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Benign Postoperative Biliary Strictures

Operate or Dilate?

HENRY A. PITT, M.D., STEPHEN L. KAUFMAN, M.D., JoANN COLEMAN, R.N., M.S., ROBERT I. WHITE, M.D., and JOHN L. CAMERON, M.D.

At The Johns Hopkins Hospital from 1979 through 1987, 42 patients had 45 procedures for benign postoperative biliary strictures. Three patients were managed with both surgery and balloon dilatation. Twenty-five patients underwent surgical repair with Roux-Y choledocho- or hepaticojejunostomy with postoperative transhepatic stenting for a mean of 13.8 ± 1.3 months. Twenty patients had balloon dilatation a mean of 3.9 times and were stented transhepatically for a mean of 13.3 ± 2.0 months. The two groups were similar with respect to multiple parameters that might have influenced outcome. Mean length of follow-up was 57 ± 7 and 59 ± 6 months for surgery and balloon dilatation, respectively. No patients died after any of the procedures. The same definition of a successful outcome was applied to both groups and was achieved in 88% of the surgical and in only 55% of the balloon dilatation patients ($p < 0.02$). Significant hemobilia occurred more often with balloon dilatation (20% *vs.* 4%, $p < 0.02$). The total hospital stay and cost of balloon dilatation was not significantly different from surgery. We conclude that surgical repair of benign postoperative strictures results in fewer problems that require further therapy. Nevertheless balloon dilatation is an alternative for patients who are at high risk or who are unwilling to undergo another operation.

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Correspondence and reprints requests to: Henry A. Pitt, M.D., Blalock 688, The Johns Hopkins Hospital, 600 N. Wolfe Street, Baltimore, MD 21205.

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From the Departments of Surgery and Radiology, The Johns Hopkins Medical Institutions, Baltimore, Maryland

RECENT REPORTS[1–5] of nonoperative balloon dilatation of benign postoperative biliary strictures have been encouraging. Reported success rates for balloon dilatation have ranged from 85% to 70%, with mean follow-up periods of 24 to 36 months. These results are very similar to those reported in recent surgical series[6–10] with mean follow-up ranging from 60 to 133 months. Comparison of the results of balloon dilatation with those of surgery has been difficult, however, because of differences in techniques of dilatation and stenting at different institutions, the definition of a successful procedure, and the length of follow-up. This analysis was undertaken, therefore, to review the results of balloon dilatation and surgery at one institution over the same period of time, with similar management techniques, and the same definition of a successful outcome.

Methods

Patient Population

From January 1979 through December 1987 all patients with benign postoperative biliary strictures managed

TABLE 1. *Patient Characteristics*

Patient Characteristics	Surgery (n = 25)	Balloon Dilatation (n = 20)
Demographics		
Age	49.2 ± 2.9	45.3 ± 4.4
Female	56%	45%
Caucasian	92%	85%
Underlying disease		
Gallstones	96%	90%
Choledochal cyst	4%	5%
Trauma	0%	5%
Associated problems		
Obstructive jaundice	48%	50%
Intrahepatic stones	32%	35%
Cirrhosis	12%	15%
Portal hypertension	8%	5%
Biliary Fistula	8%	5%

at The Johns Hopkins Hospital were evaluated. Patients with biliary strictures after surgery for biliary stones, a choledochal cyst, or trauma were included in this analysis. However two patients with severe hepatobiliary trauma requiring hepatic lobectomy plus stricture repair managed with both surgery and balloon dilatation were excluded from this report. Patients with other benign biliary strictures due to sclerosing cholangitis, chronic pancreatitis, or sphincter of Oddi stenosis were also excluded from this study. During this 8-year analysis, 42 patients with benign postoperative strictures underwent 45 procedures at John Hopkins. Twenty-five patients underwent surgical repair of their stricture, whereas 20 patients were managed with balloon dilatation. During the study period, three patients underwent both surgery and balloon dilatation. All patients were managed by both surgeons and radiologists. The choice of management technique was based on patient preference and evolving data with respect to outcome. None of the patients treated with balloon dilatation were considered to have a prohibitive risk for surgery.

Patient characteristics for the surgery and balloon dilatation groups are presented in Table 1. No differences were noted between the two groups with respect to age, sex, or race. In all but three patients (one surgery and two balloon dilatation) the underlying disease process was gallstones. Presentation with obstructive jaundice or biliary fistula and associated problems such as intrahepatic stones, cirrhosis, and portal hypertension were seen with equal frequency in the two groups. Three patients (12%) in the surgery group had right lobe atrophy and left lobe hypertrophy, whereas this atrophy/hypertrophy complex was not found in the balloon dilatation patients. A small subhepatic abscess was found at surgery in one patient.

