Radiology

Management of Biliary Strictures: State-of-the-Art Review

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Biliary strictures can be broadly classified as benign or malignant. Benign biliary strictures are most commonly iatrogenic in nature and are a consequence of hepatobiliary surgery. Cholangiocarcinoma and adenocarcinoma of the pancreas are the most common causes of malignant biliary obstruction. This article reviews state-of-the-art minimally invasive techniques used to manage these strictures. In addition, the roles of *(a)* recently introduced biodegradable biliary stents in the management of benign biliary strictures and *(b)* intraprocedural imaging and navigation tools, such as cone-beam CT, in percutaneous reconstruction of the biliary-enteric anastomosis are discussed.

Online supplemental material is available for this article.

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Learning Objectives:

After reading the article and taking the test, the reader will be able to:

- Describe etiology, diagnosis, classification, and imaging findings of the biliary strictures
- Describe radiologic management of benign biliary strictures (BBSs), including recent advances such as the role of biodegradable stents and intraprocedural imaging and navigation tools
- Describe radiologic management of malignant biliary strictures (MBSs), including the role of various kinds of uncovered, partially covered, and covered metal stents

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Strategies for the diagnosis and treatment of biliary strictures continue to evolve with advancements in minimally invasive options offered by radiologists and endoscopists. Over the past decade, advancements in imaging technology have improved diagnostic accuracy and have paved the way for more precise application of multidisciplinary treatment options. The Holy Grail in the management of both benign and malignant strictures is to achieve permanent patency and minimize the need for repeated interventions or surgical procedures. For benign strictures, newer approaches, such as large-bore catheterization, cutting-balloon dilation, and placement of retrievable covered stents, have demonstrated improved results when compared with those of previous approaches, and investigational strategies, such as placement of resorbable stents, are promising. For unresectable malignant strictures, the palliative goal of achieving patency that exceeds survival is possible in some patients via placement of permanent uncovered, partially covered, or completely covered stents. However, in many patients, internal stents are occluded due to in- or overgrowth of the tumor; these patients require reintervention. Palliation that also improves patient survival may be achievable with covered stents and with developing technologies, such as drug-coated balloons and intraductal radiofrequency ablation. Despite improvements in endoscopic management, such as double-balloon enteroscopy and US-guided sharp-puncture techniques, radiologists continue to play a critical role in the management of biliary strictures by applying advanced imaging techniques to enable diagnosis and guide tissue sampling and by using advanced percutaneous treatment options when endoscopic options fail or are not feasible. In this article, we review the current state of technology in the diagnosis and treatment of biliary strictures and discuss the role of radiologists in the context of the latest multidisciplinary advancements.

Etiology

Biliary strictures can be broadly classified as benign or malignant biliary strictures (MBSs). Benign biliary strictures (BBSs) have various origins, each with a different natural history and each demonstrating a different response to treatment (1). Iatrogenic causes, such as cholecystectomy and orthotopic liver transplantation, are the most common causes of BBS. Postoperative biliary strictures can be further classified as anastomotic or nonanastomotic. Other causes include inflammatory, autoimmune, or immunoglobulin G4–related cholangiopathy; radiation-induced sclerosing cholangitis; ischemia; and infections

Abbreviations

BBS = benign biliary stricture, CSEMS = covered SEMS, EBD = endoscopic biliary drainage, ERCP = endoscopic retrograde cholangiopancreatography, MBO = malignant biliary obstruction, MBS = malignant biliary stricture, PTBD = percutaneous transhepatic biliary drainage, PTHC = percutaneous transhepatic cholangiography, SEMS = self-expanding metal stent, USEMS = uncovered SEMS

Summary

This article reviews state-of-the-art minimally invasive techniques used to manage biliary strictures.

Essentials

- Intraprocedural cone-beam CT can be useful in three-dimensional characterization of biliary strictures and occlusions before percutaneous or surgical reconstruction of the biliary-enteric anastomosis.
- Biodegradable stents may represent an interesting treatment option for benign biliary strictures, potentially offering not only better technical results but also a better quality of life for patients.
- When self-expanding metal stents are placed via a percutaneous approach, placement of an internal-external biliary drain for 1–2 weeks enables easy interval management of complications, such as bleeding and acute reobstruction; this option represents an advantage of percutaneous transhepatic biliary drainage over endoscopic biliary drainage, as it provides additional opportunities to clear clots and debris and to replace stents in problem segments before complete removal of the catheter.
- Palliative treatment of symptoms of inoperable malignant biliary strictures continues to be the main application of percutaneous and endoscopic management; most practitioners tailor the use of covered self-expanding metal stents and uncovered self-expanding metal stents on a patient-by-patient basis to provide an option that is clinically effective, avoids unnecessary secondary procedures, and is cost effective.

(Table 1) (1,2). MBSs usually result from local malignancy, most commonly cholangiocarcinoma, pancreatic adenocarcinoma, liver metastases, hepatocellular carcinoma, ampullary carcinoma, or gallbladder adenocarcinoma. Other causes can include lymphoma and metastasis to the regional lymph nodes (3).

Classifications

The Bismuth classification is the most commonly used classification for BBSs and MBSs due to hilar cholangiocarcinoma. The Bismuth classification is based on the location of the stricture and is used to help surgeons identify the biliary level for repair and anastomosis (4). Type I strictures are located more than 2 cm distal to the confluence of the left and right hepatic ducts, and type II strictures are located less than 2 cm from the hepatic confluence. Type III strictures involve the hepatic confluence but do not affect its patency, and type IV strictures involve the confluence and interrupt it. When a stricture involves the aberrant right sectoral hepatic duct alone or with concomitant injury of the common hepatic duct, it is considered a type V lesion.

Another commonly used classification, the Strasberg classification, was originally described for laparoscopic injuries of the biliary ducts. The Strasberg classification system also takes the presence of a bile leak and lateral injuries into consideration (Table 2) (5,6).

Clinical Presentation

Clinical symptoms of biliary obstruction include jaundice, pruritus, and darkened urine from renal excretion of bilirubin. Generalized symptoms, such as weight loss, fever, nausea, vomiting, and malaise, also may be noted and depend on the underlying cause. In advanced cases, biliary obstruction can lead to ascending cholangitis, gram-negative septicemia, and hepatic abscesses. In patients with malignant biliary obstruction (MBO), distal obstruction prevents ascending cholangitis in most patients, and duct dilatation at presentation may be marked despite the absence of fever or leukocytosis. Early detection is uncommon because screening relies on clinical symptoms, which are often nonspecific and minor, despite the presence of disease too extensive for curative resection. In such patients, treatment strategies involve percutaneous and endoscopic endobiliary procedures for palliative decompression.

Imaging Diagnosis of Biliary Strictures

Invasive imaging modalities, such as percutaneous transhepatic cholangiography (PTHC) (Fig 1) are usually preceded by noninvasive options to diagnose and characterize biliary strictures. These options, which are briefly summarized in Table 3, include US (7) (Fig 2), multidetector CT (8–16), and MRI with MR cholangiopancreatography (17–24). While reported accuracy rates for characterization of stricture extent with multidetector CT are lower than those reported for MRI, more recently, intraprocedural cone-beam CT has proven to be useful in three-dimensional characterization of biliary strictures and occlusions before percutaneous or surgical reconstruction of the biliary-enteric anastomosis (Fig 1). A detailed description of the application of these tools is available in Appendix E1 (online).

