

Long-term outcome of percutaneous transhepatic drainage for benign bile duct stenoses

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Abstract

Purpose: The occurrence of benign bile duct stenoses is mostly associated with prior biliary surgery, pancreatic diseases or sclerosing cholangitis. It remains a challenging problem for gastroenterologists and surgeons, especially in case the endoscopic approach is not possible. The exact role of percutaneous transhepatic stenting for these patients has not been clearly defined yet.

Material and methods: 36 patients with symptomatic benign bile duct stenoses or strictures after surgery underwent percutaneous transhepatic stenting and were studied prospectively. We were particularly interested in how many patients would achieve resolution of the stricture and tolerate removal of the drainage in the long-run.

Results: The primary success rate of percutaneous transhepatic biliary drainage (PTBD) was 92% (33/36 patients). All patients presented improvement of jaundice and cholestasis. Relief of the stricture and clinical improvement was achieved in 72% (26/36) of patients after a median stenting time of 14.5 (6-34) months. 5.5% (2/36) required further stenting due to a persistent stricture. A clinical recovery without radiological stricture regression after stenting demonstrated 22% (8/36) of patients. Long-term failures were noted in 27% (10/36) of patients after a median follow-up of 48 months.

Conclusions: Percutaneous transhepatic stenting of symptomatic benign biliary strictures is safe and highly effective in achieving adequate internal bile drainage. There seems to be a therapeutic benefit not only for short-term

interventional treatment but also as a sufficient long-term therapeutic alternative to surgery with tolerable complication rates.

Key words: benign biliary stricture, percutaneous transhepatic drainage, long-term stenting.

Introduction

The etiology of benign bile duct stenoses is often associated with open or laparoscopic cholecystectomy, pancreatic diseases, sclerosing cholangitis and biliary anastomoses – e.g. after liver transplantation or hepaticojejunostomy [1,2]. Postoperative bile duct injuries occur in 0.2% to 0.5% of patients undergoing open cholecystectomy and in 0% to 2.7% after laparoscopic cholecystectomy. Biliary tract complications, ranging from 7% to 31% after orthotopic liver transplantation, have been reported in the literature [3-5]. Benign bile duct strictures (BBS) represent a significant clinical problem, despite technological developments that have facilitated diagnosis and management. Long-term complications may lead to recurrent chronic cholangitis in up to 9% and secondary biliary cirrhosis in about 7% of patients. Sepsis due to pyogenic liver abscess has also been described in a number of patients [6].

Two treatment modalities for management of BBS are available: surgical biliary drainage (mainly Roux-en Y hepaticojejunostomy) and the non-surgical approach with endoscopic stricture dilation (consisting of repeated balloon dilation and/or temporary insertion of a plastic stent) or percutaneous transhepatic biliary drainage (PTBD) for patients with inaccessible papilla or intrahepatic strictures. These two therapeutic modalities provide comparable results with stricture relapses demonstrated in 15% to 45% of cases after mean follow-up periods of 4 to 9 years [2,4-9]. However, surgical biliary drainage is associated with a mortality of more than 10% although a mortality of almost zero has been seen in more recent but smaller studies

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Table 1. Previous surgical interventions before PTBD

Operation	N
Cholecystectomy	13 (8 laparoscopic)
Biliodigestive anastomosis	13
Whipple's procedure	4
Hepaticojejunostomy	2
No prior surgery	4

[10-16]. Therefore, over the last decade there have been many efforts to explore endoscopic management [17]. Endoscopic biliary stenting has been proved with good long-term results in more than 80% of cases, respectively [5,8,9,18,19].

On the other side, data on the efficacy of the percutaneous transhepatic approach for BBS is based only on small uncontrolled trials. Overall, PTBD has achieved success rates of approximately 70% to 80% in patients with medium-term follow-up periods only [18,20-23]. The data are more limited with regard to long-term results, and the patients described have been subject to greater selection.

To clarify the role of PTBD, we prospectively studied the efficacy and safety of this approach for BBS in patients with an inaccessible papilla, intrahepatic stricture or in whom surgical intervention was to be avoided. Overall, the main focus was to investigate the long-term outcome of this treatment.

Material and methods

Patients

A prospective analysis of the "Ludwigshafen' benign biliary stricture register" revealed 127 cases of benign bile duct stenoses treated interventionally at the Endoscopy Unit, Department of Gastroenterology, Klinikum Ludwigshafen, Germany, from 01.01.1996 until 01.01.2004, respectively. Patients with malignant strictures or cholestasis due to distal common bile duct stricture on chronic pancreatitis were excluded. A total of 36 cases with symptomatic cholestasis were treated via the percutaneous transhepatic route. Endoscopic approach was not suitable in all 36 patients and they were referred for percutaneous transhepatic biliary drainage (PTBD) therefore.

