Endoscopic treatment of postorthotopic liver transplantation anastomotic biliary strictures with maximal stent therapy (with video)

James H. Tabibian, MD, Emad H. Asham, MD, Steven Han, MD, Sammy Saab, MD, MPH, Myron J. Tong, MD, PhD, Leonard Goldstein, MD, Ronald W. Busuttil, MD, PhD, Francisco A. Durazo, MD

Los Angeles, California, USA

Background: The optimal endoscopic protocol for treating postorthotopic liver transplantation (OLT) anastomotic biliary strictures (ABSs) has not been established.

Objective: To review the technique and outcomes of endoscopic retrograde cholangiopancreatography (ERCP) with maximal stenting for post-OLT ABSs at our institution.

Design: Retrospective study.

Setting: Tertiary-care center.

Patients: Eighty-three patients with a diagnosis of ABS.

Interventions: ERCP with balloon dilation and maximal stenting.

Main Outcome Measurements: Stricture resolution, stricture recurrence, and complication rates.

Results: Of 83 patients, 69 completed treatment, of whom 65 (94%) achieved resolution and 4 (6%) required hepaticojejunostomy (HJ). The remaining 14 patients who did not achieve a study endpoint were excluded (9 deaths or redo OLT unrelated to biliary disease, and 5 without follow-up). Comparing the resolution group and the HJ group, there were, respectively, 8.0 and 3.5 total stents ($P = .021$), 2.5 and 1.3 stents per ERCP ($P = .018$) (maximum = 9), 4.2 and 2.8 ERCPs ($P = .15$), and 20 and 22 months from OLT to ABS diagnosis ($P = .19$). There were 2 cases of ERCP pancreatitis (0.7%) and 2 cases of periprocedural bacteremia of 286 total ERCPs and no episodes of cholangitis caused by stent occlusion. In a median follow-up of 11 months (range 0-39), 2 (3%) patients had ABS recurrence that was successfully re-treated with ERCP. A multivariate Cox model demonstrated that treatment success was directly related to the number of stents used in total and per ERCP.

Limitations: Retrospective study, single endoscopist.

Conclusions: Our maximal stenting protocol for ABSs is effective, safe, rarely associated with ABS recurrence, and conducive to less frequent stent exchange and therefore fewer ERCPs compared with conventional treatment. (Gastrointest Endosc 2010;71:505-12.)

Biliary complications have been called the Achilles' heel of orthotopic liver transplantation (OLT).[1,2] Despite standardization of biliary reconstruction techniques, biliary complications occur in 5% to 34% of OLT patients.[3-6] Biliary strictures are the most common biliary complication and occur in 4% to 13% of patients after OLT.[7-10] They can be divided into main types: anastomotic and nonanastomotic biliary strictures. Anastomotic biliary strictures (ABSs) are more common and involve choledochocholedocostomy (CDCD) or choledochojejunostomy.[11] Nonanastomotic biliary strictures involve the bile ducts of the graft and are related to predisposing factors such as hepatic artery thrombosis, prolonged cold ischemia time, reperfusion injury, recurrent primary sclerosing cholangitis, and ABO incompatibility.[12-14]

Abbreviations: ABS, anastomotic biliary stricture; CBD, common bile duct; CDCD, choledochocholedochostomy; HJ, hepaticojejunostomy; OLT, orthotopic liver transplantation.

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Surgical repair and percutaneous transhepatic cholangiography have traditionally been the primary approach to managing ABSs.[11,15-17] However, over the past 10 to 15 years, therapeutic ERCP has replaced these techniques. ERCP is currently advocated as first-line management in patients with ABS at the choledococholedocal anastomosis and, to some extent, at the hepaticojejunal anastomosis.[3,18-21] Despite the favorable outcomes with endoscopic techniques, however, the optimal protocol, such as the number of stents, frequency of stent exchange, and duration of endoscopic therapy, has not been established for ABS resolution and long-term patency.

In our institution, we have been treating ABS at the CDCD with long-term maximal stent therapy, but without prophylactic stent exchange every 3 months. Instead, stents are exchanged only when signs or symptoms of biliary obstruction are detected. This regimen has allowed us to minimize the number of ERCPs needed to treat ABSs without compromising success or patient safety and has yielded a low ABS recurrence rate. In this study we review the patients who were treated with this regimen and their outcomes.

