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ORIGINAL ARTICLE

Predictors of the Feasibility of Primary Endoscopic Management of Biliary Strictures After Adult Living Donor Liver Transplantation

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Biliary strictures are a major cause of morbidity and mortality for liver transplant recipients. The endoscopic management of biliary strictures is not well established after living donor liver transplantation (LDLT) in comparison with deceased donor liver transplantation. The aims of this study were to assess the initial success rate of primary endoscopic treatment of biliary strictures after LDLT and to identify predictors of the feasibility of endoscopic management. One hundred thirty-seven adult patients who underwent LDLT and were confirmed to have biliary strictures by endoscopic retrograde cholangiopancreatography (ERCP) were enrolled. The biliary strictures were primarily managed endoscopically with internal drainage or nasobiliary catheterization. The initial success rate for the primary endoscopic management of biliary strictures after LDLT was 46.7% (64 of 137 patients), and the feasibility of endoscopic management was associated with the stricture-to-ERCP interval (the interval between the development of the total bilirubin, aspartate aminotransferase, or alanine aminotransferase level to >2 times the upper limit of normal and the performance of ERCP) as well as cholangiographic findings (eg, the stricture morphology and the tip shape of the distal duct). In conclusion, when biliary strictures are noticed after LDLT, prompt endoscopic interventions may improve the initial success rate of primary endoscopic management. In addition, the feasibility of primary endoscopic management can be predicted by the cholangiographic findings, which may help with the choice of the therapeutic modality. ***Liver Transpl* 17:1467-1473, 2011.** © **2011 AASLD.**

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Since Calne[1] first referred to the biliary tract as the Achilles' heel of liver transplantation (LT) in 1976, biliary complications, which include bile duct strictures, leaks, and cast syndrome, have remained a significant source of morbidity and mortality after LT.[2,3] Although the incidence of these complications has been reduced by improvements in organ selection, retrieval, and preservation and by the standardization of the methods of biliary reconstruction,[4-6] bile duct strictures are still frequent, and they account for approximately 40% of all biliary complications after LT.[4]

Living donor liver transplantation (LDLT) has been replacing deceased donor liver transplantation (DDLT) as a treatment for end-stage liver disease because of the shortage of cadaveric donor organs. Bile duct strictures have been estimated to occur in 12% to 24% of all LDLT patients,[7-9] and the incidence of anastomotic strictures is higher than that of nonanastomotic strictures.[10-12]

There has been a recent transition in the primary management of biliary strictures after LT from predominantly surgical management to primarily endoscopic

Abbreviations: ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; DDLT, deceased donor liver transplantation; ERCP, endoscopic retrograde cholangiopancreatography; GGT, gamma-glutamyl transpeptidase; LDLT, living donor liver transplantation; LFT, liver function test; LT, liver transplantation; ULN, upper limit of normal.

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management. Endoscopic management has the advantage over percutaneous therapy because it is not only more physiological but also less invasive. However, the success rates of endoscopic treatment for LDLT patients appear to be significantly lower than those for DDLT patients and have ranged from 60% to 75% for anastomotic strictures and from 25% to 33% for nonanastomotic strictures.[11-17] This is due to the fact that DDLT and LDLT use different types of grafts and methods of duct-to-duct reconstruction; the anastomosis of the bile duct of the graft is more peripheral and smaller in LDLT versus DDLT. The risk factors that influence the outcomes of the endoscopic management of biliary strictures after LDLT have not yet been well characterized.

Several clinical trials have evaluated the therapeutic efficacy for biliary strictures after LDLT, yet most have been based on a combined application of endoscopic and percutaneous procedures.[18-20] There are only a few reports on endoscopic therapy.[11,13-15,21,22] To the best of our knowledge, this is the second largest study evaluating the primary endoscopic treatment of biliary strictures after LDLT, and this is the first study to identify predictors of the feasibility of primary endoscopic management.

