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# Percutaneous Transhepatic Balloon Dilatation of Benign Biliary Strictures

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## Abstract

Between February 1981 and June 1984, 15 patients with benign biliary strictures were treated with percutaneous transhepatic balloon dilatation. Three of these patients had received liver transplants. The treatment began with a course of balloon dilatation therapy, after which a stent catheter was left across the stricture. Six weeks later, after duct patency had been shown by cholangiography, the stent catheter was removed from all but two patients, both of whom had intrahepatic sclerosing cholangitis. After this procedure, six patients (40%), including two liver-transplant patients, were stricture-free after one treatment for periods ranging from 27 to 56 months, and were considered to be treatment successes. Nine patients (60%) suffered stricture recurrences. In eight of these patients, the stricture was heralded by symptoms of either cholangitis or jaundice; in one patient, who was on permanent catheter drainage, the stricture was discovered only on follow-up cholangiography. All successfully treated patients had only one stricture, while all patients with more than one stricture suffered recurrences. Our data also suggest a greater responsiveness for anastomotic strictures than for nonanastomotic strictures. Of the patients with recurrences, five had symptom-free intervals of 23 months or more (up to 31 months). The fact that strictures recurred after such long periods of time underscores the importance of long-term follow-up.

In view of the number of patients helped, the favorable experience with post–liver-transplantation strictures, and the lack of any major complications in our series, percutaneous biliary balloon dilatation offers a viable alternative to surgical management of benign biliary strictures.

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Until a few years ago, surgery was the only available treatment for biliary strictures. Recently, percutaneous biliary balloon dilatation (BBD) has been used at several centers for the nonsurgical treatment of benign biliary strictures [1–6]. Important features of our series are (1) the long patient follow-up, (2) the relatively large number of patients treated at a single center, and (3) the inclusion of patients who had received liver transplants. We present our experience with 15 patients treated by BBD.

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## Materials and Methods

Fifteen patients met the study criteria by having one or more benign strictures and a minimum observation period of 12 months since completion of the initial BBD treatment cycle. Thirteen patients were women and two were men. The patients ranged in age from 31 to 81 years.

All the patients in the study had had previous hepatobiliary surgery. The operations performed included cholecystectomy (with or without primary ductal or biliary-enteric anastomosis), liver transplantation, and hepatic trisegmentectomy. Three patients had sclerosing cholangitis and had undergone cholecystectomies. Because of the history of surgical manipulation, their extrahepatic duct strictures were considered to be iatrogenic, rather than caused by sclerosing cholangitis.

The strictures were designated as (1) duct anastomotic, (2) biliary-enteric anastomotic, and (3) duct nonanastomotic. The “duct nonanastomotic” designation was given to any stricture that occurred at a nonanastomotic site, even if the patient had an anastomosis.

All the patients in the series had single, extrahepatic duct strictures, except for three patients who had more than one treated stricture. In two of these patients, the treated strictures were intrahepatic. The other patient had two extrahepatic duct strictures.

The usual clinical presentation of bile duct obstruction is cholangitis, which was the case in 12 of the 15 patients. The three patients without symptoms of cholangitis were the patients who had received liver transplants. They presented with abnormal liver function tests. The differentiation between transplant rejection and bile duct obstruction is clinically difficult, especially given that these patients are on immunosuppressive medication. Imaging studies in these three patients showed intrahepatic duct dilatation, which presumably is evidence of an anatomically significant distal duct stricture. It should be noted that 12 of 15 patients had intrahepatic duct dilatation. The only ones who did not were the patients with sclerosing cholangitis.

There were seven patients with anastomotic strictures: three with strictures at a primary ductal anastomosis and four with strictures at a biliary-enteric anastomosis. Eight patients had nonanastomotic duct strictures.

One post-transplantation patient had a nonanastomotic stricture, whereas the other two post-transplantation patients had anastomotic strictures.

The technique of BBD is as follows. A percutaneous transhepatic cholangiogram is performed, and a drainage catheter is inserted to bridge the stricture. Usually, a minimum delay of 2 days is allowed between insertion of the drainage catheter and the first BBD session. Before BBD, as with biliary drainage catheter placement, the patient is treated with broad-spectrum antibiotics.

A balloon is positioned across the stricture over a guidewire. It is then inflated three times for 15 to 20 min per inflation at the maximum allowable pressure for the balloon. Most of the patients in our series were treated with older-type balloons that could only be inflated to an approximate maximum of 5 atm ($5.05 \times 10^5$ Pa). More recently, high-pressure balloons have been used.