The patients previous surgeries are listed in *Tab. 1*. Of 36 patients, 32 had undergone biliary operations while 4 patients had had no previous surgery in the biliary system overall. However, these patients had intrahepatic strictures or had undergone Billroth-II resection of the stomach and gastroduodenectomy though that might have indirectly affected the biliary system and they were included into the analysis. The median interval between surgery and our subsequent percutaneous biliary drainage was 36.5 ± 64 (1-252) months.

Endoscopic Technique

Percutaneous access of the biliary system was achieved in case ERCP was not successful, because the papilla could not be reached due to anatomical difficulties, biliodigestive anastomoses or intrahepatic strictures. Depending on the anatomy and the site of cholestasis, a right and/or left peripheral bile duct

was punctured and a guide wire was used to pass the stricture. The technique of percutaneous transhepatic cholangiography (PTC) was performed as described previously by other authors [24]. After insertion of a 5 Fr plastic sheath over the stricture a more rigid guide wire was placed into the intestine. The transhepatic tract was sequentially (usually within 7-10 days) dilated by exchange of transhepatic plastic tubes with an increasing diameter up to 16-18 Fr until a stable cutaneobiliary fistula is achieved. We performed percutaneous transhepatic cholangioscopy (PTCS; CHFX-P20, Olympus, Hamburg, GER) in every patient to clarify the macroscopic-endoscopic dignity of the stricture and to obtain histological specimen. In patients with concomitant bile duct stones adjuvant endoscopic techniques like laser lithotripsy and electrohydraulic lithotripsy (EHL), was used and the stone fragments were pushed into the intestine or extracted with a basket afterwards.

Percutaneous transhepatic biliary drainage/stenting was carried out with transhepatic flexible tubes (Yamakawa® type, FA, Pflugbeil, Zorneding, GER). These polyethylene tubes are available with an outer diameter of 14-18 Fr and have sideholes for biliary drainage. The proximal tip of the tube was locked and positioned at the skin level. Technical success was defined as correct placement across the biliary stricture and a free flow of bile was noted through the stent into the intestine. Complications were defined immediate if related to the procedure itself or if they occurred within 1 week post-procedure. The patients were advised to flush the tube with sterile saline solution at least twice a week. Re-evaluation of the patients was scheduled every 4 months and the stents were exchanged electively to prevent complications of clogging in the follow-up. Patients who developed cholangitis received intravenous antibiotic treatment and stent exchange.

Follow-up and outcome

The charts of the patients were reviewed retrospectively for indication, effectiveness, success and complications of PTBD. Additionally, patients were contacted regularly to obtain current clinical status and to document any symptoms of stent related problems in the follow-up. Clinical and laboratory data of the patients were assessed using the patients' records and by personal interviews. Successful stenting was defined as radiological stricture regression with clinical improvement after stent removal in the long-run. Treatment was defined as not successful when patients presented no radiological and clinical stricture regression and required ongoing stenting or surgical approach in the follow-up. Prognostic factors were evaluated for a definitive successful outcome of biliary stenting. The results are specified as mean \pm standard deviation and range of values. Statistical analysis was performed using the χ^2 test to verify the independence of two variables, and the Fisher's exact test for case numbers <50 , $p < 0.05$ was defined as statistically significant.

Results

Percutaneous transhepatic biliodigestive stent therapy was carried out in 36 patients with symptomatic benign biliary stricture. There were 19 woman and 17 men with a mean age

Figure 2. High-grade biliary stricture

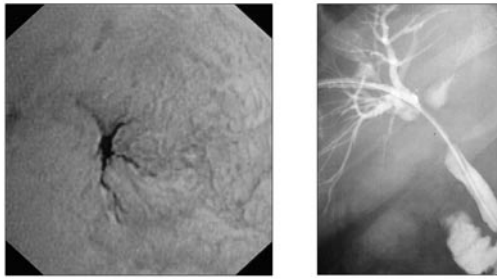
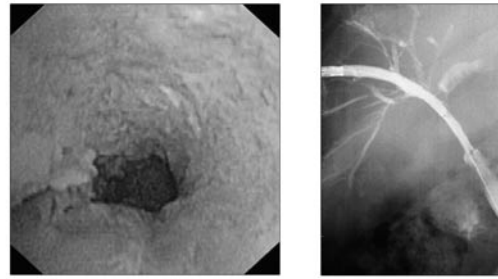