PATIENTS AND METHODS

Seven hundred thirty-five adult patients underwent LDLT between January 2000 and March 2009 at Samsung Medical Center (Seoul, Korea). One hundred seventy-six of these patients who were clinically suspected of developing biliary strictures underwent endoscopic retrograde cholangiopancreatography (ERCP). Biliary strictures were primarily suspected when patients (1) developed subjective symptoms such as jaundice or an itching sensation, (2) showed laboratory abnormalities such as elevated liver enzyme levels or hyperbilirubinemia, or (3) had dilated biliary systems according to ultrasonography or computed tomography. One hundred thirty-seven of the 176 patients who were clinically suspected of developing biliary strictures were confirmed to have anastomotic biliary strictures by ERCP and were included in this study. The other causes were leakage (16 patients), rejection (9 patients), biliary stones (5 patients), hepatitis viral reactivation (5 patients), pancreatic cancer (1 patient), aplastic anemia (1 patient), and unidentified causes (2 patients). In the 137 patients who had biliary strictures, the initial manifestations of biliary strictures were clinical symptoms [8 patients (5.8%)], laboratory abnormalities [105 patients (76.6%)], or imaging findings [24 patients (17.5%)]. Their medical records and ERCP images were retrospectively reviewed. The study protocol was approved by the institutional review board of Samsung Medical Center.

Once biliary strictures were confirmed with a cholangiogram, they were primarily managed endoscopically with internal drainage or nasobiliary catheterization. The endoscopic procedures were performed by 3 endoscopists (J.K.L, K.T.L., and K.H.L.), each of whom performed approximately 300 biliary interventions per year. The ERCP techniques for LDLT patients were similar to those for patients with benign biliary strictures. After cannulation of the ampulla of Vater, an injection of a contrast dye revealed the distal and proximal parts of the anastomosis. When the proximal part was not visualized by a simple dye injection, balloon-assisted cholangiography was tried. After biliary strictures were confirmed, a 0.025- or 0.035-inch polymer-coated guide wire (Cook, Winston-Salem, NC) was passed through the biliary strictures, and the strictures were dilated with a 6- to 8-mm balloon (Boston Scientific, Natick, MA) at 6 to 8 atm for 1 minute. The balloon sizes were chosen according to the size of the proximal duct of the anastomotic site. A Soehendra retriever with a tapered tip (Cook) was used when the balloon could not be passed through the stricture site. Then, either a biliary stent (7- to 8.5-Fr; Cook) or a nasobiliary catheter (7-Fr; Boston Scientific) was placed across the stricture for drainage. In order to ease the passage of the guide wire or the stent placement, sphincterotomy was performed in 88 of 137 patients (64.2%). The initial success of primary endoscopic management was defined as the successful placement of a biliary stent or a nasobiliary catheter after the passage of a guide wire through the stricture site with or without balloon dilatation.

In order to identify the predictors of the feasibility of primary endoscopic management, the univariate analysis included the following variables: the recipient factors, the donor factors, the laboratory results, the LT-related factors, the endoscopic procedure-related factors, and the cholangiographic findings. The cholangiographic findings were categorized according to the shape of the stricture site, the shape of the distal duct, or the angle between the proximal and distal ducts (Fig. 1).

The differences between groups were compared with the Student *t* test for continuous data and with the chi-square test for categorical data. A multivariate analysis was performed with the logistic regression method. All the statistical analyses were performed with Stata 11.1 (StataCorp, College Station, TX). The adjusted proportions of initial endoscopic success were computed with marginal standardization, and the relative risks were calculated on the basis of these adjusted proportions. Ninety-five percent confidence intervals were calculated with the delta method. P values <0.05 were considered statistically significant.

RESULTS

The baseline characteristics of the 137 patients are detailed in Table 1. The mean age of the patients was 50.0 ± 8.1 years, and 77% of the patients were male. All recipients had right lobe grafts with duct-to-duct anastomoses. The patients underwent endoscopic procedures at a mean of 6.6 ± 5.1 months after LT.