One or more previous surgical attempts at stricture repair had been undertaken in 56% of the surgical patients and in 65% of the balloon dilatation patients (Table 2). Among the patients managed with reoperation, nine (36%) had previously undergone a biliary-enteric anastomosis, and five (20%) had end-to-end surgical repairs. All 13 patients (65%) in the balloon dilatation group with a previous surgical repair had undergone a biliary-enteric anastomosis. This trend was not statistically significant but reflected early results from this[1] and other institutions,[2,11] suggesting that results of balloon dilatation were better in patients with a biliary-enteric anastomosis.

The level of biliary obstruction in the two groups is also presented in Table 2. The level of obstruction was classified in relation to the confluence of the hepatic ducts as described by Bismuth.[12] The distribution of Types 1 to 5 was similar in the two groups. All patients were managed with transhepatic biliary stents (Table 2). Surgical patients were more likely ($p < 0.05$) than balloon dilatation patients to be managed with bilateral biliary stents. Duration of stenting, however, was similar in the two groups.

Balloon Dilatation

Access to the biliary tract was initially achieved with percutaneous transhepatic drainage. Subsequent management consisted of balloon dilatation of the stricture, postdilatation stenting, stricture challenge, and catheter removal (Fig. 1), as previously described.[1,13,14] The first balloon dilatation was usually performed a few days after percutaneous drainage while the patient was still hospitalized. Dilatations were performed with commercially available angioplasty balloon catheters. Selection of bal-

TABLE 2. *Previous Repair, Level of Obstruction, Use of Stents*

Patient Characteristics	Surgery % (n = 25)	Balloon Dilatation % (n = 20)
Previous repair		
None	44	35
One	44	55
Two	4	5
Three	4	0
More than three	4	5
Level of obstruction		
Type 1* (>2 cm CHD†)	16	25
Type 2 (<2 cm CHD)	35	40
Type 3 (bifurcation)	24	15
Type 4 (hepatic ducts)	16	15
Type 5 (right branch)	8	5
Use of stents		
Right	44	90
Left	16	5
Both	40‡	5
Time (months)	13.8 ± 1.3	13.3 ± 2.0

* Bismuth classification.[12]
† CHD = common hepatic duct.
‡ $p < 0.05$ *vs.* balloon dilatation.

loon diameter was determined by the diameter of the adjacent normal bile duct. Balloon length was determined by the length of the stricture. After balloon dilatation, the strictured segment was stented with a catheter for the next several weeks. A second balloon dilatation was then performed, usually as an outpatient, and a larger stent was placed across the stricture. This procedure was repeated during the first few months until stents as large as adjacent ducts could be passed.

The mean number of dilatations was 3.9 per patient, with a range of 1 to 11. Maximum stent size was 10–12F in 11 patients, 14–16F in 6 patients, and 18–22F in 4 patients. The larger stents were made of silastic and were the same as those used after surgery. Stents were changed routinely every 3 to 4 months. Initial stenting averaged 10 months, but this mean increased to 13.3 months (Table 2) as restrictures were redilated and stented. Four of 20 patients (20%), including two children, required general anesthesia for balloon dilations. The remaining patients received local anesthesia and intravenous analgesia and sedation. In addition to balloon dilatations, seven patients (35%) had intrahepatic stones retrieved or flushed into the intestine.

Surgery

Preoperative Ring catheters were placed into one or both hepatic ducts in 12 and six patients, respectively. These percutaneous stents were placed preoperatively in 17 of the last 20 patients. Having these catheters in place at the time of operation helped in dissecting the strictured area and subsequently placing transhepatic silastic stents as previously described.[15–17] At surgery the common bile duct was divided distally early in the dissection. This maneuver facilitated cephalad dissection and separation of the biliary tree from the portal vein. Exposure of the portal vein allowed safer dissection in the more proximal scarred area. Having Ring catheters in the right and left hepatic ducts before operation aided in the identification of these strictures above the bifurcation and facilitated further dissection of hilar strictures. Moreover resection of the stricture area revealed a traumatic neuroma in four patients (16%).

After removal of the specimen, the curved tip of the Ring catheter was cut, and a long guide wire was passed through the catheter. A 12F Coudé catheter was then passed over and sutured to the Ring catheter and pulled up through the hepatic duct and liver parenchyma. The tract was progressively dilated in this fashion until a 16F or 18F silastic stent could be positioned in the biliary tree. A Roux-Y choledocho- or hepaticojejunostomy was then performed, and the stent or stents were positioned so that the side holes were situated within the ductal system and the Roux-Y loop (Fig. 2). These silastic stents were changed routinely on an outpatient basis every 3 to 4 months and were left in for a mean of 13.8 months.

