

Endoscopic stent placement above the intact sphincter of Oddi for biliary strictures after living donor liver transplantation

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Received: 27 June 2012 / Accepted: 24 October 2012 / Published online: 17 January 2013
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Abstract

Background and study aims Biliary complications are one of the most serious morbidities after liver transplantation. Inside-stent is a plastic stent placed above the sphincter of Oddi without endoscopic sphincterotomy against biliary strictures. Our aims were to analyze the long-term efficacy of inside-stent placement in patients with biliary stricture after living donor liver transplantation.

Patients and methods Ninety-four patients who experienced biliary stricture that employed duct-to-duct reconstruction were treated with inside-stent placement. Treatment outcomes, including stricture resolution, recurrence, inside-stent patency, and morbidity rate were evaluated retrospectively.

Results Ninety-two patients could be evaluated. Resolution of stricture was eventually observed in 81 of 92 patients with an average of 1.4 sessions of endoscopic retrograde cholangiography. Of the 81 patients who achieved the resolution of the stricture, recurrent biliary stricture that required intervention occurred in 8 patients. Conversely, stricture remission was achieved 73 patients (90.1 %) during 53 months follow-up after stent removal.

Median duration of patency of the initial stent was 189 (range 2–1228) days. Stent dislocation occurred in 10 patients. Adverse event related to inside-stent placement was pancreatitis in 18 cases (mild 13, moderate 5).

Conclusions Inside-stent placement achieved long-term patency and high remission rate in patients with biliary stricture after liver transplantation.

Keywords Biliary drainage · Living donor liver transplantation · Stricture · Inside-stent

Abbreviations

LDLT	Living donor liver transplantation
RYHJ	Roux-en-Y hepaticojejunostomy
DDLT	Deceased donor liver transplantation
PTBD	Percutaneous transhepatic biliary drainage
ES	Endoscopic sphincterotomy
ERC	Endoscopic retrograde cholangiography
NAS	Non-anastomotic stricture

Introduction

Biliary complications are amongst the most serious complications of liver transplantation and occur in 6–35 % of patients [1–6]. The common biliary complications are biliary leaks, strictures, and stones. The rate of biliary stricture after liver transplantation is 24–43 % in patients with choledochocholedocostomy, and 7–16 % in those with Roux-en-Y hepaticojejunostomy (RYHJ) [2–6].

In Japan, living donor liver transplantation (LDLT) is far more common than deceased donor liver transplantation (DDLT) because of a scarcity of deceased donor organs. Biliary stricture occurs more frequently in LDLT than

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DDLTL for several reasons, including a small diameter of the anastomotic portion of the bile duct, anatomical diversity of bile ducts, the complicated nature of the surgical procedure, and local ischemia of the peribiliary plexus [3–5].

Until recently, surgical intervention and percutaneous transhepatic biliary drainage (PTBD) were the most popular treatments for post-liver transplantation biliary stricture because biliary reconstruction had been commonly performed using RYHJ. However, according to the growing number of duct-to-duct reconstruction, endoscopic therapy has now become common in the treatment of biliary complication [7, 8].

Previous reports have shown endoscopic balloon dilation and/or plastic stent placement with endoscopic sphincterotomy (ES) to be the standard method used to treat biliary strictures after liver transplantation with duct-to-duct biliary reconstruction [9–13]. However, plastic stents have disadvantages, mainly because the duration of patency is at most 3–4 months in malignant biliary obstruction [14–16]. Additionally, stent placement can be complicated especially in cases with ES by acute cholangitis associated with reflux of duodenal fluid and the occlusion of stents with duodenal contents [17]. To avoid these complications and help prolong stent patency, we have been using inside-stent, that is placed proximal to the sphincter of Oddi without ES [7, 8]. Preserving the function of the sphincter of Oddi, inside-stent is expected to provide long-term patency and a lower risk of cholangitis because there is no exposure to duodenal contents. Although we previously reported the efficacy of inside-stent, the sample size was small and they were not longitudinal studies, so long-term outcome has not been evaluated [7, 8].

In the current study, therefore, we retrospectively evaluated the long-term efficacy and safety of inside-stent therapy in patients experiencing biliary stricture after LDLT.