Capsule Summary

What is already known on this topic

- ERCP with balloon dilation and stent placement is the most effective endoscopic approach to anastomotic biliary strictures after liver transplantation, yielding more durable results than balloon dilation alone.

What this study adds to our knowledge

- In a retrospective study of patients with anastomotic biliary strictures who underwent ERCP with balloon dilation and maximal stenting, strictures resolved in 65 of 69 patients with an average of 8 total stents, and 4 patients required hepaticojejunostomy with an average of 3.5 total stents.
- Multivariate analysis demonstrated that treatment success was directly related to the number of stents used.

METHODS

Study approval was obtained from the Internal Review Board of the University of California, Los Angeles.

Patients

Between March 2002 and May 2007, 83 adult deceased-donor OLT patients with clinical findings suggestive of biliary obstruction who were referred for ERCP were diagnosed with ABS at the CDCD. ABS was defined as a dominant narrowing at the anastomotic site without effective passage of contrast material, as demonstrated by cholangiography.[19] Patients with strictures more than 0.5 cm extending proximal to the anastomosis or patients with any stricture in the donor ducts were not considered to have ABS alone and were excluded. Also, if the anastomosis had a narrowing without resistance to the flow of contrast material or proximal biliary dilation, the stricture was not considered clinically significant and therefore not included in the study.

The medical records of all 83 patients were reviewed (retrospectively until August 2007 and prospectively thereafter) for pertinent clinical and laboratory data (Table 1). Liver biopsies did not show acute cellular rejection or cytomegalovirus infection, and hepatic artery thrombosis was ruled out with Doppler US, CT angiography, and/or magnetic resonance angiography. All patients were initially on a triple-drug immunosuppressive regimen consisting of cyclosporin A or tacrolimus, corticosteroids, and mycophenolate mofetil, with the latter 2 medications being tapered off at approximately 3 months and 1 year after OLT, respectively.

TABLE 1. Characteristics of 69 patients who reached a study endpoint

Demographics	
Median age, y (range)	52.5 (26–72)
Male, no. (%)	45 (65)
OLT indication, no. (%)*	
Hepatitis C	32 (46)
Alcoholic cirrhosis	11 (16)
Hepatocellular carcinoma†	9 (13)
Hepatitis B	8 (10)
Autoimmune hepatitis	5 (7)
Cryptogenic cirrhosis	5 (7)
Primary biliary cirrhosis	3 (4)
Miscellaneous‡	9 (13)
Other	
Median time from OLT to ABS, mo (range)	7 (0.25–168)

OLT, orthotopic liver transplantation; *ABS*, anastomotic biliary stricture.
*Some patients had more than 1 indication for OLT.
†Of the patients with hepatocellular carcinoma, 5 had hepatitis C, 3 had hepatitis B, 1 had hepatitis B and C, and 1 had cryptogenic cirrhosis.
‡Two patients underwent OLT for primary sclerosing cholangitis, 2 for nonalcoholic steatohepatitis, 1 for polycystic liver disease, 1 for idiopathic fulminant hepatic failure, 1 for type 1 glycogen storage disease, and 1 for hepatic artery thrombosis.

Endoscopic treatment and follow-up

Informed consent was obtained from all patients for ERCP. Prophylactic 400 mg ciprofloxacin hydrochloride

