American College of Radiology
ACR Appropriateness Criteria®
Radiologic Management of Biliary Obstruction

Variant 1:   **Initial therapeutic procedure for a patient with dilated bile ducts from choledocholithiasis.**

Procedure	Appropriateness Category
Endoscopic internal biliary catheter (removable plastic stent)	Usually Appropriate
Percutaneous internal/external biliary catheter	May Be Appropriate
Surgery	Usually Not Appropriate
Medical management only	Usually Not Appropriate
Permanent biliary metallic stent	Usually Not Appropriate
Removable biliary covered stent	May Be Appropriate
Endoscopic US-guided biliary drainage (EUS-BD)	May Be Appropriate

Variant 2:   **Initial therapeutic procedure for a patient with elevated bilirubin and suspected sclerosing cholangitis.**

Procedure	Appropriateness Category
Endoscopic internal biliary catheter (removable plastic stent)	Usually Appropriate
Percutaneous internal/external biliary catheter	May Be Appropriate
Surgery	Usually Not Appropriate
Medical management only	May Be Appropriate
Permanent biliary metallic stent	Usually Not Appropriate
Removable biliary covered stent	Usually Not Appropriate

Variant 3:   **Initial therapeutic procedure for a liver transplant recipient with elevated bilirubin and suspected biliary anastomotic stenosis or bile leak, with no dilated ducts.**

Procedure	Appropriateness Category
Endoscopic internal biliary catheter (removable plastic stent)	Usually Appropriate
Percutaneous internal/external biliary catheter	Usually Appropriate
Surgery	Usually Not Appropriate
Medical management only	Usually Not Appropriate
Permanent biliary metallic stent	Usually Not Appropriate
Removable biliary covered stent	May Be Appropriate
Endoscopic US-guided biliary drainage (EUS-BD)	Usually Not Appropriate

Variant 4:   Initial therapeutic procedure for a patient with bile leak and dilated bile ducts following laparoscopic cholecystectomy.

Treatment/Procedure	Rating
Endoscopic internal biliary catheter (removable plastic stent)	Usually Appropriate
Percutaneous internal/external biliary catheter	Usually Appropriate
Surgery	May Be Appropriate
Medical management only	Usually Not Appropriate
Permanent biliary metallic stent	Usually Not Appropriate
Removable biliary covered stent	Usually Not Appropriate
Endoscopic US-guided biliary drainage (EUS-BD)	Usually Not Appropriate

Variant 5:   Initial therapeutic procedure for a patient with dilated bile ducts and suspected biliary sepsis or acute cholangitis.

Procedure	Appropriateness Category
Endoscopic internal biliary catheter (removable plastic stent)	Usually Appropriate
Percutaneous internal/external biliary catheter	Usually Appropriate
Surgery	Usually Not Appropriate
Medical management only	Usually Not Appropriate
Permanent biliary metallic stent	Usually Not Appropriate
Removable biliary covered stent	Usually Not Appropriate
Endoscopic US-guided biliary drainage (EUS-BD)	May Be Appropriate

Variant 6:   Initial therapeutic procedure for a patient with malignant common bile duct obstruction (eg, pancreatic carcinoma).

Procedure	Appropriateness Category
Endoscopic internal biliary catheter (removable plastic stent)	Usually Appropriate
Percutaneous internal/external biliary catheter	Usually Appropriate
Surgery	May Be Appropriate
Medical management only	Usually Not Appropriate
Permanent biliary metallic stent	May Be Appropriate
Removable biliary covered stent	May Be Appropriate
Endoscopic US-guided biliary drainage (EUS-BD)	May Be Appropriate

Variant 7:   Initial therapeutic procedure for a patient with hilar biliary obstruction from malignant etiology (eg, Klatskin tumor).

Procedure	Appropriateness Category
Endoscopic internal biliary catheter (removable plastic stent)	May Be Appropriate
Percutaneous internal/external biliary catheter	Usually Appropriate
Surgery	May Be Appropriate
Medical management only	Usually Not Appropriate
Permanent biliary metallic stent	May Be Appropriate
Removable biliary covered stent	May Be Appropriate
Endoscopic US-guided biliary drainage (EUS-BD)	Usually Not Appropriate

Variant 8:   Initial therapeutic procedure for a patient with dilated bile ducts and coagulopathy (INR >2.0 or platelet count <60 K).

Procedure	Appropriateness Category
Endoscopic internal biliary catheter (removable plastic stent)	Usually Appropriate
Percutaneous internal/external biliary catheter	May Be Appropriate
Surgery	Usually Not Appropriate
Medical management only	May Be Appropriate
Permanent biliary metallic stent	Usually Not Appropriate
Removable biliary covered stent	Usually Not Appropriate
Endoscopic US-guided biliary drainage (EUS-BD)	Usually Not Appropriate

Variant 9:   Initial therapeutic procedure for a patient with dilated bile ducts and moderate to massive ascites.

Procedure	Appropriateness Category
Endoscopic internal biliary catheter (removable plastic stent)	Usually Appropriate
Percutaneous internal/external biliary catheter	May Be Appropriate
Surgery	Usually Not Appropriate
Medical management only	May Be Appropriate
Permanent biliary metallic stent	Usually Not Appropriate
Removable biliary covered stent	May Be Appropriate
Endoscopic US-guided biliary drainage (EUS-BD)	Usually Not Appropriate

RADIOLOGIC MANAGEMENT OF BILIARY OBSTRUCTION

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Summary of Literature Review

Introduction/Background

Since the late 1970s, percutaneous biliary drainage has been used in the management of biliary obstruction resulting from benign and malignant causes. In the setting of acute cholangitis, percutaneous biliary decompression can be lifesaving; for patients with cancer who are receiving chemotherapy, untreated obstructive jaundice may lead to biochemical derangements that often preclude continuation of therapy unless biliary decompression is performed [1,2] (see the ACR Appropriateness Criteria® topic on "Jaundice" [3]).

Discussion of Procedures by Variant

Variant 1: Initial therapeutic procedure for a patient with dilated bile ducts from choledocholithiasis.