Figure 3. Regression after 1-year stenting



of 67.5 ± 12.5 (38-87) years. All cases presented with signs of obstructive jaundice or cholangitis when the indication of PTBD was defined. The patients demonstrated the following laboratory data before biliary drainage: total bilirubine 3.3 ± 2.8 mg/dl (0.2-14 mg/dl), alkaline phosphatase (AP) level 687.3 ± 417 U/l (53-2412 U/l) and the median diameter of the largest pre-stenotic/ anastomotic bile duct segment measured by ultrasound was 9.52 ± 3.1 mm (5-18 mm). The length of the stricture did not exceed 15mm in most cases. Concomitant bile duct stones were present in 21 patients and were successfully removed after PTC-guided laser lithotripsy or EHL before placement of transhepatic tubes. Complete clearance of the bile ducts was achieved after 2.2 ± 0.5 treatment sessions, respectively.

Successful internal biliary drainage was achieved primarily within the PTC-procedure in 33/36 (92%) of cases and a 9 Fr transhepatic polyethylene bougie was placed with the distal tip in the intestine. After sequential dilation of the cutaneobiliary tract and the stricture to a width of at least 14 Fr, a 14-18 Fr Yamakawa® prosthesis was successfully positioned into the right hepatic duct (n=22), into the left hepatic duct (n=10) or into both ducts (n=4). The primary failed cases underwent percutaneous cholangioscopy and the biliary stricture was passed with a guide-wire under endoscopic control in all 3 patients. Therefore, of the 36 primary attempts of PTBD, all were successful. Overall, adequate internal biliary drainage was noted in 100% (36/36) of patients.

Short-term results:

Adequate drainage with significantly lowered bilirubine and alkaline phosphatase (AP) levels was recognized in the short-term follow-up in all 36 patients. Total bilirubine decreased from 3.3 mg/dl to 1.3 ± 1.4 mg/dl (0.3-10.8 mg/dl), alkaline phosphatase (AP) level from 687.3 U/l to 261.2 ± 156 U/l (76-1200 U/l) and the diameter of the proximal common bile duct diminished remarkable to a width of 5.58 ± 2.1 mm (3-9 mm), respectively. There was no problem of early clogging or perforation of the prosthesis. No procedure-related mortality was encountered. Therefore, the 30-day mortality rate was 0% while we recognized a morbidity rate of 13%, respectively.

The early complications related to the percutaneous transhepatic approach consisted of 2 cases of temporary cholangitis, 2 patients with minor bleeding episodes due to biliovenous fistulas and one patient with active arterial bleeding after dilation of the transhepatic tract. Patients with cholangitis received

antibiotics via the i.v. route and this was successful in all cases. Hemostasis due to biliovenous fistula was achieved by placement of transhepatic polyethylene tubes with no sideholes at the site of the fistula. Management of the arterial bleeding after dilation included angiography with superselective coiling of a peripheral branch of the hepatic artery. The mean hospitalization of the patients for initial PTC and PTBD was 17.5 ± 4.8 (8-29) days.

Long-term results:

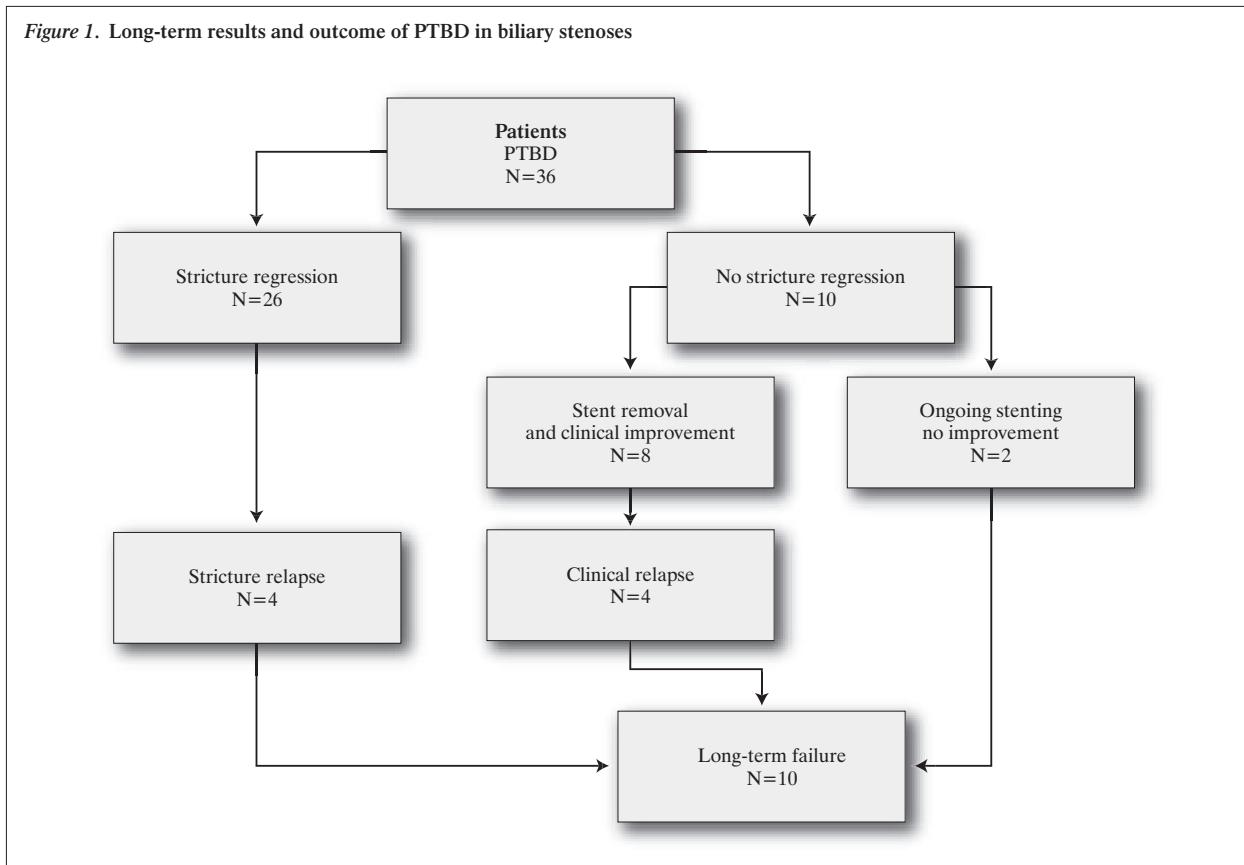
The median duration of drainage was 12 ± 9.9 (1-52) months and the subsequent follow-up for all patients irrespective of treatment allocation was 48 ± 14.2 (2-156) months. We recognized a radiological verified regression of the biliary stenosis in 26 patients after a stenting period of 14.4 ± 6.1 (4-36) months. The radiographic measurement after removal of the stent demonstrated a mean dilation of the stenotic biliary segment from 1.4 ± 0.6 (1-3) mm to 2.4 ± 2.9 (1-10) mm. However, 10 of 36 patients (27%) presented a persistent biliary stricture after transhepatic stenting therapy.

Overall, in 22 patients, the transhepatic tubes could be removed permanently while objective stricture regression and clinical improvement was observed in the long-term follow-up. The median stenting time for these patients was 14.9 ± 6.2 (6-34) months (Fig. 2,3). In 8 of the 10 patients without radiological stricture regression, we removed the drains after a median stenting time of 13.5 ± 4.7 (8-22) months and the patients demonstrated clinical improvement (no jaundice, pain or cholangitis) without a stent in situ. However, in the long-term follow-up 4 of the 8 patients were re-admitted because of recurrent jaundice, bile duct stones or cholangitis after 23.5 ± 4.6 (17-24) months.

Four patients (11%) with primary stricture regression developed relapse of cholestasis after 20.2 ± 2.6 (18-24) months. The objective radiological long-term success rate (stricture regression + clinical improvement) with percutaneous treatment was 22 of 36 patients (62%), while the overall benefit from therapy was 26 of 36 patients (72%).

The remaining 10 cases, which had to be regarded as long-term failures, should be differentiated in primary failures (no stricture regression and/or no clinical improvement after attempted PTBD extraction) and secondary failures (recurrence/relapse of stricture and/or clinical improvement in the follow-up (Fig. 1).

Figure 1. Long-term results and outcome of PTBD in biliary stenoses



Persistent stricture without clinical improvement after attempted PTBD was noted in 2 of 36 (6%) patients. The median stenting time for these patients was 11.9 ± 12 (2-52) months. The reason for ongoing stenting were contraindications for surgery in both patients. The percutaneous drainages were exchanged regularly every 4 months to prevent complications like clogging and cholangitis.