Follow-up

All 42 patients were followed until April 1989 or until death. Thus a minimum of 16 months of follow-up was available in all patients. Follow-up was obtained by review of hospital records or by telephone interview and was accomplished in all patients. Follow-up for surgery and balloon dilatation patients was 57.1 ± 6.7 months (range, 16 to 120) and 59.1 ± 5.9 months (range, 17 to 111), respectively. A successful outcome was defined as no evidence of cholangitis or jaundice requiring another procedure more than 12 months from the onset of treatment. Treatment failure was defined as the need for reoperation or dilatation, hospital death following a procedure, or late death from liver failure, biliary sepsis, or portal hypertension.

Cost Analysis

The cost of surgery and balloon dilatation were estimated from length of hospital stay and procedure charges. All calculations used charges and fees that were current for the year in which surgery was performed or balloon dilation was initiated. The cost of surgery was estimated by multiplying hospital and intensive care stay by prevailing charges and adding preoperative transhepatic drainage, surgical, and anesthesia fees, as well as the cost for postoperative stent changes. The cost of balloon dilatation was determined by multiplying total hospital stay from various admissions by prevailing charges and adding the cost of initial percutaneous transhepatic drainage, as well as multiple balloon dilatations, general anesthesia, when employed, and stent changes. The cost of major complications such as reoperation for subphrenic abscess or arteriogram and embolization for hemobilia were also included. Moreover the cost of reoperation or balloon dilatations of recurrent strictures was added to the cost of the initial procedure.

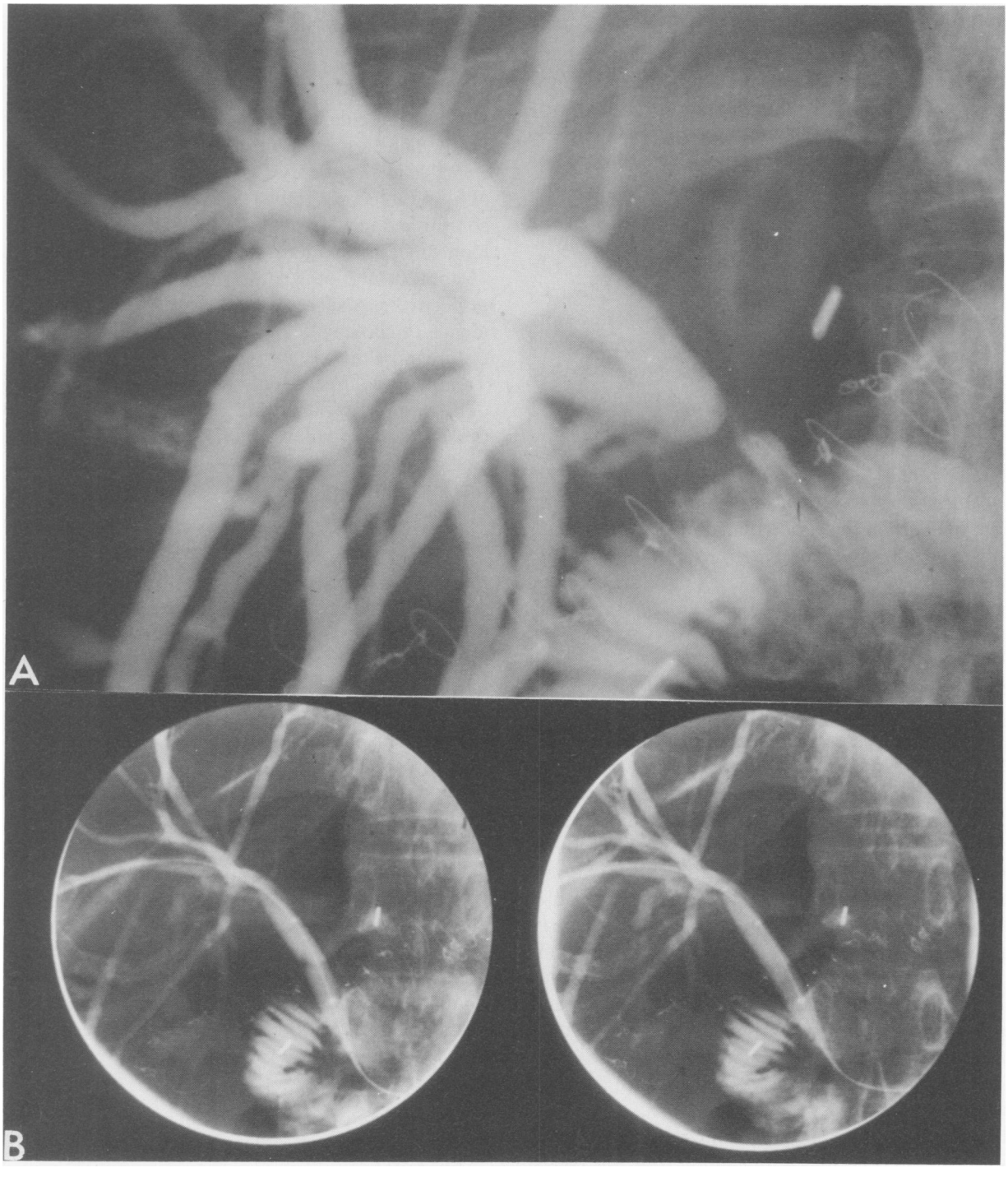
Statistical Analysis

All data are presented as mean ± standard error of the mean. Student's unpaired t test was used to compare mean age, length of stenting, hospital stay, and cost. Other patient characteristics and outcome data were compared by chi square analysis. Actuarial success rates were analyzed by the Mantel-Cox technique.