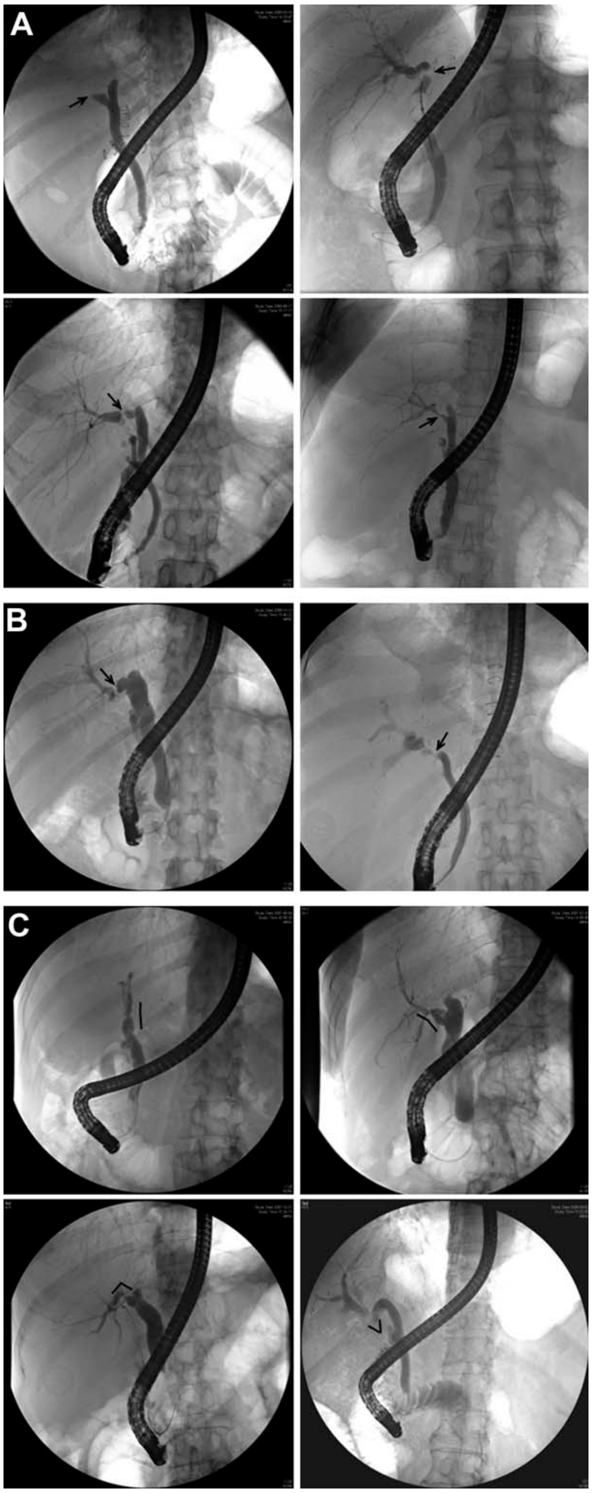

Figure 1. Representative cases of biliary strictures according to the cholangiographic findings. (A) Nonvisualization of the proximal duct (upper left), the separate duct type (the proximal duct is visualized, but the stricture site is not visualized; upper right), the narrow stricture type (the stricture site is visualized with a luminal diameter $\leq$ 2 mm; lower left), and the wide stricture type (the stricture site is visualized with a luminal diameter > 2 mm; lower right). (B) Distal ducts with round (left) and tapered shapes (right). (C) Angles between the proximal and distal ducts of 0° to 30° (upper left), 30° to 60° (upper right), 60° to 90° (lower left), and >90° (an S shape; lower right).

TABLE 1. Demographic and Clinical Characteristics of the Patients (n = 137)

Age (years)*	50.0 ± 8.1
Sex: male/female (%/%)	77/23
Child-Pugh-Turcotte class at the time of LT: A/B/C (%/%/%)	10.4/27.4/62.2
Underlying disease at the time of LT (%)	
Hepatocellular carcinoma	47.4
Hepatitis B virus– or hepatitis C virus–related cirrhosis	40.1
Cirrhosis by other causes	12.4
LT-to-ERCP interval (months)*	6.6 ± 5.1
Abnormal LFT-to-ERCP interval (days)*	21.0 ± 19.2

*The data are presented as means and standard deviations.