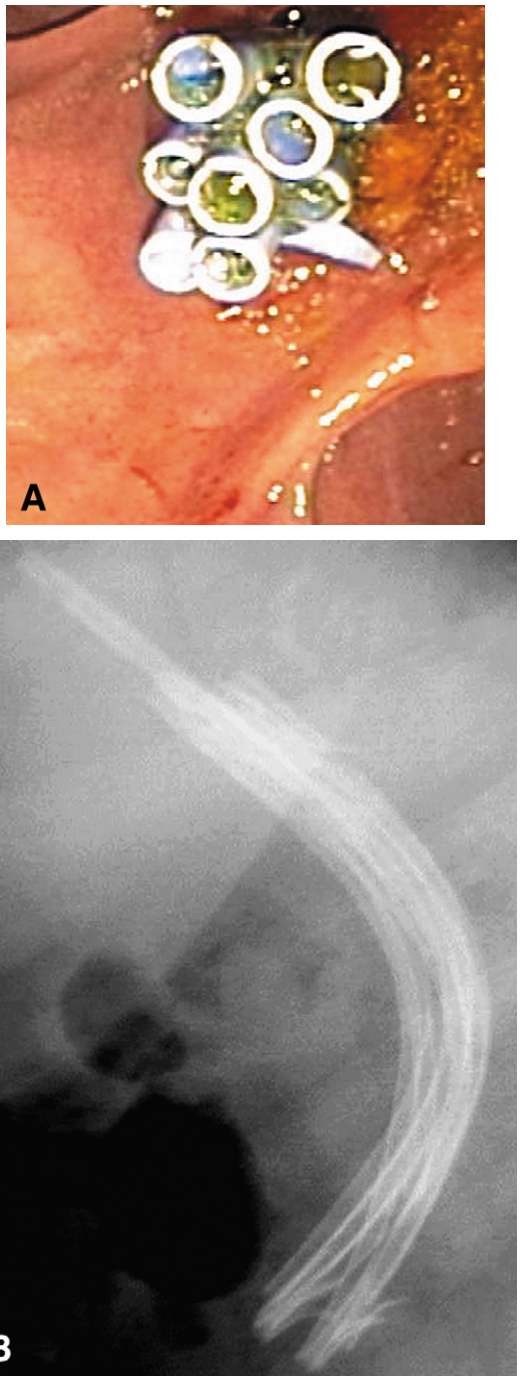


Figure 1. A, Endoscopic image of maximal stents in a sample patient. **B**, Radiographic image of maximal stenting in a sample patient.

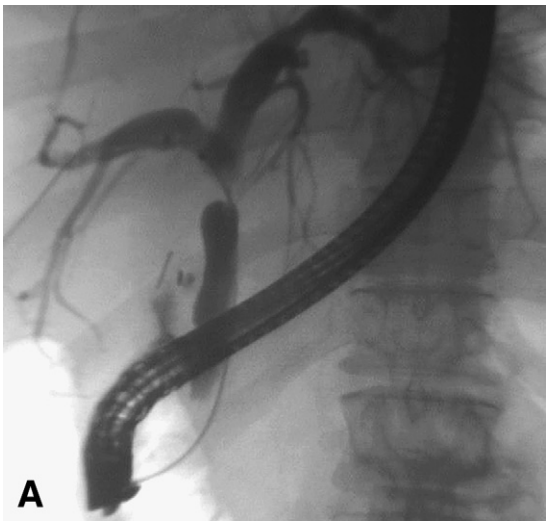
or 3.375 mg piperacillin tazobactam was routinely administered intravenously before each procedure and followed by 3 days of oral antibiotics. Moderate to deep sedation was induced with intravenous meperidine or fentanyl and midazolam. ERCP was performed with a therapeutic side-viewing endoscope (TJF 160; Olympus Optical Co, Ltd, Center Valley, Pa) in the conventional manner with standard accessories by an experienced therapeutic endoscopist (95% of cases by F.D.).

TABLE 2. Characteristics of patients who achieved anastomotic biliary stricture resolution versus those who did not

	Treatment success	Treatment failure
No. (%)	65 (94)	4 (6)
Demographics		
Median age, y (range)	53 (26-72)	49 (34-67)
Male, no. (%)	43 (66)	2 (50)
OLT indication, no. (%)		
Hepatitis C	31 (48)	1 (25)
Alcoholic cirrhosis	10 (15)	1 (25)
Hepatocellular carcinoma	9 (14)	0 (0)
Hepatitis B	8 (12)	0 (0)
Autoimmune hepatitis	4 (6)	1 (25)
Cryptogenic cirrhosis	5 (8)	0 (0)
Primary biliary cirrhosis	3 (5)	0 (0)
Miscellaneous	7 (11)	2 (50)*
Other		
Median time from OLT to ABS, mo (range)	8 (0.25-168)	1 (0.5-84)

OLT, orthotopic liver transplantation; *ABS*, anastomotic biliary stricture.
*One patient had autoimmune hepatitis, and 1 had idiopathic fulminant hepatic failure.

