Long-term Results of Metallic Stents for Benign Biliary Strictures

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Background: Historically, surgical correction has been the treatment of choice for benign biliary strictures (BBS). Self-expandable metallic stents (MSs) have been useful for inoperable malignant biliary strictures; however, their use for BBS is controversial and their natural history unknown.

Hypothesis: To test our hypothesis that MSs provide only short-term benefit, we examined the long-term outcome of MSs for the treatment of BBS. Our goal was to develop a rational approach for treating BBS.

Data Extraction: Between July 1990 and December 1995, 15 patients had MSs placed for BBS and have been followed up for a mean of 86.3 months (range, 55-120 months). The mean age of the patients was 66.6 years and 12 were women. Stents were placed for surgical injury in 5 patients and underlying disease in 10 patients (lithiasis, 7; pancreatitis, 2; and primary sclerosing cholangitis, 1). One or more MSs (Gianturco-Rosch “Z” for 4 patients and Wallstents for 11 patients) were placed by percutaneous, endoscopic, or combined approaches. We considered patients to have a good clinical outcome if the stent remained patent, they required 2 or fewer invasive interventions, and they had no biliary dilation on subsequent imaging.

Data Synthesis: Metallic stents were successfully placed in all 15 patients, and the mean patency rate was 30.6 months (range, 7-120 months). Five patients (33%) had a good clinical result with stent patency from 55 to 120 months. Ten patients (67%) required more than 2 radiologic and/or endoscopic procedures for recurrent cholangitis and/or obstruction (range, 7-120 months). Five of the 10 patients developed complete stent obstruction at 8, 9, 10, 15, and 120 months and underwent surgical removal of the stent and biliary-enteric anastomosis. Four of these 5 patients had strictures from surgical injuries. The patient who had surgical removal 10 years after MS placement developed cholangiocarcinoma.

Conclusions: Surgical repair remains the treatment of choice for BBS. Metallic stents should only be considered for poor surgical candidates, intrahepatic biliary strictures, or failed attempts at surgical repair. Most patients with MSs will develop recurrent cholangitis or stent obstruction and require intervention. Chronic inflammation and obstruction may predispose the patient to cholangiocarcinoma.


RESULTS

The MSs were successfully placed in all patients, and they were not routinely treated with ursodeoxycholic acid or antibiotics. The results are summarized in Table 1 and Table 2 for each type of MS. The mean patency rate was 30.6 months (range, 7-120 months). At the end of the observation period, 13 patients were alive; 2 patients died of unrelated causes.

See Invited Critique at end of article

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PATIENTS AND METHODS

From July 1990 through December 1995, 15 patients underwent percutaneous and/or endoscopic placement of 1 or more MSs for treatment of BBS. These patients presented with biochemical evidence of biliary hypertension and radiologic evidence of a stricture(s). In some cases, patients also had biliary sepsis. Metallic stents were placed only after failed attempts at balloon dilation and/or temporary stenting with plastic catheters. Patients were followed up through July 2000 and a retrospective analysis was performed. The mean follow-up period was 86.3 months (range, 55-120 months). The group included 12 women and 3 men, with a mean age of 66.6 years (range, 32-102 years). The biliary stricture was caused by inflammatory changes due to cholecodolithiasis in 7 patients (47%), and 2 of these patients had conditions associated with a papillary stenosis. The diagnosis of papillary stenosis was based on cholangiographic and endoscopic findings and not biliary manometry. Surgical injury during cholecystectomy was the cause in 5 cases (33%), chronic pancreatitis in 2 cases (13%), and sclerosing cholangitis in 1 case (7%). The 2 patients with associated papillary stenosis also underwent endoscopic papilloscopy and transpapillary procedures to relieve the stricture before MS placement, but the procedures failed. Applying the Bismuth type II classification of BBS, 7 patients had type I, 4 had type II, 2 had type III, and 2 had type IV disease (Figure). Metallic stents were introduced endoscopically in 7 patients, percutaneously in 6, and via a combined approach in 2. All procedures were performed under intravenous sedation and all patients received prophylactic antibiotics. Two types of MSs were used. A self-expandable Wallstent (Schnieder, Inc, Minneapolis, Minn) was placed in 11 patients and a Gianturco-Rosch “Z” MS (Cook Inc, Bloomington, Ind) in 4. The MS used had a length that varied between 6 and 8 cm and a diameter that ranged from 8 to 10 mm, based on the extent of the stricture. Usually, a 6F drainage catheter was left in the patients who received an MS by the percutaneous technique to permit a control cholangiogram 3 days after stent placement. Patients with persistent biliary hypertension and/or poor drainage required MS revision(s) for the following reasons: incomplete stent expansion, inadequate positioning, or stent migration. Follow-up data were attained by review of hospital and clinic records and/or telephone interviews with the patient or referring physician. The clinical outcome was considered good if the patient had 2 or fewer subsequent invasive interventions to maintain stent patency. A stent was considered patent if the patient had no symptoms of recurrent jaundice or cholangitis and follow-up ultrasound or computed tomography showed normal-caliber intrahepatic and extrahepatic bile ducts. Patients had a poor outcome if they required more than 2 invasive procedures.