Results

Stricture Outcome

A successful outcome was achieved in 88% of the surgery and in 55% of the balloon dilatation patients (p



FIGS. 1A–D. (A) Transhepatic cholangiogram demonstrating stricture at the previous choledochojejunostomy (Bismuth type 1). (B) Progressive dilatation of the strictured anastomosis with an angioplasty balloon catheter. (C) Postdilatation stenting of the anastomotic stricture for prolonged periods. (D) Subsequent cholangiography demonstrating resolution of the anastomotic stricture.

< 0.02, Table 3, Fig. 3). Of the 25 patients managed surgically, recurrent strictures occurred in three (12%) at 20, 30, and 78 months. Two of these three patients had undergone multiple previous attempts at surgical repair. One of these patients was subsequently managed successfully with balloon dilatation, and a second patient is presently

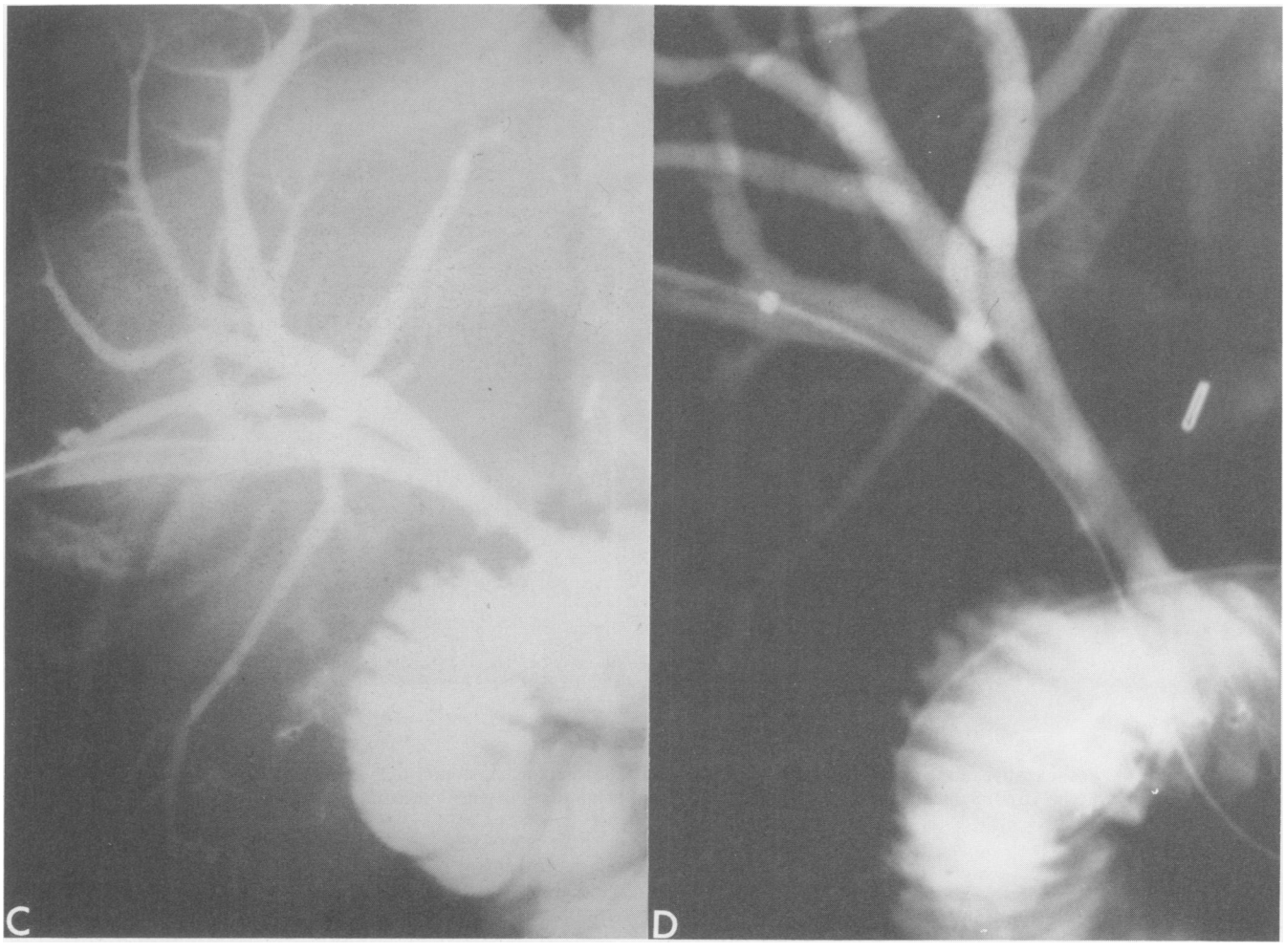
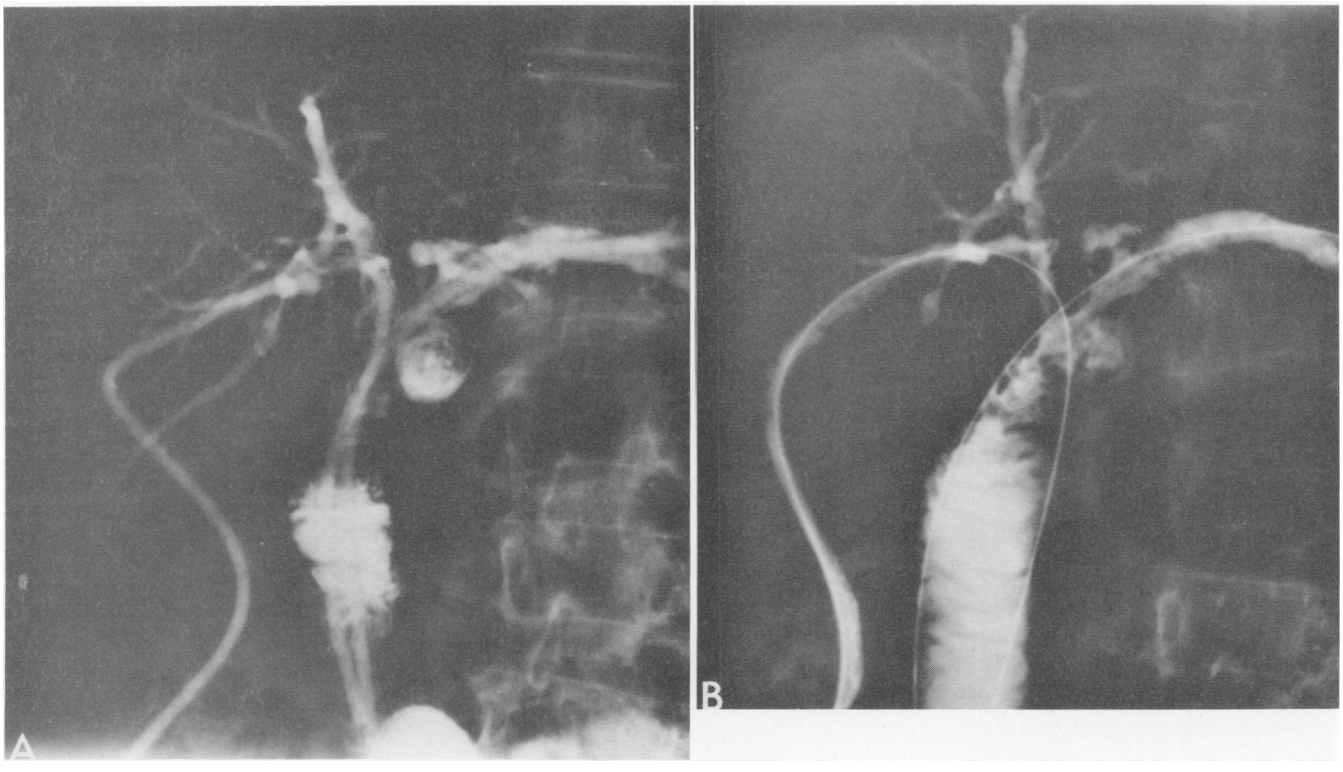


FIG. 1. (*Continued*)

undergoing this treatment. The third patient has also been managed with balloon dilatation but failed that treatment after 34 months. She was retreated with balloon dilatation beginning 15 months ago and has had her stent out now for 2 months. At latest follow-up all surgically managed patients were free of cholangitis and jaundice.

Nine of the 20 patients (45%) managed with balloon dilatation have developed recurrent strictures. All of these nine recurrent problems became apparent within 36 months of the initiation of balloon dilatation (Fig. 3). Three of these nine patients, who restrictured at 13, 16, and 27 months, underwent subsequent surgical repair 52, 14, and 7 months ago. Each of these three patients are presently well, and the first two patients have had their stents removed 40 and 2 months ago, respectively. Of the nine patients with recurrence, five restrictured at 12, 12, 15, 24, and 34 months and were managed with further balloon dilatation and prolonged stenting. Two of these five patients had their stents removed after 30 and 38 months and have been well for 59 and 11 months, respectively. The other three of these five patients have been stented continuously for 85, 49, and 45 months. The final patient, managed initially with surgery and described above, underwent repeat balloon dilatation. At last follow-up only one balloon dilatation patient, who also has Gilbert's disease, was jaundiced.

