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Long-term outcomes of endoscopic management for biliary strictures after living donor liver transplantation with duct-to-duct reconstruction

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Keywords

biliary complication, endoscopic management, living donor liver transplantation.

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Summary

Biliary strictures after living donor liver transplantation (LDLT) with ductto-duct (D-D) reconstruction are associated with postoperative morbidity and mortality. The aims of this study were to evaluate the long-term outcomes of endoscopic deployment of plastic stents, and to investigate factors associated with the stent deployment failure. Between April 2001 and May 2007, 96 patients received LDLT with D-D reconstruction at Okayama University Hospital. Among them, 41 patients (43%) had anastomotic biliary strictures, and all were referred first for endoscopic retrograde cholangiography (ERC). When deployment was unsuccessful, a percutaneous transhepatic procedure was employed. Successful stent deployment was achieved in 35 out of total 41 patients (85%) by both procedures. Among the 35 patients, 28 had their stents removed as a result of strictures resolution. Eight patients underwent ERC and repeated stent deployment as a result of recurrence of the strictures. Finally, 21 out of 41 (51%) patients with biliary stricture were completely treated by endoscopic therapy during the observation period (median 873 days: range 77-2060). By multivariate analysis, biliary leakage was associated with stent deployment failure. Endoscopic deployment of plastic stents is a first-line therapy for patients with biliary stricture after LDLT.

Introduction

Living donor liver transplantation (LDLT) has become an accepted therapeutic option for patients with end-stage liver disease, and duct-to-duct (D-D) biliary reconstruction has been preferred to cholangiojejunostomy for several reasons [1–4].

However, biliary complications such as biliary stricture, biliary leakage, or cast syndrome after LDLT with D-D reconstruction are major issues which still require resolution [1–4]. These complications may occasionally lead to graft failure, necessitating re-transplantation, or to death.

It is reported that complications occur in 16–32% of adult LDLT patients [1–4].

Endoscopic procedures such as stent deployment and/ or balloon dilatation have been reported to be effective for the management of biliary strictures after deceased donor liver transplantation (DDLT) [5–9]. However, it remains controversial whether to apply the same endoscopic procedures to LDLT patients, because LDLT differs from DDLT in the type of graft used. Moreover, D-D reconstructions vary with the biliary anatomy of the donor liver. The types of biliary strictures that occur after LDLT are more complex than those after DDLT because of the technical difficulties and critical blood supply associated with short ducts, problems which do not occur in full-size livers [3,4].

Despite several reports on endoscopic management for biliary strictures after LDLT, these reports consist of case reports on a small number of patients and describe only short-term outcomes, which are limitations. In addition, the specific type of endoscopic procedure that was used, including sphincterotomy, papillary balloon dilatation and stenting, had not been spelt out explicitly in these reports [10–13].

In our institution, an endoscopic procedure with plastic stent deployment has been performed as a first-line procedure for all anastomotic biliary strictures ever since we had begun performing LDLT with D-D reconstruction in 2001. In this study, we retrospectively evaluated the efficacy and long-term outcomes of endoscopic management for biliary strictures after LDLT. Furthermore, we analyzed the factors that were associated with stent deployment failure.

Patients and methods

Patients

Between April 2001 and May 2007, 141 patients underwent LDLT at Okayama University Hospital. Among these patients, 96 (68%) received LDLT with D-D reconstruction and the remaining with choledochojejunostomy. The type of reconstruction performed was at the surgeon's discretion after considering the conditions of the donor and recipient.

Ninety-six patients (58 men and 38 women) ranging in age from 19 to 65 years were enrolled in the study. Rightlobe LDLT was performed on 64 patients and left-lobe LDLT on 32 patients. In the graft cases with a single biliary orifice, a single D-D biliary anastomosis was performed. When a graft had two or more biliary orifices located near each other, ductoplasty was performed to construct a single biliary orifice. If these orifices were distantly located, two anastomoses were instead constructed to the orifices of the right anterior and posterior branches using the recipient's hepatic duct and cystic duct respectively. We performed this construction on five patients. An external or internal stent was routinely placed through the anastomosis. However, the type of sutures and types and duration of stenting changed over time at the surgeon's discretion to lessen the biliary complications. All patients received immunosuppression with tacrolimus hydrate or cyclosporine combined with steroids.