Percutaneous Transhepatic Cholangiography

PTHC and endoscopic retrograde cholangiopancreatography (ERCP) offer the means to perform fluoroscopic imaging, tissue sampling, and therapeutic management of obstruction. Unlike ERCP, PTHC requires creation of a parenchymal tract and is typically performed once the decision to perform biliary drainage has been made based on clinical presentation and cross-sectional imaging findings. The decision to perform PTHC using a right- or left-sided approach depends on the location of the biliary stricture (right or left side of the biliary tree) (Fig 2). In the left-sided approach, access to the biliary system is typically obtained with US guidance (Fig 3). For biliary strictures located in the common hepatic duct or the common bile duct, most interventional radiologists prefer to use the right midaxillary approach, as the majority of the liver is drained by the right-sided ductal system, and the right-sided approach is associated with lower complication rates.

In addition to acute hemorrhage, other rare complications of PTHC and biliary drainage include pneumothorax, hemothorax, injury of the gallbladder, or a combination of these three (7,25). The reported rates of major complications, such as sepsis, acute hemorrhage, pneumothorax, and mortality, are 0.5%–2.5% (26,27).

Table 1: Etiology of Biliary Strictures

Type of Disease	Description
	Benign
Iatrogenic	Postendoscopic sphincterotomy, posthepatobiliary surgery
Inflammatory	Primary and secondary sclerosing cholangitis, acute or chronic pancreatitis
Ischemic	Hepatic artery stenosis or thrombosis
Infectious	Recurrent pyogenic cholangitis, human immunodeficiency virus cholangiopathy, tuberculosis, sarcoidosis, parasitic, choledocholithiasis
Autoimmune	Immunoglobulin G4 cholangitis
Miscellaneous	Portal biliopathy, trauma, papillary stenosis
	Malignant
Cholangiocarcinoma	Involving intra- and extrahepatic bile ducts
Carcinoma in the head of the pancreas, ampullary or duodenal malignancies	Distal common bile duct stricture
Carcinoma in the gallbladder	Invading the biliary ducts
Lymphoma and metastatic lymphadenopathy	Compressing biliary ducts
Intrahepatic metastases	Invading or compressing biliary ducts

Table 2: Strasberg Classification System for Bile Duct Injuries

Type	Description
A	Leak from the cystic duct or a small duct in the liver bed
B	Occlusion of an aberrant right hepatic duct
C	Transection of an aberrant right hepatic duct without ligation
D	Lateral injury to a major bile duct
E1	Distal CHD stricture with a CHD stump ≥ 2 cm long
E2	Proximal CHD stricture with a CHD stump < 2 cm long
E3	Hilar stricture with no CHD stump but with preservation of the hilar confluence
E4	Hilar stricture with loss of communication between the right and left hepatic ducts
E5	Aberrant right hepatic duct stricture with or without concomitant CHD stricture

Note.—Adapted, with permission, from reference 5. CHD = common hepatic duct.

Technical details of PTHC and the diagnostic advantages of ERCP, PTHC (28–33), and additional modalities, such as PET and intraductal US (34–38), are summarized in Appendix E1 (online).

Management of BBSs

Several techniques are available to treat BBS; they include balloon dilation, percutaneous biliary drain placement, and stent placement. Although interventional radiologists have been involved in the management of BBS for years, no strong consensus exists regarding the ideal technique with which to treat BBS.

Balloon Dilation

Once the stricture has been crossed, the interventional radiologist must decide whether to perform balloon dilation. Particular attention should be paid to patients with early (<1 month) postoperative bilioenteric anastomotic stricture, as the stricture might be due to edema or a kink at the site of stricture; in such cases, balloon dilation would be ineffective. Furthermore, balloon dilation might damage a fresh anastomosis, potentially resulting in bile leakage. In such patients, the general recommendation is to leave an internal-external percutaneous transhepatic biliary drainage (PTBD) in place for at least 2 weeks before attempting balloon dilation (2,25).

When balloon dilation is performed, the balloon should have a diameter at least as large as the caliber of the proximal and distal bile ducts; the balloon can also be oversized by up to 25%–30% of this diameter and, ideally, should be inflated in the middle of the stricture (2,39,40). Once successful balloon dilation has been performed (20%–30% residual stenosis and spontaneous contrast material passage), an internal-external biliary drain should be left in place for at least 2–4 weeks. Some authors prefer small-caliber drainage catheters (12 F or smaller) (41), while others prefer larger catheters (18–20 F) that are left in place longer (>6 months) to achieve stricture remodeling (42).

Percutaneous balloon dilation of biliary strictures was first reported in the 1970s and 1980s, with initial studies reporting 3-year patency rates of 38%–67% (43–45). In a series of 75 patients who underwent balloon dilation for benign biliary stenosis over a 30-year period, Cantwell et al (41) reported 100% technical success and 75% successful management during follow-up. In this series, 30.6% of patients required two to four treatments. The probability of not having clinically important stricture recurrence at 5 years was 52% after the first treatment and 43% after the second treatment. In the same series, major complications occurred in four of 205 procedures (2%); these complications included two subphrenic abscesses, one hepatic arterial pseudoaneurysm, and one event of hemobilia treated with transfusion. In a retrospective series of 98 patients with BBS treated with balloon dilation and long-term (minimum 3 months) drainage,

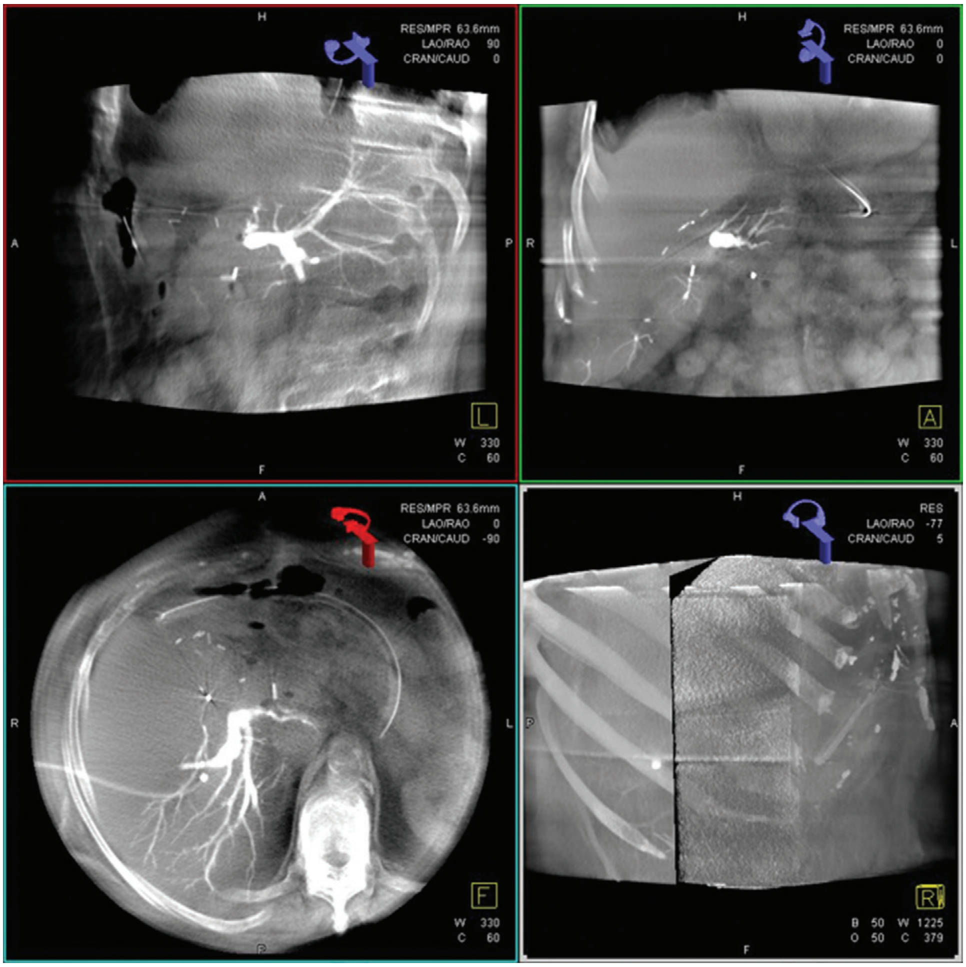


Figure 1: Intraprocedural three-dimensional reconstructed cone-beam CT images show occlusion of the right posterior hepatic duct; however, posterior ducts were communicating with caudate lobe ducts. Percutaneous reconstruction was not possible because of the acute angle of the reconstruction path. Surgical biliary enteric anastomosis was performed by using caudate lobe ducts.

