J Korean Soc Transplant | 2012;26:188-195 | http://dx.doi.org/10.4285/jkstn.2012.26.3.188

Original Article

New Strategy in Cases of Failed Endoscopic Intervention of Biliary Strictures after Living Donor Liver Transplantation: Percutaneous Transhepatic Biliary Stent Insertion and Subsequent Endoscopic Treatment

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Background: In cases of endoscopic intervention treatment for biliary stricture which fail, a percutaneous approach can be subsequently attempted. However, the quality of life is lower for those patients with percutaneous transhepatic biliary drainage (PTBD) tubes than those with endoscopic retrograde biliary drainage tubes. In this study, we report the outcome of the application of percutaneous transhepatic biliary stenting (PTBS) for use in subsequent endoscopic treatment of biliary stricture after living donor liver transplantation (LDLT).

Methods: Of 165 patients who underwent LDLT, 40 (24.2%) were diagnosed with anastomotic biliary strictures. Of these patients, seven agreed to treatment using PTBS using a plastic stent with endoscopic follow-up instead of treatment by insertion of a PTBD tube, and were enrolled in this study.

Results: In all seven patients, the use of this technique enabled effective advancement of a guide wire and successful placement of one or two plastic stents (7 or 10 Fr) into the PTBD tract. There were no PTBS-related complications associated with the procedure. The median duration for stent use was 40.3 weeks (range; 27.6~65.0). Upon final removal of all stents, the stricture had been resolved in four (57%) of the seven patients.

Conclusions: Our study data suggested that, after failed use of ERCP in the treatment of biliary stricture after LDLT, the use of PTBS and ERCP may be an effective and safe treatment.

Key Words: Bile ducts, Complication, Bile duct stent
중심 단어: 담도, 합병증, 담도 스텐트

Introduction

Liver transplantation (LT) is a widely accepted treatment for end-stage liver disease and early staged hepatocellular carcinoma. Despite great improvements in the surgical techniques and standardization of the method of biliary reconstruction, the biliary tract is still the most common site for postoperative complications(1). Biliary complications are more common in living donor LT (LDLT) patients than in deceased donor LT (DDLT) patients, occurring in up to 32% of LDLT patients compared to 10～15% of patients who undergo DDLT(2,3). The non-operative management of biliary complications following LT has become standard practice with primarily endoscopic techniques as the preferred diagnostic and therapeutic modalities, obviating the need for surgery in a majority of patients. However, technically, LDLT presents a challenge, with the most common reason for failure being the inability to traverse the stricture and complex peripheral anastomosis, rendering plastic stent placement

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Received : November 29, 2011, Revised : August 11, 2012, Accepted : August 13, 2012

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difficult(4).

The success rates of endoscopic treatment for anastomotic strictures in LDLT are significantly lower than in DDLT at 60～75%(3-6). In failed cases, a percutaneous approach can be attempted. However, an external catheter has a major potential for infection and dislodgement, and it is associated with catheter maintenance problems as well as with discomfort for the patient. In addition, the number of interventions (including tube management) was reported to be higher in the percutaneous intervention group than in endoscopic treatment group(7).

Percutaneous transhepatic biliary stenting (PTBS) is a well-established interventional radiology procedure used in patients with biliary obstruction for decompression of intra- and extrahepatic bile ducts. Subsequent endoscopic treatment after PTBS will also have a positive impact on quality of life in failed cases with initial endoscopic treatment. Therefore, we adopted a strategy of plastic stent insertion using percutaneous transhepatic biliary drainage (PTBD) and subsequent balloon dilatation and plastic stent change using endoscopic retrograde cholangiopancreatography (ERCP). The aim of this study was to evaluate both the feasibility of this new strategy in treatment of biliary stricture after LDLT and the clinical outcomes of this protocol.