Medical Management versus Decompression

Biliary disease related to gallstones is common, with an estimated 10% to 15% of the adult population in the United States having gallstones [4]. Acute biliary obstruction caused by choledocholithiasis is a potentially life-threatening condition that requires biliary decompression in nearly all cases, though initial medical management is indicated to stabilize hemodynamic status and treat local and systemic infection. Common bile duct (CBD) stones are present in approximately 10% of those with gallstone disease [4]. Even in the absence of symptoms, choledocholithiasis requires intervention because of the risk of developing obstructive jaundice, cholangitis, acute pancreatitis, and potentially secondary biliary cirrhosis. Prior to the 1970s and the widespread adoption of endoscopic retrograde cholangiography (ERCP), bile duct surgery was the mainstay of treatment for choledocholithiasis. Evaluation of nationwide therapeutic trends for choledocholithiasis by ICD-9-CM codes from 1998 to 2013 demonstrates that ERCP use for choledocholithiasis increased from 16.7 to 22.1 per 100,000. This represents an increase from 75.2% to 96.1% in the utilization of ERCP in the management of choledocholithiasis. During the same period, common duct exploration decreased from 5.2 to 0.8 per 100,000. Percutaneous management also decreased from 0.3 to 0.1 per 100,000 [5].

Endoscopic Treatment

Stone Removal

The mainstay of therapy for choledocholithiasis is endoscopic biliary sphincterotomy and stone extraction during ERCP, with a reported success rate of 90% [6-8]. In some cases, particularly those involving large (>10–15 mm) or impacted stones, additional therapy in the form of lithotripsy or stone fragmentation may be required [9]. Lithotripsy has a reported success rate of 79%; however, upwards of 30% of patients may require multiple sessions to clear the stones completely [9]. In cases of incomplete stone extraction or severe acute cholangitis, placement of an internal plastic stent is standard to ensure adequate biliary drainage.

Sphincterotomy and Stent Placement

Endoscopic sphincterotomy carries with it a 6% to 10% major complication rate; however, this increases significantly in the elderly population, in whom major complication rates are reported to be as high as 19% with a mortality rate of 7.9% [10]. Immediate endoscopic placement of a plastic biliary stent is a safe and effective method to achieve temporary biliary drainage; however, the risk of recurrent cholangitis remains until the CBD

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has been cleared [10]. Recently, endoscopic placement of covered self-expandable metal stents (SEMS) has been investigated for their prolonged patency and decreased need for multiple reinterventions as required with traditional plastic stents; however, data are limited [7,11].

Techniques for Challenging Anatomy
Additional case reports of more novel approaches to biliary decompression and stone removal exist utilizing endoscopic ultrasound (EUS)-guided placement of a fully covered metallic stent to treat stones when traditional ERCP fails; however, long-term results and larger studies are lacking [12]. Uncovered SEMS have also been investigated as a potential alternative to traditional plastic stents, though they are generally not advocated in benign disease as they cannot be removed, become completely epithelialized by 1 year, and are prone to occlusion [11].

Several endoscopic approaches exist for challenging, generally postsurgical anatomy. Conventional side-viewing endoscopes to access the papilla in a patient's Roux-en-Y anatomy has a success rate of approximately 33% [13]. Wright et al [14] reported improved success by accessing the afferent limb with a forward-facing colonoscope and subsequently passing a duodenoscope over it. With this technique, a 66% cannulation rate was reported.

Greater therapeutic success has been demonstrated with overtube-assisted techniques, which includes single-balloon enteroscopy (SBE), double-balloon enteroscopy (DBE), and spiral enteroscopy (SE). These techniques all involve pleating the small bowel sequentially over the endoscope. There have been several small studies reporting the successes of each overtube technique. In one of the largest cohorts, Siddiqui et al [15] reported successful papilla cannulation in 74% (29 of 39) of patients with Roux-en-Y anatomy using DBE-assisted ERCP. Emmett et al [16] presented 14 patients with prior Roux-en-Y with an 88% successful cannulation rate using DBE. The less time consuming and technically easier SBE-assisted ERCP has a reported success rate between 88% and 92% [17,18]. Finally, with the development of the rotating overtube series evaluating SE-assisted ERCP in surgically altered anatomy were published with a reported success rate between 61% and 80% [19]. Studies evaluating these 3 methods have failed to demonstrate any significant difference in the results of the 3 techniques [20,21].

Percutaneous Treatment
Endoscopic CBD stone removal fails in approximately 5% to 10% of cases [10], necessitating a percutaneous approach. Additionally, a subset of patients exists that may benefit from a primary percutaneous approach. This includes some patients with surgically altered upper gastrointestinal anatomy or difficult-to-reach stones (intrahepatic or associated stenosis) [6,22]. In some patients with Roux-en-Y gastrojejunostomy or Roux-en-Y hepaticojejunostomy anatomy, the duodenoscope may not have the length required to navigate a long Roux limb to reach the biliary tree. Additionally, even in those patients whose postsurgical anatomy does not preclude reaching the major papilla, such as those with Billroth II gastrojejunal anatomy, bleeding (up to 17% of patients) and luminal perforations (reported as high as 5% of patients) are more frequent in postsurgical anatomy [6,22]. In patients with hepatolithiasis, with large or impacted stones, who are elderly, or are in critical condition, a percutaneous first approach may be considered.

Multiple percutaneous transhepatic options are available, including decompression with a percutaneous biliary drain, balloon dilatation and stone removal, percutaneous transhepatic endoscopic biliary holmium laser lithotripsy, and combined endoscopic and percutaneous procedures.

Biliary Catheter Placement
In the case of biliary sepsis, biliary decompression with placement of internal/external drain or external biliary catheter where the stone cannot be primarily crossed can be lifesaving. Pessa et al [23] demonstrated resolution of sepsis in 100% of patients within 24 hours of percutaneous biliary drainage despite 17% of patients presenting with nondilated ducts and reported a 7% complication rate.