Janssen et al (46) reported 13 unsuccessful procedures (13.3%) that required surgical intervention. In the same series, another four patients required surgery for restenosis that developed after treatment.

When repeated standard balloon dilation attempts fail, use of a cutting balloon has been reported to be feasible and safe, with improved results when compared with those attained with standard balloon dilation (47). Cutting balloons have four long blades attached to the balloon and might be effective in the treatment of recalcitrant restenosis, in which subsequent balloon dilations might have resulted in more focal fibrosis and scarring. In a series of 22 patients who had undergone liver transplantation and who then underwent 49 cutting balloon dilations, Saad et al (47) reported primary success rates of 100% for primary stenosis and 90% for restenosis. These results compared favorably with historic results from the same authors when they used standard balloon dilation. Notably, no major complications occurred with this approach.

Maintained Large-Bore Catheter

A different approach proposed to enhance the patency rate of percutaneous treatment of BBSs involves the use of large-bore catheters maintained in place for 6–12 months. This technique was initially proposed in the 1970s by Ring et al (48) and is still endorsed by some authors as a successful way to reduce the restenosis rate. In a recent study, Ludwig et al (49) used this treatment strategy in 47 patients who underwent placement of a 10-F catheter across the stricture. The catheter was subsequently upsized every 1–2 weeks, until a size of 18–20 F was reached. This large catheter was left in place, with subsequent maintenance, for at least 6 months. At a mean follow-up time of 20.3 months, primary patency rates were 81.25% in patients who had previously undergone liver transplantation and 89.5% in the remaining patients. However, 11 patients in the series (23.5%) were not able to complete the treatment course, and three had treatment-related complications, including one intraprocedural injury to the hepatic artery, one Roux limb perforation during upsizing, and one event of pain at the drainage site (this patient opted out of further treatment). DePietro et al (50) reported a similar approach when using 18-F catheters in 71 patients. Kaplan-Meier analysis in this study showed stricture patency probabilities of 84%, 78%, 74%, and 67% at 1, 2, 5, and 10 years after treatment, respectively.

A different strategy based on the same concept was proposed by Gwon et al (51). With this proposed dual-catheter placement technique, an 8.5-F catheter is advanced into a 14-F catheter and then out of the catheter via a side hole so that the two catheters run parallel at the level of the stricture, reaching a total of 22.5 F. With this technique, Gwon et al reported primary patency rates of 96%, 92%, and 91% at 1, 2, and 3 years, respectively. Recurrence was reported in seven (9%) of the 78 patients at a mean of 15.4 months ± 8.9 (standard deviation).

Stent Placement

Stent placement is another treatment option for BBSs. In particular, the use of retrievable covered self-expanding metal stents (CSEMSs) has been proposed as a possible treatment strategy on the basis of *(a)* the higher expansion force and larger diameter of these stents versus those of indwelling catheters and *(b)* their sustained dilation effect (52,53). These stents are generally covered by a polytetrafluoroethylene layer

Table 3: Diagnostic Imaging of Biliary Obstruction

Modality	Sensitivity for Detection of Obstruction (%)	Specificity for Classification as Benign or Malignant (%)	Accuracy in Determining Extent of Stricture (%)	Reference No.
US	90–95	30–70	Low*	10
CT	>90	60–90	75	10, 18
MRI or MR cholangiopancreatography	95–98	30–90	88–96	11, 17–20

* No published data, as US is inferior to cross-sectional imaging in the complete evaluation of the biliary tree.

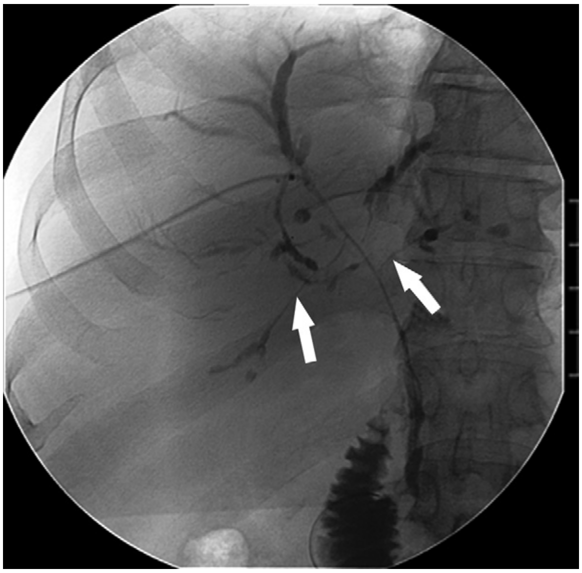


Figure 2: Fluoroscopic percutaneous transhepatic cholangiographic image shows extensive multifocal intra- and extrahepatic biliary strictures (arrows) due to intrahepatic cholangiocarcinoma.

and are equipped with a couple of drawstrings attached to the upper margin of the stent for subsequent removal (52,53). Uncovered stents are not recommended in the treatment of BBS, as epithelization and ingrowth might occur, making removal impossible. In a series of 68 patients who underwent CSEMS placement, Gwon et al (52) reported clinical success in 59 (86.8%) patients. In their series, stent migration occurred in 16.2% of patients, and 20% of patients experienced restenosis at follow-up (mean, 36 months). The mean indwelling period of the drainage catheter in this series was 5.8 months. In another series of 79 patients with BBS treated with CSEMSs, Kahaleh et al (54) reported that 90% of patients had resolution of strictures and 14% had stent migration at a median of 12 months. In preliminary reports from a large prospective multinational study of 187 patients with BBS treated with CSEMSs, removal success after an extended indwelling period (range, 10–12 months) and stricture resolution was observed in approximately 75% of patients, and serious adverse events related to the stent or its removal occurred in 27.3% of patients (55). These studies offer some promising results but highlight that there are still substantial problems to overcome, such as relatively high stent migration and complication rates.

Use of biodegradable stents has been proposed to treat BBS refractory to standard bilioplasty (56,57). These stents are made of polydioxanone, a material often used to make surgical sutures; this material degrades over approximately 3–6 months via a hydrolytic process. Biodegradable stents, which are currently under evaluation in Europe for "CE marking" (a certification mark that indicates conformity to standards for products sold within the European Economic Area), can be provided to patients only as custom-made devices; the stents must be manufactured on a patient-by-patient basis in the desired size and length. Because polydioxanone is radiolucent, these stents include two platinum markers at the extremities to make them visible on radiographs. In a recent multicenter study (58), 107 patients underwent biodegradable stent implantation to treat BBS refractory to standard bilioplasty. In this series, stricture recurrence occurred in 18% of the 97 patients with at least 6 months of follow-up, with an estimated mean time to stricture recurrence of 38 months. The estimated stricture recurrence rates were 7.2%, 26.4%, and 29.4% at 1, 2, and 3 years, respectively. Notably, because these stents are absorbed by the body, no further invasive procedures (such as those needed for catheter exchange or stent removal) are necessary after implantation, and patients are generally discharged without any external access to the biliary system. Thus, biodegradable stents may represent an interesting treatment option for BBS, potentially offering not only better technical results but also a better quality of life for patients thanks to the reduced invasiveness of this strategy (59) (Fig 4).

