Endoscopic stenting for malignant biliary obstruction

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INTRODUCTION

Malignant biliary obstruction is a tumor-related stricture or narrowing of the bile ducts. Patients with biliary obstruction from pancreaticobiliary cancers usually present with painless jaundice. There are several options to treat malignant biliary obstruction including medical management, endoscopic stent placement, percutaneous drain placement, and surgery. This topic will review issues related to the use of endoscopic retrograde cholangiopancreatography (ERCP)-guided biliary stenting and drainage to relieve malignant biliary obstruction.

The use of biliary stents for treating nonmalignant disease is discussed separately:

- Primary sclerosing cholangitis (see "Primary sclerosing cholangitis in adults: Management")
- Post-surgical biliary complications (see "Liver transplantation in adults: Endoscopic management of biliary adverse events" and "Endoscopic management of postcholecystectomy biliary complications")

Several professional societies have published guidelines on the management of malignant biliary strictures, and our approach is generally consistent with these guidelines [1-3].

CAUSES

Malignant biliary obstruction may occur at the level of the distal bile duct or at the level of the proximal bile duct/hilum of the liver (figure 1):

- Distal common bile duct obstruction may be caused by pancreatic cancer, cholangiocarcinoma, ampullary tumor extending into the bile duct, or external compression from lymph nodes.
- Proximal bile duct/hilar obstruction may be caused by cholangiocarcinoma (Klatskin tumor), gallbladder carcinoma, local extension of pancreatic cancer, metastases, or compression from lymph nodes.

The management of malignant tumors that may cause biliary obstruction is discussed separately [4]:

- Pancreatic cancer (usually located in the head and uncinate process) (see "Supportive care of the patient with locally advanced or metastatic exocrine pancreatic cancer", section on 'Jaundice' and "Overview of surgery in the treatment of exocrine pancreatic cancer and prognosis", section on 'Preoperative considerations').
- Cholangiocarcinoma (see "Treatment options for locally advanced, unresectable, but nonmetastatic cholangiocarcinoma", section on 'Patients with obstructive jaundice' and "Surgical resection of localized cholangiocarcinoma", section on 'Preoperative assessment').
- Ampullary carcinoma (see "Ampullary carcinoma: Treatment and prognosis").
- Gallbladder cancer (see "Treatment of advanced, unresectable gallbladder cancer").
- Metastatic diseases that infiltrate the common bile duct (eg, breast cancer, hepatocellular carcinoma) (see "The role of local therapies in metastatic breast cancer", section on 'Liver').

INDICATIONS

Palliative biliary drainage — Endoscopic retrograde cholangiopancreatography (ERCP) with palliative biliary stenting is indicated for patients with biliary obstruction from surgically incurable cancer. The goals of biliary decompression are [5]:

- To relieve symptoms of cholestasis (eg, pruritus, jaundice)
- To treat cholangitis, if present
- To optimize medical status prior to chemoradiation therapy (see 'Causes' above)

Preoperative biliary drainage — Placement of a biliary stent prior to surgical resection is generally reserved for patients with resectable tumor who require biliary decompression for any of the following indications [2]:

- Acute cholangitis
- Debilitating symptoms (eg, pruritus)
- Expected delay in surgical intervention, typically >2 weeks (eg, neoadjuvant chemotherapy is planned)

Patients with resectable pancreaticobiliary cancers that result in biliary obstruction are managed by a multidisciplinary team of specialists from surgery, medical oncology, radiation oncology, and advanced endoscopy. Whether endoscopic or transhepatic biliary drainage is required preoperatively is determined by the tumor type (eg, pancreatic, cholangiocarcinoma), tumor location, severity of symptoms, bilirubin level, and surgical timing. These issues are discussed in more detail separately:

- (See "Surgical resection of lesions of the head of the pancreas", section on 'Preoperative biliary drainage'.)
- (See "Initial chemotherapy and radiation for nonmetastatic, locally advanced, unresectable and borderline resectable, exocrine pancreatic cancer".)
- (See "Surgical resection of localized cholangiocarcinoma", section on 'Preoperative biliary decompression'.)
- (See "Ampullary carcinoma: Treatment and prognosis", section on 'Preoperative biliary drainage'.)

CONTRAINDICATIONS

Contraindications to endoscopic stenting for malignant biliary obstruction include:

- Patients who cannot tolerate monitored anesthesia care or general anesthesia. (See "Anesthesia for gastrointestinal endoscopy in adults".)
- Patients who are hemodynamically unstable.
- Patients with gastrointestinal (luminal) obstruction may undergo endoscopy, but the examination is limited to an area proximal to the level of obstruction. (See "Enteral stents for the palliation of malignant gastroduodenal obstruction".)

PREPROCEDURE EVALUATION

The diagnosis of malignant biliary obstruction is often suspected based on presenting symptoms (jaundice), laboratory studies, and cross-sectional imaging (computed tomography [CT] scan, magnetic resonance imaging). Additional evaluation prior to stent placement includes tissue sampling during endoscopic retrograde cholangiopancreatography (ERCP) or endoscopic ultrasound. (See "Clinical manifestations and diagnosis of cholangiocarcinoma".)