Materials and Methods

1) Patients

Of 165 patients who underwent LDLT with duct-to-duct biliary reconstruction between February 2005 and September 2009 at the National Cancer Center, Goyang, Korea, 40 (24.2%) were diagnosed with anastomotic biliary strictures. Of these 40 patients, 35 patients (87%) had undergone ERCP as an initial approach (Fig. 1). Among them, 14 patients had failure in initial endoscopic approach and received PTBD. Among them, five patients who agreed with endoscopic follow-up instead of PTBD tubes were enrolled this study. Among six patients for whom PTBD was done as an initial approach, two patients who wanted endoscopic follow-up were also enrolled in this study.

Therefore, PTBS insertion for subsequent endoscopic treatment was performed in seven patients. All patients had intolerable pain or recurrent bile leakage around the PTBD tube, and informed consents were obtained before all procedures.

2) Study definition

The first clue that a biliary complication has arisen may be an asymptomatic increase in serum transaminase or bilirubin levels. Symptoms are often non-specific and include itching and fever. The initial

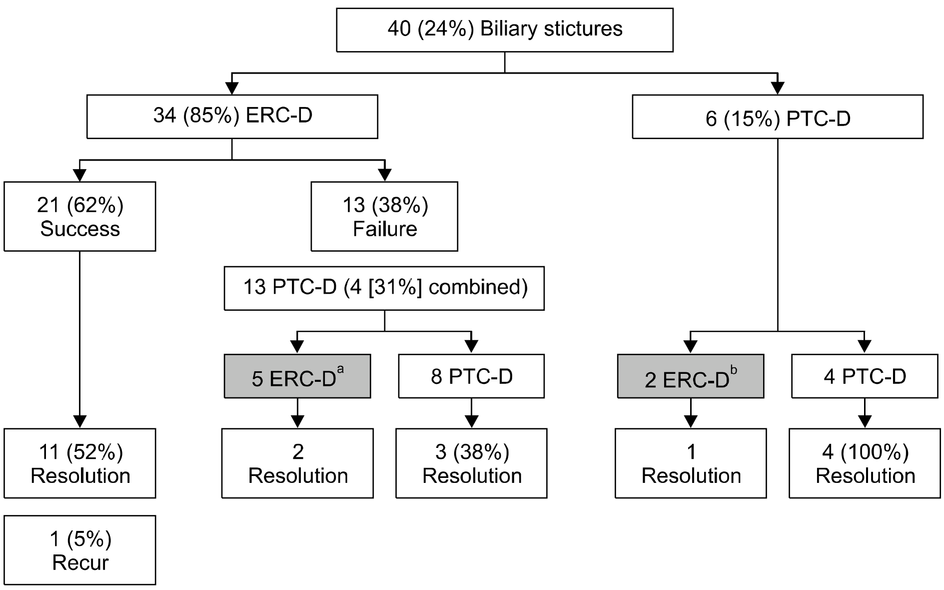

Fig. 1. Among 13 patients who had failure in initial endoscopic approach and received PTBD. Five patients [a]who agreed with endoscopic follow-up instead of PTBD tubes were enrolled this study; Among 6 patients for whom PTBD was done as an initial approach, [b]two patients who wanted endoscopic follow-up was also enrolled in this study. Abbreviations: ERC-D, endoscopic retrograde cholangiography with dilation; PTC-D, percutaneous transhepatic cholangiography with dilation.

evaluation should include ultrasonography with a Doppler examination of the hepatic vessels, followed by a liver biopsy or biliary imaging, depending on the pattern of liver test abnormalities. Anastomotic biliary stricture was defined as a dominant narrowing at the anastomotic site, without effective passage of contrast material, as identified by cholangiography. Ischemic biliary strictures, defined as strictures that extend more than 0.5 cm proximal to the anastomosis, were excluded from this study. Minimal narrowing at the site of the anastomosis that did not impede the flow of contrast material was not considered a clinically significant stricture and hence was also excluded.

A successful outcome after completion of therapy was defined as the sustained improvement in liver enzymes shown by the results of laboratory studies and by the patency of the anastomotic site shown on cholangiography. The biliary anastomosis was considered patent when an 8∼10 mm retrieval balloon could be withdrawn through the anastomosis, followed by prompt emptying of contrast material observed with fluoroscopy during ERCP.