Of the 96 patients, 41 (43%) had anastomotic biliary strictures and all were referred first for endoscopic retrograde cholangiography (ERC). Their demographic data is summarized in Table 1.

Table 1. The demographic data of the 41 patients who had duct-to-duct anastomotic biliary strictures after LDLT.

Age(years), mean (range)	55 (27–66)
Gender M/F	26/15
Disease	
Liver cirrhosis (viral or/and alcoholic)	15
Hepatocellular carcinoma	14
Fulminant liver failure	4
Others	8
Right-lobe LDLT or Left-lobe LDLT	27/14
Orifice of the graft	
Single (right lobe)	13
Single (left lobe)	14
Two or more than two (right lobe)	14
Two or more than two (left lobe)	0
Follow-up period (days), median (range)	873 (77–2060)

LDLT, living donor liver transplantation.

Referral for ERC was based on clinical symptoms including fever, jaundice, and abdominal pain, and/or increasing elevation of hepatobiliary enzymes, and/or detection of emerging dilation of the intrahepatic bile duct (IHBD) in the graft liver as confirmed by radiological studies, such as abdominal ultrasonography, computed tomography, and magnetic resonance cholangiopancreatography (MRCP).

When no emerging dilatation was detected by radiological studies irrespective of the suspicion of biliary strictures because of clinical symptoms and abnormal liver test, liver biopsy and a test for viral markers were performed to exclude rejection and recurrence of viral hepatitis respectively. After ruling out these issues, ERC was performed to confirm the strictures.

Endoscopic protocol

Written informed consent for ERC and endoscopic biliary stent deployment was obtained from all patients. As endoscopic biliary drainage is a routine procedure for patients with biliary strictures, our institute did not require ethical committee approval. Before ERC, we performed Doppler US and dynamic CT to exclude hepatic artery thrombosis. The procedures were performed under conscious sedation by intravenous diazepam (5–10 mg) and pethidine hydrochloride (35–140 mg), and duodenal relaxation was obtained with scopolamine butylbromide (10 mg) or glucagon (1 mg).

The procedures were performed with a JF240 or JF260V duodenoscope (Olympus Optical Co, Ltd, Tokyo, Japan). After selective bile duct cannulation and confirmation of biliary strictures by injection of contrast material, a 0.035-inch guidewire (Linearguide guidewire; Olympus or Radifocus guidewire, Terumo Co., Tokyo, Japan) was

advanced into the IHBD through the strictures. In rare instances, it was difficult to advance the dilation catheter through a very hard stricture after the tip of the guidewire reached the IHBD. In such cases, a Soehendra stent retriever (Cook Endoscopy, Winston-Salem, NC, USA) was employed as a dilator [14,15], and then a balloon dilation catheter (6-8 mm in diameter, Hurricane RX; Boston Scientific, Cork, Model Farm Road, Cork, Ireland) was applied for further dilation. Biliary stones or casts, if present, were removed after dilation. Usually, at the first stent deployment, a 7Fr plastic stent (Zimmon-type ERBD stent, Cook Endoscopy, Winston-Salem, NC, USA, or Flexima, Boston) was deployed through the stricture and its distal end was exposed in the duodenum lumen through the duodenal papilla. We did not use the 'inside stent' as reported by Hisatsune et al. [16]. A 6Fr or 5Fr stent was deployed when the IHBD was not dilated sufficiently, as we had some cases with liver abscess which had unexpectedly formed after the tip of the 7Fr stent became wedged into a small biliary branch. Stent length varied depending on the anatomic location of the stricture. When multiple stents or a large-bore stent (8.5-10Fr) were deployed, endoscopic sphincterotomy (EST) was performed. In addition, difficult cannulation sometimes occurred because of left graft hypertrophy or postoperative adhesions, and needle-knife precutting papillotomy (NKPP) was performed in those cases. Successful deployment was associated with the improvement of clinical symptoms, biochemical tests and radiological studies. If improvement was not seen after the first deployment, ERC was repeated. Successful stent deployment that occurred only via the endoscopic procedure was defined an 'immediate success'. If 'immediate success' was not obtained, a percutaneous transhepatic procedure was performed. After puncturing the target branch that was not amenable to the endoscopic procedure, the catheter was advanced into the recipient's common bile duct through the stricture using a guidewire. In some cases, no improvement of the stricture was obtained regardless of repeated percutaneous balloon dilatations of the stricture. The rendezvous technique was then employed to lessen the duration the percutaneous catheter had to be kept in [17,18]. A guidewire was advanced through a transhepatic route to the duodenal papilla, at which point the tip of the guidewire was captured by a snare and retracted into a channel of the duodenoscope. The plastic stent was successfully deployed across the stricture over the guidewire. Successful stent deployment via both endoscopic and percutaneous procedures was defined an 'eventual success'.