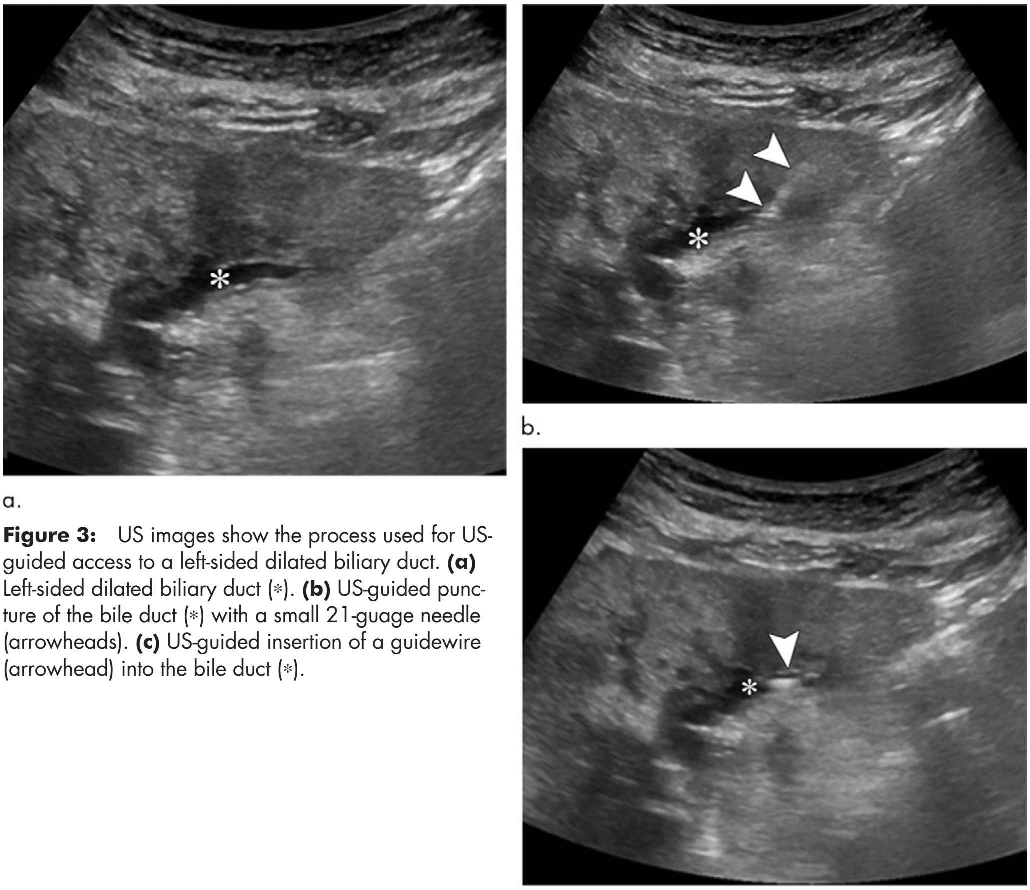
Intraprocedural imaging and guidance tools, such as cone-beam CT, have revolutionized the management of challenging almost occlusive or occlusive biliary strictures that are not otherwise surgical candidates. These tools can increase the operator's confidence in performing complex procedures, such as percutaneous recanalization of occluded hepaticojejunostomy, that are complex and risky due to the proximity of biliary ducts to major vascular structures, such as the portal vein (15) (Fig 5).

Management of MBSs

The stage of MBS determines whether the patient is a candidate for curative surgical resection or less invasive palliative therapy and is determined according to the extent of local invasion and the presence of distant disease.

Medical and Surgical Options

Candidacy for medical and surgical treatment options should be considered before minimally invasive palliative options are implemented. Temporary options for biliary decompression are more appropriate than permanent options if timely resolution of MBO is predicted with medical management. For example, MBO caused by lymphoma or metastatic lymphadenopathy



a. b. c.

Figure 3: US images show the process used for US-guided access to a left-sided dilated biliary duct. **(a)** Left-sided dilated biliary duct (*). **(b)** US-guided puncture of the bile duct (*) with a small 21-guage needle (arrowheads). **(c)** US-guided insertion of a guidewire (arrowhead) into the bile duct (*).

may resolve with chemotherapy and supportive care, without the need for invasive therapies (60). In such patients, management options might include plastic stents, retrievable covered metal stents, and internal or external biliary drainage catheters.

When clinicians are considering options for curative resection, aggressive surgical strategies developed in the past few decades may be better options than palliative drainage. For example, aggressive resection of hilar cholangiocarcinoma in conjunction with temporary biliary drainage and interval portal vein embolization has been associated with improved survival when compared with minimally invasive drainage options and chemotherapy only (61–63). In a study by Kosuge et al (61), biliary decompression was performed in 70.8% of the patients before surgical resection; 87.0% of these patients underwent PTBD. Preoperative portal vein embolization was performed in all patients (100%) who underwent left trisegmentectomy, in 78.9% of patients who underwent extended right hepatectomy, and in 9.7% of patients who underwent extended left hepatectomy. Mean and median survival in patients who underwent surgical resection were 73.6 and 28.0 months, respectively. In patients who underwent surgical resection, 1-, 5-, and 10-year survival rates were 78.2%, 32.8%, and 26.2%, respectively. In contrast, most of the patients who did not undergo surgical resection died within 2 years. In another study by Nimura et al (62), multiple uni- or bilateral preoperative PTBD procedures were performed to relieve jaundice in 133 (94%) of the 142 patients who underwent surgical excision of hilar cholangiocarcinoma. A total of 287 PTBD catheters were placed in 133 patients who underwent resection, and the success rate to relieve jaundice (bilirubin level <2 mg/dL [34.2 μmol/L]) was 100%. Similarly, research has shown that aggressive resection of hepatocellular carcinoma in conjunction with interval portal vein embolization, thermal ablation, chemoembolization, and temporary biliary drainage for biliary obstruction is associated with improved survival when compared with minimally invasive drainage options and chemotherapy (63,64).

Preoperative Biliary Drainage

The most common application of minimally invasive biliary drainage of MBO is palliation of symptoms in patients who are unable to undergo resection. However, this technique is also used for preoperative drainage before curative resection. This indication is controversial, as published reports provide contradictory evidence regarding its benefits and risks. Preoperative drainage is standard practice in the setting of infectious cholangitis, and it is routinely used to prevent atrophy of the affected liver in patients who require a long interval before surgical resection (65). However, in the absence of signs of infection, preoperative instrumentation of the biliary tree carries a theoretical risk of postoperative wound infection and infectious cholangitis (66). Several studies have shown either no improvement in surgical morbidity and mortality after preoperative drainage (67,68) or an actual increase in infection-related surgical morbidity (63,69,70). In contradistinction, other published reports support the use of preoperative biliary drainage. A retrospective review of 82 patients who underwent resection of ampullary carcinoma demonstrated a marked reduction in wound infection in patients who underwent preoperative drainage versus those who underwent no preoperative drainage (2.9% vs 25.5%, $P = .01$) (71). The groups were otherwise matched for infectious risk factors and survival rates. For patients undergoing pancreatic head resection, routine preoperative biliary drainage has been associated with reduced perioperative bacteremia and bleeding (72), reduced postoperative hospitalization, and reduced postoperative morbidity (73).

