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CLINICAL INVESTIGATION NON-VASCULAR INTERVENTIONS

Long-Term Efficacy of Percutaneous Internal Plastic Stent Placement for Non-anastomotic Biliary Stenosis After Liver Transplantation

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Abstract

Purpose We aimed to evaluate the long-term efficacy of percutaneous management of non-anastomotic biliary stenosis after liver transplantation, using plastic internal biliary stents.

Materials and Methods This study included 35 cases (28 men, 7 women; mean age: 52.09 ± 8.13 years, range 34–68) in 33 patients who needed repeated interventional procedures because of biliary strictures. After classification of the biliary strictures, we inserted percutaneous biliary plastic stents through the T-tube or percutaneous transhepatic biliary drainage tracts. Stents were exchanged according to percutaneous methods at regular 2- to 6-month intervals. The stents were removed if the condition improved, as observed on cholangiogram as well as based on clinical findings. The median patient follow-up period after initial diagnosis and treatment was 6.04 years (range 0.29–9.95 years). We assessed treatment success rate and patient and graft survival times.

Results During the follow-up period, 14 patients (14/33, 42.42 %) were successfully treated and were tube-free. The median tube-free time, time without a stent, was 4.13 years (range 1.00–9.01). In contrast, internal plastic stents remained in 9 patients (9/33, 27.27 %) until the last follow-up. These patients had acceptable hepatic function. Among the remaining 10 patients, 3 (3/33, 9.09 %) were lost to regular follow-up and the other 7 (7/33, 21.21 %) patients died. The overall graft loss rate was 20.0 % (7/35). The median time from initial treatment to graft loss was 1.84 years (range 0.42–4.25).

Conclusions Percutaneous plastic stents placement is technically feasible and clinically useful in patients with multiple biliary stenoses following liver transplantation.

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Keywords Catheter drainage · Stenting · Bile duct · Liver · Stenosis · Non-vascular interventions

Abbreviations

AS	Anastomotic strictures
BM	Bilateral multifocal
CO	Confluent
DDLT	Deceased donor liver transplantation
DN	Diffuse necrosis
IHBS	Intrahepatic biliary stricture
LDLT	Living donor liver transplantation
LT	Liver transplantation
NAS	Non-anastomotic intrahepatic stricture
PTBD	Percutaneous transhepatic biliary drainage

Introduction

Biliary stricture, a common complication after liver transplantation (LT), can cause severe morbidity and mortality [1–3] and often requires surgical or interventional treatment. Although surgical techniques have recently undergone substantial development, the reported incidences of biliary stricture range from 5 to 15 %, following deceased donor liver transplantation (DDLT) and from 28 to 32 %, following living donor liver transplantation (LDLT) [4]. While bile leaks predominate in the early post-transplant period (<3 months), biliary stricture typically occurs in the late post-transplant period (>3 months) with gradual progression [5].

Biliary strictures after LT have been classified as anastomotic strictures (AS) and non-anastomotic intrahepatic stricture (NAS) in site [3, 6, 7], each of which has a different etiology and prognosis [4]. Ischemia, fibrosis, or bile leaks resulting from suboptimal surgical techniques are believed to be the etiology underlying AS. Most cases of AS usually have a single-level stricture and show a favorable response to interventional management [8–10]. In contrast, a variety of entities shows the signs of non-anastomotic stenosis with a variety of underlying causes. Clinically, NAS is characterized by multifocal, complicated, and progressive biliary strictures that results in poor response to interventional management, high recurrence rates, and graft loss [5, 10–14].

In order to manage NAS with interventional treatment, maintaining as many drainable bile ducts as possible is important. For this reason, three types of interventional strategies can be considered, including maintaining multiple external tubes (percutaneous transhepatic biliary drainage, and PTBD), multiple internal metal stent deployments, or multiple internal plastic stent placements. Although PTBD insertion is technically easy to perform, maintaining multiple PTBDs is difficult because of low patient compliance resulting from daily discomfort. As reported by Gabelman et al. [15], the deployment of multiple metal stents may not be the best therapeutic management for benign biliary strictures, considering their poor long-term patency rates. Therefore, at our institution, percutaneous plastic stent placements have been widely used in patients with multifocal biliary stenosis or biliary cast syndrome. In this study, we aimed to evaluate the long-term efficacy of the percutaneous management of multifocal NAS after LT using plastic internal biliary stents.