Stone Removal
After appropriate biliary decompression, various techniques are used to remove stones, including balloon dilatation of the papilla and/or biliary strictures, forceful irrigation, and use of balloon-tipped catheters to sweep the stones into the duodenum [6,22,24]. Following stone removal, an internal/external catheter should be placed to ensure adequate decompression of the biliary tree. The drain can be removed when free flow of contrast into the duodenum is confirmed on follow-up evaluation [25]. Success rates utilizing a percutaneous approach have been reported upwards of 95% to 100% in small series; however, this is dependent on equipment used and experience of the operator [24]. For this document, it assumed all procedures are performed by an expert.

Ozcan et al [25] presented 261 symptomatic patients who underwent percutaneous bile duct stone removal. Once percutaneous access was obtained, percutaneous transhepatic balloon dilatation of the papilla of Vater was performed, and the stone was pushed into the duodenum with a Fogarty balloon. For stones >15 mm, basket lithotripsy was performed prior to balloon dilation. Once the ducts were cleared of stones, an external biliary drain was left for a minimum of 2 days. A follow-up cholangiogram would then be performed, and if free flow of contrast into the duodenum was confirmed, the catheter was withdrawn. They reported a success rate of 95.7% with a 6.8% major complication rate. Complications included cholangitis, biloma, hematoma, abscess, CBD and duodenal perforation, bile peritonitis, gastroduodenal artery pseudoaneurysm, and right hepatic artery transection.

Techniques for Challenging Anatomy
A rendezvous technique is occasionally used in the case of a papilla that is difficult to cannulate endoscopically, often when prior endoscopic attempts have failed [26]. Percutaneous access into the biliary ducts and a guidewire is navigated into the small bowel and presented to the endoscopist. The endoscopist then snares this guidewire and utilizes it to help navigate the endoscope and cannulate the papilla. Calvo et al [26] reported their experience with the rendezvous technique. Over a 7-year period, 1,753 ERCPs were performed. ERCP failed to resolve the obstruction in 12 patients with choledocholithiasis who were considered poor surgical candidates. The rendezvous technique was successful in all but 1 patient. One complication, a retroperitoneal perforation caused by sphincterotomy, was reported.

In some cases, nondilated biliary ducts may prove difficult to cannulate. Percutaneous access into the gallbladder is an alternative path to decompress the biliary tree. Okuno et al [27] describe a series of 6 patients with choledocholithiasis and nondilated intrahepatic ducts who had previously failed ERCP in the setting of surgically altered anatomy. In all cases, percutaneous access was made into the gallbladder and a guidewire was passed through the CBD into the small bowel. With this method, successful biliary cannulation by the enteroscope was made in all cases, and the stones cleared in 5 of the 6 cases.

Surgery
Surgical CBD exploration was the procedure of choice several decades ago; however, it is now generally considered only when stones cannot be managed nonsurgically. Open CBD exploration carries a morbidity of 20% to 40% and mortality of 1.3% to 4%, and it may fail to clear the duct of all stones. More recently, laparoscopic exploration of the CBD has grown in popularity and is generally indicated in patients with a wide CBD (>9 mm) to avoid subsequent development of strictures [25]. Laparoscopic CBD exploration is highly successful, with reported success of up to 95% and complication rates of 5% to 18% [25]. In patients undergoing a laparoscopic cholecystectomy, laparoscopic CBD exploration may be preferable to endoscopic duct clearance before or after surgery [28].

Variant 2: Initial therapeutic procedure for a patient with elevated bilirubin and suspected sclerosing cholangitis.

Sclerosing cholangitis is a heterogeneous group of syndromes resulting in inflammation, scarring, and destruction of the bile ducts. Cholangitis can be divided into 3 broad categories: primary sclerosing cholangitis (PSC), secondary cholangitis, and immune cholangitis.

Medical Management
PSC is a chronic progressive cholestatic disease characterized by inflammation and fibrosis of the intrahepatic and extrahepatic bile ducts. Currently the only definitive treatment is transplantation; however, multiple medical and interventional therapies exist to treat symptoms and complications of the disease. Medical therapy, including ursodeoxycholic acid and corticosteroids, along with endoscopic and percutaneous dilatation of biliary strictures and drainage, or surgical resection of isolated biliary strictures, may improve quality of life; however, definitive evidence of prolonged survival is lacking [29,30]. Because of this, many advocate treating these patients in a tertiary hospital to facilitate a multidisciplinary approach without jeopardizing future transplantation [29,30].

Selection of antibiotics should include those with a broad range of antimicrobial activity with good penetration into the bile ducts. Examples include third-generation cephalosporins, ureidopenicillins, carbapenems, and fluoroquinolones [31].

The beneficial role for antibiotics in PSC is controversial. While a high rate of positive cultures has been reported for PSC patients, antibiotic therapy for 12 weeks with rifaximin resulted in no significant effects on the clinical course of PSC [32]. Conversely, vancomycin with ursodeoxycholic acid therapy resulted in decreased liver

enzymes [33]. Similarly, metronidazole with ursodeoxycholic acid therapy resulted in significantly decreased alkaline phosphatase enzyme when compared to ursodeoxycholic acid and placebo [34].

Endoscopic versus Percutaneous Treatment
The development of focal, high-grade strictures, also known as dominant strictures, may develop de novo or on a background of diffuse ductal disease and result in impaired biliary drainage, resulting in pruritus, jaundice, and recurrent cholangitis. Prior to 1990, these strictures were managed surgically with biliary resection or bilioenteric anastomosis [35]. Current management favors an endoscopic approach as it is less invasive, can be performed as an outpatient procedure, and can be repeated as necessary [29]. Dilatation of biliary strictures is preferred over medical management alone as it improves symptoms and delays the need for orthotopic liver transplant [29]. When compared with a percutaneous approach, an endoscopic approach also offers patients a better quality of life without an external drain [35]. However, there are instances in which an endoscopic approach is unable to treat a stricture necessitating a percutaneous approach.