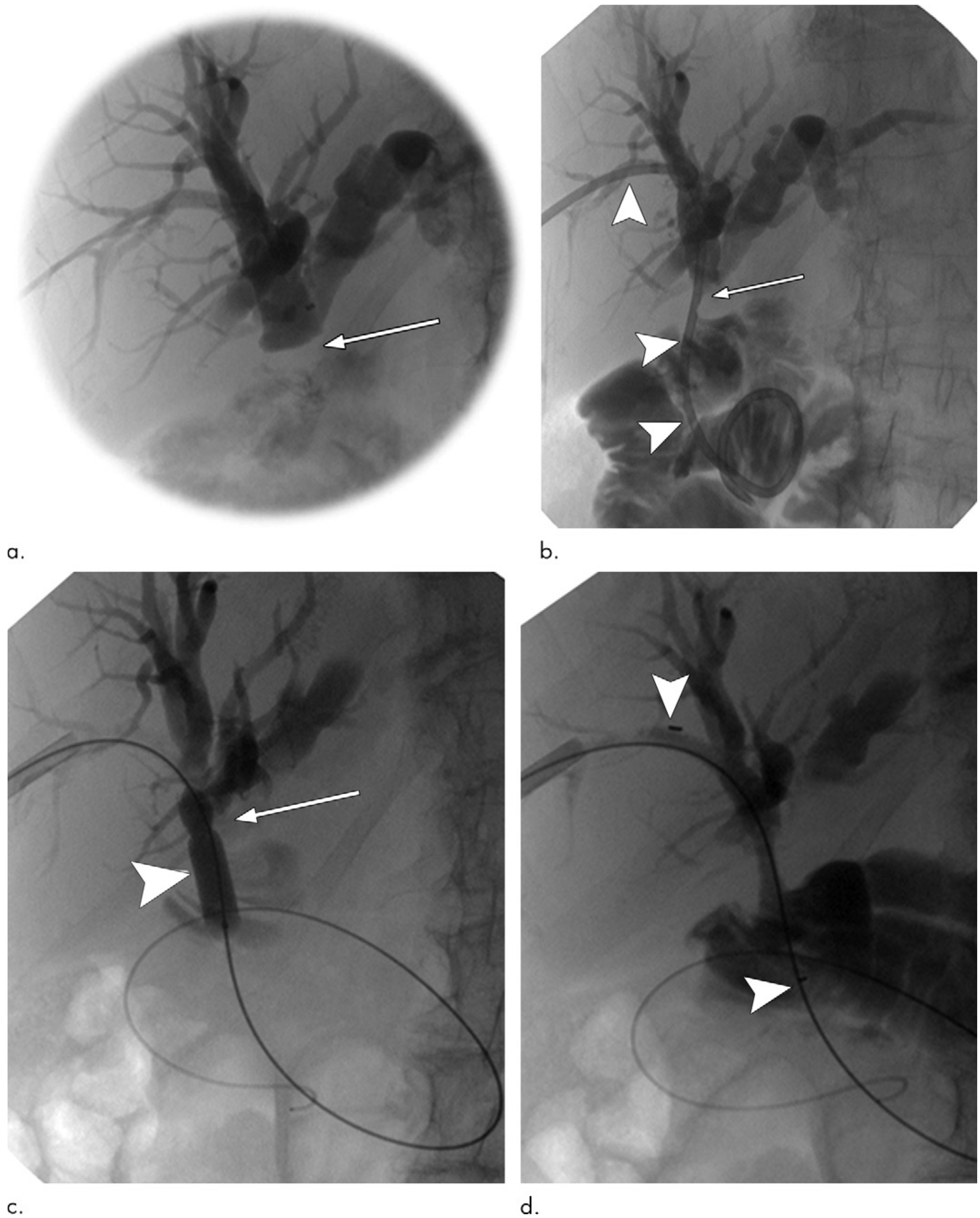


Figure 4: Percutaneous cholangiographic images in an 83-year-old-woman who underwent pancreaticoduodenectomy for carcinoma in the pancreas and who had recurrent benign biliary stricture at the site of hepaticojejunostomy. She underwent percutaneous biliary drainage and balloon dilation and received a biodegradable biliary stent. **(a)** Dilated intrahepatic biliary tree and almost-occlusive stricture of the bilioenteric anastomosis (arrow). **(b)** Placement of a percutaneous biliary drainage catheter (arrowheads) crossing the biliary stricture (arrow), with subsequent contrast opacification of a bowel loop. **(c)** Balloon (arrowhead) dilation of the stenosis (arrow). **(d)** Resolution of the stricture after placement of a biodegradable biliary stent (arrowheads) indicate platinum markers at the ends of the stent.

PTBD may be preferable to endoscopic biliary drainage (EBD) for preoperative drainage. An observational study of 115 patients undergoing resection of hilar cholangiocarcinoma compared preoperative EBD with PTBD. The technical success rates were 81% and 100%, respectively (P = .20), and infectious complications occurred in 48% and 9% of patients, respectively ($P < .05$) (74). PTBD enabled successful salvage of all patients with failed EBD (n = 30), including nine with failed initial endoscopic cannulation, and the PTBD group also required fewer subsequent interventions.

Success and route of biliary drainage.—In most patients and depending on local practice, EBD tends to be the first choice over PTBD when EBD is anatomically feasible, as using the endoscopic pathway avoids the discomfort and potential complications of external catheters, such as dislodgment