Patients and methods

Patients

This retrospective study was approved by our institutional review board. Between January 2000 and December 2009, 894 patients received LDLT at Kyoto University Hospital. Among them, 121 patients experienced biliary strictures after LDLT with duct-to-duct biliary reconstruction. We tried to insert inside-stents in 118 cases, and successful placement was achieved in 94 patients (79.7 %). Two cases were lost to follow-up before removing the first inside-stent, so 92 cases were eventually evaluated. Some of the present cases had been included in our previous reports [7, 8]. Anastomotic biliary strictures were diagnosed by endoscopic retrograde cholangiography (ERC). Based on the number of biliary strictures, we classified them into the four types, as described previously: unbranched, fork-shaped, trident-shaped, and multibranch (more than three strictures) (Fig. 1) [7, 8]. Non-anastomotic stricture (NAS) was defined as a stricture involving the donor hepatic duct proximal to the anastomosis.

Endoscopy protocol

ERC was performed with side-viewing duodenoscope (TJF-240, TJF-260V, Olympus Medical Systems Co. Ltd, Tokyo, Japan) in the standard fashion under conscious sedation using diazepam and pethidine hydrochloride, and with continuous pulse oximeter monitoring of oxygen saturation. After cannulation of the bile duct, cholangiography was performed. The biliary strictures were assessed and then a balloon catheter (Hurricane RX Biliary Balloon Dilatation Catheter; Boston Scientific Japan, Tokyo, Japan) was used to dilate the strictures. Balloon sizes ranged from 6 to 10 mm, depending on the diameter of the bile duct. The balloon was inflated gradually until the waist of the balloon had disappeared on fluoroscopic examination. The

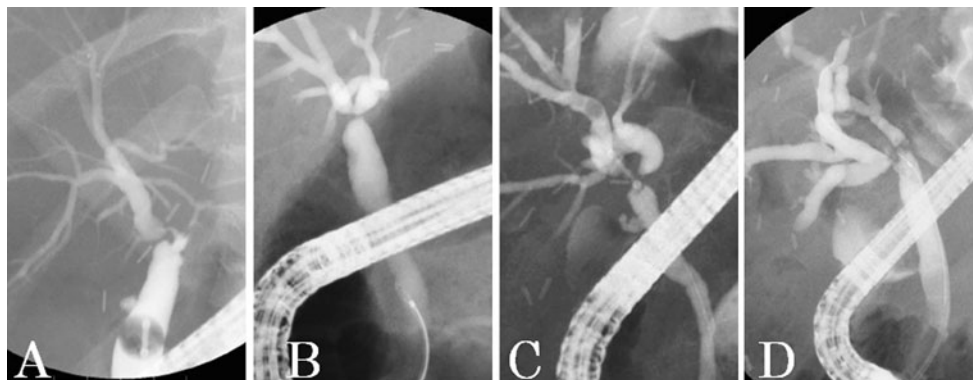


Fig. 1 The shape of the anastomotic stricture was classified into 4 types. **a** An unbranched stricture; **b** fork-shaped stricture; **c** trident-shape stricture; **d** multibranch stricture

expanded balloon was maintained in position for 15 s and then deflated and removed. Any stones and/or sludge present were then removed with basket or balloon catheter without performing ES, and a 6F nasobiliary tube was placed endoscopically to clean bile juice. Nasobiliary tube was replaced with an inside-stent within 1 week.

Inside-stent placement

Inside-stents were placed within the choledochus above the sphincter of Oddi, as previously described (Fig. 2a, b) [8]. A fluorinated-ethylene-propylene endoprosthesis (Olympus) was modified to create the inside-stent. Briefly, the distal flap of the inside-stent was removed to easily enable its insertion through the papilla of Vater (Fig. 2d). To permit easy retrieval of the inside-stent, a knotted nylon thread was attached to the distal side hole (Fig. 2d). Then the endoprosthesis was inserted by the standard procedure, keeping its position above the sphincter of Oddi with

dropping the thread from common bile duct to duodenum through the papilla of Vater (Fig. 2e). The stent size was 10–12 F, and number and length of the stent inserted varied depending on the location and types of stricture(s). In case of multiple stenting, each intrahepatic bile duct was selected by guidewire followed by inside-stent insertion.