ERCP WITH BILIARY STENT PLACEMENT

Patient preparation — The preprocedure preparation for patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) with stent placement is similar to that described for patients undergoing ERCP for other indications (see "Overview of endoscopic retrograde cholangiopancreatography (ERCP) in adults", section on 'Patient preparation'):

- Adjusting medications – Most patients do not need to discontinue aspirin or nonsteroidal anti-inflammatories when undergoing ERCP. The management of antiplatelet and anticoagulant therapy is typically individualized, managed in conjunction with the prescribing subspecialist, and discussed separately. (See "Management of antiplatelet agents in patients undergoing endoscopic procedures" and "Management of anticoagulants in patients undergoing endoscopic procedures" and "Gastrointestinal endoscopy in patients with disorders of hemostasis".)

- Antibiotic prophylaxis – Prophylactic antibiotics are given to patients with biliary obstruction who are at risk for incomplete drainage (eg, patients with malignant hilar obstruction) (table 1). (See "Antibiotic prophylaxis for gastrointestinal endoscopic procedures".)

  For patients with cholangitis, antibiotics are required as part of their routine care; thus, additional prophylactic antibiotics are not needed for such patients. (See "Acute cholangitis: Clinical manifestations, diagnosis, and management".)

- Anesthesia – The procedure is typically performed using monitored anesthesia care or general anesthesia. Anesthetic management for endoscopic procedures including preprocedure fasting is discussed separately. (See "Anesthesia for gastrointestinal endoscopy in adults".)

Types of biliary stents

Metal stents — For patients with malignant biliary obstruction undergoing ERCP, self-expandable metallic stents (SEMS) are often placed for biliary drainage. We do not typically perform biliary sphincterotomy prior to SEMS placement because it may lead to increased rates of stent migration and other complications (eg, bleeding) [6,7].

Specific features of biliary SEMS include (see 'Adverse events' below and "Pancreatic stenting at endoscopic retrograde cholangiopancreatography (ERCP): Indications, techniques, and complications", section on 'Adverse events'):

- Covering – SEMS may be uncovered (meshwork is bare wire) (picture 1) or fully or partially covered (meshwork is partially or fully covered to decrease tissue growth into the stent) (picture 2). Some fully covered metal stents have fenestrations in their covering without any exposed bare metal struts.

  - **Uncovered SEMS** – Advantages of uncovered metal stents include:

    - Versatility – Uncovered SEMS may be placed in any part in the biliary tree (including the proximal bile duct).

    - Low rates of stent migration. Several trials reported very low rates of stent migration with uncovered SEMS for malignant biliary obstruction (0 to 2 percent), presumably related to embedding of the stent in the tumor and the surrounding normal tissue [8-11].

    The disadvantages of uncovered SEMS include the inability to remove it and possibly higher rates of tumor ingrowth than covered stents. Although tumor ingrowth is a common cause of uncovered SEMS occlusion, tumor ingrowth can also occur in covered stents if the covering wears down or becomes compromised.

  - **Covered SEMS** – An advantage of fully covered SEMS (FCSEMS) is that they are potentially removable. However, such devices do not have approval from US Food and Drug Administration (FDA) for delayed removal, whereas some FCSEMS are approved for removal during the initial placement procedure (eg, stent was deployed incorrectly).

    Disadvantages of covered SEMS include increased risk of stent migration and possibly cholecystitis. Covered SEMS have reported migration rates that range from 6 to 8 percent [8,12-15]. Risk of stent migration may be linked to the covering that prevents the stent from becoming embedded in the tumor and surrounding tissue. (See 'Stent migration' below and 'Cholecystitis' below.)

Some covered SEMS have fenestrations that allow for bile drainage through the side holes and into the main lumen of the stent, while the stent's metal struts are covered with a coating such as silicone [16]. The fenestrations may allow for more options for positioning the covered stent (eg, placing the stent across the cystic duct orifice in patients with an intact gallbladder).

- Material – The metal component of SEMS may be stainless steel, nitinol (a combination of nickel and titanium), or Platinol (a platinum core with nitinol encasement). Nitinol has traditionally been used due to its ability to maintain the shape of a curved lumen, but Platinol provides flexibility when placing a stent in a tortuous bile duct [17,18]. Covered stents can be lined with various materials such as silicone, polyurethane, or polytetrafluoroethylene (PFTE) [19].

- Shape – Biliary SEMS are cylindrical in shape and made by interwoven alloy wires, with some stents having proximal and distal flaring to help anchor the stent (picture 3).

- Deployment system – Biliary SEMS are deployed with through-the-scope (TTS) delivery systems that have outer diameters ranging from 6 to 8.5 Fr. SEMS come pre-constrained within delivery catheters. Most stents are deployed via the removal or withdrawal of an outer restraining sheath, although the delivery catheter types and mechanisms vary widely. Some SEMS shorten upon deployment, which should be taken into consideration when selecting a stent length. After deployment, the stent material embeds into the tumor and surrounding normal tissue by expansile, radial pressure.

- Size – Metal biliary stents are available in 5, 6, 8, and 10 mm diameters (15, 18, 24, and 30 Fr, respectively). Whether stent diameter is a risk factor for stent occlusion in patients with malignant biliary obstruction is uncertain [10,20,21]. Some studies have shown no significant difference in rates of stent occlusion for smaller diameter stents (eg, 8 mm) compared with larger stents (10 mm) [20,21]. However, other studies have suggested that smaller stent diameter (6 mm) has been linked to risk of stent occlusion [10].