3) PTBS insertion

All PTBD procedures were conducted throughout the study by the same experienced interventional radiologist (H.B. Kim). Under the guidance of ultrasound or a C-arm for fluoroscopy, the postero-inferior or postero-superior segmental duct of the transplanted liver was targeted with a 21-gauge puncture needle. After obtaining a cholangiogram, a guidewire (Terumo Medical Co., Tokyo, Japan) was passed through the stricture segment of the bile duct (anastomosis site). Then, an 8.5 Fr drainage catheter with multiple side holes (Cook Medical Inc., Bloomington, IN, USA) was placed across the stricture. A two-stage procedure for transhepatic stent placement was used. An 8.5 Fr drainage catheter was placed on the first day. Five to 7 days later, the transhepatic tract and the anastomotic stricture were dilated up to 12 Fr, and a 7 or 10 Fr plastic stent (Wilson-Cook Medical Inc., Winston-Salem, NC, USA) was inserted (Fig. 2). The distal ends of the stents were placed across the ampulla into the duodenum to make subsequent endoscopic treatments easy.

Procedure-related cholangitis was defined as the onset of fever ($>38.2^{o}C$) and/or leukocytosis (white blood cell count $>10,000/mm^3$) along with abdominal pain or tenderness in the right upper quadrant. Pancreatitis was diagnosed when serum amylase levels rose to more than 3 times the normal limit (60∼180 U/L) with notable persistent abdominal pain for more than 24 hours after the procedure. Significant bleeding was defined as a requirement either for a blood transfusion of more than 2 units or for hemostatic procedures after PTBS.

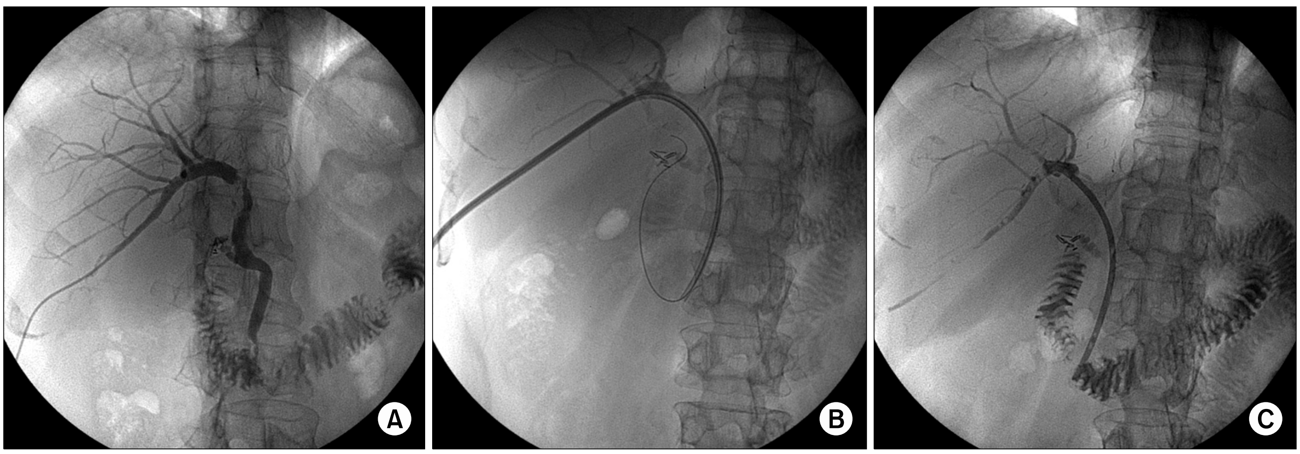

Fig. 2. Percutaneous transhepatic biliary stent insertion. (A) The anastomotic stricture before stent insertion. (B) The placement of the guidewires and the insertion of the plastic stent at the anastomotic stricture. (C) The plastic stent left in place after treatment.