Follow-up

The patients were followed up after the placement of the inside-stents. They were evaluated by interview, abdominal X-rays, and biochemical tests of liver function every 2–3 months. If there were any signs of stent occlusion, ERC was performed. Basically, initial inside-stents were left in place for 6–12 months, expecting the resolution of strictures if there were no sign of occlusion. At a follow-up session, the stent(s) was removed and endoscopic cholangiography was performed to evaluate the persistence of stricture. If the stricture was improved, the duct was left

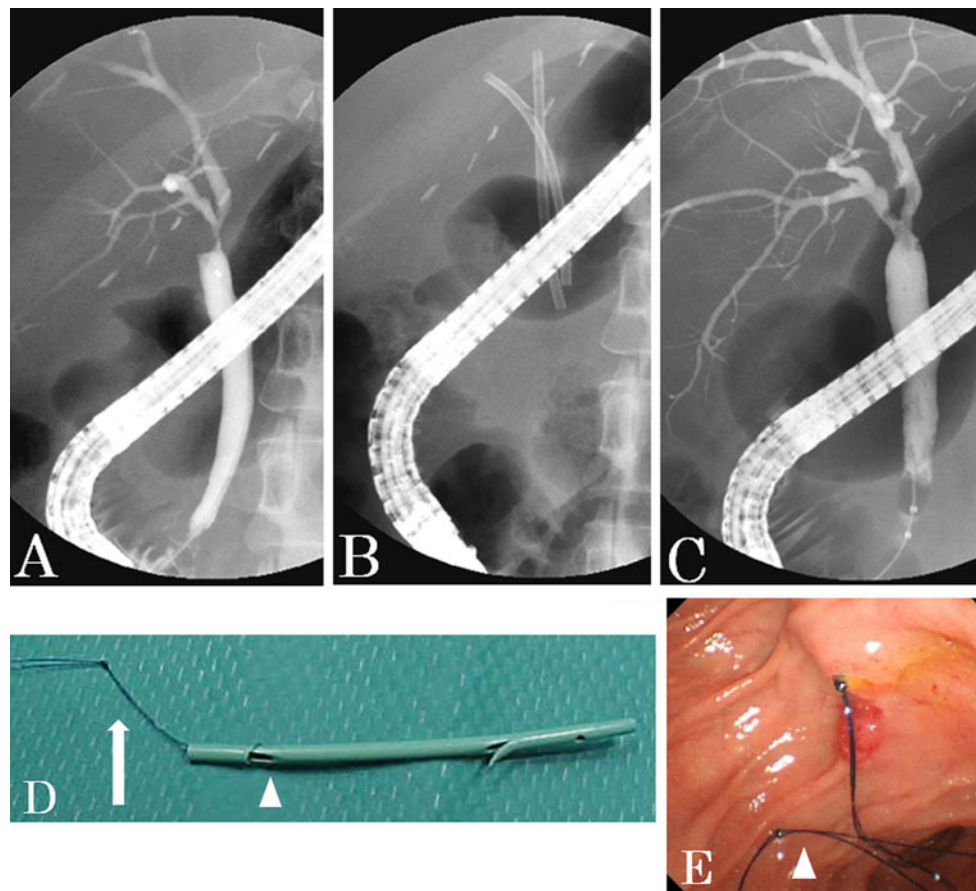


Fig. 2 Insertion of an inside-stent into a biliary stricture. **a** Cholangiogram shows a fork-type postoperative biliary stricture. **b** Placement of two inside stents (10 F) across both forks of the biliary strictures immediately above the sphincter of Oddi. **c** 7 months after stent insertion. Cholangiogram shows the resolution of the strictures. **d** Whole view of an inside stent. **e** An endoscopic view of the papilla

of Vater after insertion of inside stent. To migrate the inside-stent easily into the bile duct, a distal flap of the stent is removed (**d**, arrowhead). A nylon thread is attached to the distal side hole (**d**, arrow) to aid removability of the stent. The inside-stent can be removed by retrieving the nylon thread (**e**, arrowhead)

stent-free (Fig. 2c). Otherwise, a new inside-stent was placed. The above procedure was repeated every 6 months until the stricture was relieved. When any signs of stent occlusion occurred before 6 months after the first stenting, ERC was performed and a new inside-stent was placed again if the strictures still remained. If the stricture was improved, even within 6 months after the stent insertion, the duct was left stent-free. The patients were also followed every 3 months after removal of the inside-stents to evaluate recurrences of strictures based on interview, routine laboratory tests, and US or CT when needed.