Endoscopic and percutaneous biliary dilatation of dominant strictures results in clinical and biochemical improvements in approximately 80% of noncirrhotic patients and has even shown reversal of secondary liver fibrosis [29,36,37]. The 5-year transplant-free survival rates of patients undergoing endoscopic treatment of a dominant stricture is 81% to 94%, as compared to the 65% to 78% predicted by the Mayo Clinic model [38]. An initial endoscopic approach generally includes placement of a stent intended to improve patency of the duct; however, biliary stents are associated with increased risk of cholangitis (up to 50%) because of their occlusion over time [39]. Small retrospective reports of short-term stenting (<2 weeks) demonstrate improvements in clinical and biochemical parameters for 83% of patients, without reintervention at 1 year for 80% of patients [29,38]. Randomized controlled trials comparing short-term stenting versus balloon dilatation are underway with results pending. Currently, both European and American guidelines recommend that stricture dilatation alone be undertaken as the treatment of choice for dominant strictures [35].

It should be noted that rates of ERCP-related adverse events are higher among PSC patients than non-PSC patients, reported at 7% to 18% and 3% to 11%, respectively [29]. Some authors attribute this difference to the complexity of the patient's disease, resulting in prolonged ERCP procedures and increased number of required intraprocedural maneuvers [29].

Stent Options
As with other benign biliary strictures, polymeric temporary stents (aka plastic stents) remain the mainstay of endoscopic therapy when stenting is desired. SEMS were an attractive alternative for management of benign strictures because of their larger diameters and radial expansion. In theory, they should provide continuous centrifugal dilatation with improved resolution of a stenosis. However, in practice, these stents are less desirable in the treatment of benign diseases as they induce tissue hyperplasia with subsequent tissue ingrowth and occlusion [11]. In answer to this problem, covered SEMS were introduced. These provide the same benefits of a bare SEMS; in addition, the presence of a silicone coating allows for their endoscopic removal, making them more attractive for benign disease. However, this same silicone coating increases the risk of stent migration [11]. Additionally, increased rates of cholecystitis and pancreatitis are noted to follow the placement of covered metallic stents compared with plastic stents [40].

Surgery
Ahrendt et al [41] retrospectively compared the results of surgical resection versus nonoperative management of dominant strictures in 146 PSC patients. This study showed the greatest decline in serum bilirubin and overall 5-year survival in those patients undergoing resection as compared to percutaneous or endoscopic treatment. They concluded that surgical resection provides a durable result in well-selected patients. More recent data supports surgical extrahepatic biliary resection, including the hepatic duct bifurcation in the explant, as an alternative to transplantation in patients without cirrhosis. Pawlik et al [42] reported on 50 patients who underwent resection, none of whom subsequently developed cholangiocarcinoma over a 10-year follow-up period, in which the historical risk of cholangiocarcinoma was 6% to 20% usually within the first 2 years of diagnosis. This success is thought to be the result of the inclusion of the hepatic duct bifurcation in the resected tree, as transplant data have shown that 70% of cancers are incidentally found at the bifurcation in the explant [43].

Variant 3: Initial therapeutic procedure for a liver transplant recipient with elevated bilirubin and suspected biliary anastomotic stenosis or bile leak, with no dilated ducts.

Biliary complications following orthotropic liver transplantation (OLT) are an important cause of graft loss and are associated with significant morbidity and mortality. The incidence of biliary complications is between 17% and 25%, over half of which are caused by biliary strictures [44,45]. Bile ducts in the transplanted liver are extremely sensitive to injury and can manifest as anastomotic strictures, nonanastomotic strictures, anastomotic leak, and biliary obstruction. Each complication is unique in its timing in the postoperative period and optimal management.

Bile Leaks—Endoscopic versus Percutaneous Treatment
Bile leaks occur in 5% to 15% of OLTs, usually within 1 month of transplant, as a result of technical problems or insufficient arterial bile duct vascularization [46]. Late bile leaks are most often related to T-tube removal, which is reported in approximately 1% of cases [46,47]. Smaller leaks may be successfully treated with endoscopic sphincterotomy or percutaneous drainage of a biloma; however, endoscopic stents are required for larger leaks with short-term follow-up and removal [48]. In the case of failed endoscopic approach or hepaticojejunostoic anastomosis, a transhepatic percutaneous approach with internal-external drainage is highly effective but can be technically challenging in the absence of ductal dilatation [46].

Biliary Strictures—Endoscopic versus Percutaneous Treatment
Biliary strictures are generally considered late complications, occurring within 6 months of transplantation [46]. An anastomotic biliary stricture, as the name implies, involves an anastomotic site and is thus isolated. Dilation of the narrowed portion of the duct either endoscopically or percutaneously has largely replaced surgery because of the lower morbidity and mortality rates [49], with the endoscopic approach being favored when feasible because of reduced morbidity and better patient comfort [46]. Endoscopic sphincterotomy, balloon dilatation, and plastic stent placement has a reported success rate of approximately 75% [46,50].

A recent meta-analysis evaluated outcomes of endoscopic intervention for biliary anastomotic strictures after liver transplant using balloon dilatation alone versus balloon dilatation with insertion of a plastic stent. The incidence of initial treatment failure was lower with balloon dilatation alone (5%) than with balloon dilatation with plastic stent (8%). However, this meta-analysis also found that the rate of stricture recurrence was higher when initial treatment was with balloon dilatation alone versus balloon dilatation and stent placement (33% versus 27%) [51].

A randomized clinical trial comparing fully covered metal stents (n = 10) versus plastic stents (n = 10) for anastomotic strictures after liver transplantation found similar rates of successful endoscopic treatment and stricture recurrence but a 40% reduction in absolute risk of endoscopic therapy in the metal stent group compared with the plastic stent group [52]. This study was limited by the small number of enrolled patients.

There are instances in which the postsurgical anatomy may be difficult for endoscopic treatment. Such instances include a "crane neck deformity" in which the size discrepancy in the CBD of the donor and recipient results in a sharp angulation at the anastomosis [53,54]. When leaks occur in conjunction with strictures, difficulty can arise when attempting to cross the stenosis endoscopically as the guidewire may preferentially slip into the discontinuity [54]. In these settings, a percutaneous approach is appropriate.

Several techniques to dilate the biliary stricture using a percutaneous technique have been described. These include placement of an internal-external biliary drain with sequential upsizing, stenting via the percutaneous route, and a rendezvous technique. The latter minimizes the need for percutaneous tract dilatation [54,55].