Materials and Methods

We obtained the approval of our institutional review board to conduct a retrospective review of the patients' medical records and image data (IRB No.1104-019-357).

Patients

Of 993 patients who were followed at our institution after LT, 596 LTs were performed within the country and 397 LTs were performed outside the country, from January 2005 to July 2010. Among 88 patients (71 men, 17 women; mean age, 55.0 ± 10.6 years; DDLT: 41, LDLT: 47) who needed repeated biliary interventional procedures for strictures, 35 grafts (28 men, 7 women; mean age, 52.09 ± 8.13 years, range 34–68 years; DDLT: 34, LDLT: 1) in 33 patients (including 2 patients who had undergone LT twice due to graft loss) with multiple non-anastomotic biliary strictures were finally included in this study. Thirty-one cases out of total 35 LTs were performed out of the country, mostly in China, and the others were performed at our own institution. Patient follow-up was conducted until July 2014. Because perioperative patient data were not available for patients who underwent LT out of the country, we could not determine the details of individual patient's warm or cold ischemic time, type of perfusion solution, or the surgical technique used in the LT procedure. Since we were unable to obtain the data for the procedures performed out of the country, we utilized a previous report from China [16] and assumed that most of the deceased donor organs were retrieved from uncontrolled deceased cardiac death donors. In cases of remaining 4 patients who underwent LT in the country, deceased brain death donor organs were used in 3 DDLT and a living donor organ was used in one LDLT.

Classification of Intrahepatic Strictures

The classification of the type of multifocal biliary disease was determined by a single radiologist (B.J-H) with

10 years of experience, using conventional cholangiography and was based on a previous study of Lee et al. [2]. The confluent (CO) type involved cases with several strictures at the confluence level. The bilateral multifocal (BM) type included cases with multiple bilateral strictures, while cases with diffuse involvement of the biliary tree were classified as the diffuse necrosis (DN) type.

Procedure Details

For Insertion

The creation and stabilization of the PTBD tract is necessary before the percutaneous placement of the plastic stents. In cases of patients with T-tubes, the T-tube tract can also be used as an access route. Various types of biliary plastic stents with different diameters and lengths can be chosen depending on the location, length, and the degree of strictures. Routinely, we use 5, 7, or 10 cm-long plastic stents with 7 or 10-french (Fr) external diameters (Percuflex™, Boston Scientific, Spencer, IN). For the insertion of 7-Fr plastic stents, a 7-Fr introducer sheath (Radiofocus® Introducer II; Terumo, Tokyo, Japan) system was used (Fig. 1). For the insertion of plastic stents with 10-Fr diameter, the endoscopic biliary stent introduction system, OASIS® (One Action Stent Introduction System, Cook medical, Bloomington, IN) was used as an introducer (Fig. 2).

For Removal

In order to remove the previously inserted stents, we used two kinds of devices, the 8.5-Fr stone basket [Wittich Nitinol Stone Baskets, Cook Medical, Bloomington, IN)] and/or the reusable endoscopic alligator jaw grasping forceps (FG-7L-1, Olympus, Tokyo, Japan). A 8.5-Fr stone basket is usually used as a snare to remove plastic stents or sludge and cast in the bile duct in the manner similar to that depicted previously by Saad [17]. If grasp the end of plastic stents with the stone basket is difficult, we use the endoscopic alligator forceps via the percutaneous tract.

Regular Changes of Plastic Stents

Patients with multifocal NAS underwent evaluation of disease status and change of stents at regular 2 to 6-month intervals using the percutaneous methods described above. Therefore, keeping at least one PTBD or T-tube tract was necessary. The follow-up interval was determined based on the disease status, the patient's symptoms (itching sense or fever), liver function (total bilirubin level in serum), and the patency of the drainage tube.

Procedure-Related Complications

We assessed procedure-related complications by a retrospective review of all procedure reports ($n = 329$) and electronic medical records in case of inpatient procedures. However, we could not check all minor complications, such as abdominal pain or transient fever, because most of the procedures were performed as outpatient treatment. For prevention of procedure-related infection, oral prophylactic antibiotics (i.e., Cephalexin) were routinely used for 3 days for outpatients.