Study definitions

Technical success was defined as the achievement of inside-stent insertion. The duration of first inside-stent patency was defined as the time interval between stent insertion and the first exchange. Stent occlusion was defined as the presentation of jaundice, cholangitis, or cholestasis without stent dislocation. Functional success was defined as having been achieved when there was cholangiographic confirmation that was no stricture at the time of stent removal, along with clinical and biochemical improvement. Recurrent stricture was defined as the presence of clinical symptoms, such as cholangitis and/or elevated biochemical tests of liver function (total serum bilirubin, alanine aminotransferase, aspartate aminotransferase, γ -glutamyltransferase, and alkaline phosphatase), together with ERC findings of a recurrent stricture requiring further treatment. Adverse events related to ERC procedures were evaluated according to modified lexicon for endoscopic adverse events 2010 and the severity of pancreatitis was graded according to the system developed by Cotton et al. [18].

Statistical analysis

Statistical analysis was performed using SPSS, version 11.0 (SPSS, Inc., Chicago, IL, USA). All continuous variables were expressed as the median (range). The stent patency period was calculated as the interval between stent insertion and its obstruction or death in the presence of a patent stent. Cumulative bile duct patency after the stent removal was estimated by the Kaplan–Meier analysis.

Results

In the present study, 94 patients who received inside-stent placement against biliary strictures after LDLT with duct-to-duct reconstruction were analyzed. The patients' characteristics are shown in Table 1. Fifty-seven men and 37

women with median (range) age of 53 (10–69) years were included. The most common indication for transplantation was hepatocellular carcinoma (44.7 %). Median time of diagnosis for biliary stricture after LDLT was 6.4 months with a range from 1 month to 6 years. Eighty-nine patients had anastomotic stricture and the remaining 5 had NAS. The most common stricture type was fork-shaped stricture (56.4 %). Of the 5 cases of NAS, 3 had ABO blood type incompatibility, and 2 were due to primary sclerosing cholangitis.

The overall outcomes of the patients are summarized in Fig. 3. Among 94 patients, 92 (97.9 %) could be followed up until the removal of first inside-stents or patients' death. Post-LDLT biliary stricture was eventually resolved in 88.0 % (81/92) of the cases by inside-stent therapy, so that their stents could be removed (functional success group, Fig. 3). Functional success rate of each stricture type was shown in Table 2. Of the remaining 11 cases whose stricture could not be resolved, 4 ended in death secondary to liver failure that was not related to stent therapy before removal of the inside-stents, and 7 still required interventions at the end of this study. Of those 7 cases, 2 received RYHJ and the remaining 5 are still undergoing inside-stent therapy (Fig. 3). Table 3 shows the number of inside-stent exchanges required for stricture resolution in the functional success group. In 52 cases (64.2 %), the strictures were resolved with only one session without exchanging stent. The average of ERC session was 1.4 times in total.

Table 1 The characteristics of patients with inside-stent placement

Age in years, median (range)	53 (10–69)
Sex, male/female	57/37
ABO type incompatible (%)	17 (18.1)
Donated liver, right lobe/left lobe	86/8
Interval from LDLT in month, median (range)	6.4 (1.1–76.5)
Indication for transplantation (%)	
Hepatitis C	18 (19.1)
Hepatitis B	5 (5.3)
Associated hepatocellular carcinoma	42 (44.7)
Fulminant hepatitis	10 (10.6)
Primary biliary cirrhosis	8 (8.5)
Others	11 (11.7)
Stricture type (%)	
Anastomotic stricture	89 (94.7)
Unbranched	25
Fork-shaped	53
Trident-shaped	10
More than three	1
Non anastomotic stricture	5 (5.3)