One author reported a technical success rate of ERCP in post-transplant patients of 75%, with the majority of these patients successfully treated with a percutaneous approach. They reported 9% of patients failed both ERCP and percutaneous transhepatic biliary dilatation. These patients required hepaticojejunostomy [56].

Early reports of percutaneous treatment of anastomotic biliary strictures had varied results with recurrent strictures occurring in 16% to 44% of cases [49]. More recently, Gwon et al [49] described a dual catheter technique for percutaneous dilatation of anastomotic strictures in 79 patients with a reported primary patency of 91% at 3 years.

Surgery
Patients with anastomotic bile leaks and biliary strictures refractory to endoscopic or percutaneous treatment may be candidates for surgical revision. In addition, nonanastomotic or diffuse biliary strictures have a more guarded

prognosis resulting from ischemic events. While medical therapies with ursodeoxycholic acid and antibiotic prophylactics and long-term stenting of ducts are described, these patients often require retransplantation [46,57,58]. Independent of the underlying etiology, early diagnosis and intervention following OLT increases patient survival [59].

Variant 4: Initial therapeutic procedure for a patient with bile leak and dilated bile ducts following laparoscopic cholecystectomy.

Bile duct injuries occur in approximately 0.5% of patients annually after laparoscopic cholecystectomy [60,61], leading to high morbidity and mortality, reduced long-term survival, and impaired quality of life [60,61]. Approximately 25% to 32% of bile duct injuries are recognized at the time of initial surgery [62]; however, the majority of biliary injuries go unrecognized at the time of cholecystectomy, only to manifest days, months, or years later [61].

Once identified, the management of iatrogenic bile duct injury will be largely dependent on the type, extent, and level of injury that has occurred, the patient's condition, and availability of experienced hepatobiliary surgeons. For this document, it is assumed all procedures are performed by an expert. Several classification schemes exist to aid in management. The Bismuth Classification [63] is an early system based on experience with open cholecystectomy, whereas Strasberg et al [64] took laparoscopy into consideration. A more recent classification offered by Bektas et al [65] gives greater detail of each lesion with better correlation between injury and management.

Acute Biliary Injury–Endoscopic versus Percutaneous Treatment
Damage to small peripheral ductal branches or the cystic duct stump can be definitively treated with endoscopic placement of a biliary stent or sphincterotomy to reduce intraductal pressure and divert the flow of bile away from the injured duct [61,62,66]. This approach has a reported efficacy of 80% to 100%, with favorable long-term outcomes [62,66]. In cases when endoscopic biliary stent placement fails or is not feasible, placement of a percutaneous internal or external biliary drain is efficacious [61].

Injuries to the larger right/left hepatic duct or sectoral duct are rarely amenable to endoscopic treatments; however, successful endoscopic treatment of these lesions has been reported [66]. Targeted percutaneous drainage of the involved hepatic sector will allow for immediate control of biliary leakage. If technically feasible, an internal/external biliary drain should be placed for appropriate biliary diversion. In cases when the injured duct cannot be crossed, an external drain can be placed with the tip positioned immediately proximal to the site of injury, thus providing the surgeon a palpable landmark at the time of surgery [61].

Acute Biliary Injury—Surgery
Surgical repair of iatrogenic bile injury, when feasible, has better long-term outcomes as compared to percutaneous and endoscopic treatment [67-69]. The timing of surgical repair when presenting after the initial surgery is the subject of debate. Arguments in favor of delayed surgical repair include allowing the patient to improve clinically, allowing inflammation to subside, and allowing sufficient time for the full extent of changes to manifest [69]. These patients often require endoscopic or percutaneous management in the interim.

Delayed Complications–Endoscopic versus Percutaneous Treatment
Late biliary complications manifest as biliary strictures, liver atrophy, cholangitis, and intrahepatic lithiasis [67]. Biliary strictures, the most common late complication, can present as jaundice, intrahepatic lithiasis, cholangitis, or intrahepatic abscess formation [67]. These strictures can develop anywhere from 6 weeks to 15 years after the initial insult [67]. Endoscopic biliary stricture dilatation with stent placement is reported to be highly successful (68%–90%); however, recurrent stenosis after stent removal has been observed in up to 20% of patients [66,70]. Traditionally, plastic stents have been utilized in this setting, but the successful use of covered stents has been described recently [71].

Similar to patients with iatrogenic bile leaks, percutaneous biliary drainage is indicated in those patients in whom endoscopic approaches fail or are not feasible. Definitive management with a percutaneous approach requires biliary-enteric continuity [68]. Balloon dilatation of the stricture can be initiated at the time of initial percutaneous access, though it is generally advisable to wait 2 to 4 weeks after the initial access [69]. Because recoil is often seen after balloon dilation, large caliber catheters should be used to maintain the patency of the duct and determine the minimum diameter for scarring after dilatation [69]. There is no consensus for the duration of

catheter indwell time after dilatation; however, studies have shown improved patency with stenting for >6 months compared with <4 months without stenting [68,69].

Delayed Complications—Surgery
As with other methods, restenosis can occur after percutaneous dilatation. In a comparison of surgical versus percutaneous therapy, overall patency of 58.8% at 76 months after percutaneous treatment and 94% at 57.7 months after surgical management was reported [68].

Variant 5: Initial therapeutic procedure for a patient with dilated bile ducts and suspected biliary sepsis or acute cholangitis.

Medical Management
Acute cholangitis is characterized by fever, jaundice, and abdominal pain in the setting of biliary stasis and infection, with the most important predisposing factor being biliary obstruction. Experimental and clinical models demonstrate that cholangitis is not produced without obstruction [72]. As such, in addition to best medical management with antibiotics, fluids, and correction of coagulopathies, establishing successful biliary drainage is critical in the treatment of biliary sepsis [73].

In patients presenting with acute cholangitis, timely initiation of antimicrobial therapy is key to improving survival. For patients presenting with sepsis, appropriate antibiotics should be initiated within 1 hour of diagnosis. In less severe cases, appropriate antibiotics should be administered within 6 hours of diagnosis [74]. While drainage of the obstructed bile ducts remains the mainstay of therapy, many patients can undergo elective drainage procedures rather than emergent procedures [75,76].