After selective cannulation of the common bile duct (CBD), a cholangiogram was obtained to evaluate the native CBD, anastomosis, and intrahepatic ducts. Once the ABS was identified, a guidewire was passed through it into the donor's ducts to perform dilation. The implementation of maximal stenting depended on the length of time since OLTand the dose of steroids; if the patient had undergone OLTwithin 3 months or was taking more than 5 mg of prednisone per day, dilation was done with a 10F biliary dilator (Soehendra dilator; Cook Endoscopy, Winston-Salem, NC), and a 10F stent placed for 12 weeks. During a subsequent ERCP, the stent was removed, and balloon dilation was performed (balloon dilator; Cook Endoscopy) with a balloon ranging from 6 to 10 mm in diameter, according to the size of the donor's and recipient's ducts (the duct with the smaller diameter, donor or recipient, determined the diameter of the balloon) for 1 minute. When balloon dilation was completed, a sphincterotomy was performed with the standard technique (Ultratome; Boston Scientific, Natick, Mass), and a maximal number (up to 9) of 8.5F to 11.5F stents (Cotton-Leung; Cook Endoscopy) were placed across the anastomosis (Fig. 1). If a waist could be seen in



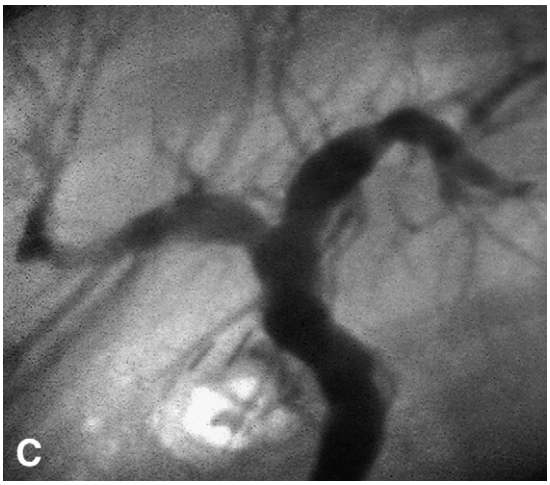


Figure 2. Sample patient treated with balloon dilatation and 1, 3, and 8 biliary stents. **A**, Initial cholangiogram. **B**, Maximal stenting in a sample patient at second ERCP. **C**, Final cholangiogram.

the balloon dilator after 1 minute, 1 more dilation was performed. After the second balloon dilation, a sphincterotomy was performed with the standard technique, and the maximal number of stents was placed across the anastomosis, as previously described, regardless of effacement of the waist in the balloon during dilation.

In the subset of patients who underwent OLT more than 3 months previously and were taking less than 5 mg prednisone per day at the time of ABS diagnosis, 1-minute balloon dilation was performed at the initial ERCP followed by placement of the maximal number of stents at the initial and subsequent ERCPs.

Patients were followed with monthly liver tests and clinic visits every 12 weeks. When only 1 or 2 stents were in place, ERCP was performed at 3-month intervals or earlier if signs and/or symptoms of biliary obstruction were present. If 3 or more stents were in place, stent exchange was not performed on a fixed basis, but only when signs or symptoms of biliary obstruction were detected or after 1 year had passed without stent exchange, whichever came first. This protocol was chosen based on previously described findings.[22]

ABSs were stented for a minimum of 12 months until cholangiographic resolution was achieved. After completion of endoscopic treatment, patients were seen for follow-up every 3 months and/or as clinically indicated. Routine laboratory tests, including liver function tests, and abdominal US were performed at every follow-up visit. After exclusion of other causes (eg, allograft rejection), stricture recurrence was defined as the return of clinical symptoms such as pruritus and jaundice, elevation of alkaline phosphatase or total bilirubin, cholangiographic evidence of ABS causing bile flow impairment, and the need for subsequent interventional procedures such as surgical revision of the biliary tract. Narrowing without signs or symptoms of bile flow impairment was not considered diagnostic for stricture recurrence.

TABLE 3. Comparison of predictors of outcome between success and failure groups

	Treatment success, n = 65 (94%)	Treatment failure, n = 4 (6%)*	*P* value	
			t test	M-W test†
Total stents (mean ± SD)	8.0 ± 5.0	3.5 ± 2.4	.021	
Stents per ERCP (mean ± SD)	2.5 ± 1.3	1.3 ± 0.47	.0040	.023
No. ERCPs (mean ± SD)	4.2 ± 2.8	2.8 ± 1.5	.15	
Time from OLT to ABS, mo	20 ± 31	22 ± 42	.95	.19

MW, Mann-Whitney; *OLT*, orthotopic liver transplantation; *ABS*, anastomotic biliary stricture.
*The 4 patients in whom endoscopic therapy failed had a median age of 48.5 years, were 50% male, underwent OLT for hepatitis C and alcoholic cirrhosis, primary sclerosing cholangitis, fulminant hepatic failure, and autoimmune hepatitis, and had an OLT to ABS diagnosis time interval of 1 month (range 0.5-84).
†Mann-Whitney test (performed for non-normally distributed variables).