In addition to surgical management, two other factors, the type of stricture and the level of obstruction, correlated with a successful outcome (Table 3). The 22 patients with a primary stricture were significantly more likely to have a good outcome than the 23 patients with anastomotic strictures (86% *vs.* 61%, $p < 0.05$). This same trend was present when the 17 patients with no previous attempt at surgical repair were compared with the 28 patients who had undergoing a biliary-enteric or end-to-end anastomosis (82% *vs.* 68% success). This difference, however,



FIGS. 2A and B. (A) Postoperative tube cholangiogram *via* bilateral transhepatic stents demonstrating individual hepaticojejunostomies after resection of stricture (Bismuth type 4). (B) Subsequent cholangiographic assessment demonstrating patent anastomoses.

did not achieve statistical significance. All nine patients with a Bismuth type 1 stricture had a successful outcome compared to a 67% success rate for the remaining 36 patients with more complex strictures ($p < 0.05$, Table 3). Other potential risk factors such as age, sex, race, presentation with jaundice, intrahepatic stones, or cirrhosis did not correlate with outcome.

Morbidity and Mortality Rates

Morbidity and mortality data are presented in Table 4. Significant hemobilia requiring transfusion was the most frequent complication and occurred more often in patients managed with balloon dilatation (20% *vs.* 4%, $p < 0.02$). All four balloon dilatation patients with hemobilia required arteriography and embolization to control hemorrhage. The one surgical patient's bleeding subsided spontaneously. Pancreatitis, defined as an elevation of serum amylase greater than two times normal with typical clinical signs and symptoms, occurred in three patients, one postoperatively and two after balloon dilatation. After surgery two patients had bacteremias with organisms also isolated from bile, and this complication occurred once in patients managed by balloon dilatation. One surgical patient developed a subphrenic abscess that required reoperation for drainage. Overall procedure-related mor-

TABLE 3. *Factors Influencing Outcome*

Factors	Successful Outcome
Surgery *versus* dilatation	
Surgery	88%*
Balloon dilatation	55%
Type of stricture	
Primary	86%†
Anastomotic	61%
Level of stricture	
Type 1‡ (>2 cm CHD§)	100%‖
Type 2 (<2 cm CHD)	59%
Type 3 (bifurcation)	87%
Type 4 (hepatic ducts)	71%
Type 5 (right branch)	33%

* $p < 0.02$ *versus* balloon dilation.
† $p < 0.05$ *versus* anastomotic.
‡ Bismuth classification.[12]
§ CHD = common hepatic duct.
‖ $p < 0.05$ *versus* Types 2–5.

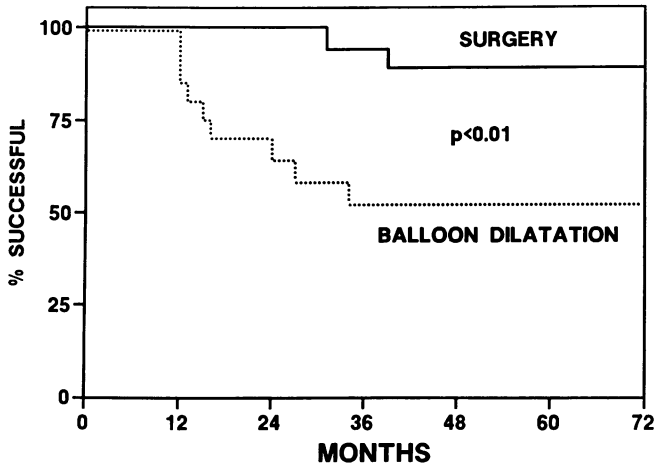


FIG. 3. Actuarial success rates over 72 months for surgery (89%) and balloon dilatation (52%). The difference is statistically significant ($p < 0.01$).

bidity was higher for balloon dilatation (35% *vs.* 20%), but this difference was not statistically significant.

None of the patients died while hospitalized following surgery or balloon dilatation (Table 4). Four of the 42 patients (10%) have died during follow-up. One late death occurred in the surgical group whereas three deaths followed balloon dilatation (4% *vs.* 15%, $p < 0.02$). One 74-year-old surgical patient died 46 months after operation of unrelated causes. Two of the late deaths in the balloon dilatation patients also occurred in elderly patients (ages 75 and 64) of unrelated causes at 46 and 86 months. The third late death after balloon dilatation was caused by a perforated gastric ulcer with generalized peritonitis. This 36-year-old patient had secondary biliary cirrhosis, but her stent had been out for 39 months without problems when she became ill. Therefore she was considered to have had a successful outcome from her balloon dilatation.