Overall, a good clinical result was achieved in 5 patients (33%) who had stent patency for 55 to 120 months. Four patients remain asymptomatic at 50, 85, 88, and 120 months after MS placement. One elderly patient remained asymptomatic for 30 months after stent placement and died of unrelated causes. These patients had normal liver function and no evidence of biliary dilation on subsequent imaging. Ten (67%) of 15 patients had poor clinical outcomes and required more than 2 radiologic or endoscopic procedures for recurrent cholangitis or stent obstruction during the study period. Four of 5 patients with MS placement for surgical injury of the common bile duct (CBD) developed clinical symptoms of biliary obstruction at 9, 10, 15, and 60 months after stent placement and eventually underwent surgical removal of the MS and biliary reconstruction. Only 1 of the 7 patients with MSs for stone-related strictures developed early stent obstruction (8 months) and underwent surgical removal of the MS. In all of the surgical cases, biliary reconstruction consisted of Roux-en-Y hepaticojunostomy. After surgical removal, 4 of 5 patients remained asymptomatic and 1 died 9 months following the operation. This 70-year-old patient had an MS placed endoscopically for a Bismuth type II biliary stricture after an open cholecystectomy and CBD exploration. He had no history of biliary tract disease. After years of stent patency, he developed recurrent cholangitis and jaundice due to stent obstruction. Additional endoscopic procedures to establish stent patency were effective for only short periods. At the age of 80 years, he underwent surgical removal of the MS and biliary reconstruction. The resected portion of CBD contained cholangiocarcinoma, and the patient died 9 months later from metastatic disease.

In 5 patients, MS patency was maintained by repeated percutaneous or endoscopic biliary manipulations. Two patients with type IV strictures had intrahepatic MSs placed and both had poor outcomes. One patient with primary sclerosing cholangitis who presented with additional episodes of cholangitis due to MS obstruction 14 months after placement eventually died of multiple myeloma at 36 months. Stent occlusion was caused in most cases by the presence of bile sludge and/or stones, and this was clearly established at the time of biliary manipulation. Stent obstruction inevitably resulted in biliary sepsis.

Surgical repair has been the traditional method of treatment for BBS. Recent reports have demonstrated that biliary reconstruction affords good to excellent long-term results for 80% to 90% of patients with BBS. However, surgical repair, especially reoperative biliary surgery, is technically challenging and has a recognized risk of morbidity and in some cases mortality. Advances in interventional endoscopic and percutaneous techniques have made possible the use of alternative methods for treatment of biliary strictures. Percutaneous balloon cholangioplasty and placement of plastic endoprostheses for BBS have resulted in initial success rates of 67% to 93%. However, the long-term results are less impressive because of a recurrence rate of greater than 30%. Efforts at improving the long-term results have led to the use of self-expandable MSs to maintain duct patency. When examining stent patency, one must choose whether or not to consider all subsequent interventions as a failure of therapy. Because the MSs are placed under fluoroscopic...
guidance, it is not unusual for patients to need a revision or adjustment of the stent. Thus, allowing up to 2 revisions, we defined clinical outcome based on the presence of recurrent cholangitis and jaundice and the need for more than 2 invasive procedures for these symptoms.

Our retrospective study was intended to establish the role of MSs for the management of BBS with particular emphasis on long-term patency. By definition, this excludes patients with malignant strictures who have a short life expectancy. The use of MSs in small series of BBS has been reported by several groups; however, the clinical follow-up is short. Deviere et al reported their results in 20 patients treated with Wallstent placement for BBS secondary to chronic pancreatitis. With a mean follow-up of 33 months, 90% of the MSs were patent. In a European multicenter study, 11 patients with BBS were treated with Gianturco-Rosch stents. With a follow-up of 6 to 21 months, 8 of 11 patients were asymptomatic with patent stents. Maccioni et al reported the results in 18 patients with MSs for recurrent BBS who were considered nonsurgical candidates. They achieved a mean patency rate of 68.7% at 3 years. Hauserg et al evaluated the effectiveness of Wallstents for different types of BBS in 20 patients. Median patency rate was 32 months, and only 6 patients (30%) had good results. Our mean follow-up was 86.3 months, with a range of 55 to 120 months. The mean patency rate was only 30.6 months, and only 5 (33%) of 15 patients had good long-term outcomes.