After successful stent deployment, clinical symptoms and biochemical tests were evaluated every month. Stent exchange was performed every 3–6 months until the stricture was improved. Anastomotic strictures were evaluated by opacification of the intrahepatic duct from the recipient-

side injection of contrast material. If the intrahepatic duct was opacified without delay and fading of the contrast material was obtained within 30-60 s, then the stricture was considered resolved and the stent was removed. If the stricture did not show signs of improvement, balloon dilatation was performed and a stent was deployed again. In stent re-deployment, the decision to increase the size of the stent depended on the case parameters. In some cases, a thicker diameter stent did not fit the donor-side bile duct. Stent obstruction or dislocation was suspected when the patient had fever and/or jaundice with abnormal laboratory parameters that indicated cholestasis. When this occurred, the stent was immediately exchanged. Even after stent removal based on successful resolution of strictures, re-stricture was suspected when the laboratory data was abnormal and IHBD dilatation was noted on radiological studies. In this case, ERC was performed; if it confirmed re-stricture, then stent deployment was performed.

Complications related to ERC procedures were defined and their severity graded according to the classification of Cotton *et al.* [19]. Pancreatitis was defined as severe abdominal pain that required an analgesic in conjunction with a serum amylase level elevated more than three times.

Statistical analysis

Comparisons of variables were analyzed using either Fisher's exact test when any of the expected values were <5 and the chi-squared test for all others. A *P*-value < 0.05 was considered significant. If there was more than one significant variable by univariate analysis, stepwise multivariate analysis with logistic regression analysis was carried out. All statistical analyses were performed with Statistical Analysis System software, version 8 (SAS Institute, Inc, Cary, NC, USA).

Results

ERC findings and therapy

Table 2 summarizes the ERC findings and endoscopic therapies. Biliary strictures were clinically diagnosed in 41 patients, and a total of 223 ERCs were performed on these patients. None of the patients had nonanastomotic biliary stricture and none had leakage from the transected liver parenchymal surface. EST was performed in 16 patients (39%) to deploy multiple stents (n = 4), a largebore stent (n = 7) and both (n = 5). In 10 patients (24%), NKPP was performed because of difficulty in cannulating. The number of stents placed was one each in 26 patients and two each in another nine patients. Stent size ranged from 5Fr to 11.5Fr.

Table 2. ERC findings and endoscopic therapies.

Time from LDLT (days), median (range)	85 (22–421)
No. ERC per patient, median (range)	5 (1–18)
Biliary leakage	14/41 (34%)
Stones	1/41 (2%)
EST	16/41 (39%)
NKPP	10/41 (24%)
Balloon dilatation	21/41 (51%)
Endoscopic therapy duration (days), median (range)	500 (21–1189)

ERC, endoscopic retrograde cholangiography; LDLT, living donor liver transplantation; EST, endoscopic sphincterotomy; NKPP, needle knife precutting papillotomy.