Liver Biopsy Data

We retrospectively obtained ultrasound-guided percutaneous biopsy results in 22 of 35 cases within 3 months from initial treatment through the review of electronic medical records at our institution.

Statistical Analysis

We used Medcalc® software version 14.8.1 to generate a Kaplan–Meier survival curve and evaluate the demographic data of the study participants. We defined 'tube-free' as removal of all internal or external stents as "tube free" status in this study, which means a completed treatment.

Results

The primary etiology of the cases included hepatitis B virus ($n = 32$), C virus ($n = 1$), chronic non-B, non-C hepatitis ($n = 1$), and primary biliary cirrhosis ($n = 1$). The median patient follow-up after transplantation was 6.50 years (range 0.42–10.10 years), and median patient follow-up after initial diagnosis and treatment was 6.04 years (range 0.29–9.95 years) (Table 1). We obtained US-guided percutaneous biopsy results in 22 of 35 cases within 3 months from initial treatment. The obtained data show that 2 cases were of acute cellular rejection and one case was of diffuse and mild centrilobular necrosis. The remaining 19 cases revealed mild periportal inflammation ($n = 15$), normal ($n = 3$), and bile duct obstruction ($n = 1$).

Among the 35 patients with non-anastomotic stenosis, 3 had the CO type stenosis, 25 had the BM type, and 7 had the DN type. The median number of internal plastic stenting procedures in each patient was 7 (range 1–26), and the mean number of plastic stents used per procedure in each patient was 2.42 ± 1.20 (range 1.00–5.42). The total number of sessions in all included patients ($n = 35$) was 329, and we used 1034 stents in this study overall.