4) Subsequent ERCP

The ERCP was performed by one of two experienced endoscopists (S.M. Woo and W.J. Lee). ERCP was scheduled electively at intervals of 2～3 months for evaluation of the stricture and for stent exchange after PTBS. ERCP was performed earlier in cases of cholangitis or worsening liver function indicated by test results. At subsequent ERCP, the stents were extracted using the polypectomy snare or a large forceps. After selective biliary cannulation, a cholangiogram was obtained to evaluate the biliary anastomosis. When the stricture was determined to be clinically significant (as defined above), a biliary sphincterotomy was performed to allow placement of multiple stents. The anastomotic stricture was then dilated by using high-pressure pneumatic biliary dilation balloons that ranged in size 4～10 mm (Hurricane RX Dilation Balloons; Microvasive Endoscopy, Boston Scientific Co., Natick, MA, USA). The balloon diameter was limited by the diameter of the intrahepatic bile ducts. The maximum number of polyethylene straight stents that could be accommodated within the stricture was inserted. A cholangiogram was then obtained by occluding the distal common bile duct with a distended retrieval balloon (8.5～15 mm). If the cholangiogram showed a patent anastomotic stricture, then treatment was discontinued. If the stricture persisted, balloon dilation and maximal stent placement were repeated. The patient then returned at intervals of 2～3 months for further courses of endoscopic treatment until the stricture was patent or until the completion of 12 months of therapy.

5) Immunosuppression and peri-procedural management

All the patients were initially on a triple-drug immunosuppressive regimen that consisted of cyclosporine A or tacrolimus, corticosteroids, and mycophenolate mofetil, with the latter two medications being tapered off at approximately 3 months and 1 year after LT, respectively. When taking the immunocompromised status into consideration, antibiotics (1 g cefotaxime, or 200 mg ciprofloxacin intravenously for patients with allergies) were routinely administered before and after an endoscopy or PTBD for the initial and subsequent procedures.

Results

The seven patients were six males and one female and the median age of the recipients was 54 years

Table 1. Patient characteristics

No. of patient	Characteristic		Indication for LDLT	Time to diagnosis of strictures (wk)	No. of anastomoses (donor to recipient)	Cause of failure in primary endoscopic treatment	Time from PTBD to PTBS (wk)
	Age (yr)	Sex					
1	52	M	Hepatocellular carcinoma	10.3	2 : 1	Failure of guidewire insertion	1.6
2	54	F	Post-hepatitis liver cirrhosis	15.7	1 : 1	Failure of guidewire insertion	16.7
3	54	M	Hepatocellular carcinoma	16.1	1 : 1	Failure of dilator insertion	2.9
4	48	M	Hepatocellular carcinoma	22.0	1 : 1	Failure of cannulation	24.0
5	49	M	Post-hepatitis liver cirrhosis	16.3	2 : 1	Failure of guidewire insertion	26.0
6	59	M	Hepatocellular carcinoma	42.3	2 : 1	Failure of guidewire insertion	90.0
7[a]	63	M	Hepatocellular carcinoma	8.6	1 : 1		4.6

Abbreviations: LDLT, living donor liver transplantation; PTBD, percutaneous transhepatic biliary drainage; PTBS, percutanous transhepatic biliary stenting.
[a]PTBD was used as initial approach for biliary stricture.

(Table 1). Indications for LT were as follows: hepatocellular carcinoma in six patients (86%) and post-hepatitis liver cirrhosis in one (14%). The median time of onset of biliary stricture and time from PTBD to PTBS were 16.1 weeks (range; 8.6∼42.3) and 16.7 weeks (range; 1.6∼90.0), respectively. Of these seven patients, six patients had undergone ERCP as an initial approach. However, the stricture site could not be passed with a guidewire or dilator in five patents and selective biliary cannulation failed in one patient.

In all patients, the positions of the distal end of the initial biliary stents via PTBD tubes had been extended 0.5∼1.0 cm out of the Vater's ampulla. In all patients, this technique enabled correct advancement of a guide wire and successful placement of one or two plastic stents (7 or 10 Fr) through the PTBD tract (Table 2). There were no PTBS-related complications including cholangitis, pancreatitis, or bile leakage. Two patients (28.6%) exhibited a normal bilirubin level before the procedure.