The balloon diameter is chosen on the basis of the estimated diameter of the adjacent nonstrictured bile duct. Starting with balloons that are slightly smaller than the estimated diameter of the normal duct, progressively larger diameters are used on successive days of dilatation. Typically, a 6-mm balloon is used initially; then 8-mm, 10-mm, and possibly 12-

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mm balloons are used. Rarely have larger balloons been used. Usually, the same-diameter balloon is used for all inflations performed during one day. After the dilatation is concluded, a biliary drainage catheter is reinserted across the strictured segment.

A BBD "session" designates a single day on which three balloon inflations are performed. Usually, a 1-day rest period is allowed between individual sessions. A BBD "cycle" consists of a group of two or three BBD sessions clustered within a 5–8 day period. After the last session in a BBD cycle, an 8.3- or 10-French drainage catheter is left in place across the stricture for 6 weeks. The catheter is capped for internal drainage before the patient is discharged. The drainage catheter is removed after confirming anatomic lumen patency on a cholangiogram. In two of the three patients with sclerosing cholangitis, the drainage catheters were never removed because of concern that reentry into the patients' nondilated, diseased ducts might not be possible in the event of a restricture. In some patients, biliary pressure measurements were obtained, though not routinely.

Follow-up information after BBD has been obtained from subsequent hospital visits, direct telephone contact with the patients, and/or contact with the referring physicians. Total follow-up is measured from the time the drainage catheter was removed after the initial BBD cycle. In those patients whose catheters were never removed, total follow-up is measured from the time of the last session of the initial BBD cycle.

## Results

Six (40%) of 15 patients were treated successfully. Treatment was considered successful if patients remained stricture-free after one BBD cycle. Included in this group was a patient who had underlying sclerosing cholangitis and a common bile duct stricture. The stricture was presumed to be related to surgical injury during cholecystectomy and common duct exploration. She received a liver transplant 36 months after BBD, necessitated by hepatic failure due to progressive intrahepatic sclerosing cholangitis. Her drainage catheter was never removed after BBD. Nonetheless, she is considered a BBD success because, at surgery, the previously treated common bile duct was still patent. All other patients in this group have been stricture-free for periods ranging from 27 to 56 months without further treatment; four of these have been stricture-free for 42 months or more. Four (67%) of six successfully treated patients had anastomotic strictures.

The nine remaining patients who experienced temporary relief followed by restricture enjoyed symptom-free intervals of varying length. The symptom-free interval is defined as the time period between the removal of the drainage catheter after a BBD cycle and the discovery of a restricture. This time period serves as a measure of symptom remission after BBD. In any one patient with multiple recurrences, there have been large differences between the longest and shortest symptom-free intervals. In all but one patient, stricture recurrence was heralded by symptoms of cholangitis or jaundice; one patient had sclerosing cholangitis and had never had her drainage catheter removed. Her restricture was discovered on routine follow-up cholangiography. Six (67%) of the nine patients with restrictures had nonanastomotic strictures.

Five patients with temporary relief followed by restricture enjoyed symptom-free intervals of 23 months or more. One of these patients had been symptom-free for 31 months after the initial BBD cycle before restricture occurred. One of the post-transplantation patients has been stricture-free for 31 months, but only after a second BBD cycle that was necessitated by a restricture 4 months after the first BBD cycle.

There were two patients in the restricture group whose course differed from that of the other patients. One patient died from progressive liver failure. She had initially presented for liver

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transplantation, but was deemed ineligible because she was 67 years old. The other patient had four restrictures after the initial BBD cycle, and the symptom-free intervals were so short that she finally underwent surgical revision of her duct.

The complications of BBD were minor. These consisted of pain during balloon inflation and hemobilia after BBD. The use of lidocaine, directly instilled into the biliary tree immediately before balloon inflation, in conjunction with IV hydromorphone (1–2 mg), appears to almost eliminate the pain of dilatation. The hemobilia, in our experience, has been self-limited, and has never necessitated transfusion.

It should be noted that often the dilated stricture did not appear to have improved on the immediate post-BBD cholangiogram, but significant improvement was seen on the pre-BBD cholangiogram of the subsequent session. This phenomenon is probably attributable to acute edema of the duct immediately after dilatation.