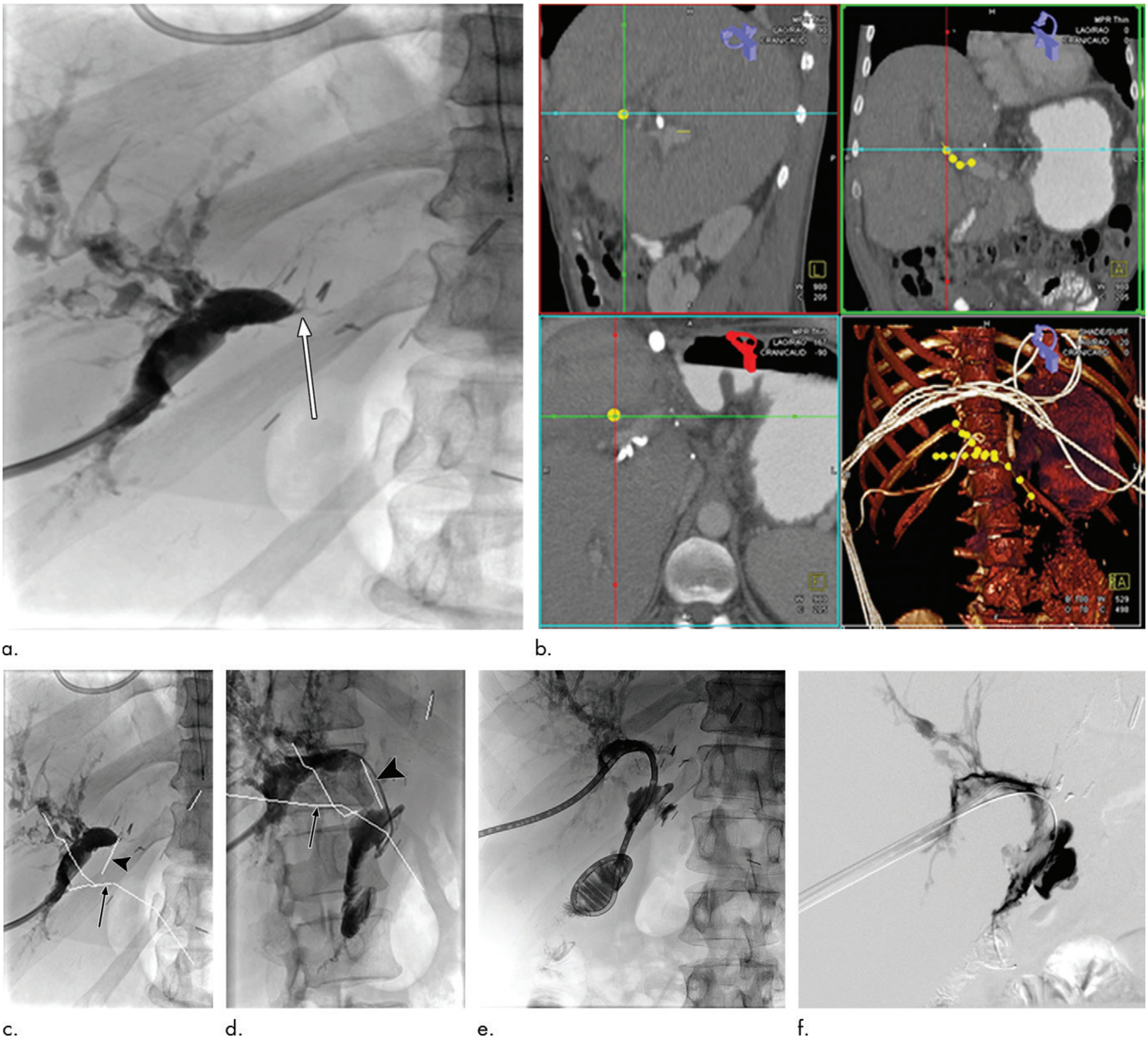


Figure 5: Images in a 34-year-old man with a history of congenital biliary atresia who had previously undergone left hepatic lobectomy and the Kasai procedure and who reported repeated episodes of acute cholangitis. US revealed intrahepatic biliary duct dilatation. Percutaneous transhepatic cholangiography and biliary drainage were performed, and percutaneous reconstruction of the biliary-enteric anastomosis was planned. **(a)** Percutaneous cholangiogram shows markedly irregular intrahepatic biliary ducts that are compatible with changes consistent with chronic cholangitis. There is an occlusive stricture at the site of hepaticojejunostomy (arrow). **(b)** Fusion of an intraprocedural unenhanced cone-beam CT image with prior contrast-enhanced CT images and drawing of the biliary-enteric anastomosis reconstruction path using intraprocedural guidance system software. **(c)** Fluoroscopic image shows outline of the portal vein (arrow) and biliary-enteric anastomosis reconstruction path (arrowhead) superimposed over a fluoroscopic image. **(d)** Percutaneous access into the jejunal loop across occluded hepaticojejunostomy. Sharp recanalization of occluded hepaticojejunostomy was performed by using a pediatric transhepatic portosystemic shunt needle (Cook, Bloomington, Ind). Contrast enhancement is seen in the jejunal loop. **(e)** Cholangiogram shows placement of a 12-F internal-external biliary drainage catheter. **(f)** Sheath cholangiogram at 13-month follow-up shows widely patent hepaticojejunostomy. Biliary catheter was removed. (Reprinted, with permission, from reference 121.)

(66,75). In general, PTBD is usually reserved for patients with failed or infeasible EBD, although this practice varies depending on the patient and local expertise, and both techniques remain common options for all levels of obstruction. The use of double-balloon endoscopy for therapeutic EBD in the setting of altered anatomy, such as Roux-en-Y hepaticojejunostomy, has reduced the need for PTBD; a meta-analysis of 10 studies involving 301 patients found that therapeutic success with this technique was 63.55% (95% confidence interval: 53.7%, 72.86%) (28). Hilar cholangiocarcinoma is often considered an exception to this rule, as reports have demonstrated higher technical and clinical success rates for PTBD than for EBD in such patients. In a study by Lee et al (76) comparing endoscopic retrograde biliary drainage, external PTBD, and internal biliary stent placement via the

PTBD tract (IPTBD), the duration of patency of endoscopic retrograde biliary drainage was comparable to that of IPTBD in Bismuth type II and III lesions. On the other hand, this study found that stent patency and drainage were statistically superior with IPTBD versus endoscopic retrograde biliary drainage for Bismuth type IV lesions. In Bismuth type IV lesions, the mean durations of patency in patients who underwent IPTBD, endoscopic retrograde biliary drainage, and external PTBD were 251 days ± 36 (standard deviation), 102 days ± 19, and 60 days ± 9, respectively ($P < .01$). These results can potentially be explained by the difficulty in selectively placing a stent in the most optimal bile duct in Bismuth type IV lesions while using endoscopic retrograde biliary drainage. On the other hand, a meta-analysis of 264 screened articles and three randomized controlled trials including 183 patients with cancer found no difference in success rates between PTBD and EBD when data collected before 1990 were excluded (3).

One caveat to the rule of routinely using PTBD to salvage failed transpapillary access during EBD is another technique that is now available: the use of sharp transgastric, transduodenal, or transhepatic puncture of the biliary system with direct endoscopic US guidance to bypass the obstructed papilla and place plastic stents or covered metal stents across the tract. Reported technical success rates in short-term pilot studies of this technique have exceeded 90% (77–79), but larger series evaluating the safety and clinical success of these techniques are not yet available. Future studies may identify the best use of sharp EBD, balancing the increased risk of bleeding against the improved rate of technical success.

Complications of biliary drainage.—Management of MBO with either PTBD or EBD is associated with a higher risk of complications than management of benign biliary obstruction, likely because of the poorer health of these patients (66). That said, published data suggest similar 30-day mortality and complication rates should be expected for PTBD and EBD in the management of MBO (odds ratio, 1.81; 95% confidence interval: 0.22, 15.12; $P = .583$) (3), particularly when the risk factors of coagulopathy and ascites are corrected before PTBD is performed (66,75,80).

Potential major complications of both PTBD and EBD include bleeding, biliary sepsis, pancreatitis, and cholecystitis (81). In one study, the rates of cholangitis were not significantly different between the two techniques (33% for EBD, 22% for PTBD) (82). Another study found that the incidence of early cholangitis was higher in the EBD group than in the PTBD group (48% vs 11%, $P = .002$); however, the rates of procedure-related mortality were similar in the two groups (PTBD, 4%; ERCP, 8%; $P = 1.00$) (83). A relatively recent study demonstrated an overall complication rate of 28%, with no significant difference between groups (EBD, 29%; PTBD, 25%) (84).

When bleeding occurs after PTBD, the source of bleeding is usually a portal vein branch because of its close proximity to one of the side holes of the catheter. In such cases, it is usually sufficient to perform cholangiography and adjust the position of the side holes. Occasionally, it is necessary to use a bigger catheter. If this is a small branch, the bleeding will stop by itself, as the portal vein is a low-pressure system; exceptions may be seen in patients with abnormal coagulation parameters, those with cirrhosis, and those with damage to a large portal branch. Thus, it is important to access the peripheral biliary system.

Arterial injury is uncommon in these patients. When arterial injury does occur, it manifests as severe pulsatile bright red bleeding, continuous slowly decreasing hematocrit levels (or an acute large decrease), or melena. Another clue to arterial bleed ing is leakage of bright red blood around rather than through the catheter. In these cases, arteriography should be performed, and embolization of the bleeding artery should be performed at the hepatic artery pseudoaneurysm or active extravasation site.