Number of patients are shown unless otherwise specified

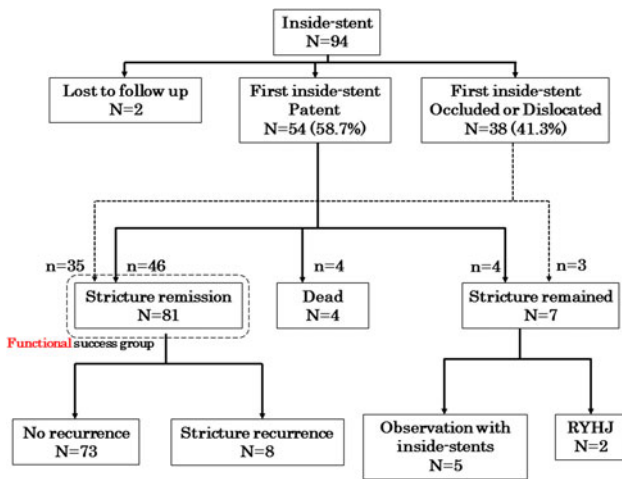


Fig. 3 Clinical outcome in 94 patients who received inside-stent placement against biliary strictures after LDLT with duct-to-duct reconstruction. In the functional success group, some patients needed multiple exchanges of inside-stent until achieving stricture remission

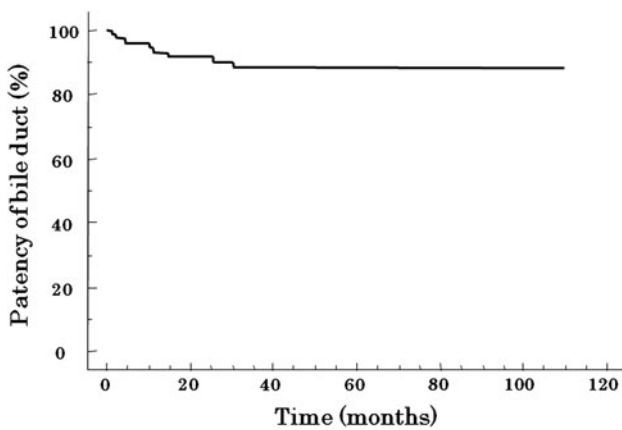


Fig. 4 Kaplan–Meier graph showing cumulative duration of stricture remission after removing inside-stent (in the functional success group)

Table 2 Functional success rate of inside-stent therapy according to the stricture type

Stricture type	Success	Not success	Total
Anastomotic stricture	78	10	88
Unbranched	20	5	25
Fork-shaped	48	4	52
Trident-shaped	10	0	10
More than three	0	1	1
Non anastomotic stricture	3	1	4
Total (%)	81 (88.0)	11 (12.0)	92

Figure 4 shows a Kaplan–Meier plot of cumulative duration of stent-free period after the removal of inside-stents. During a median follow-up of 53.0 months (range

Table 3 Intervention sessions required for final resolution of biliary stricture

Number of the sessions	n (%)
1	52 (64.2)
2	22 (27.2)
3	7 (8.6)

0.1–109.7), 90.1 % (73/81) of functional success group achieved persistent stricture remission. In contrast, stricture recurrence was observed in 8 cases (9.9 %) of the functional success group (Fig. 3). In these cases, 5 were managed with repeated inside-stent placement, and the remaining 3 were managed with endoscopic balloon dilatation, PTBD, or repeated liver transplantation.

In 54 of 92 cases (58.7 %), the first inside-stents were exchanged without stent occlusion in 7.1 months (median; range 0.2–40.9) after the first stenting. Although the inside-stent were expected to have longer patency, the period was calculated as duration of stent patency in these cases. Dislocation occurred in 10 cases (10.9 %) in relatively early period (median duration was 1.6 months; range 0.2–8.5) and stent occlusion was observed in 28 cases (30.4 %) at 4.7 months (median; range 0.1–30.1) after stent insertion. Median duration of patency of the initial stent was 189 days (range 2–1228).

The rates of adverse events related with inside-stent insertion were 22.3 % (21/94) in total. The most frequent adverse event was pancreatitis ($n = 18$; 19.1 %). Of the 18 cases of pancreatitis, 5 were of moderate severity and the remainders were of mild severity. The remaining adverse event was cholangitis ($n = 3$; 3.2 %). There was no severe adverse event.