Metal biliary stents are available in varying lengths, diameters, and delivery systems. Newer stents may be brought to market, and availability varies by geographic area. Thus, this is not a comprehensive list of all stents (table 2):

- WallFlex (Platinol) stents (Boston Scientific) – WallFlex stents are available in the following types:

  - Uncovered, partially covered, or fully covered Platinol stents. All WallFlex stents have deployment systems that allow the stent to be reconstrained and repositioned during

deployment up to a predetermined "point of no return," after which the stent must be deployed and cannot be reconstrained. Fully and partially covered WallFlex stents are lined with Permalume (silicone polymer membrane).

- Uncovered or partially covered nitinol stents.

- Evolution Biliary Controlled-Release Stent (Cook Medical) – Uncovered non-foreshortening nitinol stent.
- FLEXXUS stent (ConMed Corporation) – Uncovered non-foreshortening nitinol stent.
- ALIMAXX-B stent (MeritMedical Systems, Inc.) – Uncovered non-foreshortening nitinol stent.
- X-Suit NIR biliary stent (Olympus, Inc.) – Uncovered non-foreshortening nitinol stent.
- Viabil stent (The W.L. Gore & Associates, Inc., marketed by ConMed Corporation) – Fully covered nitinol stent with a lining of expanded PFTE.
- Bonastent Biliary (EndoChoice, Inc.) – Uncovered and covered foreshortening nitinol stent.
- Protégé EverFlex (Medtronic) – Self-expandable uncovered biliary stent.

Plastic stents — Plastic biliary stents are generally reserved for treating selected patients with malignant biliary obstruction (ie, patients with limited prognosis) (picture 4). Plastic stents can be made from multiple materials including polytetrafluoroethylene, polyurethane, and polyethylene. Stent shapes include straight, single-pigtail, and double-pigtail. Straight stents have one, two, or four flaps at each end to help anchor the stent. Available stent diameters include 7, 8.5, 10, and 11.5 Fr with lengths ranging between 5 and 15 cm. If longer stent lengths are needed, nasobiliary drains can be cut to a desired length, although they are prone to migration given the lack of flaps.

Selecting a stent for palliative drainage — The choice of biliary stent for palliative drainage is informed by several factors including location of biliary obstruction, patient prognosis, risk of stent dysfunction (eg, stent occlusion, stent migration), endoscopist preference, and stent availability (figure 1 and figure 2) [5].

Patients with distal biliary obstruction — For patients with distal biliary obstruction from unresectable cancer and expected overall survival greater than three months who require endoscopic drainage, we typically place a SEMS that is 8 to 10 mm in diameter. SEMS provide effective drainage and remain patent for longer than plastic stents, and several studies

reported that the mean or median duration of SEMS patency was >270 days [1,9,22-24]. In a meta-analysis of seven trials and four studies including 947 patients with malignant distal biliary stricture, SEMS resulted in lower risk of stent occlusion (odds ratio [OR] 0.48, 95% CI 0.34-0.67) and cholangitis (OR 0.46, 95% CI 0.30-0.69) compared with plastic stents [25]. Overall patient survival was longer with SEMS compared with plastic stents (157 versus 121 days).

Plastic biliary stents may be used as an alternative to SEMS for malignant biliary obstruction caused by unresectable cancer, and we typically use plastic stents for patients with limited prognosis and expected overall survival ≤3 months. Plastic stents are effective for short-term drainage; however, stent malfunction is common because plastic stents often become occluded by sludge and/or bacterial biofilm. Maintaining biliary drainage frequently requires repeat ERCP with stent removal and replacement (ie, stent exchange). In a systematic review of 11 studies including 947 patients with malignant distal biliary obstruction, the pooled duration of plastic stent patency was 73 days (95% CI 70 to 77 days) [25].

The choice of uncovered or covered SEMS depends on the location of the obstruction, angulation of the stricture, tumor type, and presence of an intact gallbladder. As an example, patients with intraluminal tumors (eg, cholangiocarcinoma) who do not have a gallbladder may benefit from a covered SEMS to minimize risk of tumor ingrowth. (See 'Adverse events' below and "Pancreatic stenting at endoscopic retrograde cholangiopancreatography (ERCP): Indications, techniques, and complications", section on 'Adverse events'.)

Several trials have evaluated differences in stent patency rates between covered and uncovered metal stents for treating distal malignant biliary disease. Individual trials have had variable results, with some trials showing increased patency rates for covered stents, whereas others do not [8,12,26-33]. In a meta-analysis of 11 trials including 1272 patients with malignant distal biliary strictures, there was no significant difference in the risk of stent failure for covered stents compared with uncovered stents (HR 0.68, 95% CI 0.40-1.17) [34]. However, compared with uncovered stents, covered stents had higher risk of stent migration (OR 5.11, 95% CI 1.84-14.17) and sludge formation (OR 2.46, 95% CI 1.37-4.43), whereas and the risk of tumor ingrowth was lower (OR 0.21, 95% CI 0.09-0.50). There were no significant differences in other adverse events including cholecystitis, cholangitis, pancreatitis, perforation, or bleeding between the two devices. In a subsequent trial including 119 patients with pancreatic cancer, rates of successful biliary drainage were not significantly different in patients with covered stents compared with uncovered stents (72 versus 73 percent) [35]. For patients with stent failure, rates of stent migration were higher with covered stents (7 versus 0 percent), while rates of tumor ingrowth were lower with covered stents (0 versus 17 percent).

Patients with proximal biliary (hilar) obstruction — Patients with unresectable cancer and malignant hilar obstruction (eg, hilar cholangiocarcinoma) should be managed by a multidisciplinary hepatobiliary team including advanced endoscopists, oncologists, and interventional radiologists. Endoscopic stenting of unresectable hilar biliary obstruction is complex and technically challenging, and some patients may require multiple endoscopic stents and/or percutaneous transbiliary drainage to relieve the obstruction [2,36]. (See "Systemic therapy for advanced cholangiocarcinoma".)