A large, multicenter international observational study was recently published on the epidemiology and microbiology of patients with acute cholangitis. This study found that the most frequently isolated organism was *Escherichia coli*, irrespective of severity at presentation [74]. The newly updated Tokyo Guidelines 2018 (TG18) provide recommendations for the appropriate antimicrobials for acute cholangitis [74].

Biliary Decompression
Timing of biliary decompression is dictated by the severity of acute cholangitis. The Tokyo Guidelines set forth a grading system to stratify severity and guide the timing of intervention. Severe (grade 3) acute cholangitis requires urgent decompression, whereas moderate (grade 2) acute cholangitis requires early decompression, and mild (grade 1) acute cholangitis can be initially observed on medical treatment. A multicenter case series evaluated the benefit of early biliary drainage (defined as <24 hours after admission) on the 30-day mortality of patients presenting with acute cholangitis. The study found significantly lower 30-day mortality in grade 2 acute cholangitis treated with early biliary drainage as compared to those who had more delayed drainage. No significant difference was seen in patients presenting with grade 1 or grade 3 acute cholangitis. The authors note that an improved outcome may be seen in grade 3 acute cholangitis if biliary drainage is performed at an even earlier stage; however, additional studies are needed [77]. Another study demonstrated that hospital stays for patients treated with biliary drainage within 24 hours of hospital admission were shorter, irrespective of severity [78].

Endoscopic Biliary Drainage
An important nuance to patients with severe biliary sepsis is a focus on biliary decompression rather than definitive treatment of the obstruction with the least manipulation of the biliary tree as possible [77]. ERCP with stent placement is the procedure of choice for biliary decompression. This is based on several studies demonstrating ERCP to be the safest and most effective method compared with a percutaneous transhepatic biliary drain (PTBD) or surgery [79,80]. Endoscopic transpapillary biliary drainage is the recommended first-line procedure for biliary drainage by the TG18, citing lower risk of adverse events and less invasiveness than percutaneous drainage or surgical drainage [81]. Open surgical drainage is currently extremely rare because of the widespread use of endoscopic or percutaneous techniques [81].

While endoscopic biliary drainage is considered the safest method of biliary decompression, it is not without complications. ERCP-related pancreatitis is the most common serious complication, with an incidence of approximately 3.5% but ranges widely (1.6%–15.7%), depending on patient selection [82,83]. A meta-analysis of 21 prospective trials reported the rate of ERCP-related hemorrhagic complications was 1.3% (95% CI, 1.2%–1.5%), with 70% of these episodes classified as mild [82]. Post-ERCP cholangitis occurs after less than 1% of

procedures [84]. Other stent-related complications include stent migration, stent occlusion, perforation, and injury to the bile duct [85].

Percutaneous Biliary Drainage
PTBD is a second-line procedure and generally reserved for patients who have failed ERCP or who have difficult anatomy. These patients may require temporary placement of an external drain if the obstruction cannot be easily traversed, with intent to convert to an internal/external drain when the acute infection has resolved [69]. Similarly, injection of contrast under pressure should be avoided as this may lead to cholangio-venous reflux and exacerbate the septicemia [77].

Endoscopic US-Guided Biliary Drainage
A newer technique developed as an alternative to endoscopic internal stent placement and percutaneous internal/external stent placement is therapeutic EUS-guided biliary drainage (EUS-BD), first reported by Giovannini et al in 2001 [86]. Subsequently, in 2011, a consortium of 40 expert endoscopists met to standardize indications for EUS-BD. They concluded that in the hands of a trained pancreaticobiliary endoscopist with appropriate surgical and radiologic backup, EUS-BD is a reasonable approach to biliary drainage after failed conventional ERCP, altered anatomy, tumor-occluding access to the biliary tree, and contraindications to percutaneous access [87]. Minaga et al [88] reported a small series of patients with acute obstructive suppurative cholangitis who were successfully treated with urgent biliary decompression using EUS-BD. While reports such as these are promising, experience and procedure-specific tools remain limited, leaving the vast majority of patients treated with more traditional endoscopic and percutaneous techniques. For this document, it is assumed all procedures are performed by an expert.

Variant 6: Initial therapeutic procedure for a patient with malignant common bile duct obstruction (eg, pancreatic carcinoma).

Medical Management versus Decompression
Malignant biliary obstruction often presents with yellowing of the skin and sclera, darkening of the urine, and acholic stools. Patients may also present with pruritus, which can manifest out of proportion to serum bilirubin levels and significantly impair a patient's quality of life. Once identified, malignant biliary obstruction is broadly divided into 2 groups, distal biliary obstruction and hilar obstruction, with the former being the focus of this discussion and the latter discussed in Variant 7. Each group carries with it clinical considerations impacting the approach to effective biliary decompression to assist in symptoms management and improvement of overall prognosis [89]. Even in the palliative setting, decompression of an obstructive biliary system is preferred, if feasible, over medical management of resulting symptoms as it has been shown to improve overall quality of life [89].

Important causes of distal malignant biliary obstruction include pancreatic cancer, distal cholangiocarcinoma, ampullary cancer, and, less commonly, gallbladder cancer and metastasis [90]. Methods for palliative biliary drainage include surgical drainage, percutaneous transhepatic drainage, and endoscopic transpapillary drainage. On the other hand, there is an ongoing debate on whether preoperative biliary drainage is necessary in the setting of a resectable tumor [91-94].

Endoscopic Biliary Drainage
Endoscopic biliary drainage is the preferred first-line approach as it is minimally invasive and preserves the patient's quality of life [89]. Current controversy exists as to the most appropriate method to achieve successful and lasting endoscopic biliary drainage. Options to achieve endoscopic drainage include plastic stents, uncovered metallic stents, and covered metallic stents.

Plastic stents are the oldest device available for biliary drainage. They have little risk of migration and have reported successful deployment rates of 85.2% to 100% [89]. However, patency rates beyond 3 months are poor, requiring maintenance exchanges to ensure continued adequate ductal drainage [89,90]. The use of plastic stents may be preferable in cases of obstructive lesions that may respond to chemotherapy or radiotherapy (eg, lymphoma) or in patients whose histological diagnosis has yet to be made.