Potential major complications unique to EBD include bowel perforation and bleeding from sphincterotomy and from sharp transgastric and transduodenal puncture techniques. Pancreatitis can result from distention of the pancreatic duct due to contrast material, injury, or obstruction by sludge, stones, or stents. In patients with MBO, the risk of pancreatitis is less than 5% after PTBD but can exceed 15% after EBD (26,85). When external catheter drainage is necessary because of failed internal access, short- and long-term complications include electrolyte abnormalities and malnutrition. Excessive loss of bicarbonate-rich bile can cause orthostatic hypotension, prerenal insufficiency, hyponatremia, and a decrease in serum bicarbonate level. These abnormalities reverse when catheter internalization is achieved; therefore, repeated attempts at catheter internalization are warranted and are often successful (86). Major complications specific to the placement of metal stents are discussed later in this article.

Stent Placement

Self-expanding metal stents (SEMSs)—either uncovered SEMS (USEMS), partially covered, or completely CSEMS—have become standard palliative options in the management of MBS because of their ease and accuracy of placement, high technical and clinical success rates, and high long-term patency rates (Fig 6). When compared with SEMSs for MBS, plastic stents are more expensive and inconvenient over the long term because of their lower long-term patency and the need for more endoscopic procedures (87,88). That said, plastic stents can serve as a temporary means for decompression pending biopsy and imaging results that will be used to determine clinical management. When clinical management centers on palliation, the goal is for stent patency to exceed survival to ameliorate symptoms and minimize the need for repeat interventions. Plastic stents can be used to achieve this goal if the prognosis is poor and expected survival is less than 3 months (89), but for the most common causes of inoperable MBO (pancreatic carcinoma and cholangiocarcinoma), SEMSs are more appropriate, as median survival in these patients ranges from 2 months to 1 year (90–92). For example, a retrospective multicenter European study of 240 patients yielded 78% and 67% patency rates at 25 weeks for nitinol and stainless steel USEMSs, respectively, in a patient population with 25- and 50-week survival rates of 42% and 16%, respectively (93).

Biliary reconstruction for MBS is best accomplished with careful consideration of the anatomic features that may affect the

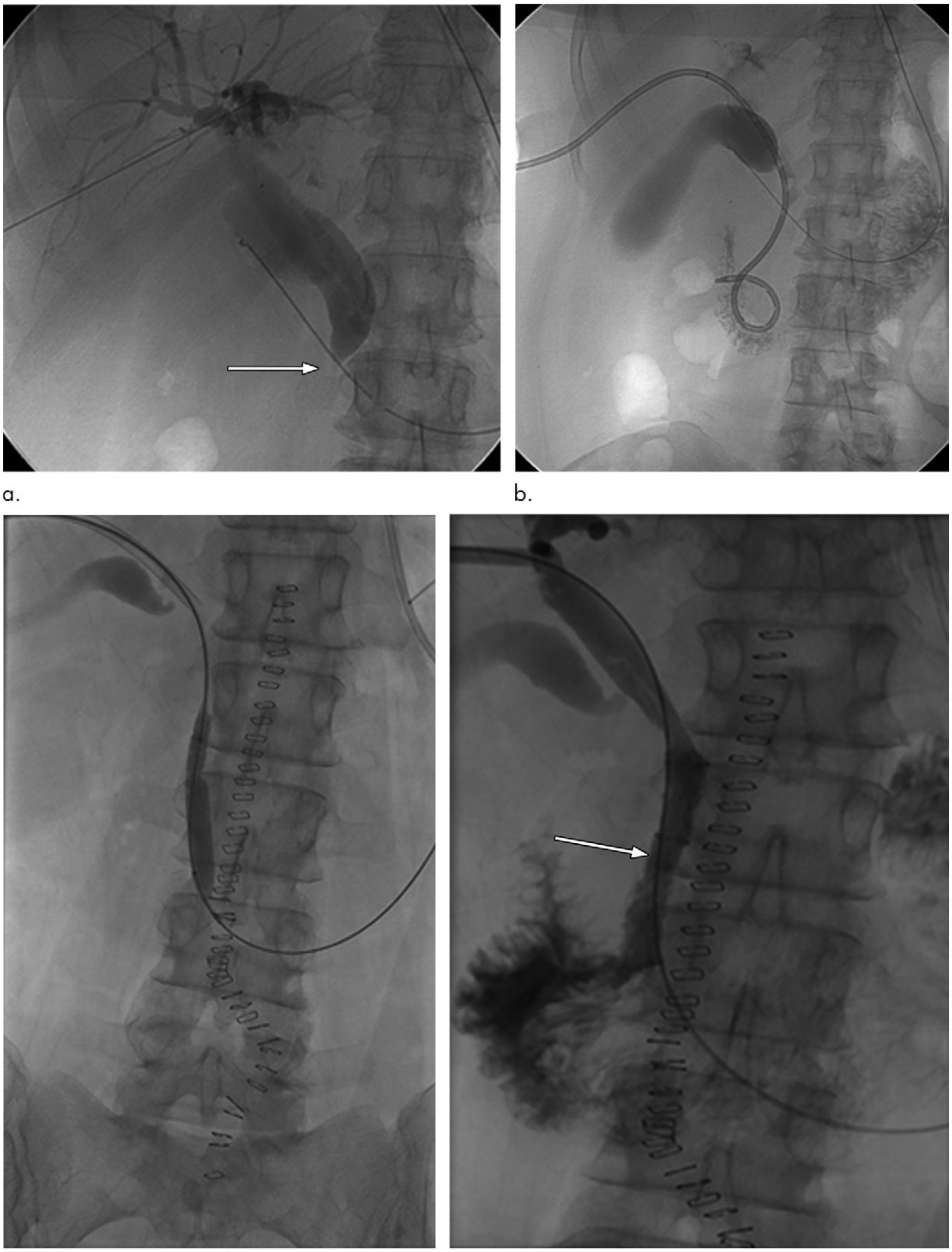


Figure 6: Images in a 58-year-old man with gradually progressive jaundice. **(a)** Cholangiographic image shows complete occlusion (arrow) of the distal common bile duct (CBD) due to distal CBD cholangiocarcinoma and marked dilatation of the CBD and central intrahepatic biliary ducts. **(b)** Placement of an internal-external biliary drainage catheter. **(c)** Balloon dilation of the stricture using an 8 × 40-mm balloon. **(d)** Fluoroscopic image shows placement of a 10-mm-diameter partially covered stent graft (Viabil; Gore Medical, Flagstaff, Az) (arrow) across the stricture and injection of contrast material, enabling confirmation of a widely patent stent. Good flow of contrast material across the stent graft was noted.

outcome. For this reason, percutaneous stent placement should be preceded by biopsy and imaging studies, particularly ERCP or MR cholangiopancreatography (94), to establish the diagnosis of malignancy and to guide stent placement. For patients with complete hilar or segmental obstruction, MR cholangiopancreatography offers an added advantage over ERCP in demonstrating the length and location of obstructed ducts that are inaccessible for contrast material injection during ERCP. Additional information can be obtained from balloon-assisted clearance of sludge and debris during stent placement, revealing the true length of the obstruction; this step minimizes the length of the stent required and the need for extension of the stent across the hilum, cystic duct, or papilla, thereby minimizing the risks of recurrent biliary obstruction, cholecystitis, and pancreatitis, respectively.

For obstruction of the hilum and proximal common bile duct, avoiding stent placement across the papilla has been shown to improve long-term patency and to reduce the risk of ascending cholangitis (95,96) and pancreatitis (97). Placement of SEMSs across the papilla in patients with hilar obstruction is controversial. A retrospective review of 172 patients who underwent either trans- or suprapapillary SEMS placement for hilar MBS showed no difference in success rates, stent patency duration, or stent occlusion rates (97).