Patients with malignant hilar obstruction who require endoscopic drainage typically undergo ERCP with uncovered SEMS placement to avoid occluding drainage from the contralateral biliary system (figure 2). Similarly, we use uncovered SEMS for treating hilar obstruction to avoid blocking the left or right hepatic duct.

Features of uncovered SEMS that confer an advantage over plastic stents include:

- Open wire mesh design that does not occlude the side branches of intrahepatic bile duct
- Delivery system facilitates passage through tight biliary strictures (eg, sharp tip)
- Availability of stents with smaller diameter (eg, 8 mm) for proximal lesions

For patients with malignant hilar obstruction, data from clinical trials and observational studies have suggested that SEMS had higher rates of clinical success and required fewer reinterventions than plastic stents [37-42]. In a trial including 188 patients with unresectable hilar cholangiocarcinoma, SEMS placement resulted in higher rates of successful drainage (70 versus 46 percent) and longer overall patient survival (median 126 versus 49 days) compared with plastic stents [39]. In a trial including 60 patients with unresectable hilar strictures, SEMS resulted in higher patency rates at six months (81 versus 20 percent) and fewer reinterventions (0.63 versus 1.80 interventions per patient) compared with plastic stents [41].

For patients with unresectable cancer and hilar obstruction, we typically place bilateral SEMS when technically feasible to maximize biliary drainage and when both liver lobes are obstructed. Prior to ERCP, a computed tomography scan and/or magnetic resonance cholangiopancreatography imaging is used to identify the dominant biliary system that can be targeted for single (unilateral) stent placement if bilateral stent placement is not technically possible.

Liver drainage volume impacts the effectiveness of drainage [36,43-45]. It had been well accepted that draining at least 25 percent of the liver volume was required for relief of jaundice. However, some studies have suggested that drainage of ≥50 percent total liver volume (assessed by computed tomography) was associated with improved overall survival [45]. If a

single stent does not provide symptomatic relief by draining ≥50 percent total liver volume, ERCP-guided bilateral stenting and/or percutaneous drainage can be performed.

Single, unilateral stent placement provides adequate drainage and symptomatic relief (eg, jaundice, itching) for some patients. Whether bilateral rather than unilateral drainage results in improved outcomes is uncertain [23,46]. In a meta-analysis of seven studies including 634 patients with malignant hilar obstruction, bilateral stenting was not associated with significant differences in rates of clinical response, stent occlusion, cholangitis, or patient mortality compared with unilateral stenting [23]. However, in a subsequent trial including 133 patients with malignant hilar obstruction treated with SEMS, the risk of stent failure was lower for bilateral stenting compared with unilateral stenting (hazard ratio [HR] 0.30, 95% CI 0.17-0.52) [46].

Patients with resectable cancer — The choice of stent for treating malignant biliary obstruction due to resectable disease is informed by location of the obstruction, tumor type, timing of surgery, and plan for neoadjuvant therapy. As an example, we typically place a short self-expandable metallic stent (SEMS; ie, stent length 40 or 60 mm) for patients with distal malignant obstruction, especially if surgery is likely to be delayed (eg, neoadjuvant therapy is planned) [47,48]. Data have suggested that preoperative biliary drainage with SEMS was associated with fewer endoscopic procedures than plastic stents. In a meta-analysis of four studies including 704 patients with resectable tumors causing biliary obstruction, SEMS were associated with lower rates of reintervention compared with plastic stents (3 versus 15 percent), while there were no significant differences in surgical morbidity or mortality between the groups [47]. Preoperative management for patients with resectable pancreatic and hepatobiliary tumors is discussed separately:

- (See "Surgical resection of lesions of the head of the pancreas", section on 'Preoperative biliary drainage'.)
- (See "Overview of surgery in the treatment of exocrine pancreatic cancer and prognosis", section on 'Role of preoperative biliary drainage'.)
- (See "Initial chemotherapy and radiation for nonmetastatic, locally advanced, unresectable and borderline resectable, exocrine pancreatic cancer".)
- (See "Surgical resection of localized cholangiocarcinoma", section on 'Preoperative biliary decompression'.)
- (See "Ampullary carcinoma: Treatment and prognosis", section on 'Preoperative biliary drainage'.)

Post-procedure care — Routine post-procedure care following ERCP is discussed separately. (See "Overview of endoscopic retrograde cholangiopancreatography (ERCP) in adults", section

on 'Post-procedure care'.)

For hospitalized patients, we check bilirubin and alkaline phosphatase levels on the day following biliary stent placement. A gradual improvement in laboratory values is expected for patients with SEMS because 48 hours may be required to allow for complete stent expansion.

Patients who are discharged from the endoscopy unit following biliary stent placement typically have liver biochemical tests performed in one week as an outpatient and prior to starting chemotherapy.

Alternatives to ERCP-guided stent placement — For patients with malignant distal biliary obstruction and unsuccessful ERCP-guided biliary drainage, a reasonable alternative for achieving drainage is EUS-guided choledochoduodenostomy (EUS-CDS) with a lumen-apposing metal stent or a fully covered metal biliary stent [49-52]. In a trial comparing EUS-CDS with ERCP-guided stent placement in 155 patients with malignant distal biliary obstruction, there were no significant differences between the interventions in rates of clinical success (94 versus 91 percent) or stent patency after one year (91 versus 88 percent) [49]. In an earlier observational study of 256 patients with malignant distal biliary obstruction and unsuccessful ERCP, EUS-CDS was associated with technical and clinical success rates of 93 and 96 percent, respectively [50].