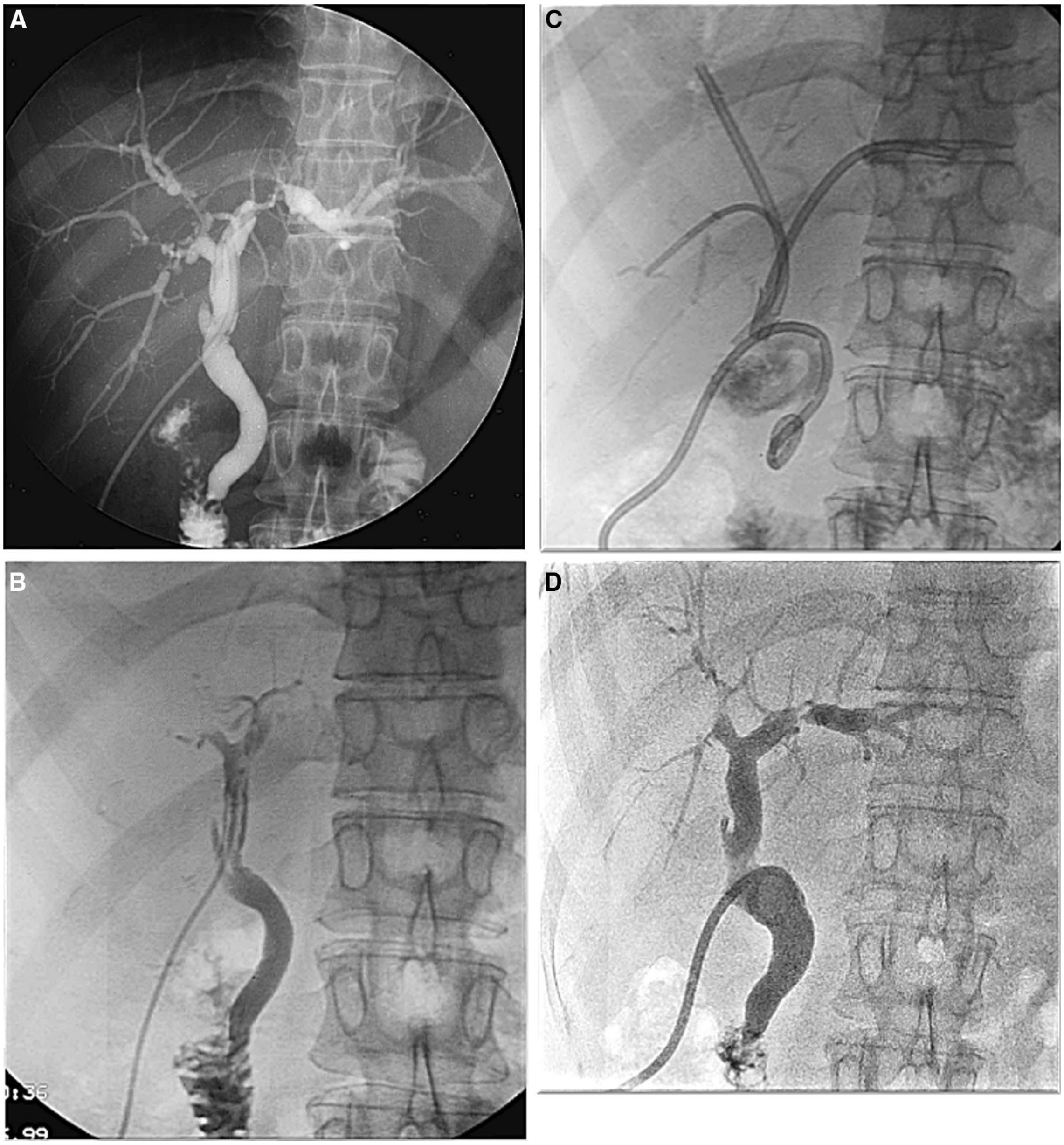
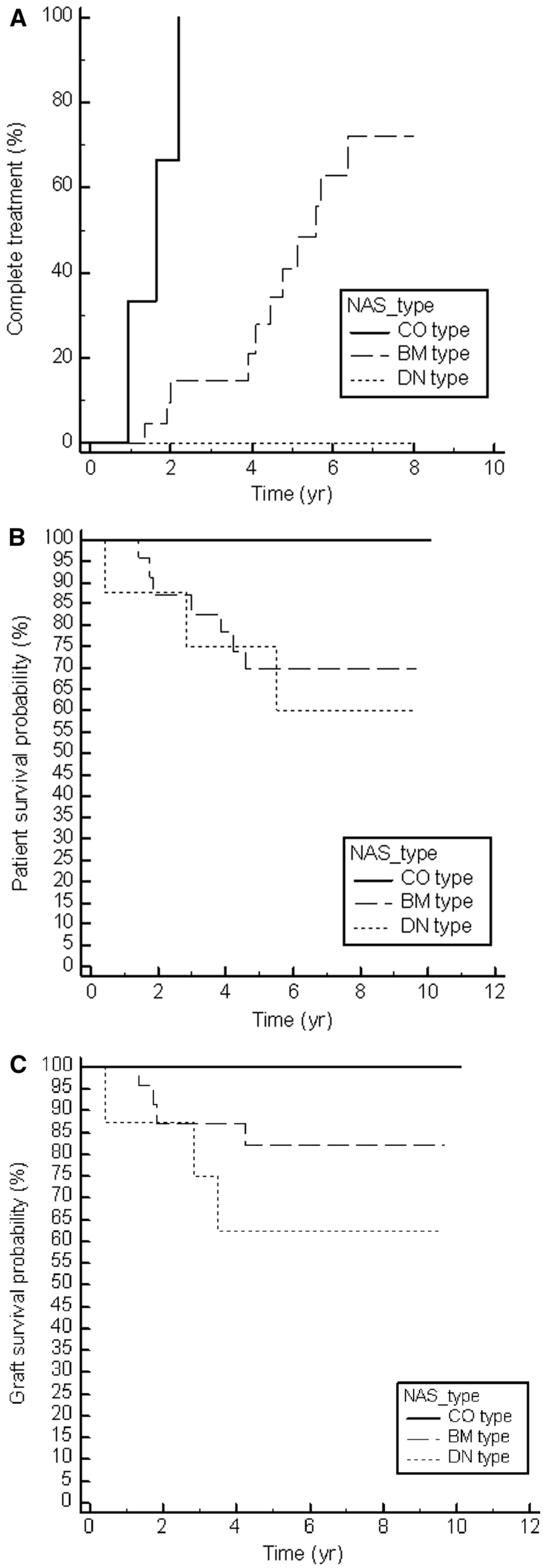