The mean interval between the development of abnormal liver function tests [LFTs; any test results for total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), and gamma-glutamyl transpeptidase (GGT) beyond the normal limits] and the endoscopic procedure was 21.0 ± 19.2 days. The endoscopic procedure was successfully performed in 64 of the 137 patients (46.7%) on the first attempt. Another 4 cases succeeded during the second attempt. Stents were removed from 38 of 68 patients who were maintained with endoscopic therapy. They underwent 4.8 ± 3.0 ERCP sessions until stent removal. The main cause of endoscopic failure was the failure of the guide wire to pass through the stricture site (56/73 or 76.7%). Other causes were the failure to cannulate the common bile duct (4/73 or 5.5%) and the failure of the stent or nasobiliary catheter to pass through the stricture site (13/73 or 17.8%). Patients for whom the endoscopic management of biliary strictures failed underwent percutaneous drainage. Cholangitis was the most common post-ERCP complication. There was no difference between the success or failure groups (28.1% versus 23.3%, $P = 0.52$). The other complications were bleeding (4/137), leakage (1/137), and pancreatitis (1/137). No patient lost a graft because of complications of endoscopic management.

In the univariate analysis, none of the recipient, donor, laboratory, or LT-related factors were significantly different between the success and failure groups (Table 2). Instead, the initial success of primary endoscopic management was significantly correlated with the interval between LT and the performance of ERCP (the LT-to-ERCP interval), the interval between the detection of biliary strictures and the performance of ERCP (the stricture-to-ERCP interval), and the shape of the bile ducts on the cholangiogram. The LT-to-ERCP interval was considerably shorter for the success group (5.61 months) versus the failure group (7.46 months, $P = 0.03$). In order to determine the stricture-to-ERCP interval, we plotted the time versus the total bilirubin, AST, and ALT levels (Fig. 2). Although the initial manifestations of biliary strictures included

TABLE 2. Univariate Analysis of the Variables for the Initial Success of Primary Endoscopic Management (n = 137)

	Success Group (n = 64)	Failure Group (n = 73)	*P* Value
Recipient factors			
Age (years)*	49.9 ± 8.6	50.0 ± 7.5	0.91
Male sex (%)	79.7	75.3	0.68
Donor factors			
Age (years)*	32.4 ± 10.4	31.2 ± 10.1	0.54
Male sex (%)	74.5	57.1	0.08
Laboratory results*			
Total bilirubin (mg/dL)	4.9 ± 5.2	6.4 ± 5.8	0.10
AST (IU/dL)	103.8 ± 96.0	104.5 ± 72.2	0.96
ALT (IU/dL)	180.0 ± 207.0	161.8 ± 142.1	0.55
ALP (IU/dL)	347 ± 190	405 ± 280	0.17
GGT (IU/dL)	378.3 ± 39.2	375.3 ± 39.7	0.96
LT-related factors			
Operation time (minutes)*	601 ± 97	621 ± 129	0.33
Cold ischemia time (minutes)*	95 ± 43	98 ± 54	0.82
Warm ischemia time (minutes)*	37 ± 20	43 ± 38	0.26
Multiplicity of bile ducts (%)	29.6	23.5	0.54
Ductal stent insertion (%)	11.3	16.4	0.60
Duct reconstruction (%)	18.8	16.4	0.72
Number of donor ducts: 1/2/3 (%/%/%)	71.9/23.4/4.7	75.3/21.9/2.7	0.85
Endoscopic procedure–related factors			
LT-to-ERCP interval (months)*	5.61 ± 4.62	7.46 ± 5.40	**0.03**
Abnormal LFT-to-ERCP interval (days)†			
Total bilirubin > normal limit (122)	14.63 ± 14.81 (53)	28.82 ± 45.73 (69)	**0.03**
AST or ALT > normal limit (125)	26.09 ± 33.74 (58)	39.54 ± 37.04 (67)	**0.03**
Total bilirubin, AST, or ALT > 2-fold (135)	14.53 ± 12.74 (62)	26.61 ± 22.01 (73)	**<0.001**
Cholangiographic findings (%)			
Stricture morphology			**<0.001**
Wide stricture	100	0	
Narrow stricture	77.3	22.7	
Separate duct	33.3	66.7	
Nonvisualization of the proximal duct	0	100	
Tip shape of the distal duct‡			**<0.001**
Tapered tip	81.8	18.2	
Round tip	29.4	70.6	
Angle between the proximal and distal ducts‡			**0.001**
$0° \leq - \leq 30°$	84.1	15.9	
$30° < - \leq 60°$	57.7	42.3	
$60° < - \leq 90°$	45.0	55.0	
>90° or S shape	30.0	70.0	