ADVERSE EVENTS

Adverse events reported with endoscopic retrograde cholangiopancreatography (ERCP)-guided biliary stent placement may be related to the ERCP or to stent placement.

ERCP-related — Complications associated with ERCP may be due to the endoscopy itself (eg, pancreatitis) or due to anesthesia (eg, hypotension). These complications are discussed in more detail separately. (See "Overview of endoscopic retrograde cholangiopancreatography (ERCP) in adults", section on 'Complications' and "Anesthesia for gastrointestinal endoscopy in adults", section on 'Complications'.)

Stent-related — Common complications of biliary stent placement include stent occlusion and stent migration. Less common complications include cholecystitis, cholangitis, perforation, and bleeding [53].

Stent occlusion — Stent occlusion is a common complication in patients with biliary stents for malignant obstruction. Stent occlusion may be caused by:

- Tumor ingrowth (or regrowth) – Stents may become occluded by the ingrowth of malignant tumor through the mesh of an uncovered SEMS. Tumor ingrowth is the most common cause of occlusion in uncovered SEMS (image 1) [10,11], while it is less common with covered SEMS. In a study including 241 patients with unresectable malignant biliary obstruction who were treated with uncovered SEMS, stent occlusion occurred in 65 patients (27 percent), and the most common etiology of stent occlusion was tumor ingrowth (52 percent) [10].

- Tumor overgrowth – As tumor burden increases, tumor overgrowth (ie, occlusion of the ends of the stent by tumor) can cause stent occlusion. Overgrowth due to nonmalignant tissue hyperplasia can also occur. Data have suggested that tumor overgrowth was more common with covered SEMS. In a meta-analysis of five trials including 781 patients with malignant biliary obstruction, covered SEMS were more likely to develop tumor overgrowth compared with uncovered SEMS (relative risk [RR] 2.02, 95% CI 1.08-3.78) [54].

- Luminal impaction from biliary sludge – Biliary sludge can collect within the lumen of a metal or plastic stent, resulting in stent occlusion [55,56].

Patients with stent occlusion often present with elevated liver enzymes in a cholestatic pattern (disproportionate elevation in serum alkaline phosphatase compared with serum aminotransferases) and/or acute cholangitis (ie, fever, jaundice). (See "Approach to the patient with abnormal liver biochemical and function tests", section on 'Laboratory tests' and "Acute cholangitis: Clinical manifestations, diagnosis, and management".)

Patients with suspected stent occlusion typically undergo ERCP to confirm and treat stent occlusion. For patients who present with nonspecific symptoms only (eg, abdominal pain), cross-sectional imaging with CT (computed tomography) scan is usually performed prior to repeat ERCP to evaluate for other causes or complications (eg, cholecystitis) [57,58].

Occluded SEMS can be treated by balloon sweeping the stent lumen to remove sludge and debris or by placing a second stent (plastic or metal) within the lumen of the obstructed stent. Insertion of a plastic or a second metal stent has been shown to be safe and effective [59,60]. If a plastic stent that was placed initially becomes occluded, it is generally removed and replaced with a SEMS.

Stent migration — Patients with stent migration typically present with abdominal pain, elevated liver enzymes in a cholestatic pattern, and/or cholangitis. Abdominal imaging with a computed tomography scan or a radiograph of the abdomen can be helpful in determining if a biliary stent has migrated. However, if a patient develops cholestatic liver enzymes and/or cholangitis after biliary stent placement, we often proceed directly to repeat ERCP to confirm

that the stent has migrated. During ERCP, the malpositioned or migrated stent can be removed and/or replaced [61,62].

Biliary sphincterotomy may be a risk factor for stent migration after SEMS placement [6,7]. (See 'Metal stents' above.)

Cholecystitis — For patients with an intact gallbladder, cholecystitis may occur if a SEMS is placed across the origin of the cystic duct, resulting in a functional gallbladder obstruction [32,63]. Patients with acute cholecystitis typically complain of abdominal pain, most commonly in the right upper quadrant or epigastrium. The diagnosis and management of cholecystitis are discussed separately. (See "Acute calculous cholecystitis: Clinical features and diagnosis" and "Treatment of acute calculous cholecystitis".)

Uncovered SEMS are often used for patients with an intact gallbladder if the stented area includes the cystic duct take-off. However, placement of a covered metal stent for such patients is also a reasonable option because data on the risk of cholecystitis with covered SEMS have been mixed [32,34,64]. In a meta-analysis of 14 trials including 1417 patients with malignant distal biliary obstruction, there was no significant difference in rates of cholecystitis for patients with uncovered SEMS compared with covered SEMS (5 versus 5 percent) [64]. Similarly, in another meta-analysis of 11 trials including 1272 patients with malignant distal biliary stricture, there was no significant difference in rates of cholecystitis for uncovered SEMS compared with covered SEMS [34]. In a subsequent study of 457 patients with a malignant bile duct stricture and an intact gallbladder, patients who underwent covered stent placement had higher rates of cholecystitis compared with uncovered SEMS (8 versus 1 percent) [32].

One covered stent (Viabil) is available with fenestrations that can be placed over the origin of the cystic duct in patients with an intact gallbladder to potentially reduce the risk of cholecystitis. (See 'Types of biliary stents' above.)

