American College of Radiology
ACR Appropriateness Criteria®

Clinical Condition: **Radiologic Management of Benign and Malignant Biliary Obstruction**

Variant 1: **Initial therapeutic procedure for a patient with dilated bile ducts from benign biliary obstruction (eg, choledocholithiasis).**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	6	Most appropriate whenever endoscopic treatment is unsuccessful.
Surgery (transplant or hepaticojejunostomy)	2	
Medical management only	2	
Permanent biliary metallic stent	1	
Removable biliary covered stent	4	If the case involves a benign, postinflammatory stricture.
Endosonography-guided biliary drainage (ESBD)	4	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

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

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	6	Depends on location and extent of stricture formation.
Surgery (transplant or hepaticojejunostomy)	2	Surgery rarely indicated except in cases of endoscopic and percutaneous failure.
Medical management only	6	
Permanent biliary metallic stent	1	
Removable biliary covered stent	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 3: **Initial therapeutic procedure for a patient with malignant common bile duct obstruction (eg, pancreatic carcinoma).**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	7	
Surgery (transplant or hepaticojejunostomy)	5	May be appropriate in some cases; however, must be individualized based on patient's comorbidities and likelihood of cure.
Medical management only	3	May be palliative care in a terminal patient.
Permanent biliary metallic stent	5	
Removable biliary covered stent	5	
Endosonography-guided biliary drainage (ESBD)	4	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Clinical Condition: **Radiologic Management of Benign and Malignant Biliary Obstruction**

Variant 4: **Initial therapeutic procedure for a patient with hilar biliary obstruction from malignant etiology (eg, Klatskin tumor).**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	6	
Percutaneous internal/external biliary catheter	8	
Surgery (transplant or hepaticojejunostomy)	5	May be appropriate in some cases; however, must be individualized based on patient's comorbidities and likelihood of cure.
Medical management only	2	
Permanent biliary metallic stent	6	
Removable biliary covered stent	5	
Endosonography-guided biliary drainage (ESBD)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 5: **Initial therapeutic procedure for a patient with elevated bilirubin and dilated bile ducts from unknown etiology.**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	7	Most appropriate whenever endoscopic treatment is unsuccessful.
Surgery (transplant or hepaticojejunostomy)	2	
Medical management only	2	
Permanent biliary metallic stent	1	
Removable biliary covered stent	3	
Endosonography-guided biliary drainage (ESBD)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 6: **Initial therapeutic procedure for a patient with dilated bile ducts and coagulopathy (INR >2.0 and/or platelet count <60 K).**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	6	Most appropriate whenever endoscopic treatment is unsuccessful and after attempting to correct coagulopathy.
Surgery (transplant or hepaticojejunostomy)	2	
Medical management only	4	
Permanent biliary metallic stent	1	
Removable biliary covered stent	2	
Endosonography-guided biliary drainage (ESBD)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Clinical Condition: **Radiologic Management of Benign and Malignant Biliary Obstruction**

Variant 7: **Initial therapeutic procedure for a patient with dilated bile ducts and moderate to massive ascites.**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	5	Most appropriate whenever endoscopic treatment is unsuccessful and after drainage of ascites.
Surgery (transplant or hepaticojejunostomy)	2	
Medical management only	4	Manage ascites prior to therapeutic intervention.
Permanent biliary metallic stent	2	
Removable biliary covered stent	4	
Endosonography-guided biliary drainage (ESBD)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 8: **Initial therapeutic procedure for a patient with dilated bile ducts and suspected biliary sepsis/acute cholangitis.**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	8	
Surgery (transplant or hepaticojejunostomy)	2	
Medical management only	2	
Permanent biliary metallic stent	1	
Removable biliary covered stent	2	
Endosonography-guided biliary drainage (ESBD)	4	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 9: **Initial therapeutic procedure for a liver transplant recipient with elevated bilirubin and suspected biliary anastomotic stenosis and/or bile leak, with no dilated ducts.**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	Individualize based on local expertise and patient anatomy.
Percutaneous internal/external biliary catheter	8	
Surgery (transplant or hepaticojejunostomy)	3	Typically not appropriate as the initial treatment. However, may be needed as a definitive therapy.
Medical management only	2	
Permanent biliary metallic stent	1	
Removable biliary covered stent	5	Depends on accessibility endoscopically.
Endosonography-guided biliary drainage (ESBD)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Clinical Condition: **Radiologic Management of Benign and Malignant Biliary Obstruction**