P values <0.05 are expressed as bold.
*The data are presented as means and standard deviations.
†The data are presented as means and standard deviations. Figures in parentheses are the numbers of patients who developed abnormal LFTs.
‡Thirty-three patients whose proximal ducts were not visualized by cholangiography were excluded from the analysis.

clinical symptoms (8 patients or 5.8%), laboratory abnormalities (105 patients or 76.6%), and imaging findings (24 patients or 17.5%), laboratory results were the most common manifestations and the most unbiased variables, especially in the retrospective data collection. Thus, we chose laboratory results for estimating the time at which biliary strictures had developed. Schematically, the profile of the total bilirubin, AST, and ALT levels after LDLT had the following pattern: an initial drop to the normal range and then a gradual increase. We measured the interval between the development of abnormal LFTs and the performance of ERCP. Among the several combinations of abnormal LFTs, the *P* value was lowest when any of the test results for the total bilirubin, AST, and ALT levels was >2 times the normal limit. Thus, we defined the stricture-to-ERCP interval as the interval between the development of the total bilirubin, AST, or ALT level to >2 times the upper limit of normal (ULN) and the performance of ERCP.

As for the cholangiographic findings, the wide stricture type had a higher success rate than the narrow stricture type or the separate duct type. When the proximal duct was not visualized on a cholangiogram, endoscopic management failed. The success rate was higher when the distal duct had a tapered shape versus a round shape. The bigger the angle was between the proximal and distal ducts, the lower the success rate was.

The multivariate analysis, which used variables with P values < 0.05 on the univariate analysis, revealed that the stricture-to-ERCP interval, the stricture morphology, and the tip shape of the distal duct (but not the angle between the proximal and distal ducts) independently predicted the initial success of primary endoscopic management (Table 3). When endoscopic management was delayed by 1 day, the success rate was lowered by 4%.

According to the marginal analysis, the expected success rates of primary endoscopic management for the separate duct type, the narrow stricture type, and the wide stricture type were 45.9%, 66.7%, and 100%, respectively. When the distal duct had a tapered tip, the expected success rate was 71%, whereas the expected success rate was 36% with a round tip.

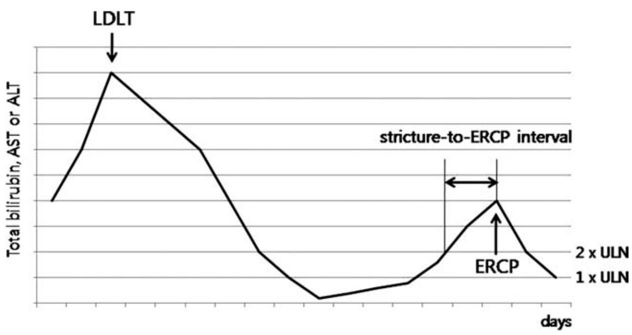

Figure 2. Definition of the stricture-to-ERCP interval. After LDLT, the LFT profile (including the total bilirubin, AST, and ALT levels) showed the following pattern: an initial drop to the normal range and then a gradual increase. The stricture-to-ERCP interval was defined as the interval between the development of the total bilirubin, AST, or ALT level to >2 times the ULN and the performance of ERCP.

DISCUSSION

In recent years, endoscopy has played a progressively greater role in the diagnosis and management of biliary strictures after LT. Endoscopic dilatation with the placement of 1 or more plastic stents is currently the standard first-line management for biliary strictures, and this avoids the need for percutaneous transhepatic procedures and surgical management in most cases.

Although it is standard to use large-caliber/multiple plastic stents in the management of benign biliary strictures due to common conditions other than LDLT, the nature of LDLT makes this standard of care difficult to follow. When biliary strictures are being managed, the initial success of the stent insertion is important for preventing unwanted cholangitis and avoiding further hepatic damage, especially in LT patients. However, the small intrahepatic duct of the donor liver is anastomosed to the large common bile duct of the recipient in LDLT, and this size discrepancy makes biliary strictures complex. In comparison with other conditions, the angle between the proximal and distal ducts tends to be more acute, and the diameter of the stricture site tends to be narrower. This is the reason that the success rate of ERCP for LDLT cases is lower than that for patients with benign biliary strictures due to common conditions, and large-caliber/multiple stents cannot be used in the initial attempt at stenting in LDLT cases. If the first attempt is successful, a larger stent can be tried in the next session of ERCP.