Other complications — Other complications related to biliary stent placement include:

- Cholangitis – Ascending cholangitis is a complication of biliary stenting, especially in cases of incomplete drainage. This topic is discussed elsewhere. (See "Infectious adverse events related to endoscopic retrograde cholangiopancreatography (ERCP)", section on 'Acute cholangitis'.)

- Bleeding – Bleeding is an uncommon complication that may result from the stent becoming impacted in or irritating the opposing duodenal wall. Patients will present with symptoms of upper gastrointestinal bleeding (eg, melena), and upper endoscopy is performed for diagnostic evaluation. Some patients will have hemobilia and may require

endoscopic examination with a side-viewing duodenoscope to identify the bleeding site. (See "Approach to acute upper gastrointestinal bleeding in adults" and "Causes of upper gastrointestinal bleeding in adults", section on 'Hemobilia'.)

- Perforation – Duodenal perforation and fistula formation are rare complications of biliary stenting [65,66].

Pancreatitis is a known complication of ERCP itself, possibly related to manipulation of the biliary orifice or contrast injection. (See "Post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis".)

Data have suggested that the risk of pancreatitis was not linked to stent type. In a meta-analysis of eight studies including 1078 patients with malignant biliary obstruction, there was no significant difference in risk of post-ERCP pancreatitis for patients with uncovered SEMS compared with covered SEMS (OR 1.58, 95% CI 0.65 to 3.86) [67].

SAFETY OF MRI

Most self-expandable metallic stents (SEMS) appear safe for performing magnetic resonance imaging (MRI). However, factors such as stent shape, magnetic field orientation, and alloy composition may influence signal intensity in vitro; thus, stent characteristics and its orientation to the magnetic field should be reviewed before MRI is performed [68]. (See "Patient evaluation for metallic or electrical implants, devices, or foreign bodies before magnetic resonance imaging".)

SOCIETY GUIDELINE LINKS

Links to society and government-sponsored guidelines from selected countries and regions around the world are provided separately. (See "Society guideline links: Biliary infection and obstruction".)

SUMMARY AND RECOMMENDATIONS

- **Causes** – Endoscopic biliary stent placement is used for patients with malignant biliary obstruction caused by pancreaticobiliary malignancy, metastatic disease, or external compression by lymph nodes. (See 'Causes' above.)

- **Indications:**

- Palliative biliary drainage – Endoscopic retrograde cholangiopancreatography (ERCP) with palliative biliary stenting is indicated for patients with biliary obstruction from surgically incurable cancer. The goals of biliary decompression are (see 'Palliative biliary drainage' above):

  - To relieve symptoms of cholestasis (eg, pruritus, jaundice)
  - To treat cholangitis, if present
  - To optimize medical status prior to chemoradiation therapy

- Preoperative biliary drainage – ERCP with placement of a biliary stent prior to surgical resection is generally reserved for patients with resectable tumor who require timely biliary decompression for any of the following indications (see 'Preoperative biliary drainage' above):

  - Acute cholangitis
  - Debilitating symptoms (pruritus)
  - Expected delay in surgical intervention, typically >2 weeks (eg, neoadjuvant chemotherapy is planned)

- **Distal biliary obstruction** – For most patients with unresectable distal malignant biliary obstruction who have an expected overall survival of greater than three months, we suggest placement of a self-expandable metallic stent (SEMS) rather than a plastic stent (**Grade 2B**). SEMS provide effective drainage and typically remain patent for a longer duration than plastic stents. (See 'Patients with distal biliary obstruction' above.)

  Plastic stents are reserved for patients with unresectable cancer and distal biliary obstruction who have a limited prognosis.

- **Proximal biliary (hilar) obstruction** – For patients with malignant hilar obstruction who require endoscopic drainage, we suggest placing an uncovered SEMS rather than a plastic stent (**Grade 2C**). The open wire mesh design of uncovered SEMS allows for drainage from the contralateral biliary system.

  When technically feasible, bilateral stents are placed. (See 'Patients with proximal biliary (hilar) obstruction' above.)

- **Adverse events** – Common complications of biliary stents include stent occlusion (secondary to tumor ingrowth, tumor overgrowth, and/or sludge) and stent migration. Less common complications of biliary stents include cholecystitis, cholangitis, perforation, and bleeding. (See 'Adverse events' above and "Pancreatic stenting at endoscopic

retrograde cholangiopancreatography (ERCP): Indications, techniques, and complications", section on 'Adverse events'.)

If the stent becomes occluded due to tumor ingrowth, we place a plastic or a second metal stent within the original metal stent to reestablish biliary drainage.

For patients with malignant biliary obstruction and an intact gallbladder, we often place an uncovered SEMS if the stented area includes the cystic duct take-off. However, data on the risk of cholecystitis based on stent type are mixed; thus, placement of a covered stent in patients with an intact gallbladder is a reasonable option if such a stent is preferred based on other factors (eg, stricture location, angulation, etiology). (See 'Cholecystitis' above.)