Blumgart reported that the etiology, location, and extent of the BBS are important prognostic indicators, which may assist in selecting the appropriate treatment. In our series, patients with strictures from iatrogenic causes had poor results with the use of MSs, and 4 of 5 patients ultimately required removal of the stent and biliary reconstruction. Similar outcomes were seen by Rossi et al, who reported 2 cases of CBD injury initially treated with MSs. Both patients ultimately required stent removal and biliary enterostomy due to the recurrent episodes of stent obstruction and cholangitis. Surgical injuries of the CBD may result in devascularization and ischemia, resulting in strictures less amenable to nonoperative management.

We observed a total or partial MS occlusion in 10 of 15 cases. Mucosal hyperplasia of the bile duct has been documented in animal studies and proposed as a potential source of MS obstruction. It has also been hypothesized that occlusion may be associated with bile sludge and stone formation due to persistent bile infection and partial MS incorporation to the CBD wall. In patients who underwent surgical removal, we found that the stent was embedded in the wall of the bile duct and that sludge and stones were present in the lumen. The incorporation of the stent into the bile duct wall caused severe inflammation, which complicates stent removal. In some patients, the MS was removed in fragments. One patient with stent placement at the age of 70 years eventually developed recurrent cholangitis and stent obstruction and required surgical removal and biliary enterostomy due to the recurrent episodes of stent obstruction and cholangitis. We believe the chronic inflammation predisposed the patient to cholangiocarcinoma. Six months

### Table 1. Results of Gianturco-Rosch Metallic Stents

<table>
<thead>
<tr>
<th>Patient No./Sex/Age, y</th>
<th>Cause of Stricture</th>
<th>Type of Stricture</th>
<th>Clinical Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/M/62 Injury II</td>
<td>Good</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/F/92 Primary sclerosing cholangitis IV</td>
<td>Poor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/F/63 Pancreatitis I</td>
<td>Poor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4/F/39 Injury II</td>
<td>Poor*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Surgical removal.

### Table 2. Results of Metallic Wallstents

<table>
<thead>
<tr>
<th>Patient No./Sex/Age, y</th>
<th>Cause of Stricture</th>
<th>Type of Stricture</th>
<th>Clinical Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/F/68 Gallstones I</td>
<td>Good</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6/F/102 Gallstones I</td>
<td>Good</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7/F/94 Gallstones I</td>
<td>Good</td>
<td></td>
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</tr>
<tr>
<td>8/F/80 Gallstones III</td>
<td>Good</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9/F/32 Injury III</td>
<td>Poor*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10/F/57 Gallstones I</td>
<td>Poor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11/F/63 Injury II</td>
<td>Poor*</td>
<td></td>
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<tr>
<td>12/F/60 Gallstones I</td>
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<td>13/M/69 Gallstones IV</td>
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<tr>
<td>14/F/71 Pancreatitis I</td>
<td>Poor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15/M/70 Injury II</td>
<td>Poor*</td>
<td></td>
<td></td>
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</tbody>
</table>

* Surgical removal.
after stent removal, the patient had metastatic disease in the liver. Although the risk of cholangiocarcinoma is well known in patients with benign strictures due to primary sclerosing cholangitis, this risk has not been reported in patients with strictures from stones or surgical injury.

The decisions to place MSs in this cohort of patients were based on limited data and a perceived efficacy. Our study, as well as others in the literature, demonstrates the poor results of MSs used for BBS. Patency is usually short-term, and most stents eventually obstruct. This obstruction leads to cholangitis and often necessitates additional procedures and costs. Two thirds of our patients had poor clinical results and 50% of these required major operative intervention. More important, we report that 1 of the patients with an MS in place for 10 years developed cholangiocarcinoma. Although the new endoscopic and percutaneous biliary procedures offer an alternative to surgery for patients with inoperable malignant neoplasms, they should be used selectively in patients with BBS in whom effective long-term drainage is required. Because of the poor long-term outcomes and the recurring problems associated with MSs, they have rarely been used in patients with BBS at our institution after 1995. We currently advocate the use of MSs for BBS only as palliation for patients with high surgical risk due to significant comorbidities or inoperable intrahepatic biliary strictures or for patients in whom multiple attempts at surgical repair have failed. Surgical repair, with its excellent long-term results, remains the treatment of choice in patients with iatrogenic strictures, those with surgically amenable lesions, and young patients with minimal operative risk.