The median follow-up period after PTBS and the median stent duration were 75.7 weeks (range; 34.9∼79.7) and 40.3 weeks (range; 27.6∼65.0), respectively (Table 3). There were 19 ERCPs performed in the seven patients. The median number of subsequent ERCPs performed per patient was three (range; 1∼5). The median number of maximum plastic stents placed per patient was two (range; 1∼2). The follow-up ERCP and stent change was performed earlier than scheduled in three patients with acute cholangitis. There were no ERCP-related complications including cholangitis, pancreatitis, or bile leakage. The stricture had resolved in four (57%) of the seven patients at the time of final removal of all stents. Overall, two patients required PTBD during the follow-up period after PTBS. One patient (No. 2) presented with cholangitis due to stent migration during follow-up. However, the stricture site could not be passed with a guide wire in

Table 2. Outcomes of percutanous transhepatic biliary stenting (PTBS) insertion, liver chemistries in individual patients

No. of patient	Success of PTBS	PTBS-related complication	Total bilirubin (mg/dL)		Alkaline phosphatase (IU/L)		Alanine aminotransferase (IU/L)	
			Pre	Post	Pre	Post	Pre	Post
1	Yes	No	1.8	1.4	750	478	45	732
2	Yes	No	5.6	5.5	820	717	251	169
3	Yes	No	2.1	1.0	72	63	155	9
4	Yes	No	0.7	0.8	325	278	16	13
5	Yes	No	0.8	0.7	95	116	15	22
6	Yes	No	6.1	5.5	278	261	121	105
7	Yes	No	1.8	1.4	144	332	18	12

Table 3. Outcomes of percutanous transhepatic biliary stent insertion and subsequent endoscopic retrograde cholangiopancreatography (ERCP), balloon size, maximum number of stents in individual patients

No. of patient	Stent duration (wk)	Total No. of subsequent ERCP	Maximum balloon size (mm)	Maximum No. of stents	Current state
1	64.9	5	6	2	Success
2	37.3	1	6	1	Failure[a]
3	40.3	3	8	2	Success
4	27.6	2	6	2	Failure[b]
5	65.0	3	6	1	Success
6	32.6	2	6	2	Ongoing
7	54.0	4	6	2	Success

[a]Failure due to guidewire insertion in subsequent ERCP; [b]Failure due to invasion of recurrent hepatocellular carcinoma at common hepatic duct.

subsequent ERCP. Another patient (No. 4) required PTBD because of invasion of recurrent hepatocellular carcinoma at the main bile duct.

Discussion

Treating anastomotic strictures with endoscopic techniques, i.e., stricture dilation and stent placement has been largely successful in DDLT (68～90%)(8-10). However, results of endoscopic maneuvers are disappointing for biliary strictures after LDLT, and the success rate is 60～75% for anastomotic strictures(1,4,6,7,11-15). The causes for the low success rates of endoscopic intervention therapy are the presence of multiple ductal anastomoses, smaller size, peripheral location, and a pouched shape of biliary anastomosis(3,6,14,16). In right hemi-liver-LDLT patients with duct-to-duct biliary reconstruction, most anastomotic biliary strictures develop in a fork-shaped or trident-shaped fashion even if the biliary system had been reconstructed in a single duct-to-duct fashion(15). In this regard, endoscopic biliary stenting appears to be efficacious for treating multibranched biliary strictures because multiple stenting permits the drainage of each segmental branch of the stricture. In the present study, one or more stents were inserted into each segmental branch of the stricture in five patients (71.4%) at subsequent ERCP.

The consequences of percutaneous and endoscopic drainage differ largely in terms of restoration of the enterohepatic cycle and bacterial colonization and inflammation of the biliary tract(17). Because complex biliary reconstructions in LDLT are increasing, percutaneous treatment options will gain easy access to the biliary system. However, their use is limited in patients with a minimally dilated bile duct or impaired liver function because of an increased risk of bleeding complications(18). In addition, the number of interventions (including tube management) was higher in the percutaneous intervention group than in endoscopically treated patients. This may have been caused by the accidental removal of PTBD tubes at home(7). Percutaneous intervention is believed to have a negative impact on quality of life, compared to endoscopic intervention. Endoscopic approaches provide direct access to the biliary system in a less invasive manner and direct access to the biliary tract by sphincterotomy. However, the endoscopic approach is associated with the risk of pancreatitis and cannot be used in recipients with bilioenteric anastomosis. Nevertheless, no randomized controlled trial has compared the risk/benefit ratios of different endoscopic and percutaneous techniques. A previous study reported that success rate and patency were not different for endoscopic and percutaneous approaches, although percutaneous intervention showed a tendency to be associated with a greater immediate clinical improvement than the endoscopic method(7,19).