Cost Analysis

Initial hospitalization was longer for surgery than for balloon dilatation. However when rehospitalization for further dilatations, complications, and recurrences were considered, total hospital stay did not differ significantly (Fig. 4). Mean total hospital stay for surgery was 26.4 ± 2.5 days and for balloon dilatation it was 21.4 ± 1.7 days. Moreover since 1984 mean total hospital stay for surgery was down to 17.9 ± 1.5 days compared to 21.2 ± 1.7 days for balloon dilatation. Cost data paralleled hospitalization data and did not differ significantly between groups (Fig. 4). Estimated total cost for surgery was $20,988 ± $1376 and for balloon dilatation was $17,728 ± $1688.

TABLE 4. *Morbidity and Mortality*

Morbidity and Mortality	Surgery % (n = 25)	Balloon Dilatation % (n = 20)
Procedure morbidity		
Hemobilia	4	20*
Pancreatitis	4	10
Bacteremia	8	5
Subphrenic abscess	4	0
Total	20	35
Hospital mortality	0	0
Late deaths	4	15*

* $p < 0.02$ *versus* surgery.

Discussion

From 1979 through 1987, 25 patients underwent surgical repair with Roux-Y choledocho- or hepaticojejunostomy while 20 patients had balloon dilatation a mean of 3.9 times at The Johns Hopkins Hospital. Both groups of patients were managed with prolonged transhepatic stenting. Mean length of follow-up was 57 ± 7 and 59 ± 6 months for the surgery and balloon dilatation groups, respectively. No patients died after any of the procedures. A successful outcome was achieved in 88% of the surgical and in only 55% of the balloon dilatation patients ($p < 0.02$). Significant hemobilia occurred more often with balloon dilatation (20% *vs.* 4%, $p < 0.02$). Because of repeated hospitalization and procedures, the total hospital stay and cost of balloon dilatation was not significantly different from surgery.

In this retrospective analysis, the surgery and balloon dilatation groups were amazingly similar with respect to age, sex, race, initial biliary pathology, associated problems, number of previous attempts at surgical repair, and level of biliary obstruction. Relatively more balloon di-

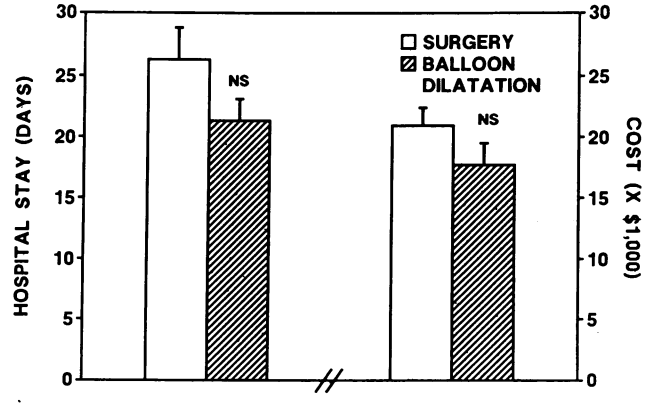


FIG. 4. Total hospital stay (left) and cost (right) for surgery and balloon dilatation. Differences were not statistically significant (NS).

latation patients had undergone a biliary-enteric anastomosis because early reports[1,2,11] suggested that results were best in these patients. The relative incidence of this subgroup of patients, however, was not statistically different between the two groups.

One important advantage of this analysis over previous reports is that all surgical and balloon dilatation patients were managed at one institution by one group of radiologists and surgeons. As a result certain techniques such as the method of percutaneous drainage, the types of stents used, the philosophy of stenting, and the assessment of results were standardized. Even the definition of a successful procedure as "no evidence of cholangitis or jaundice requiring another procedure more than 12 months from the outset of treatment" was agreed on among the authors before this series was analyzed. This definition is very similar to that recently reported by Trambert et al.[18] who "considered treatment successful if patients remained stricture-free after one biliary balloon dilatation cycle." In comparison, Muller et al.[3] chose patency at 36 months as their end point, thereby ignoring late restrictures. Moreover, Williams and his colleagues[4] judged success as "the absence of recurrent symptoms following stent removal," which creates a problem with data analysis if stents are left in place for prolonged periods.

Another advantage of this study over previous reports of balloon dilatation is the length of follow-up. Both Pitt et al.[6] and Pellegrini and his associates[9] have demonstrated that prolonged follow-up is necessary to determine the true recurrence rate after surgical repair. In both of these analyses approximately 80% of recurrent strictures developed after five years, but late recurrences were observed for up to 20 years after surgery. Thus success rates for balloon dilatation[1-5] of 85% to 70% at 2 to 3 years would be expected to decrease with longer follow-up. The mean follow-up of 59 months for balloon dilatation in this study is the longest yet reported and explains, at least in part, the lower, 55%, success rate.