Some data are available about the endoscopic management of biliary strictures after LDLT.[11,13-15,21,22] Chang et al.[21] reported the efficacy and long-term outcomes of endoscopic treatment for biliary strictures after LDLT. Stent insertion or stricture dilatation was successful in 90 of 113 patients who underwent ERCP for the treatment of biliary strictures. However, this number included 27 patients

TABLE 3. Multivariate Analysis of the Variables Affecting the Initial Success of Primary Endoscopic Management

Variable	Odds Ratio	95% Confidence Interval	*P* Value
LT-to-ERCP interval (months)	0.94	0.83-1.07	0.33
Stricture-to-ERCP interval (days)	0.96	0.92-0.99	**0.02**
Stricture morphology*			**0.04**
Separate duct	1		
Narrow stricture	3.81	1.10-13.24	
Tip shape of the distal duct			**0.002**
Round tip	1		
Tapered tip	7.64	2.12-27.49	
Angle between the proximal and distal ducts			
0°≤-≤30°	1		
30°<-≤60°	0.37	0.08-1.69	0.20
60°<-≤90°	0.39	0.07-2.17	0.28
>90° or S shape	0.22	0.03-1.44	0.11

P values <0.05 are expressed as bold.
*All 4 types (nonvisualization of the proximal duct, separate duct, narrow stricture, and wide stricture) were included in the analysis; however, the odds ratios for the nonvisualization of the proximal duct and the wide stricture were not obtained because of the zero-valued cells.

who had undergone percutaneous transhepatic biliary drainage as an initial treatment. Thus, the success rate of primary endoscopic treatment was 55.8% (63/113). Kim et al.[22] attempted the endoscopic management of biliary strictures in 147 LDLT recipients, and they reported an immediate endoscopic success rate of 55.8% and a final success rate of 36.9%. They also compared patients who did and did not achieve final endoscopic success, and they identified the time from LDLT to the first ERCP session as the only significant factor that predicted final endoscopic success. The present study included 137 adult patients, and 64 of these patients (46.7%) were successfully managed endoscopically; this result is comparable to the results of previous reports.

Unlike previous studies that evaluated the long-term outcomes of endoscopic treatment, the present study was focused on the feasibility of primary endoscopic treatment for biliary strictures after LDLT. We sought to identify the predictors of the feasibility of primary endoscopic management. We found that the stricture-to-ERCP interval, the stricture morphology, and the tip shape of the distal duct were independent predictors of the feasibility of primary endoscopic management. Technically, the most common cause of the failure of therapeutic ERCP for biliary strictures is the presence of a stricture that is too tight to allow access to the proximal duct.[23,24] Most likely, the stricture-to-ERCP interval and cholangiographic findings (eg, the stricture morphology and the tip shape of the distal duct) represent the degree of tightness of the stricture site after LDLT. Accordingly, the present study demonstrated that the luminal diameter of the stricture site was closely associated with the feasibility of primary endoscopic management. In addition, Yazumi et al.[12] described a subset of patients with a sharp angulation or crane neck deformity of the bile duct after LDLT, and they reported a very low success rate of endoscopic management in this subset (20% or 1 of 5 patients). Similarly, the present study showed that a sharper angle between the proximal and distal ducts was indeed significant in the univariate analysis, but it only trended toward significance in the multivariate analysis. This study was mainly limited by its retrospective data collection. A lack of a systematized description of subjective symptoms and irregular follow-up intervals might have kept us from estimating the exact time at which biliary strictures had developed. It is also highly likely that we underestimated the rate of post-ERCP complications.

In conclusion, the endoscopic management of biliary strictures in LDLT recipients is a challenging issue. In the present study, approximately 50% of biliary strictures after LDLT were successfully managed by the endoscopic approach. Prompt endoscopic interventions after the detection of biliary strictures may improve the initial success rate of endoscopic management. In addition, cholangiographic findings that can be assessed by noninvasive imaging (eg, magnetic resonance cholangiopancreatography) may help with the preselection of patients who are amenable or resistant to endoscopic management and may also help with choosing between several therapeutic modalities.

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