Short-term outcome

Figure 1 summarizes the clinical outcomes of the patients who had anastomotic biliary strictures. Ten patients (24%) had strictures that were not amenable to endoscopic procedures alone; the guidewire could not be passed through the strictures in seven patients, the fiberscope did not reach the duodenal papilla because of previous gastrectomy with Billroth II reconstruction in

one patient, stent removal was needed for cholangitis after stent deployment in yet another patient, and in the remaining case, the stricture with biliary leakage did not improve by stent deployment alone. These patients were subjected to the percutaneous procedure. Thereafter, two patients were not referred for ERC because the strictures were resolved, while four patients received endoscopic stent deployment after the percutaneous procedure. The same endoscopic procedure was performed on these four patients, and their clinical symptoms and laboratory data improved. However, the strictures of the remaining four patients who underwent both endoscopic and percutaneous procedures were not resolved; one underwent re-transplantation 169 days after the first ERC, two had a percutaneous transhepatic biliary drainage (PTBD) tube inserted and died of another disease 368 and 558 days afterwards, and one with biliary leakage underwent a surgical procedure but died of liver failure 85 days after transplantation. The median number of ERCs to achieve the first successful stent deployment with improvement of clinical symptoms was one (range 1-5) (Table 3).

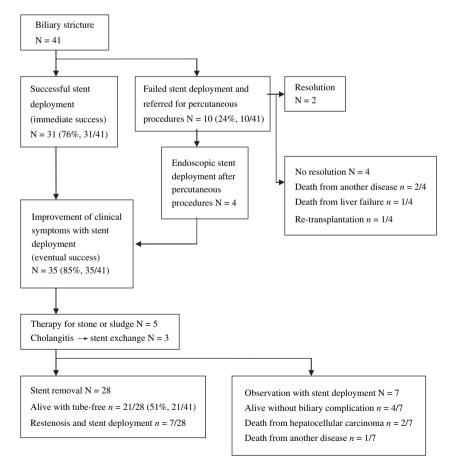


Figure 1 Clinical outcomes of the 41 patients who had anastomotic biliary strictures.

Table 3. Number of ERC in 35 patients in whom the first successful stent deployment was achieved.

No. ERC	1	2	3	4	5
No. patients	25	5	0	3	2
Cumulative success rate of 41 patients (%)	61	73	73	80	85

ERC, endoscopic retrograde cholangiography.

Long-term outcome

Among the 35 patients, 28 had their stents removed because the strictures were considered resolved. The median time from stent deployment to removal was 436 days (range 21-1189), and the median number of ERCs was four (range 1-11). In 21 of these 28 patients, there was no further requirement for therapeutic interventional procedures for a median of 658 days (range 322-1240). Therefore, using the intention-to-treat baasis, 21/41 (51%) patients had the successful outcome of stricture resolution and stent retrieval (Fig. 1). However, the remaining seven patients underwent ERC and repeated stent deployment because of recurrence of the strictures at a median of 280 days (range 30-1369) after stent removal. All of these patients have recovered from morbidity with stenting. In these patients, the median number of ERCs from stent deployment to removal was six (range 1-9) (Fig. 2). These patients required frequent stent exchanges for stent dislocation and early stent obstruction followed by cholangitis.

Among the seven out of 35 patients who had stents deployed without removal by the end of the observation period in this study, four have been well with stenting for a median of 711 days (range 584–1053). Of the remaining three patients, two died of hepatocellular carcinoma recurrence 237 and 601 days after stent deployment and one died of another disease 77 days after.

Complications

Complications related to ERC procedures and stent deployment occurred in eight (19%) of the 41 patients

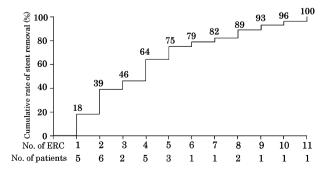


Figure 2 Number of ERC from stent deployment to removal.

Table 4. Complications related to endoscopic retrograde cholangiography procedures.

Cholangitis (moderate)	2/41 (5%)
Liver abscess	1/41 (2%)
Biliary stones	5/41 (12%)
Proximal side of the stricture	1
Distal side of the stricture	1
Both sides of the stricture	3

who had biliary strictures. Cholangitis occurred in two patients and one had liver abscess. Biliary stones as a consequence of stent placement occurred in five patients (Table 4). All patients with cholangitis were treated with stent exchange and intravenous antibiotics. One patient with liver abscess was treated with percutaneous drainage, stent exchange and intravenous antibiotics. All biliary stones were successfully removed without any surgical procedure. No post-ERC pancreatitis occurred.