Variant 10: **Initial therapeutic procedure for a patient with bile leak and dilated bile ducts following laparoscopic cholecystectomy.**

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	8	Most appropriate whenever endoscopic treatment is unsuccessful and after drainage of ascites.
Surgery (transplant or hepaticojejunostomy)	4	
Medical management only	1	
Permanent biliary metallic stent	1	
Removable biliary covered stent	1	
Endosonography-guided biliary drainage (ESBD)	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

RADIOLOGIC MANAGEMENT OF BENIGN AND MALIGNANT BILIARY OBSTRUCTION

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Summary of Literature Review

Since the late 1970s percutaneous biliary drainage has been used in the management of jaundice caused by malignant and benign biliary obstruction. In the setting of acute cholangitis, percutaneous decompression of an obstructed biliary system can be lifesaving. For patients with cancer who are receiving chemotherapy, untreated obstructive jaundice leads to biochemical derangements that often preclude continuation of therapy unless biliary decompression is performed [1,2]. (See the ACR Appropriateness Criteria® topic on "Jaundice.")

Diagnostic Imaging

Diagnostic studies are used to identify the underlying etiology of clinical jaundice, confirm the presence and extent of a mechanical obstruction, and exclude extrahepatic metastatic disease. Accurate preoperative identification of the location and extent of the underlying cause of the obstructive jaundice is most beneficial in planning surgical or interventional treatment. Noninvasive diagnostic imaging includes ultrasound (US), helical computerized tomography (CT), and magnetic resonance cholangiopancreatography (MRCP) [3-5].

Over the past two decades, CT and US have been the primary imaging tools in the evaluation of bile duct pathology. Preoperative imaging of the liver and surrounding structures has improved the identification of the extrahepatic spread of tumor and invasion of portal vein/hepatic artery, thereby greatly assisting with presurgical planning. With advances in CT technology, helical CT imaging has achieved marked improvement in anatomic detail, providing exceptional imaging of the liver, bile ducts, and periportal area [3]. MRCP provides excellent imaging of bile duct segments, allowing more detailed, three-dimensional imaging of the entire biliary system [6]. As with Klatskin type lesions, MRCP allows visualization of isolated bile duct segments that no longer communicate with the main biliary system and may not be visualized with either percutaneous transhepatic cholangiography (PTC) or endoscopic retrograde cholangiopancreatography (ERCP).

PTC and ERCP are invasive diagnostic procedures and are most often performed during placement of a percutaneous or endoscopic biliary drainage catheter or stent. Since these two procedures gain access to the biliary system, they also may allow further diagnostic tests to be performed (eg, bile cytology, bile duct biopsies, intraductal US, and PTC) [7,8].

Endoscopic versus Percutaneous Drainage

With the availability of percutaneous, endoscopic, and surgical approaches, the selection of the most appropriate modality with which to provide biliary drainage will largely depend on the interventional options available to the patient at the time of presentation. For those who are not surgical candidates due to nonresectability of disease or to comorbidities, the choice of percutaneous versus endoscopic route may largely depend on the location and extent of the obstructing lesion in addition to the expertise of the operator.

In recent years, endoscopic retrograde biliary drainage (ERBD) has overtaken percutaneous transhepatic biliary drainage (PTBD) as the initial procedure of choice in patients with distal bile duct obstruction. Much of this trend

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can be attributed to the availability of trained gastroenterologists at most institutions and to reported lower complication rates with ERBD [9,10]. In contrast, some authors have recommended that patients with hilar neoplasm (Klatskin tumor) may be better managed by a percutaneous approach. These publications note that ERBD too often provides ineffective drainage of isolated bile duct segments that become opacified during ERCP and as a result develop biliary sepsis [11-14].

Contraindications to PTBD are relatively few but might include severe coagulopathy or ascites [15]. Absolute contraindications to ERBD would include pharyngeal or esophageal obstruction or active coagulopathy. Relative contraindications to ERBD might include acute pancreatitis, severe cardiopulmonary disease, and previous Roux-en-Y surgery [16].