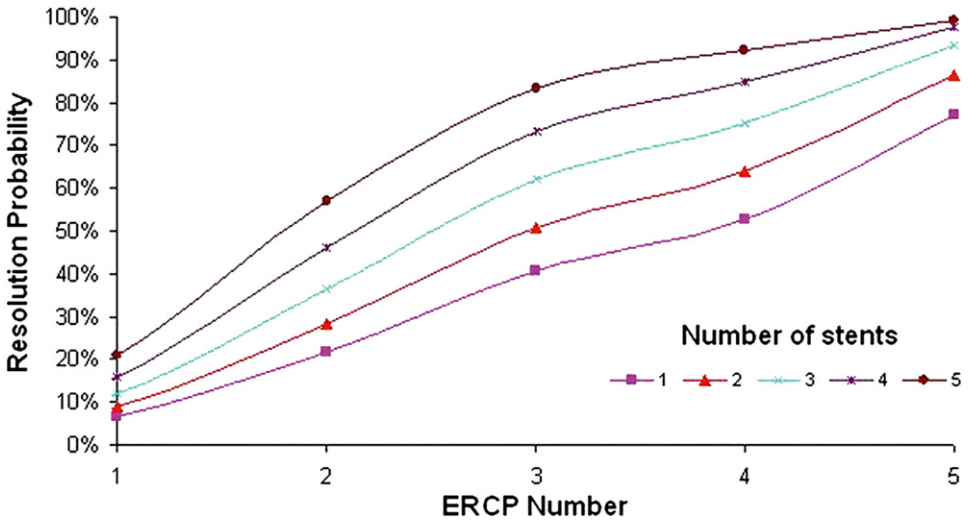


Figure 3. Cox proportional hazard model demonstrating ABS resolution probability as a function of number of stents at each ERCP.

Data analysis

The study endpoint was either ABS resolution (endoscopic treatment success) or hepaticojejunostomy (HJ), other surgical biliary revision, or death related to biliary causes or as a complication of endoscopic therapy (endoscopic treatment failure). Four variables were evaluated as potential predictors of outcome: time from OLT to ABS diagnosis, total number of stents, mean number of stents per ERCP, and number of ERCPs (including the final completion ERCP whereby stents were removed).

Bivariate comparisons were made with *t* test for normally distributed variables and the Mann-Whitney test for non-normally distributed variables. A multivariate Cox proportional hazard model was used to estimate resolution rate as a function of number of stents and ERCPs.

At the time of data collection and analysis, 69 patients had reached an endpoint. Baseline data are summarized for these 69 patients in Table 2. Of the 14 who did not complete treatment, there were 9 deaths or redo OLTs unrelated to biliary disease or complications of endoscopic therapy, and 5 were lost to follow-up despite efforts to contact them and/or their providers by phone or mail (patients presumably moved out of area, state, or country). These 14 patients were excluded from data analysis.

RESULTS

The median endoscopic treatment time was 15 months (range 12-60 months), during which a median of 3 ERCPs (range 2-7 ERCPs) were performed per patient. Of 69 patients, 65 (94%) achieved resolution of ABS (Fig. 2). The remaining 4 (6%) patients required HJ. Table 2 shows the baseline characteristics of patients who achieved resolution of ABS next to the ones in whom treatment failed and who required HJ, and Table 3 compares these 2 groups with respect to the 4 potential predictors of outcome. Figure 3 shows the multivariate Cox proportional hazard model, which demonstrates that treatment success was directly related to the number of stents used in total

TABLE 4. Resolution, recurrence, and complication rate of endoscopic treatment with balloon dilation and stenting for post–orthotopic liver transplantation anastomotic biliary strictures