Factors in stent deployment failure

We investigated the factors contributing to the failure of 'eventual success' that is, the stent deployment via both endoscopic and percutaneous procedures. The cut-off value of the length of the biliary stricture was defined by referring to its median value in all patients who had biliary strictures. By univariate analysis (Table 5), we found that two variables, the reach of the stricture and biliary leakage, were associated with stent deployment failure. By multivariate analysis, only the biliary leakage was significant.

Discussion

Biliary stricture is one of the most common complications in patients receiving liver transplantation with D-D biliary reconstruction, and this complication arises in both LDLT and DDLT. Despite this, D-D reconstruction of the bile duct at liver transplantation is preferred to choledochojejunostomy for several reasons [1-4]. Therefore, endoscopic stent deployment is used to ameliorate this morbidity, which can become fatal unless successfully treated, although the nature of the biliary strictures depends on the cases. There are several reports on the effectiveness of endoscopic therapy for biliary complications in DDLT [5–9]. LDLT has the potential to substantially increase the number of livers available for transplantation and therefore decrease the overall mortality for candidates awaiting DDLT [20,21]. Therefore, to optimize the outcomes of recipients, the complications that occur after LDLT should be managed by less invasive procedures than open surgery. In this study, we demonstrated not only the efficacy and safety of endoscopic management but its limitations,

Table 5. Univariate and multivariate analysis of risk factors for stent deployment failure.

Risk factors (n)	No. patients with failure (%)	<i>P</i> -value (univariate)	
Graft			
Right (27)	6 (22.2)	0.15	
Left (14)	0 (0)		
Single orifice and single and	astomosis		
Yes (27)	5 (18.5)	0.61	
No (14)	1 (7)		
Reach of the stricture			
Over the first branch (6)	3 (50.0)	0.04	0.089
Short into the first	3 (8.6)		
branch (35)			
Length of the stricture			
≥4 mm (25)	4 (16.0)	0.89	
<4 mm (16)	2 (12.5)		
Biliary leakage			
Yes (14)	5 (35.7)	0.02	0.045
No (27)	1 (3.7)		
Time from LDLT			
≥85 days (21)	2 (9.5)	0.61	
<85 days (20)	4 (20.0)		

LDLT, living donor liver transplantation.

because all patients with biliary complications after D-D reconstruction were initially subjected to endoscopic therapy from the beginning of the LDLT.

The reported rate of biliary strictures after LDLT is 16-32%. The rate of this complication in our series was to some extent higher (43%), and we cannot explain exactly why. D-D reconstructions in LDLT patients localize at the hepatic hilum unlike those in DDLT. The bile ducts around the hepatic hilum tend to anatomically become ischemic, and ischemia can be a factor leading to biliary strictures. The anatomical factor may be one of the reasons for the high incidence of biliary strictures in LDLT. According to the localization of strictures, they can be classified as anastomotic or nonanastomotic. As a special type of nonanastomotic strictures, the term 'ischemic-type biliary lesions (ITBLs)' recently emerged in DDLT [22]. The reported incidence of ITBLs differs greatly between different series, ranging from 1% to 19% in DDLT. The incidence of ITBLs in LDLT is unknown. They often start at the bile duct bifurcation and progress to the IHBDs. ITBLs are still difficult to deal with [23]. In our series, a typical case of ITBL was not found. Risk factors for ITBL can be divided into three different categories: ischemia-related injury to the biliary epithelium, immunologically mediated injury, and cytotoxic injury induced by bile salts [23]. The same risk factors may contribute to the high incidence of anastomotic strictures in LDLT patients, because D-D reconstruction is done at the hepatic hilum.