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REFERENCES

tough have they been to remove, and, more importantly, do you think they add to the difficulty of the subsequent operation? We see this in plastic stents at the time of Whipple procedures because of the infection and inflammation.

Finally, you don’t allude to this in your paper, but what has happened to those patients with poor results who have then been reoperated on? How have you followed them? Has biliary cirrhosis been seen in these patients as a result of this adventure? Have they all been permanently cured by surgery or do they continue to have biliary problems? I know the ones who have not had surgery continue to have problems, but how about the ones who have had it?

Michael B. Farnell, MD, Rochester, Minn: I noted in the abstract that one of the indications for stent placement was an intrahepatic stricture. One of the solutions to an intrahepatic stricture is a hepatic resection. If one uses a Wallstent for an intrahepatic stricture, which you pointed out was 6 to 8 cm in length, it may bridge the confluence and enter the common hepatic duct. This would make hepatic resection technically difficult because one would then have to try and get the stent out of the common hepatic duct or even resect the extrahepatic duct, necessitating a hepaticojejunostomy to the remaining hepatic lobe. Do you have any comment from your experience in this regard and any lessons that you learned relative to your use of the stents for intrahepatic strictures? I think this paper is going to be oflic quoted in the future as evidence not to place MSs in patients with BBS. I certainly appreciate the authors bringing this to the attention of the membership.

Jack Pickleman, MD, Maywood, Ill: I suspect there are few in this room who need convincing. I want to comment about that one lonely patient who developed cholangiocarcinoma. I think some of you are probably assuming that he might have had one of these microcholangiocarcinomas all the while and it only showed up 10 years later, and maybe that is possible. More likely, I think, it is the result of chronic choledochitis, as we know that chronic inflammation can predispose to malignancy. I would think that a permanent MS in a young patient is going to produce choledochitis, and we shouldn’t be surprised that it induces a malignant state.

Theodore X. O’Connell, MD, Los Angeles, Calif: I would like Dr Lopez to comment on the subsequent biliary reconstruction that they had to do in these patients. Because in my experience, not only is the removal of the stent difficult, but it also makes your biliary reconstruction that much more difficult because the proximal duct that you’re going to tap into is now scarred and partially destroyed by the MS. So you please comment on that?

Richard A. Prinz, MD, Chicago, Ill: I would like the authors to tell us how they get these stents out. One of my patients with chronic pancreatitis had a Wallstent protruding into the duodenal lumen. The metal prongs caused ulcerations on the opposite duodenal wall, which were symptomatic. In the operating room and even picking the patient up by the protruding metal struts would not budge the stent at all. We had to do a pancreaticoduodenectomy to remove it. If you have any tricks on how to get these out short of removing the entire surrounding tissue, I think you should share it with us.

Dr Lopez: I’ll start by addressing the questions that Dr Madura raised. The first one was with regard to endoscopic papillectomy. This series represents only a small number of patients who develop strictures from stones and/or papillary ste-

osis. The great majority of patients at our institution are also treated with endoscopic papillectomy and most of them have successful outcomes. The patients in this series represent the few who did not have satisfactory results with the endoscopic papillectomy and required additional procedures in an effort to maintain duct patency. His next question had to do with the patients who had good outcomes.

All 5 of the patients who had good outcomes had strictures from stones. The exact reason for this is unclear. It is unknown if their patients had less inflammation, and thus the strictures were more amenable to balloon dilation and stenting. In patients with iatrogenic injuries resulting in biliary strictures, there is a component of devascularization of the duct, and as all of us know, this is a very important consideration when we attempt to dilate these ducts or to reconstruct them. Ischemic strictures are difficult to treat and any reconstruction requires adequate vascular supply.