Discussion

Biliary stricture is the most common post-operative complication that can affect the prognosis of the patients after liver transplantation [1–6]. Although endoscopic management with balloon dilatation and/or stent placement has been developed especially for biliary strictures after duct-to-duct biliary reconstruction, several problems, such as stent occlusion that requires multiple endoscopic sessions and reflux cholangitis associated with ES, still remain. In the present study, we evaluated the long-term efficacy of inside-stent (plastic stent placement above the sphincter of Oddi without ES) against biliary strictures after LDLT, and showed that inside-stent placement provides long-term patency and a significantly high rate of stricture relief without major complications.

Despite the high incidence of biliary stricture after liver transplantation, the optimal endoscopic treatment has not been established. Previous reports have shown that the initial success rate of endoscopic treatment with balloon dilatation and plastic stent placement varies from 51.2 to 96.6 % depending on the technique used, with recurrence rate varying from 13.3 to 26.1 % depending on the technique and duration of follow-up [1–3, 9, 19–21]. Recently, several reports have demonstrated the efficacy of multiple plastic stent or metallic stent placement for biliary strictures after liver transplantation [10, 11, 22]. Although multiple stents placement required a high number of endoscopic sessions (needed to exchange stents every 2–3 months), the procedure provided favorable outcomes with the resolution rate of the biliary stricture ranging from 87 to 100 % and the recurrence rate varying from 0 to 18.1 %. However, metallic stent placement still showed room for improvement for high rate of stent migration (13.6 %) and stricture recurrence (47.4 %) [11].

We previously reported the efficacy of inside-stent placement without ES for biliary stricture after LDLT [7, 8]. Short duration of the stent patency is a major problem in the conventional biliary stenting across the papilla, because bacterial biofilm formation and sludge deposition along the stent lumen commonly develops by reflux of duodenal fluid [23–26]. By preserving the function of the sphincter of Oddi, inside-stents promise longer patency. Furthermore, preservation of intact sphincter of Oddi is especially important in cases of liver transplantation with immunosuppressive medications, in which patients are at increased risk for serious bile duct infections. In the present study, we extended our previous study and evaluated 121 post-LDLT cases with biliary stricture among which 94 cases received inside-stenting. The median duration of patency of the initial stent was 6.3 months, which is longer than those in previous reports [1–6]. Of note, in this study inside-stent placement achieved a high rate of stricture resolution (88.0 %) by minimal endoscopic sessions (average 1.4

times). Furthermore, despite the longer follow-up period (53 months), the stricture recurrence rate was lower in the present study (9.9 %) than in previous reports [13, 27–30] (3.1–18 %) with conventional biliary stenting (Table 4). Thus, prevention of duodenal fluid reflux into the bile duct by preserving intact sphincter of Oddi might be important not only for long-term patency of inside-stents but also for decreased stricture recurrence after the stent removal. From this point of view, the concept of inside-stent, i.e. the placement of a removable stent wholly inside the bile duct without ES, could be said to be rationally designed for treatment of biliary stricture after liver transplantation. Indeed, a recent report showed the feasibility and efficacy of removable covered metal stents endoscopically placed wholly inside the bile duct against anastomotic biliary stricture after DDLT [10, 11]. In contrast to our plastic inside-stent, the reported metal inside-stent is still not applied to treatment of hilar biliary stricture that account for 100 % of biliary strictures after LDLT with duct-to-duct reconstruction. However, the metal stent promises a stronger radial expanding force than our 10–12 Fr plastic stent, and may better contribute to dilation and resolution of biliary strictures. On the other hand, the development of biodegradable pancreatic and biliary stents has been recently actively promoted in vivo and in vitro [31]. In the near future, clinical application of those biodegradable stents that do not need to be removed is expected for treatment of benign biliary stricture including anastomotic stenosis after liver transplantation.