Stent Options
In patients with a projected survival >4 months and requiring long-term biliary stenting, a meta-analysis favors placement of a metal stent [95]. In a randomized controlled trial evaluating stent patency, Mukai et al [96] reported that the 6-month patency is significantly higher for metallic stents (81%) than plastic stents (20%).

Additionally, patients receiving the metallic stent had fewer reinterventions [96]. Furthermore, despite earlier concerns from surgeons regarding metal stent placement in patients with planned pancreaticoduodenectomy, more recent reports demonstrate they should not interfere with the surgery when not involving the hilum [97].

With regards to selection of a covered or uncovered self-expanding metallic stent, there are several considerations. The main mechanism of occlusion for metallic stents is tumor ingrowth between the stent interstices, or tumor overgrowth, which results in the blockage of either the proximal or distal end of the stent [90]. Covered metallic stents were introduced in hopes of prolonging patency. Additionally, while uncovered metallic stents cannot be removed once deployed, covered metallic stents have the advantage of being removable. Studies comparing the patency of a covered versus an uncovered metallic stent have demonstrated mixed results [90,98,99]. Krokidis et al [98] compared the clinical effectiveness of covered stents with uncovered stents for palliation of malignant jaundice in setting of pancreatic head cancer. They reported significantly increased primary patency and reduced tumor ingrowth in the covered stent group. Conversely, a randomized multicenter study of 400 patients with distal malignant biliary obstructions found no significant differences in stent patency time between covered and uncovered stents [99]. The frequency of stent migration is much higher with covered metallic stents as compared to uncovered metallic stents [90]. More novel stent options, including drug-eluting or dissolving stents, are also under investigation [100-103].

Endoscopic US-Guided Biliary Drainage
EUS-BD placement is becoming more widely accepted as an alternative to a percutaneous approach in the hands of skilled endoscopists. While early reports of EUS-BD demonstrated adverse event rates up to 20%, more recent reports have shown adverse event rates as low as 11%, suggesting improved outcomes with experience [104-106]. The first prospective, randomized trial comparing EUS-BD via a transluminal approach (choledochoduodenostomy) to PTBD in a small cohort of 25 patients demonstrated a similar success rate and complication rate between the 2 methods [107]. However, this is a technically demanding procedure offered only in limited expert centers [108]. For this document, it is assumed the procedure is performed by an expert.

Percutaneous Biliary Drainage
In cases when endoscopic biliary drainage is not feasible or has failed, a PTBD is the procedure of choice. A meta-analysis comparing percutaneous versus endoscopic biliary drainage demonstrated no significant difference with regards to mortality, complications, or therapeutic response rates, making percutaneous biliary drainage a validated second-line therapy in these patients [109]. Alternatively, in patients who would otherwise be a candidate for endoscopic internal metallic stent placement, percutaneous placement of self-expanding stent placement has demonstrated safety and effectiveness similar to their endoscopically placed counterparts [110-112].

Surgery
Surgical bypass has a low rate of recurrent jaundice (2% to 5%); however, the surgery itself carries with it high morbidity and mortality [113]. Some authors have advocated for surgical decompression in the case of a patient with a long projected survival despite inoperable tumor or at the time of laparotomy when a planned tumor resection is discovered to be unresectable, as a surgical decompression offers longer decompression without need for frequent reintervention [114]. However, a meta-analysis comparing surgical bypass versus endoscopic stenting found similar success rates for each approach but better outcomes after endoscopy with less mortality and fewer complications [115]. Anastomotic biliary strictures following pancreatoduodenectomy can be either benign or malignant. A retrospective review of over 1,500 patients found that anastomotic strictures occurred in 2.6% of patients and that the median time to stricture was 13 months [116]. In this study, all patients were managed successfully with percutaneous drainage.

Variant 7: Initial therapeutic procedure for a patient with hilar biliary obstruction from malignant etiology (eg, Klatskin tumor).

Medical Management versus Decompression
Malignant obstruction involving the hilar and perihilar regions is generally secondary to cholangiocarcinoma (Klatskin tumors) or extension of gallbladder carcinoma. There is a regional bias in the initial approach to biliary drainage of these patients. In Japan and China, the method of choice is percutaneous biliary drainage [117]. In contrast, North American and European nations favor endoscopic biliary drainage in the setting of a hilar obstruction [118,119]. As discussed previously in Variant 6, even in the palliative setting, decompression of an

obstructive biliary system is preferred, if feasible, over medical management of resulting symptoms as it has been shown to improve overall quality of life [89].

Endoscopic versus Percutaneous Biliary Drainage

A randomized trial examining percutaneous biliary drainage versus endoscopic drainage using plastic stents, demonstrated both lower complications (18% versus 52%, P = .04) and higher therapeutic success (89% versus 41%, P < .001) in the percutaneous arm [120]. A subsequent retrospective evaluation of percutaneous versus endoscopic placement of SEMS for palliative biliary drainage in the setting of hilar cholangiocarcinoma favored the percutaneous approach given its higher initial success rate [121]. Patients in whom biliary drainage was successful initially, regardless of the technique, had a significantly longer median survival as compared to those who failed an initial attempt for biliary drainage (8.7 months versus 1.8 months, P < .001) [121]. Several studies have demonstrated high conversion rates from endoscopic to percutaneous drainage in patients with Klatskin tumors; however, none reported conversion in the opposite direction [118,122]. Kloek et al [119] demonstrated shorter time to adequate therapeutic drainage among patients drained via percutaneous drainage when compared to endoscopic drainage (11 weeks versus 15 weeks, P = .033).

Endoscopic US-Guided Biliary Drainage

In patients with a strong preference for internal drainage, several case reports demonstrate the feasibility of EUS-BD [123-126]. This can be accomplished via a transgastric or transduodenal approach [123-126]. This remains a novel approach, requiring a high level of technical expertise, thus offered in few larger tertiary centers. For this document, it is assumed all procedures are performed by an expert.