The use of endoscopic US to guide ERBD in patients with difficult anatomy and/or after failed attempts at endoscopic cannulation of the ampulla of Vater has been described in recent literature [17-20]. Studies have described the successful placement of biliary drainage catheters using the transgastric [17] or transduodenal approach [18]. 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, this approach requires a higher level of endoscopic skills and experience not routinely seen outside of major medical centers and teaching facilities. Although this technique may provide an important alternative to percutaneous drainage catheters, further well-conducted studies are needed.

Preoperative Biliary Drainage

Percutaneous and endoscopic biliary decompression prior to surgery has been performed for many years. When surgery is delayed, percutaneous or endoscopic drainage of an obstructed biliary system not only relieves the associated symptoms of jaundice (eg, nausea, pruitis) but also helps to correct the biochemical derangements caused by prolonged biliary obstruction. Preoperative drainage allows time for surgical planning, detailed imaging, and proper laboratory testing. Correction of nutritional and biochemical derangements prior to surgery may result in improved surgical outcomes [21-24].

The surgical and clinical benefits of preoperative biliary drainage, however, remain questionable, and its benefits have been widely debated. External biliary drainage alone does not allow the bile salts to return to the gastrointestinal system, thereby potentially causing severe metabolic alterations. Early randomized trials assessing the benefits of preoperative external biliary drainage failed to demonstrate any reduction in surgical morbidity [25-27]. In contrast, internal biliary drainage, by alleviating cholestasis without loss of bile salts, has been shown to improve postoperative results [28]. In 1987, Lygidakis et al [29] published a prospective randomized study demonstrating the benefits of preoperative internal biliary drainage by reducing surgical mortality rate from 10% to 0% and associated morbidity from 70% to 16%. Other investigators have published trials in support of Lygidakis' findings [30,31]. In contrast, several studies have reported an increase in postoperative complications, especially infection rates, following preoperative biliary drainage [32-36]. The increase in postoperative infections was attributed to the contamination of the sterile bile from direct communication with skin and gut flora following percutaneous and endoscopic drainage. A meta-analysis by Saleh et al [37] in 2002 failed to show either any positive or adverse effect of preoperative endoscopic stenting prior to pancreaticoduodenectomy. More recent literature has suggested that selective biliary drainage of the remnant liver as opposed to total biliary drainage in conjunction with portal vein embolization prior to an extended hemihepatectomy can significantly promote hypertrophy of the future remnant liver segment [38].

Plastic versus Metal Stents for Malignant Disease

The choice of plastic or metallic stents for the optimal percutaneous or endoscopic palliation of patients with nonresectable malignant biliary obstruction is not clear. Metallic stents have been shown to be more cost-effective, with fewer reinterventions needed when placed in patients with life expectancies of 6-12 months [39,40]. Metallic stents also provide a better quality of life for the terminally ill patient by eliminating the need to care for an external prosthesis [41]. The long-term patency of metallic stents, on the other hand, is not good, with an occlusion rate of 30%-40% by 6 months, and nearly all patients requiring reintervention within a year [42-44].

Although there are no clear data in the literature, the temporary use of plastic stents may be preferable in cases of obstructive lesions that may respond to chemotherapy/radiotherapy (eg, lymphoma), in patients who have hilar lesions with multiple isolated biliary segments, or in patients whose histological diagnosis has yet to be made.

The use of polytetrafluoroethylene (PTFE)-covered self-expandable stents in the treatment of malignant biliary obstruction has been demonstrated to provide better patency rates than metallic noncovered stents and offer the option of removal if occluded. Further studies are needed, as this approach is undergoing preliminary evaluation to identify which patient populations will most benefit [45-48]. The use of drug-eluting or dissolving stents is also under investigation [49-52].

Metal Stenting in Benign Disease

The use of metallic biliary stents for malignant biliary obstruction has been well accepted, especially for inoperatable patients whose life expectancies are 6-12 months. The use of permanent metallic stents to treat benign strictures of the biliary tree (eg, bile duct strictures from chronic pancreatitis, postoperative bilioenteric anastomotic strictures) has been described in the literature but remains highly controversial [53-55]. Some studies have shown very poor clinical results, with short-term patency and a need for extensive surgery to correct the eventual biliary obstruction [56]. To date there is not enough evidence in the literature to support the use of permanent metallic stents to treat benign biliary strictures, especially in cases where surgical revision remains an option, and percutaneous treatment by balloon dilatation and long-term internal/external drainage has proven to be effective and safe [57,58]. The use of covered metal stents in benign biliary disease provides additional options for patients who are not optimal surgical candidates [59-61]. The temporary placement of fully covered metallic stents in benign biliary strictures has been shown to have good results, with 83% resolution of the benign stricture by 3.3 months and an associated complication rate of only 14% [62].