In this study, in addition to surgical repair, a primary, as opposed to an anastomotic, stricture correlated with a good outcome (86% *vs.* 61%, $p < 0.05$). Three early reports[1,2,11] with a total of 21 patients with strictured biliary-enteric anastomoses suggested that balloon dilatation was successful in 90%. However recent reports[3-5] from several institutions confirm the present observation that primary strictures do better with balloon dilatation. Mueller et al.,[3] reporting data on 61 patients with postoperative strictures from four institutions, found that success rates at 36 months for primary and anastomotic strictures were 76% and 67%, respectively. Similarly Williams and his Mayo Clinic associates[4] found success rates at 28 months of 88% for primary and 73% for anastomotic strictures. Finally Moore et al.[5] at Duke reported a successful outcome at 33 months of 86% and 82% for primary and anastomotic strictures, respectively.

Endoscopic balloon dilatation of benign strictures has also been proposed. This technique, however, has the potential disadvantages of only being possible for primary strictures or choledochoduodenal anastomoses and requiring repeat endoscopies for endoprosthesis change if an indwelling stent is employed. Kiil et al.[19] from Denmark have reported successful endoprosthesis placement in 33 of 36 patients (92%) with benign strictures. Unfortunately no follow-up data are provided in this report, which focuses largely on patients with malignant obstruction. Huibregtse et al.[20] from the Netherlands also reported successful endoprosthesis placement in 27 of 29 patients (93%) with benign strictures. Clinical follow-up for at least 6 months in 23 patients suggested an excellent or good result in 19 (83%). However intubation of proximal strictures was difficult, follow-up was short, and one endoscopic failure died of sepsis after percutaneous transhepatic cholangiography. Moreover Foutch and Sivoh[21] reported two hospital deaths, a respiratory arrest, and a common bile duct perforation among nine patients with benign strictures managed endoscopically.

Another method for managing these patients is intermittent postoperative balloon dilatation through a choledochojejunocutaneous or subcutaneous fistula.[22-24] To date this technique has been used most often in patients with sclerosing cholangitis. However in two recent reports[23,24] a total of eight patients with benign postoperative strictures have been managed in this fashion with success claimed in six over a short follow-up period. With this technique no internal or external tubes were required and dilatation intervals were longer than in the present study. Presently more data are necessary to adequately evaluate this treatment modality. The most recent modification of this technique reported by Maroney and Ring[25] is percutaneous transjejunal catheterization of Roux-Y biliary-enteric anastomoses. This method does not require a cutaneous or subcutaneous fistula and may become an option in highly selected patients.

As with balloon dilatation by whatever route, the length of follow-up remains a key element in comparing the results of surgical stricture repair. Recent reports from the University of California at Los Angeles[6] and the Cleveland Clinic,[7] both with a mean follow-up of 60 months, document a successful outcome after surgery in 86% and 82% of patients, respectively. Thus the 88% success rate at 57 months in the present series is comparable to these reports. Analyses from the Lahey Clinic[8] and the University of California at San Francisco (UCSF)[9] report a successful outcome in 78% of patients at 64 and 102 months, respectively. Perhaps the longest follow-up data come from the St. George's Hospital in London where a successful

outcome has been documented in 72% of patients at 133 months.

Debate continues as to the optimal surgical approach and the use and length of stenting. Some authors[12,26–28] advocate no stents with various surgical approaches to the left hepatic duct. One recent report from Ohio State[26] documents an 87% success rate in 22 patients with a mean follow-up of 72 months. However in the Hammersmith series[27] success was achieved in only 79% of 72 patients at 40 months. Advocates of a relatively short period (1 to 3 months) of stenting at the Cleveland Clinic[7] and UCSF[9] have reported success rates of 82% and 78% at 60 and 102 months, respectively. An early report[29] of the mucosal graft technique suggested a 90% success rate; but as follow-up has been extended to 11 years, this figure has decreased to 72%.[10] Finally advocates[6,15,30] of prolonged transhepatic stenting (12 to 24 months) have consistently reported success rates of 88% to 90% at 5 years as reported in this analysis.

The debate about the optimal surgical and nonsurgical treatment of these patients will undoubtedly continue unless properly designed randomized studies are performed. Until such studies are undertaken, this analysis and review of the literature suggests that surgical repair of benign postoperative strictures results in fewer problems with cholangitis or jaundice that require further therapy. Because of the need for multiple procedures and the high recurrence rate, the cost of balloon dilatation is similar to that of surgery. Nevertheless balloon dilatation is an alternative for patients who are at high risk or are unwilling to undergo another operation.

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