Study (year)	Total no.	No. completed endoscopic treatment	Resolution rate (%), per protocol*	Recurrence rate at X mo average follow-up	Complications per ERCPs
Rizk et al[21] (1998)	10	10	90	N/A	3/91 (3.3%)†
Rossi et al[18] (1998)	15	12	100	2/11 (18.1%) at 12	2/55 (3.6%)
Schwartz et al[24] (2000)	15	14	50	N/A	4/23 (17.4%)
Mahajani et al[26] (2001)	30	30	86.6	4/30 (13.3%) at 18	5/77 (6.5%)
Chahin et al[27] (2001)	22	19	100	2/19 (10.5) at 12	2/62 (3.2%)‡
Morelli et al[20] (2003)	25	22	100	2/22 (9.1%) at 60	3/79 (3.7%)
Thethy et al[23] (2004)	30	26	26.9	N/A	N/A
Shah et al[28] (2004)	18	13	84.6‡	N/A	N/A
Akay et al[29] (2006)	20	11	90.9	N/A	4/33 (12.1%)
Graziadei et al[30] (2006)	65	57	87.7	N/A	5/424 (1.2%)†
Alazmi et al[31] *(2006)*	143	148	96.6	24/131 (18.3%) at 28	N/A
Elmi et al[32] (2007)	15	7	100	0/7 (0%) at 17.5	5/53 (6.8%)
Holt et al[33] (2007)	53	49	71.4	1/35 (2.9%) at 18‡	11/180 (6.1%)
Pasha et al[19] *(2007)*	25	22	100	4/22 (18.1%) at 21.5	5/105 (4.8%)
Polese et al[34] (2007)	19	19	73.7	1/14 (7.1%) at 17	1/58 (1.7%)
Solmi et al[35] (2007)	12	11	100	0/11 (0%) at 17‡	0/64 (0%)‡
Morelli et al[20] *(2008)*	38	38	87	5/33 (15.1%)	2/131 (1.5%)
Tabibian et al[22] *(2009)*	83	69	94.2	2/65 (3.1%)	4/286 (1.4%)

N/A, Not available.
Maximal or multiple (≥4) stenting studies are italicized.
*Refers to the number of patients with anastomotic biliary stricture at the beginning of the study. Per protocol resolution rate not based on this total number, but rather on the number who were able to reach an endpoint of endoscopic treatment (patients who died of nonbiliary causes or who were stented without balloon dilation were excluded).
†Based on combined anastomotic biliary stricture and nonanastomotic biliary stricture data (data were inseparable).
‡Article unclear; value entered based on best estimate/interpretation.

and per ERCP. Notably, the maximal number of stents inserted was nine 10F stents, but more commonly, patients received up to 5 to 8 stents at the final stent placement, after which stents were removed and endoscopic treatment was considered complete.

There were no major complications in this study. Of the 286 total ERCPs performed in the 69 patients who reached an endpoint, complications were limited to 2 cases of post-ERCP pancreatitis, 2 cases of periprocedural bacteremia requiring hospital admission, and no episodes of cholangitis caused by stent occlusion. Of note, some patients did have brief chills during ERCP despite prophylactic intravenous antibiotics, suggesting transient bacteremia, but they recovered uneventfully after the procedure and were sent home the same day without sequelae.

In a median follow-up of 11 months (range 0-39 months, mean 12 months), 2 (3%) of the 65 successfully treated patients had a recurrence of ABS, 1 at 8 months and the other at 23 months. In both cases, recurrent ABS was successfully re-treated with ERCP.

DISCUSSION

An ABS at the CDCD tends to be a challenging long-term management problem. The initial success rate of endoscopic therapy for ABS varies from 27% to 100%, depending on the various techniques used, with recurrence rates varying from 1.2% to 17.4%, depending on technique and the duration of follow-up.[7,8,18,23,24] ERCP with balloon dilation and stent placement has emerged as the most effective endoscopic approach, given that it yields substantially more durable results than monotherapy with balloon dilation alone, but an optimal protocol has not been established.[24]

In 2001, Costamagna et al[25] were the first to report the successful use of ERCP with balloon dilation followed by

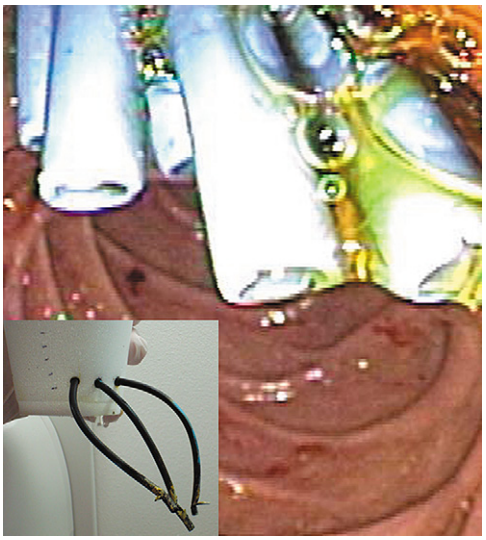


Figure 4. Endoscopic image of occluded biliary stents with evidence of biliary drainage through interstent channels; inset demonstrating patency test (no flow through biliary stents under 10 cm of water pressure).

