube following LT. This is due to the concerns that straightforward clamping may lead to dysfunction of the sphincter of Oddi after long term decompression through the stent tube. However, it has not been known whether stepwise clamping truly yields a better outcome, and there has been no report examining this matter, especially in cases of liver transplantation.

Therefore, we investigated 40 LDLT patients who were randomly allocated into two groups using different clamping methods for the biliary drainage tube.

Methods

Patients

Of 66 patients transplanted between May 2006 and October 2009, we performed 65

adult-to-adult LDLTs. Of those 65, 40 patients who underwent duct-to-duct biliary reconstruction with a tube splint at the anastomotic site and survived beyond 3 months were included in this study. This prospective randomized control study was conducted under the permission of institutional ethics committee. Six ABO incompatible patients received a single dose of rituximab 1 week prior to LDLT.[4]

Biliary drainage tube placement.

As reported previously, we used a chloride vinyl tube of 2mm in diameter, which was originally used for retrograde transhepatic biliary drainage, for our LDLT patients.[3] The tube was equipped with a malleable metallic dull-tipped splint at one end. Prior to duct-to-duct biliary anastomosis, the metallic splint of the tube was inserted from the lumen of the recipient's side of the hepatic duct and externalized through the common bile duct above the upper edge of the duodenum. Subsequently, duct-to-duct anastomosis was performed with interrupted sutures of 6-0 PDS-II, and the tube was placed inside the graft intrahepatic bile duct for decompression and splinting. After the placement, the externalized site of the common bile duct was treated with purse-string sutures using 6-0 PDS-II. Ductplasty was performed in 4 patients of the right lobe graft in whom two tubes were placed in both anterior and posterior bile ducts in the 3 patients.

In other patient with right lobe graft, two tubes were placed since the anterior and posterior bile ducts were distant for which ductplasty was impossible.

Groups.

When the serum levels of total bilirubin were lower than 5 mg/dl, and negativity for any biliary complications (leakage or severe stricture) and a good passage of contrast media to duodenum were confirmed using fluoroscopic study, an attempt to clamp the biliary drainage tube was initiated 1 day after the fluoroscopic study. The following two methods were used for the clamping: For stepwise clamping (n=20), the drain tube was clamped for 3 hours on day 1, 6 hours on day 2, 12 hours on day 3 and 24 hours per day thereafter. After each temporary clamping, the biliary drainage tube was opened and externally drained. For the straightforward clamping (n=20), the drain tube was clamped and remained closed.

After the clamping, liver function tests (T. Bil: total bilirubin, ALT: alanine aminotransferase, ALP: alkaline phosphatase, GGT: gamma glutamyl transpeptidase) were performed on days 1 and 3. During the clamping period, the patients continued to eat hospital meals three times a day.

Statistics.

All data were expressed as the median values with ranges. The statistical analysis was performed using the Mann-Whitney U-test for continuous values. Statistical significance was defined as a p-value of < 0.05. The StatView 5.0 software program (Abacus Concepts, Berkeley, CA, USA) was used for all statistical analyses.

Results

Table 1 shows the characteristics of the patients in the study. There were no statistical differences in age, gender, graft type, the starting day of clamping after LDLT and ABO incompatibility between the groups.

At the time of the clamping, there was also no significant difference in the serum levels of T. Bil, ALT, ALP and GGT. After each type of clamping of the biliary drainage tube, there were no significant difference between the groups in the serum levels of total bilirubin, AST, ALP or GGT on days 1 and 3. There was no clamping failure in either of the groups.

Discussion

In the present study, we demonstrated that there were no differences in the patient

outcomes after using the stepwise versus the straightforward clamping method for the biliary drainage tube after LDLT.

Biliary splinting plays an important role in LDLT, as the rate of biliary complications is higher in LDLT than in diseased donor whole LT.[1,2] We generally use a 2-mm tube for stenting at the biliary anastomosis, externalize it through the lower common bile duct, and fistulize it using the duodenal serosa.[3] The safety of the two-step procedure for removal of the splint tube was reported previously by our group.[3] In this report, in order to clarify the effects of the stepwise clamping method, a prospective study was performed.

In our patients, there were no differences in the distribution in graft type, thus indicating no differences in the use of right lobe grafts, right posterior grafts and left lobe grafts. After the clamping, we observed no differences between the outcomes in the patients treated using the two different clamping methods. In addition, in the subgroup analysis of graft type within each group, there were no significant differences in any of the parameters. Moreover, ABO incompatible patients did not show any additional response after clamping of the biliary drainage tube, regardless of the clamping method used.

In one patient, we started to clamp the tube when the level of total serum bilirubin was still more than 5 mg/dl because of a lack of any biliary complications at 2 months after LDLT. As a result, there was no increase in any of the parameters in the patient in the straightforward group.

Studies on the duration of the clamping procedure have only been performed in the area of total knee arthroplasty.[5-8] In one of those studies, a reduction of blood loss was confirmed when 1-hour clamping was applied as compared to a 4-hour clamping method.[5] However, there has been no previous report describing the clamping method or duration of use for a biliary drainage system, therefore, even specialists in this field sometimes adopt the conventional stepwise method after LDLT

In conclusion, we performed a randomized control study to examine the differences arising due to the use of different clamping methods. Our results indicate that the straightforward clamping method could be a simple and reasonable method to successfully close biliary drainage tubes after LDLT.

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Table 1 . Patient characteristics and liver function test after the clamping.

	Stepwise (n-20)	Straightforward (n=20)	
Age	56 (31-67)	57 (33-68)	n.s.
Gender (M:F)	13:7	13:7	n.s.
Graft type (Right side graft : Left lobe graft)	10:10	10:10	n.s.
Bile duct plasty	3	1	n.s.
Double tubes	3	0	n.s.
ABO incompatible	1 (5%)	5 (20%)	n.s.
The starting day of the clamp	22 (12-54)	29 (9-59)	n.s.
T. Bil before clamp	1.9 (0.6 – 5.6)	2.0 (0.6 – 11.1)	n.s.
after 1 day	1.9 (0.5 – 5.4)	1.8 (0.7 – 9.6)	n.s.
after 3 days	1.5 (0.5 – 4.6)	1.5 (0.4 – 7.2)	n.s.
ALT before clamp	73 (24 - 177)	89 (5 - 537)	n.s.
after 1 day	67 (21 - 178)	80 (7 - 567)	n.s.
after 3 days	60 (16 - 177)	81 (8 - 542)	n.s.
ALP before clamp	377 (115 – 1,744)	369 (176 – 1,100)	n.s.
after 1 day	382 (136 – 1,736)	377 (107 – 1,260)	n.s.
after 3 days	345 (138 – 1,698)	380 (169 – 1,410)	n.s.
GGT before clamp	94 (13 - 368)	100.5 (17 - 538)	n.s.
after 1 day	113 (17 - 358)	150 (16 - 549)	n.s.
after 3 days	94.5 (14 - 365)	100 (16 - 577)	n.s.

n.s.: not significant, T. Bil: total bilirubin, ALT: alanine aminotransferase, ALP: alkaline phosphatase, GGT: gamma glutamyl transpeptidase