Eight patients (22%) developed relapse of the biliary stricture or recurrence of clinical symptoms (jaundice, cholangitis, cholestasis) after 21.8 ± 4.4 (17-24) months. The median stenting period of these patients was 14.2 ± 5.1 (4-36) months. Of these 8 patients, 2 were managed by insertion of a percutaneous self-expandable metal stent, one patient underwent biliary drainage surgery and 5 patients were treated with ongoing percutaneous drainage again. Four patients (11%) with primary PTBD could be switched to a biliodigestive stenting via the endoscopic route. All patients with continued percutaneous transhepatic stenting have remained well, with uneventful exchanges of the Yamakawa drains every 4 months. Currently, 4/36 patients with persistent stenosis or stricture relapse have stents in place at the time of writing.

Possible influencing factors for determining superior long-term outcome like age, gender, etiology of the stricture, stricture location, cholestatic serum parameters, width of the common bile duct and treatment time were investigated as well. Statistical analysis (Fisher's exact test) revealed minor significance only for proximal or intrahepatic location, anastomotic strictures, short strictures ($p=0.07$) and extended percutaneous stenting

time ($p=0.08$). All other variables demonstrated no significant influence for successful long-term outcome.

Long-term complications

Stent occlusion was the predominant late complication and was found in 14 (38%) of 36 patients. In total, we observed 19 (9.5%) occlusions of 198 stents in 36 patients. There was no early or late perforation of the prosthesis in our patients. Diameter and the length of the prosthesis were irrespective parameters for stent occlusion. However, Yamakawa drains with sideholes beginning at 7.5 cm from the proximal tip seems to be superior to drains with sideholes beginning at 15 cm from the proximal tip. An occlusion occurred more frequently in patients with stent renewal "on demand" than in patients with elective replacements every 4 months.

Discussion

Benign bile duct stricture (BBS) caused by prior biliary surgery (open/laparoscopic cholecystectomy), pancreatic diseases, sclerosing cholangitis or biliary anastomoses represent a difficult clinical challenge for gastroenterologists and surgeons [6,11,15,25]. If untreated, there is a high risk of repeated cholangitis, biliary cirrhosis, hepatic failure, or death [10,13,19]. Many patients have undergone various treatment approaches before admission to specialized centers [3,5,9]. However, adequate management of these patients is based on a "skilled team

approach” between endoscopists and surgeons. Dependant factors for the “team approach” are patient’s age, comorbidities, course and etiology of the stricture [6,7,11-13].

Today, emerging endoscopic and transhepatic treatment modalities are particularly attractive because of their low morbidity in comparison to surgical approaches [1,2,8,26]. The characteristics of BBS as well as the success of the non-surgical treatment are well documented in the literature [5]. Surgery and endoscopic approach have demonstrated similar long-term success rates [2,9,13,16,26]. Bergman et al. found a long-term success of biliary stenting in 80% of their patients while 20% suffered from stricture relapse within the first 2 years of stent therapy. They advise endoscopic treatment as the initial management of choice for postoperative bile duct stenosis [26]. For patients with tight benign strictures, an endoscopic dilation therapy for a minimum of one year is recommended [1,2,7,17,26].

Indications for surgery are complete transection, failed previous repairs and failure of initial interventional therapy. All other patients should be candidates for endoscopic stenting as initial and definitive treatment [3,5,9,11]. However, only a few direct comparisons between long-term results of surgery and interventional techniques have been made until today.

More favorable long-term results have been demonstrated in uncontrolled series for percutaneous transhepatic treatment, with a success rate between 70% to 93% at a mean follow-up of 24 to 36 months [18,20,27-29]. The goal of the percutaneous transhepatic approach, especially in patients with inaccessible papilla and intrahepatic stenoses, is to establish adequate internal biliary drainage to prevent cholestasis, cholangitis, and sludge or stone formation. Obviously, it is necessary that the new interventional and minimal invasive techniques like percutaneous transhepatic treatment should be compared with surgical results. However, it is difficult to assess the relative value of the new interventional and percutaneous approaches in comparison to surgery, and not only because of the limited patient numbers published in the literature until today. Moreover, it is problematical to give guidelines on when the percutaneous transhepatic tube can be removed and there is lack of confidence about the time of stenting as well.