## Discussion

Benign bile duct strictures are generally a postoperative complication. In a series of 2665 noncancerous biliary strictures, 1539 (58%) of these were due to surgical trauma [7]. Most of the operations have been cholecystectomies, which was the case in 10 of our 15 patients. The advent of liver transplantation and extensive hepatic trisegmentectomies has created other sources of iatrogenic strictures. This was the case in five out of 15 patients, three of whom had received liver transplants, and two of whom had undergone hepatic trisegmentectomies. Surgery has been the traditional method of managing biliary strictures, and some authors have reported reasonably good repair rates [8–11]. However, restricture is a major problem. Recurrence rates have been reported as high as 45% for end-to-end anastomoses and as high as 32% for biliary-enteric anastomoses [11]. Surgical bile duct repair has an associated mortality, reported to be as high as 13%, and often results in loss of ductal tissue available for any subsequent revision. Also, surgical revision of proximal strictures near the porta hepatis is difficult and is nearly impossible in the case of intrahepatic duct strictures [11]. Thus, a nonsurgical technique that does not require general anesthesia is a significant addition to the available treatment options.

Our results should be viewed in the context of the type of patients referred. Many of our patients had clinical and laboratory evidence of advanced liver disease. Five patients were actually referred for liver transplantation. Percutaneous BBD was performed as a last resort before proceeding to transplantation. In such patients, providing a relatively symptom-free interval, even if only for 6 months, should be considered worthwhile. The one death in the series was that of a woman who was initially referred for transplantation but who was disqualified on the basis of her age (67 years). Because of a long history of recurrent cholangitis, she had severely damaged liver function and died of progressive liver failure.

Of the five patients referred for liver transplantation, two were successfully managed with only BBD. One of these two patients had undergone a cholecystectomy 8 years earlier, followed by five subsequent failed surgical revisions of her hepaticojejunostomy. This patient has enjoyed the best result so far. She has been symptom-free for 56 months after one BBD cycle. The other patient referred for transplantation, but treated successfully with only BBD, had sclerosing cholangitis and progressive liver failure and responded to one BBD cycle. She has been symptom-free for 52 months. The one patient in the series who actually proceeded to liver transplantation is considered a BBD success because her previously strictured extrahepatic duct was widely patent at the time of transplantation 36 months after BBD treatment.

Of the three patients with post–liver-transplantation strictures, two were treated successfully. Their strictures were at the choledochocholedochostomy anastomosis. The third post-

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transplantation patient had a nonanastomotic stricture. She restrictured 4 months after the initial BBD cycle. After a second cycle, she remains asymptomatic 31 months later. Thus, in this patient, BBD has precluded the need for surgical revision. Because of the single restricture, she is included in the temporary-relief-with-restricture category, rather than being considered a treatment success.

That restricturing occurs is disappointing. However, of the nine patients who restrictured after BBD, five (56%) had maximum symptom-free intervals of at least 23 months. Thus, despite restricture, most patients in this group were helped for long periods of time by BBD. The importance of long-term follow-up is illustrated by the recurrence of a stricture after 31 months.

Although the numbers are small, our data suggest that patients with more than one stricture are more likely to have a recurrence. The three patients in our series (20%) with two or more strictures have all suffered more than one stricture recurrence. Also, our data suggest that anastomotic strictures are more responsive to BBD than are nonanastomotic strictures.

We postulate that anastomotic strictures are localized narrowings caused by circumferential fibrosis, probably induced by wound-healing. Nonanastomotic strictures possibly arise as a result of ductal ischemia from a variety of causes, including inadvertent stretching or crushing during surgery [11] and hepatiC artery occlusion [12]. The reason for the apparent reduced responsiveness of nonanastomotic strictures to BBD is uncertain, but it may be related to eccentricity of the stricture and/or thicker, more tenacious periductal fibrosis in the area of the stricture.

There are unanswered questions concerning BBD technique. The optimal length of time that the balloon should be left inflated across the stricture is unknown. We have arbitrarily selected 15–20 min per inflation, repeating this three times, with several minutes of deflation in between. Salamonowitz et al. [4] have tried inflations lasting 24 hr. This raises the theoretical question of whether there is an increased risk of bile duct ischemia if the balloon is kept inflated beyond a certain time. Another unanswered question concerns the length of time a stent catheter needs to be kept across the dilated stricture. Warren et al. [11] suggest that a postoperative anastomosis should be stented for at least 6 months and preferably 1 year or more. Others have questioned whether long-term stenting may do more harm than good, even accelerating the process of restricture [6,13,14]. We have arbitrarily chosen to stent our patients for 6 weeks after the last BBD session of the cycle. Finally, how long need a patient be stricture-free before being considered “cured”? Despite the fact that one patient restrictured after 31 months, four patients who are currently stricture-free have been so for 42 months or more, and their outlook for continued stricture-free existence is probably good. One of these four patients, however, still has underlying sclerosing cholangitis. Longer follow-up in more patients is required to answer these questions.

In conclusion, patients who have severe progressive hepatic failure or a history of multiple failed surgical anastomotic revisions can benefit from BBD, forestalling and sometimes obviating further surgical procedures or liver transplantation.

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