Variant 8: Initial therapeutic procedure for a patient with dilated bile ducts and coagulopathy (INR >2.0 or platelet count <60 K).

Endoscopic Biliary Drainage

Abnormal coagulation is not uncommon in patients with malignant obstructive jaundice and is often the result of multiple factors, including underlying liver disease, vitamin K deficiency, chemotherapy, and systemic inflammation [127]. Endoscopic biliary drainage is the procedure of choice in patients with coagulopathy given the lower associated risk of bleeding [81]. The bleeding risk associated with therapeutic ERCP is largely associated with biliary sphincterotomy, with a reported rate of 1% to 2% [128]. Alternative endoscopic approaches, such as balloon sphincteroplasty, can be performed in patients with coagulopathy when reversal is difficult or contraindicated [128]. When a stent is placed endoscopically, stent choice will be dictated by the patient's underlying pathology.

Percutaneous Biliary Drainage

PTBD is generally the second-line option for biliary decompression when ERCP has failed or is not possible. While overall PTBD is a safe procedure with high technical success, it is associated with bleeding complications in approximately 2.5% of cases [81,129]. In the presence of coagulopathy, this risk is higher; thus, PTBD is contraindicated in a patient with an uncorrected coagulopathy [129]. Several case reports and small series discuss transjugular insertion of a bare metal biliary stent in patients with malignant obstructive jaundice and uncorrected coagulopathy who are not able to have stent placement endoscopically [130]. The benefit of this approach is biliary decompression without violation of the liver capsule, the most common source of bleeding with the percutaneous approach [130].

Variant 9: Initial therapeutic procedure for a patient with dilated bile ducts and moderate to massive ascites.

Medical Management Prior to Biliary Drainage

Moderate to massive ascites is a relative contraindication for PTBD. Initial access into the ducts can be technically more challenging because of frequent buckling of catheters between the liver and abdominal wall [131]. Despite the additional challenges, placement of the catheter is usually successful. However, once in place, bleeding and bile leakage leading to increased blood loss and bile peritonitis is not insignificant [131-133]. This said, most patients do well, with little risk of increased complication if the ascites are drained immediately prior to the procedure [131]. Some authors advocate for placing a peritoneal pigtail to minimize ascites accumulation until a tract can mature [132]. Optimal medical therapy to manage ascites accumulation both before and after placement of the biliary tube will assist in minimizing these risks.

Endoscopic versus Percutaneous Biliary Drainage

Given the potential risks associated with percutaneous access into the biliary tree in the setting of massive ascites, an endoscopic approach is strongly preferred in these patients. In the event that an endoscopic approach is not feasible or has failed, percutaneous primary metallic biliary stenting with tract embolization is feasible with a reported clinical success rate of 87.5% in one series [133].

Endoscopic US-Guided Biliary Drainage

Alternatively, the development of EUS-BD has demonstrated promising results in patients who fail endoscopic stent placement and have relative contraindications to PTBD, such as in the case of ascites [134,135]. Although this approach may offer access to the biliary ducts in patients whose anatomy precludes routine endoscopic placement of drainage catheters/stents via the ampulla of Vater, it requires a higher level of endoscopic skills and experience not routinely seen outside of large academic hospitals or major tertiary care centers. For this document, it is assumed all procedures are performed by an expert. This technique may provide an important alternative to percutaneous drainage catheters; however, further studies are needed [134,135]. Surgical biliary decompression is generally reserved in cases when alternative options have been exhausted. Surgical biliary decompression is associated with 9% to 67% morbidity and up to 3% mortality in the postoperative period [135].

Summary of Recommendations

- **Variant 1:** An endoscopic internal biliary catheter with a removable plastic stent is usually appropriate as an initial therapeutic procedure for patients with dilated bile ducts from choledocholithiasis.

- **Variant 2:** An endoscopic internal biliary catheter with a removable plastic stent is usually appropriate as an initial therapeutic procedure for patients with elevated bilirubin and suspected sclerosing cholangitis.

- **Variant 3:** An endoscopic internal biliary catheter with a removable plastic stent or a percutaneous internal/external biliary catheter is usually appropriate as the initial therapeutic procedure for a liver transplant recipient with elevated bilirubin and suspected biliary anastomotic stenosis or bile leak with no dilated ducts. Either procedure may be appropriate depending on the patient's anatomy and availability of resources and institutional preferences.

- **Variant 4:** An endoscopic internal biliary catheter with a removable plastic stent or a percutaneous internal/external biliary catheter is usually appropriate as the initial therapeutic procedure for a patient with bile leak and dilated bile ducts following laparoscopic cholecystectomy. Either procedure may be appropriate depending on the patient's anatomy and availability of resources and institutional preferences.

- **Variant 5:** An endoscopic internal biliary catheter with a removable plastic stent or a percutaneous internal/external biliary catheter is usually appropriate as the initial therapeutic procedure for a patient with dilated bile ducts and suspected biliary sepsis or acute cholangitis. Either procedure may be appropriate depending on the patient's anatomy and availability of resources and institutional preferences.

- **Variant 6:** An endoscopic internal biliary catheter with a removable plastic stent or a percutaneous internal/external biliary catheter is usually appropriate as the initial therapeutic procedure for a patient with malignant common bile duct obstruction (eg, pancreatic carcinoma). More often, an endoscopic procedure is the first-line procedure in this case, but occasionally a percutaneous procedure may be used depending on the patient's anatomy.

- **Variant 7:** A percutaneous internal/external biliary catheter is usually appropriate as an initial therapeutic procedure for patients with hilar biliary obstruction from malignant etiology (eg, Klatskin tumor).

- **Variant 8:** An endoscopic internal biliary catheter with a removable plastic stent is usually appropriate as an initial therapeutic procedure for patients with dilated bile ducts and coagulopathy (INR >2.0 or platelet count <60 K).

- **Variant 9:** An endoscopic internal biliary catheter with a removable plastic stent is usually appropriate as an initial therapeutic procedure for patients with dilated bile ducts and moderate to massive ascites.

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at https://acsearch.acr.org/list. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

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