Liver Transplant/Postoperative Dilation

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%, of which over half are caused by biliary stricture [63,64]. Bile ducts in the transplanted liver are extremely sensitive to injury, typically as a result of injury to the hepatic artery; ischemic injury to the bile ducts can manifest as biliary stricture and/or bile leak. It is notable that even in the case of significant obstruction or stricture of the biliary anastomosis, the bile ducts within a transplanted liver often fail to dilate.

The failure rate of PTC is reportedly higher in nondilated systems (35%) as compared to dilated systems (5%) [57]. In a study by Funaki et al [65] of 117 patients, the technical success rate using a 21-gauge needle and an 0.018-inch wire to gain initial access into a nondilated biliary system was 90%, with a major complication rate of only 4%. Following OLT, biliary strictures can be found in two forms: anastomotic and nonanastomatic or diffuse biliary strictures. Anastomotic strictures have a better prognosis and can be treated with percutaneous or endoscopic biliary drainage followed with repeated biliary dilatations. Occasionally, anastomotic strictures will require reoperation. Nonanastomotic or diffuse biliary strictures are multiple and often require retransplanataion [66,67]. Independent of the underlying etiology, early diagnosis and intervention following OLT increase patient survival [68]. The use of endoscopic and/or percutaneous transhepatic therapy has proven to be effective in the management of anastomotic and nonanastomotic strictures and biliary leaks following liver transplantation [69-73].

Complications of Percutaneous Biliary Drainage

Percutaneous biliary drainage is one of the most challenging procedures performed by interventional radiologists. The reported technical success rate of PTC/PTBD is between 90%-95% [57,74-76]. Related periprocedural mortality rates of 0.7% to 8.6% have been reported [57,75]. Drainage-related complications such as hemorrhage (3%-7%), acute sepsis (3%-5%), and pleural transgression (1%-5%) can occur during the placement of the catheter, and delayed complications such as pericatheter bile leak (15%-20%), catheter dislodgement (10%-20%), catheter obstruction with or without cholangitis (47%), and tumor spread along the catheter tract have been described weeks to months following catheter placement [57,76-80].

One of the most frequent complications associated with biliary drainage is cholangitis. It has been reported to occur in up to 47% of patients treated [77]. The pathophysiology behind the development of cholangitis following biliary drainage is complex and has been described in the literature [77,81]. The use of larger catheter size has been shown to reduce the incidence of catheter obstruction and catheter-related cholangitis [82]. The use of choleretics, oral antibiotics, antibiotic-impregnated stents, and frequent biliary catheter exchanges have all been recommended to decrease biliary catheter occlusions and recurrent cholangitis.

Summary

- Endoscopic biliary drainage is generally considered the best initial therapeutic procedure when biliary drainage is necessary.
- PTC for biliary drainage has evolved over the past three decades and has established itself as an important diagnostic tool and treatment modality in the management of patients with malignant and nonmalignant obstructive jaundice.
- The choice between percutaneous (PTC/PTBD), endoscopic, or surgical therapy will greatly depend on the clinical status (comorbidities) of the patient, the etiology and extent of the biliary pathology, and the expertise of the clinical specialist. The choice between percutaneous biliary drainage techniques and endoscopic or surgical techniques will vary from institution to institution depending on operator expertise.
- In nonoperable biliary obstruction, endoscopic drainage is recommended. If it is unavailable or has failed, percutaneous drainage is recommended.
- Although the use of permanent metallic stents in malignant biliary disease is well accepted. Its use in benign disease is not. The temporary use of removable covered stents for benign biliary strictures may play an important role.
- The best therapeutic management of patients with biliary obstruction involves a team approach leveraging the experience and expertise of the primary physician, interventional radiologists, gastroenterologists, and surgeons.

Supporting Documents

- ACR Appropriateness Criteria® Overview
- Evidence Table

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