Using endoscopic therapy, we were able to avoid open surgery in most of the cases with biliary complications. However, the initial success rate (76%) of endoscopic therapy was not as high as we had hoped, and the number of endoscopic interventions was considerable. Furthermore, in some cases, the duration of therapy between the deployment and the removal of the plastic stents was over a year. Given these results, we intend to improve our endoscopic management of biliary strictures after LDLT, which is a very conventional procedure, by refining techniques and devices to obtain more favorable results.

The main reason for these results is that negotiation of the biliary strictures was very difficult in the LDLT patients, because the strictures were sometimes hard and twisted, probably resulting from fibrosis around an anastomosis and hypertrophy of the transplanted liver. In this study, we demonstrated by univariate analysis that the strictures overreaching the first branch of the donor's bile duct from anastomosis and the biliary leakage increased the risks of stent deployment failure. Furthermore, only the biliary leakage was significant by multivariate analysis, probably because biliary leakage often accompanied a complicated stricture. However, our success rate in this study was comparable to those of other studies (58-75%) [10-13]. In LDLT, an anastomosis forms in the hilar portion. As the transplanted liver enlarges, the bile duct sometimes kinks at the hilar portion [24]. Moreover, in some cases of complicated bile ductoplasty in a right lobe graft, it can be very difficult to seek anterior or posterior branches with a guidewire, if one of them has never been opacified by contrast material caused by severe strictures. In addition, in cases complicated with biliary leakage, the strictures were also not amenable to endoscopic therapy because the leaking of contrast material obscured the anastomotic site. Consequently, in these situations, we could not negotiate these strictures with the tip of the guidewire. Therefore, a percutaneous approach was necessary to overcome these difficulties.

There is one more reason why endoscopic management of biliary strictures in LDLT is difficult: namely, the size and number of plastic stents that can be used are limited. As an anastomosis is constructed at the hilar portion, the distance between the anastomosis and second branch is very short, especially in the case of rightlobe LDLT. Furthermore, intrahepatic ducts did not always sufficiently dilate in spite of the strictures. Therefore, deployment of a large-bore plastic stent or multiple plastic stents [25,26], which facilitate dilating strictures, is not technically feasible. In some cases, the proximal end of a plastic stent became stuck in a small branch when a proper plastic stent had not been selected. Thus, although very occasionally, segmental cholangitis was

induced and liver abscess was formed. Accordingly, we were forced to employ thin plastic stents after balloon dilatation.

As complications, cholangitis and biliary stones were observed, and could be treated endoscopically. In this study, we employed a conventional endoscopic procedure, that is, plastic stent deployment with the distal end of the stent exposed to the duodenum. Moreover, EST was performed on some patients who had multiple stents deployed. Therefore, there is a strong possibility that digestive juice regurgitates into the graft bile duct. When this occurs, it is difficult to avoid complications. Hisatsune *et al.* [16] employed an 'inside stent' without EST to reduce the possibility of complications. Although the complication rate in this study was not as high as those in other reports associated with LDLT, we need to make further efforts to reduce it.

There are potential limitations in this study: namely, the single arm, retrospective nature, and the small number of patients in this study. To optimize the outcomes of patients with biliary strictures after LDLT, further studies are needed because many factors, such as the types of graft, types of anastomoses, types of stent, and time of exchange contribute to the development, resolution, and recurrence of this morbidity. In this study, we could not analyze the outcomes of these factors because the number of cases was small. Furthermore, the observation period was too short to adequately elucidate the association among these factors. However, biliary complications that are not successfully treated are sometimes severe and occasionally fatal. At present, we recommend that a greater number of outcomes resulting from various endoscopic therapies be accumulated before conducting prospective studies.

In conclusion, because of the high success rate and acceptance by patients, we found that endoscopic deployment of plastic stents is viable first-line therapy for patients with biliary strictures after LDLT. To obtain more favorable outcomes, more effective procedures with refined devices need to be established.

Authorship

HK: designed research/study; performed research/study; analyzed data; wrote the paper. HK: designed research/study; performed research. KT, RH, MF, KH, NK, OM, EI, TO, and HF: performed research/study; analyzed data. KY and TY: final approval of the manuscript.

Disclosure

The authors report that there are no disclosures relevant to this publication.

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