When SEMSs are placed via a percutaneous approach, a 1- to 2-week period of internal-external biliary drain placement allows for easy interval management of complications, such as bleeding and acute reobstruction. This option represents an advantage of PTBD over EBD, as it provides additional opportunities to clear clots and debris and to replace stents in problem segments before complete catheter removal.

If possible, stent placement across major branch points should be avoided to optimize long-term patency; however, for hilar obstruction, MBS involves the confluence of large ducts, and two options exist for stent placement: a unilateral USEMS that cages the side without a stent or a bilateral Y-configured USEMS or CSEMS that extends from the common bile duct to both the right and left intrahepatic ducts. In one study, Freeman et al (94) observed 77% clinical success and a median patency of 5.4 months in 35 patients who underwent unilateral USEMS placement for hilar biliary obstruction. Other authors have achieved similar success with unilateral USEMS and CSEMS placement (98) and with Y-configured CSEMS placement (99). For hilar obstruction, a USEMS is preferable to a CSEMS if preservation of the contralateral duct patency is possible (100). Nevertheless, unilateral USEMS placement may result in atrophy of the excluded lobe (86); therefore, stent placement into the most viable lobe is recommended. The aim should be biliary drainage of more than 50% of the liver volume, as this is associated with decreased cholangitis after stent placement and increased survival (101).

CSEMSs cost more than USEMSs, which has triggered a debate regarding their value and appropriate application in the management of MBS. Perhaps the best use of CSEMSs is in patients with MBS and longer-than-typical predicted survival, as reported long-term patency rates for CSEMSs often far exceed those of USEMSs for comparable indications of MBS (102–107). For patients with shorter predicted survival, either option would yield sufficient patency, making the lower-cost USEMSs more attractive. For example, a meta-analysis of 20 randomized controlled trials involving 1713 patients showed no significant difference in 6- or 12-month patency rates for USEMSs and CSEMSs (108). A related debate centers on whether CSEMSs improve survival when compared with USEMSs for comparable indications of MBO. A cohort observational study of 80 patients who underwent CSEMS placement for MBS showed typically low survival rates of 40% and 20.2% at 6 and 12 months, respectively; these rates are comparable to most published rates for USEMS placement (104). Furthermore, patency rates of 95.5%, 92.6%, and 85.7% at 3, 6, and 12 months, respectively, demonstrate the clinical effectiveness of CSEMSs but call into question their cost effectiveness in patients with a projected survival of less than 12 months. Comparative studies have also failed to demonstrate improved survival after CSEMS placement versus USEMS placement. For example, a large randomized multicenter trial of 400 patients with distal MBS demonstrated no significant difference in patency in or survival of patients undergoing either CSEMS or USEMS placement (109). In addition, a meta-analysis of 13 studies involving 2239 patients undergoing either USEMS or CSEMS placement demonstrated no statistically significant survival benefit with CSEMSs (110). On the other hand, in a prospective randomized trial of MBO caused by pancreatic cancer, 80 patients underwent either CSEMS or USEMS placement; mean patency was 234 days for CSEMS placement and 166 days for USEMS placement ($P = .007$), and median survival was 247 and 203.2 days, respectively ($P = .06$) (111). Because survival and stent patency were longer in the CSEMS group, the cost per survival day in the CSEMS group was comparable to that in the USEMS group.

Complications of Metal Stents for MBS

Complications of metal stents for MBS include bleeding, cholangitis, cholecystitis, pancreatitis, stent migration, and obstruction (109). CSEMSs migrate and obstruct side branches more frequently than do USEMSs. Some manufacturers have added features, such as flared ends, barbs, and partial coverings, to reduce such complications. Bleeding risk is more closely related to the point of biliary access during the initial PTBD than to the type of SEMS and placement technique. In a retrospective study of 446 patients analyzed with multivariate logistic regression, bleeding risk was progressively reduced by accessing more peripheral ducts, from lobar to segmental to subsegmental (112). That said, bleeding risk is exacerbated by overzealous poststent placement dilatation, which is not necessary, as SEMSs continue to expand after placement. Dilatation after stent placement can result in laceration of the tumor and bleeding from the tumor vascularity. Conservative balloon sizing and avoidance of poststent dilatation may minimize the risk of this complication (109).

Cholangitis is the most common infectious complication of stent placement, and so the use of periprocedural antibiotics is recommended in all patients (66). Fever and leukocytosis usually resolve with intravenous antibiotics and, if percutaneous catheter access has been maintained, with delayed fluoroscopically guided balloon-assisted clearance of clots and debris. Cholangitis after stent placement is less common with percutaneous stent placement than with endoscopic stent placement (113), possibly because of the rapid duct decompression and the short interval of internal-external catheter placement associated with the percutaneous approach. In a meta-analysis of 13 studies involving 2239 patients with MBO, there was no significant difference in the overall adverse event rate with CSEMSs versus USEMSs; however, CSEMSs seemed to have significantly lower occlusion rates, increased odds of migration, and an increased risk of pancreatitis compared with USEMSs (110). Other studies have shown similar rates of pancreatitis and cholecystitis after CSEMS and USEMS placement (66,108). Pancreatitis after stent placement is usually caused by contrast material injection into the pancreatic duct and is not affected by the choice of a CSEMS or USEMS (114). Acute cholecystitis after stent placement is almost always caused by cystic duct involvement by the tumor in combination with SEMS placement across the cystic duct orifice (115). This complication is managed by placement of a percutaneous cholecystostomy catheter that can be removed after resolution of symptoms, a trial of catheter capping, and performance of over-the-wire tractography to verify tract formation, typically after 4–6 weeks. Demonstration of patency of the cystic duct is helpful before catheter removal; however, this finding may be unnecessary after a symptom-free capping trial and resolution of tube output. In patients with persistent obstruction of the cystic duct and persistent or recurrent symptoms of cholecystitis, indefinite external drainage or chemical ablation of the gallbladder may be necessary (116).

Acute recurrent obstruction after stent placement may result from dilatation after stent placement and may lead to either hemobilia with obstructive clot formation or extrusion of the tumor through the interstices or around the edges of the stent. Chronic recurrent obstruction usually results from tumor overgrowth at the margins of the SEMS or ingrowth across the interstices of the USEMS (76). If survival exceeds patency, repeat endoscopic or percutaneous drainage is necessary to replace the stent in the tumor progression and to clear debris or stones. If extended patency cannot be achieved, placement of a permanent internal or external catheter might be required (113).

Palliative treatment of symptoms of inoperable MBO continues to be the main application of percutaneous and endoscopic management. Most practitioners tailor the use of CSEMSs and USEMSs on a patient-by-patient basis to provide an option that is clinically effective, avoids unnecessary secondary procedures, and is cost effective. Because survival rates in patients with MBO are limited, existing technologies, such as USEMS and CSEMS, yield adequate patency in most patients, and the future applicability of newer strategies hinges on demonstration of a clear survival advantage.

Investigational Strategies

Investigational strategies for MBS aim to improve survival and patency rates by suppressing local tumor growth. Such strategies include intraductal radiofrequency ablation and the placement of drug-eluting SEMSs. Pilot studies have demonstrated the safety of devices under development for the delivery of intraductal radiofrequency ablation to improve the long-term patency of SEMSs for MBS (117). In addition, limited studies of intraductal radiofrequency ablation have suggested improvements in patency with this method (118,119), although larger series are needed to verify the statistical significance. Pilot studies of drug-coated SEMSs for MBS have demonstrated improvements over reported patency rates for SEMSs, although such studies are underpowered to demonstrate improvements in survival. In one multicenter pilot study, paclitaxel-encoated SEMSs for MBS had a mean patency of 429 days (120).

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