This manuscript is the first published paper presenting long-term (>4 years) results of the treatment with percutaneous transhepatic drains (Yamakawa® prosthesis) in benign biliary strictures. The transhepatic prosthesis should not be left in place longer than 4 months. After this time the Yamakawa® drainage should be replaced in case of persistent stricture every 4 months up to 1 year. We defined successful treatment as stricture regression and/or ongoing clinical absence of cholestasis after removal of the prosthesis. Our results show that of 36 patients with BBS who were treated during an 8-year period, about 72% were able to benefit from the percutaneous treatment. In the long-term follow-up of 48 months, we noted an acceptable rate of stricture relapse (22%) and a reasonable rate of complications (13%).

Our short- and medium-term results are comparable with the results from previously published data. Despite of these promising outcome, we should take into consideration the shortcomings of our data. First, the patient number in our study was 36 and this makes a reliable statistical comparison more difficult. Second, the uncontrolled character of the study may

Table 2. Stricture location and overall success rate of PTBD

Stricture location	Success of treatment
Anastomotic	9/10
Distal common bile duct	1/7
Mid/proximal common bile duct	3/7
Intrahepatic	12/12
All locations	26/36 (72%)

lead to an inhomogenous patient group. Therefore a systemic bias concerning outcome variables and complication rate cannot be ruled out.

On the other side, as our study involves unselective consecutive patients, we conclude that our results provide a realistic and reliable assessment of the outcome of percutaneous transhepatic stent therapy in the clinical reality.

In 21 patients (58%) concomitant intrahepatic stones were diagnosed due to intrahepatic or anastomotic stricture. The overall stone-free success rate after 2.2 treatment sessions was 100% without any complications using laser lithotripsy or electrohydraulic lithotripsy (EHL). Comparable high success rates of 83-100% were reported with the practice of different techniques of lithotripsy under cholangioscopic control [24,30,31].

Long-term success defined as no further stricture and no recurrence of cholestasis or cholangitis is the vital issue for patients with benign biliary strictures. The overall success rate in the present study is comparable with those demonstrated in most of the published reports [18,20,22,29]. In accordance to the findings of Citron et al., treatment was more successful in strictures located intrahepatic or in the upper parts of the common bile duct while their lowest success rates were in the distal common bile duct (Tab. 2) [32].

Direct comparison of results between surgery and interventional techniques is difficult because data have rarely been published. The success rate of primary operation is about 80% and after 6-8 years varies between 75% and 90% [9-11,16]. In comparison with these data we had a primary success rate of 94% (34 of 36 patients), and 26 of 36 (72%) of patients were asymptomatic after percutaneous therapy after a long-term follow-up of 48 months.

As shown in our results, over 70% of patients presented a radiological verified regression of the stricture in the follow-up. However, on the other hand, 22% of our patients demonstrated an unchanged radiological stricture but clinical improvement after stent removal in the long-run. We therefore presume that the bile duct diameter alone is not the only factor influencing biliary clearance function.

The success of treatment probably also depends on the period during which the stents were in place, as the present results also show. Until now, there are no data on how long a transhepatic tube should remain in place. From our experience we conclude that percutaneous transhepatic tubes should be placed for up to 1 year. A stricture remaining after this length of treatment should be operated, because it is unlikely that conservative treatment would be successful. However, ongoing percutaneous transhepatic stent therapy should become the therapy of choice in poor surgical candidates or those who deny surgery.

The decision on when to remove the transhepatic tube is difficult, since a new percutaneous tract into the small bowel has to be created if there is a recurrence, and this is sometimes problematic, especially after surgical interventions. Born et al. reported two different approaches to solve the problem [18]. They tried to leave a small-diameter (7 Fr) non-functioning catheter in place for 2 to 4 months in order to maintain the cutaneobiliary tract for follow-up radiographics. After this time the likelihood of stricture recurrence may be lower. Another option is to leave a shortened percutaneous tube in place, not bridging the stenosis but keeping the sinus tract open. However, we have to keep in mind the high rate of tube dislocation and cholangitis in the follow-up with this approach.

Conclusions

In conclusion, taking into account all the available data, however, the problem of what to recommend to the individual patient is difficult. Despite the improving success rates with surgical anastomosis [9,10,12,15,25] the minimal invasive approach with transhepatic stenting should be performed as first line therapy - and not only for patients with high surgical risk [14,28,33], since we have to keep in mind the substantial differences in the success rates and associated risks involved in primary and repeated interventions for surgical repair [17]. Moreover, we recommend that the transhepatic approach should be the definitive treatment of choice for patients with intrahepatic strictures, inoperable cases or after hepaticojunostomy. Percutaneous transhepatic stent therapy for BBS is an effective and low-risk procedure and its associated long-term results promise a real alternative to surgery.

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