Placement of biliary stents above the intact sphincter of Oddi (the inside-stent) was initially described in 1991 in an animal model [32]. The study first developed the concept that inside-stent placement improves the duration of patency compared to the conventional technique of stent placement across the sphincter of Oddi, possibly due to preserving the function of the sphincter of Oddi and thus preventing bacterial colonization in the biliary tree. The first prospective randomized clinical study comparing the

Table 4 Technical success, functional success, and recurrence rate of endoscopic treatment for biliary strictures after liver transplantation

References	Type of transplantation	Type of stent	Technical success rate	Functional success rate	Recurrence rate at X months median follow-up
Our data	LDLT	Inside-stent	79.7 % (94/118)	88.0 % (81/92)	9.9 % (8/81) at 53.0 months
Zoepef et al. [20]	LDLT	PS	58.3 % (7/12)	100 % (7/7)	14.3 % (1/7) at 9.5 months
Kato et al. [19]	LDLT	PS	85.4 % (35/41)	80 % (28/35)	28.6 % (8/28) at 29.1 months
Chang et al. [21]	LDLT	PS	79.6 % (90/113)	60 % (54/90)	11.1 % (6/54) at 22 months
Mahajani et al. [12]	DDLT	PS	100 % (30/30)	86.7 % (26/30)	13.3 % (4/30) at 17.9 months
Rossi et al. [13]	DDLT	PS	80 % (12/15)	100 % (12/12)	18.1 % (2/11)
Alazmi et al. [31]	DDLT	PS	96.6 % (143/148)	88.5 % (131/148)	18.3 % (24/131)
Tabibian et al. [10]	DDLT	Multiple plastic stents	83.1 % (69/83)	94.2 (65/69)	3.1 % (2/65) at 11 months
Hu et al. [22]	DDLT	Metallic stent	–	92.3 % (12/13)	8.3 % (1/12) at 8 months

usefulness of stents placed above and across the sphincter of Oddi in malignant biliary obstruction showed no significant difference in the duration of stent patency between the two techniques, probably because of a greater tendency for dislocation of the inside-stents [33]. However, a subsequent study demonstrated the median patency of the stents placed above the sphincter of Oddi to be significantly longer than that of the stents placed across the sphincter of Oddi [34]. Thus, inside-stent placement may be efficacious not only in benign/short-segment biliary strictures such as anastomotic strictures (AS) after liver transplantation, but also in malignant/long-segment strictures. Indeed, in the present study, we experienced 5 cases of NAS, which is known to be much more difficult to manage than AS. Although the sample size was small in our cases, the initial success rate against NAS was 75 % (3/4, one case was lost to follow-up), which is not worse than the previous studies demonstrating the success rate from 16 to 60 % [8, 9, 11]. From these observations, including the higher resolution rate against refractory strictures of bile duct, inside-stent placement could be applicable to various biliary strictures including malignant hilar obstructions.

The most frequent adverse event related to insertion of the inside-stent was pancreatitis, which occurred in 19.1 % of the present cases. This rate seems to be higher than the conventional method, and might be related to ductal strain caused by insertion of a large caliber stent through a duodenal papilla that has not undergone sphincterotomy. Decreasing the stent size from 10–12 to 7–8.5 F might reduce the rate of pancreatitis. However, considering the fact that most cases of pancreatitis (72.2 %) were mild and all were cured within 10 days, we believe the risk/benefit ratio favors larger stent placement for long-term patency and lower rate of biliary stricture recurrence. Another problem in with inside-stent placement is stent dislocation. In the present study, stent dislocation occurred in 10.6 % of cases, mostly observed within 2 months after the inside-stent placement. One potential cause for the stent dislocation might be the removal of a distal flap of the stent prior to the placement, which is done for the purpose of easier stent insertion above the duodenal papilla. Also, to decrease the incidence of stent migration, there is still plenty room for improvement in stent length, shape, material, or insertion technique.

In conclusion, inside-stent placement is an effective modality for managing biliary strictures after LDLT. By preserving the function of the sphincter of Oddi, the procedure provides long-term patency, a high rate of stricture relief, and a low rate of recurrence. Stent dislocation and pancreatitis associated with stent insertion are the two major problems that remain to be solved. Large scale, prospective, randomized, comparative studies are needed to establish this procedure as a useful method for biliary stenting.

Conflict of interest The authors of this manuscript have no conflicts of interest to disclose.

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