When the common bile duct cannot be cannulated or a guidewire cannot be passed through the biliary anastomosis site at ERCP, percutaneous transhepatic cholangiography may allow passage of a wire or drain, resulting in successful retrograde access at a later 'rendezvous' procedure(20), but the maneuver is complex and time-consuming. This technique requires re-intubation with the duodenoscope, and approach involved grasping the wire by a forceps, a snare, or a basket catheter, and withdrawing it via the accessory channel of the duodenoscope, which remains in position throughout(21). Hydrophilic wires may be difficult to grasp, however, and kinking of the wire may occur on withdrawal, then making it difficult to pass a catheter over it. The coating of the guidewire can be damaged and the guidewire can even become kinked at the level of the angled tip of the duodenoscope. An interventional radiologisit needs to feed the guidewire through the stricture site as it is withdrawn by the endoscopist. Compared to this rendezvous technique, PTBS can enable to avoid the laborious process including re-intubation with the duodenoscope, and reduce total procedure time.

Percutaneous placement of biliary endoprostheses is now a widely accepted procedure for palliative treatment of obstructive jaundice caused by malignancy. The complication rates appear to be similar to those in previous studies using either plastic stents or metallic expandable stents(22,23). These complications may have resulted from transhepatic drainage instead of the stent itself. The main advantage of metal stents is their internal diameter, which is larger than that of plastic stents (generally 10 mm, i.e., 30 Fr). Recently, covered metal stents have been introduced in the treatment of benign structure. These devices have the benefit that removal is possible, as the risk of embedding into the biliary wall is reduced or even negligible. This capacity, combined with the larger diameter of the covered metal stent makes stepwise dilation, as is performed with multiple plastic stents, unnecessary and may thus reduce the number of procedures(24). The clinical experience with covered metal stents for benign biliary strictures has until now been only limited(24,25). Covered metal stent placement for benign biliary strictures is still associated with relatively high complication rates (39.6%). In addition, the use of covered metal stents in biliary strictures after LDLT can cause occlusion of the contralateral hepatic duct.

In plastic stent insertion by the percutaneous approach, large-bore devices with a diameter of 10～14 Fr can be used(22). Insertion of large prostheses, however, increases the trauma to the patient, particularly during transhepatic procedures. Therefore, a two-step procedure has been recommended for transhepatic placement of large endoprostheses. Initially, an 8-Fr external-internal biliary catheter was inserted for preliminary decompression. Five to 7 days later, after transhepatic tract formation, dilation and placement of the large-bore endoprosthesis was performed. For lesions in a high location, accurate positioning requires a peripheral entry to the ductal system to achieve a long free upper end. Care must be taken not to leave the stent end protruding from the duct into the liver parenchyma. It may be necessary to place the distal end of the stent across the ampulla into the duodenum for smooth subsequent endoscopic treatments. We did not observe duodenal ulcers or pancreatitis as a result of placement of a stent across the ampulla. Initial success rate of PTBS in this study was 100% without immediate complication. Even though two patients including one patient with bile duct tumor thrombi needed additional PTBD during follow-up, the outcome of this protocol was comparable with the patients with initial success in endoscopic treatment. Furthermore, all patients were satisfied with this protocol because there was no uncomfortable external tube during follow-up.

Conclusion

Our preliminary data suggest that PTBS for subsequent ERCP may be an effective and safe strategy after failed ERCP in treatment for biliary stricture after LDLT. This new strategy may improve the quality of life for an LT recipient with biliary stricture, as well as improving graft survival.

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