Fig. 1 A 55-year-old woman who underwent deceased donor liver transplantation. **A** On cholangiogram, obtained 4 months later since transplantation, multiple non-anastomotic biliary strictures are noted in both livers. **B** Another 4 months later, most intrahepatic ducts disappeared on cholangiography. **C** She was treated with multi-session biliary stent placements and changes for 5 years. **D** The final cholangiography shows marked improvement of multifocal biliary strictures, compared with the cholangiogram before treatment (**B**)

During the follow-up period, 14 patients were successfully treated and became tube-free. Conversely, 9 patients retained their internal plastic stents until the very last follow-up visit. These patients maintained acceptable hepatic function, even though two of them had undergone re-transplantation because of the same etiology of NAS. Among the remaining 10 patients, 3 were lost to regular follow-up. The remaining 7 patients died due to multi-organ failure, including hepatic failure ($n = 5$), acute respiratory distress syndrome associated with sepsis ($n = 1$), and unrelated causes ($n = 1$, rupture of cerebral arterial aneurysm). The median tube-free time of the 14 patients who had successfully finished their treatment was 4.13 years (range 1.00–9.01). In terms of IHBS type, all 3 cases with the CO type were successfully treated and eligible for tube-free status. In contrast, none of DN type could be tube-free. Among the 6 disease-related deaths, 4 had BM type stricture and the other 2 patients had the DN type. None of the patients who died had the CO type of biliary stricture. From two cases of graft loss and re-



◀**Fig. 2** Kaplan–Meier plots presenting the complete treatment rate (**A**, $P < 0.0001$), patient survival probability (**B**, $P = 0.49$), and graft survival probability (**C**, $P = 0.32$)

Table 1 Demographic distribution of the 35 study patients

Item	Number of cases
Male: female	28:7
Age	52.09 ± 8.13, range 34–68
Underlying diseases	
HBV	32
HCV	1
Others	2
Method of transplantation	
DDLT	34
LDLT	1
Median follow-up after transplantation	6.50 years (range 0.42–10.09 years)
Median follow-up after the initial diagnosis and plastic stenting procedure	6.04 years (range 0.29–9.95 years)
Types of biliary stricture	
Confluence	3
Bilateral multifocal	25
Diffuse necrosis	7
Approach route	
T-tube only	15
PTBD only	16
T-tube and PTBD	4

transplantation, one case had the BM type and the other case had the DN type. The overall graft loss rate was 20.0 % (7/35), while 2 patients underwent re-transplantation and 5 patients died due to hepatic failure. The median time from the initial treatment to graft loss was 1.84 years (range 0.42–4.25) (Table 2).

When we analyzed the procedure-related complications, we found no major complications such as mortality or massive bleeding. However, we could find minor to moderate complications among all procedures ($n = 329$); hemobilia or minor venous bleeding ($n = 12$), cholangitis ($n = 4$), sepsis ($n = 2$), tractitis ($n = 2$), and intrahepatic bioloma ($n = 1$).

Discussion

Non-anastomotic biliary strictures are generally considered to be the most serious type of biliary complications following LT, with a graft loss rate of up to 42 % after 2 years [7]. An incidence rate of 5–15 % has been reported for

Table 2 Outcomes of patients with non-anastomotic and multifocal biliary strictures after treatment with percutaneous plastic stenting

	CO type	BM type	DN type
Tube-free	3	11	0
Ongoing stenting	0	6	3
Lost to follow-up	0	2	1
Re-transplantation	0	1	1
Hepatic failure-related death	0	3	2
Unrelated death	0	2	0
Total number of cases	3	25	7

NAS in most series [1, 18, 19], and recently, the incidence of NAS has increased at many centers due to the extended donor criteria that include donors after cardiac death [20, 21]. However, standardized treatments or recommendations for the management for NAS that are effective in maintaining liver function or in graft/patient survival remain unavailable [5]. Although tremendous improvement in the endoscopic management of anastomotic strictures has been seen in the last decade, the results of NAS treatments remain disappointing, especially in LDLT, which shows a success rate of less than 35 % [5]. Furthermore, Verdonk et al. [22] previously reported the absence of differences in severe outcomes between the 28 patients who received an interventional treatment, such as ERCP, PTBD, or surgery, and 53 patients who did not receive any intervention ($P = 0.389$).