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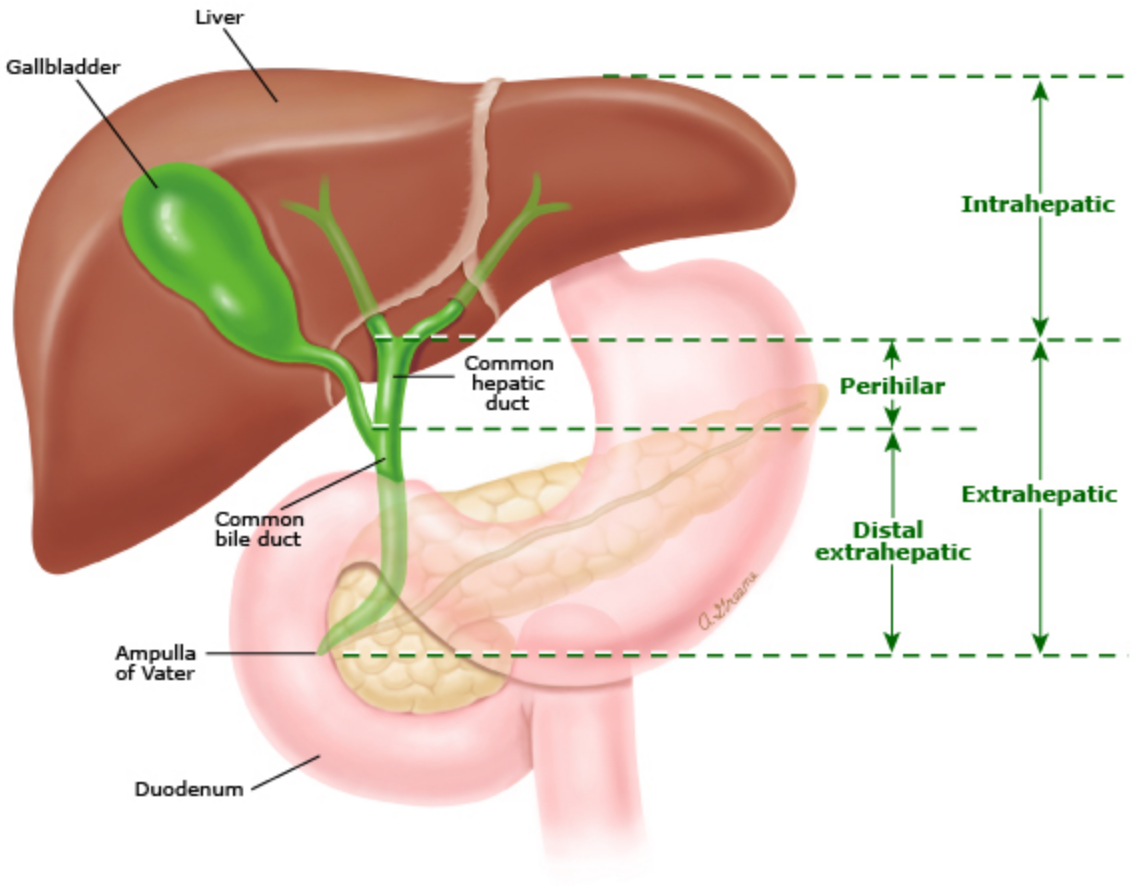
Topic 13925 Version 38.0

GRAPHICS

Anatomic classification of cancers of the human biliary tract



Classifications defined by: American Joint Committee on Cancer (AJCC) Cancer Staging Manual, 8th Edition, Amin MB (Ed), Chicago: Springer Science+Business Media, LLC, 2017.

Graphic 52489 Version 6.0

Antibiotic regimens: Prophylaxis for endoscopic procedures

Procedure	Condition(s)	Antibiotic and dose*	Interval for intraoperative re-dose for prolonged procedure (timed from initiation of preoperative dose)
High-risk endoscopic procedures needing antibiotic prophylaxis¶ Δ			
PEG/PEJ placement	MRSA risk absent	Cefazolin 2 g for patients weighing <120 kg, 3 g for patients weighing ≥120 kg (pediatric dose 30 mg/kg) IV within 60 minutes before procedure. **If penicillin or cephalosporin hypersensitivity:** Clindamycin 900 mg (pediatric dose 10 mg/kg) IV within 60 minutes before procedure.	Cefazolin: four hours Clindamycin: six hours
	MRSA risk present Pre-procedural screening for MRSA and attempted decontamination before feeding tube placement is recommended if practical	Vancomycin 15 mg/kg (maximum 2 g) IV infused over 60 to 90 minutes and beginning within 120 minutes before surgical incision.	Vancomycin: re-dosing is generally not required
ERCP◇	- Biliary obstruction AND cholangitis - Biliary obstruction unlikely to be successfully drained at ERCP (including malignant hilar	Ciprofloxacin 500 mg (pediatric dose 15 mg/kg§) orally given within 60 to 90 minutes prior to procedure or 400 mg (pediatric dose 10 mg/kg§) IV over 60	Ciprofloxacin: re-dosing is generally not required

	obstruction and primary sclerosing cholangitis) - Inadequate biliary drainage following ERCP - Biliary complications following liver transplantation if drainage is unlikely	minutes beginning within 120 minutes prior to procedure **AND/OR**	
		Amoxicillin-clavulanate 1750 mg (pediatric dose 45 mg/kg) orally within 60 minutes prior to procedure or ampicillin-sulbactam 3 grams (pediatric dose 50 mg/kg ampicillin component) IV within 60 minutes prior to procedure **OR**	Amoxicillin-clavulanate: two hours
		Ampicillin 2 grams (pediatric dose 50 mg/kg) IV **plus** gentamicin¥ 5 mg/kg (pediatric 2.5 mg/kg) IV within 60 minutes before procedure. **If penicillin hypersensitivity:** Substitute vancomycin 15 mg/kg (maximum 2 g) IV infused over 60 to 90 minutes beginning within 120 minutes before procedure plus gentamicin¥ 5 mg/kg IV (pediatric 2.5 mg/kg) within 60 minutes before procedure.	Ampicillin: two hours Vancomycin: re-dosing is generally not required Gentamicin: single dose only
		ALL above regimens are discontinued post-procedure when drainage is established absent evidence of cholangitis. For antibiotic dosing post-procedure with incomplete drainage,	