insertion of multiple stents for the treatment of postoperative biliary strictures. This regimen consisted of balloon dilation of ABS and placement of at least 2 biliary stents followed by stent exchange and insertion of additional stents approximately every 2 to 3 months for up to 1 year. The number of stents inserted depended on the size of the donor and recipient ducts, the maximum being 6 stents.

Recently, several authors have used this regimen for OLT patients with ABS with success. For example, Pasha et al[19] used aggressive endoscopic therapy with combined biliary dilation and maximal stent placement (up to 4 stents) over a median of 4.6 months for the treatment of ABS in 25 OLT patients with a 91% resolution rate (per protocol analysis; 88% by intent-to-treat) and minimal complications. During a median follow-up of 11 months, 4 (18%) patients had recurrent ABS, 2 of whom were successfully re-treated endoscopically and 2 of whom required surgical intervention. Morelli et al[20] also used multiple stents (up to 6) in 38 OLT patients, but as part of a protocol with rapid-sequence balloon dilation followed by insertion of multiple stents; stricture resolution was achieved in 87% of patients with only minimal complications. During the follow-up period, 13 (34%) patients required another ERCP at a mean of 69.3 days, 5 (15%) of whom had ABS recurrence.

In this study, we sought to review the outcomes of the endoscopic protocol for treating ABS with the long-term maximal stent therapy that we use at our institution. We found our outcomes to be very favorable, with a high primary and long-term success rate and few complications (Table 4). Our protocol is similar to that of previous studies of maximal endoscopic stenting, which we believe maximizes the likelihood of ABS resolution, as demonstrated in Figures 1 and 2, with only a few differences that may offer possible advantages.

Maximal number of stents

Previous studies have used as many as six 10F biliary stents. At our institution, patients may receive as many as nine 10F biliary stents. Progressive maximal stenting with such a large number of stents may help to:

1. Maintain the stretched duct diameter that is achieved with balloon dilation by forcing the CBD to remodel around the stents and not allowing an anatomical opportunity for stented ducts to narrow appreciably when stents are still in place;
2. Provide an anatomical buffer per se so that even if narrowing occurs after endoscopic treatment is complete, the CBD is large enough so that mild to moderate narrowing may not cause significant impediment to biliary flow;
3. Allow longer intervals of time between ERCPs so that the number of patient interventions is minimized, thereby decreasing procedural risk and cost;
4. Reduce the incidence of cholangitis caused by ample biliary flow, which can continue to occur for a period of time in the interstent space even when all stents are occluded (Video 1, available online at www.giejournal.org; Fig. 4).

Duration of endoscopic stenting

We have been adhering to a longer stenting duration (at least 12 months) than what is reported in the literature.[19,24,33,34] This seems to:

1. Improve the rate of primary success by allowing sufficient time for more complete and patent anastomotic healing around a maximal number of stents;
2. Minimize anastomotic collapsibility and thus ABS recurrence once endoscopic therapy has been completed and stents are removed, likely by the same mechanism.

This study is, to our knowledge, the second largest of its kind in the published literature, and we believe that our protocol may represent a robust and successful protocol for ABS at the CDCD.[31] Its main limitation is its semiretrospective design and reliance on one endoscopist. The question as to what is the optimal endoscopic protocol (ie, most effective, lowest ABS recurrence, minimal complications, and cost-effective) will best be answered in the future by a large, randomized trial. Until such a study is conducted, we recommend and would ask that other institutions prospectively evaluate our endoscopic treatment protocol for the management of ABS.

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Current affiliations: Dumont-UCLA Liver Transplant Center (J.H.T., E.H.A., S.H., S.S., M.J.T., L.G., R.W.B., F.A.D.), Los Angeles, California, Johns Hopkins Medical Institution (J.H.T.), Osler Medical Residency Program, Baltimore, Maryland, USA.

Reprint requests: James H. Tabibian, MD, 924 North Broadway, Baltimore, MD 21205.

If you would like to chat with an author of this article, you may contact Dr. Tabibian at jhtabib@ucla.edu.