Dr Madura’s next comment is very appropriate and spoken like a true general surgeon. He questioned how to classify our outcomes, good vs poor. Our first reaction was to classify any patient who required an additional procedure as a poor outcome. This was met with considerable objection from our gastroenterologists and radiologists who insisted at times patients need a second or third procedure for revision. Oftentimes, this revision amounts to balloon dilation of the stent once it is in place. So, in an effort to try to convince our endoscopists and radiologists that we were looking at truly those patients with poor outcome, we elected to select those patients who required more than 2 invasive procedures after stent placement. There were several questions about the incorporation of the stent into the bile duct wall, how it is removed, and how this complicates the subsequent operation. It is without doubt a very difficult problem in this group of patients. Most of the time, the stent will become incorporated into the wall of the duct and encased in dense inflammatory and fibrous tissues. The Gianturco-Rosch stents, which are fortunately not used to any great degree now, are the most difficult to remove because of the ligatures that link them together. You cannot pull just one fragment out without either cutting the individual wires or pulling the entire stent out. The Wallstents become embedded in the duct wall, and when we transect the duct we have been able to remove these stents ofentimes wire by wire. The Wallstents have no ligatures linking them together so they can be removed one at a time. The stent removal clearly complicates the reconstruction. You end up with a segment of duct or ducts that is devascularized and very inflamed. Often, reconstruction requires a very proximal hepaticojejunostomy, and, in some cases, bilateral hepaticojejunostomies. One of the most serious complications in these patients is the severe biliary sepsis. As a result of the biliary sepsis, they have longer hospital stays, primarily because of the need to treat the ongoing infection, and some develop highly resistant bacterial infections.

There was another question about how the patients in whom we have removed the stents have done. As I have mentioned, we have removed the stents in 5 patients. One of the patients had cholangiocarcinoma. And a few comments on this. I do not believe the patient had an underlying cholangiocarcinoma prior to the stent placement 10 years ago. I have never seen nor am I aware of a patient with a cholangiocarcinoma who survived 10 years without a resection. I clearly believe that the carcinoma developed subsequent to stent placement. Was it due to the ongoing inflammation and infection? We believe so. We are following these other patients to see if any of them will develop this terrible malignancy. The one patient with cholangiocarcinoma now has metastatic disease in his liver and a very short life expectancy. Four of the 5 patients for whom we have removed stents have done extremely well. One patient had stents into the right duct. That patient has subsequently developed some atrophy of the right lobe and compensatory hypertrophy of the left lobe. We are quite nervous about the changes in the right lobe and have performed several percutaneous biopsies that document the presence of fibrosis. The big question for us to address in this young patient, whose stricture was the result of a laparoscopic cholecystectomy 10 years ago, is whether or not the patient should undergo a right hepatic lobectomy. Clearly, many of us are seeing more complications as a result of MSs being placed within.
The article represents a retrospective review of 15 patients who underwent placement of expandable metallic stents for treatment of benign biliary strictures. The review represents the longest follow-up of any study that has used metallic stents for benign strictures. The study's mean follow-up of 86.3 months is significantly longer than previously reported durations of 33 months, 32 months, and 36 months.1-3 Expandable stents have been attractive for palliation of patients who have unresectable lesions due to malignant bile duct invasion or compression of the biliary tree. The metallic stent can be expanded to a larger diameter (8-10 mm) when compared with the small diameter (3-4 mm) plastic stents.

The authors conclude that results are poor (67%) with the metallic stents when they are used for benign biliary strictures. They advocate their use only in patients who are at high operative risk, with intrahepatic biliary strictures, or following failed attempts at operative repair. However, many of the poor results in the study are seen in patients who have had previous bile duct injury, a situation not unlike strictured or failed operative anastomoses. Patients who developed strictures secondary to inflammation and biliary lithiasis actually had good results with expandable stent placement. Another group that did poorly in the series was a subset of patients with pancreatitis who had Bismuth type 1 strictures. This is not unexpected considering the relative incompressibility of the cicatrizied tissue in the head of the pancreas in patients who develop chronic pancreatitis.

The article does not specify the number of attempts that were made in patients who underwent biliary duct dilation and plastic stent placement before the expandable metal stent was placed. Endoscopic manipulation of the biliary ducts and placement of indwelling plastic stents frequently incites ductal and periductal inflammation with resultant luminal narrowing and diminished compliance of the duct wall. These conditions predispose to poor results when an expandable stent is eventually placed. No primary expandable stent placement was described in this study. The authors discuss operations on patients with metal stents, and they indicate that inflammation is present and that the stent becomes incorporated in the duct wall. I have had this experience, and indeed the metal struts of the stent can become deeply imbedded in the wall and hard to remove at the time of operation. The take-home message from the article is that although metal stents may be a last resort in some patients, operative management of biliary strictures remains the gold standard. Temporizing in some patients with a metal stent may be appropriate; however, the traditional plastic stent will suffice in most instances.

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San Antonio, Tex