Currently, because of the lack of consensus on the best method for treating NAS, the varying prognosis by the location, and severity of NAS, an early, multidisciplinary, and individualized treatment approach is important to increase the odds of graft survival [21]. In terms of therapeutic interventions, repeated procedures with baskets and balloons, as well as avoiding the loss of drainable bile ducts through the placement of stents are necessary in severe cases [23, 24]. However, in cases of NAS beyond the second-order branches, the endoscopic approach has limitations with respect to distance and angle, in reaching the diseased bile duct. Moreover, it is difficult to place multiple stents (more than 3) within the intrahepatic bile ducts, because the tip of the plastic stent should be located in the duodenum via papilla of Vater for removal and regular changes. Alternatively, maintaining multiple PTBDs for interventional treatment remains complicated. Their maintenance is difficult and decreases quality of life, unless the patient is familiar with and skilled in managing the drainage tubes. Although a recent report showed good preliminary result of percutaneous placement of biodegradable biliary stents in treating benign refractory biliary strictures, including a post-LT case [25], it needs further validation. In this context, our internal plastic stenting protocol with a percutaneous approach has several advantages in overcoming the limitations of other endoscopic or percutaneous management approaches. First, plastic stents can be deployed regardless of the number and location with one access route. In the present study, up to 7 internal plastic stents were placed in bile ducts simultaneously through one T-tube tract. Increasing the number of stents usually does not cause patient discomfort because the number of routes of entry does not usually change. Second, the patient compliance in this case is much better than in maintaining multiple external tubes. Since internal drainage is possible in most cases, the drainage tube that functions as an access route can be routinely clamped. Therefore, patients can be free from a redundant line of bile bags, which further improves the quality of life. Third, if the patient develops procedure-related complications such as cholangitis or hemobilia, an immediate conversion to the external drainage is possible by connecting the bile bag to the entry T-tube or PTBD. Because patients have to continue immunosuppressants for lifetime, they are vulnerable to infection. However, the possibility of procedure-related cholangitis or bleeding is unavoidable. For that reason, life-threatening-repeated cholangitis is one of the major problems during management of biliary complications after LT [22]. If the percutaneous tube is maintained to decompress infected or stagnant bile, the risk of cholangitis could be reduced.

Compared with the previous literature [7], the overall graft survival (80.0 %) in the present study, with a median follow-up of 6.50 years, is much higher. Because we especially included problematic cases that needed repeat interventional treatments, the usefulness of this technique appears quite promising. Although we could not expect a complete cure in severe cases such as in the DN type of NAS, prolonged graft survival can provide the patient with additional time while waiting for the next donor. In the two cases of re-transplantation in this study, one patient waited for 42 months and the other patient waited for 16 months.

Unfortunately, only a historical control group is available because currently, we routinely perform this procedure for all NAS. In our own experience, when we used multiple PTBDs, patients underwent interventional procedures every 1–2 months owing to frequent tube dislodgement. Furthermore, numbers of drainable hepatic segments were limited to 3 or less because one tube as an external tract per segment was necessary. Since we apply new techniques to the patients with NAS, number of treatment procedures could be reduced to 1 per 3–6 months based on the patient's condition and patients' compliance. We cannot provide graft survival data of conventional multiple PTBD treatment because of the limitation of case number and available data.

This study has several disadvantages. First, this procedure needs a complicated set of technical skills. Technical learning and training should precede performance of the procedure on patients. Second, the study population is relatively small because we enrolled severe NAS cases that needed repeat interventional treatments. Thus, there is a limitation in evaluating statistical significance. Last, we could not confirm the direct etiology of NAS in most cases.

In conclusion, percutaneous plastic stents placement is technically feasible and clinically useful in patients with multifocal, non-anastomotic biliary stenoses following LT.

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Compliance with Ethical Standards

Conflict of Interest All the authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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