		refer to the individual Lexicomp drug information monograph.	
EUS-FNA of cystic lesion(s)‡	- Mediastinal cysts	Ciprofloxacin 500 mg orally (pediatric dose 15 mg/kg§) 60 to 90 minutes prior to procedure or 400 mg IV (pediatric dose 10 mg/kg§) IV given over 60 minutes beginning within 120 minutes prior to procedure. Continue 3 days post-procedure.	Ciprofloxacin: re-dosing is generally not required
Interventional EUS procedures including transmural or transluminal drainage of pancreatic fluid collections	- Mediastinal cysts - Pancreatic cysts - Cysts outside pancreas (excluding solid lesions) - Walled-off pancreatic necrosis	Ciprofloxacin 500 mg orally (pediatric dose 15 mg/kg§) 60 to 90 minutes prior to procedure or 400 mg IV (pediatric dose 10 mg/kg§) IV given over 60 minutes beginning within 120 minutes prior to procedure. Continue 3 days post-procedure.	Ciprofloxacin: re-dosing is generally not required
Natural orifice transluminal endoscopic surgery (NOTES)	Insufficient data to make recommendation. Antibiotic prophylaxis seems reasonable.		
High-risk patients needing antibiotic prophylaxis¶			
All endoscopic procedures with high risk of bacteremia, including procedures not listed above (eg, routine endoscopy with esophageal stricture dilation or	- Immunocompromised patients (eg, severe neutropenia [absolute neutrophil count <500 cells/mm^3], advanced hematologic malignancy)†	Amoxicillin 2 grams (pediatric dose 50 mg/kg) orally within 60 minutes before procedure **OR**	Amoxicillin: two hours
		Ampicillin 2 grams (pediatric dose 50	Ampicillin: two hours Clindamycin: six hours

endoscopic sclerotherapy); For procedures in the biliary tree (eg, ERCP with drainage or EUS-FNA of any lesion type) in a patient who is at high risk for infection, refer to antibiotic recommendations listed above	- Cirrhosis with ascites**	mg/kg) IV or IM within 60 minutes prior to procedure. **If penicillin hypersensitivity:** Clindamycin 600 mg (pediatric dose 20 mg/kg) orally within 60 minutes before procedure or 900 mg IV (pediatric dose 10 mg/kg IV) within 60 minutes prior to procedure.	

The preprocedural antibiotic recommendations presented in this table are generally consistent with those of American Society for Gastrointestinal Endoscopy[1] and the 2013 guidelines developed jointly by the American Society of Health-System Pharmacists and collaborating organizations[2]. A 2009 guideline available from the British Society of Gastroenterology[3] also recommends antibiotic prophylaxis in these conditions, but includes, in some cases, different choices and dosing regimens depending upon specific clinical scenarios. When available, recent culture and sensitivity results should be considered in selecting antibiotic prophylaxis.

PEG: percutaneous endoscopic gastrostomy; MRSA: methicillin-resistant *Staphylococcus aureus*; ERCP: endoscopic retrograde cholangiopancreatography; EUS-FNA: endoscopic ultrasound-guided fine-needle aspiration; GI: gastrointestinal.

* Pediatric dose should generally not exceed adult dose. Doses shown in table are for patients with normal renal function. Dose modification for renal impairment is needed for some agents.

¶ Antibiotic prophylaxis solely to prevent infective endocarditis is **not** recommended in patients undergoing endoscopic procedures. For patients with the highest-risk cardiac conditions (eg, prosthetic heart valve, prior endocarditis) who have ongoing GI or genitourinary tract infection or who are undergoing a procedure for which antibiotic therapy to prevent wound infection or sepsis is indicated, the American Society for Gastrointestinal Endoscopy (ASGE) and American Heart Association (AHA) suggest an antibiotic regimen that includes an agent active against enterococci (eg, ampicillin, piperacillin-tazobactam, or vancomycin). Refer to topic review of antimicrobial prophylaxis for bacterial endocarditis section on gastrointestinal tract.

Δ A separate table that summarizes the types of procedures and patients needing antibiotic prophylaxis is available in UpToDate. Low-risk endoscopic procedures that do not need routine antibiotic prophylaxis in most patients (eg, routine upper endoscopy, colonoscopy, flexible sigmoidoscopy, others) are listed in that table.

◇ Patients with cholangitis require antibiotic therapy and additional prophylaxis is not required.

§ While fluoroquinolones have been associated with an increased risk of tendinitis/tendon rupture in all ages, use of these agents for single-dose prophylaxis is generally safe.

¥ Gentamicin use for surgical antibiotic prophylaxis should be limited to a single dose given preoperatively. Dosing is based on the patient's actual body weight. For overweight and obese patients (ie, actual weight is greater than 120% of ideal body weight), a dosing weight should be used. A calculator to determine ideal body weight and dosing weight is available in UpToDate.

‡ While antibiotic prophylaxis is recommended by the ASGE for all patients undergoing EUS-FNA of cystic lesions, we generally reserve antibiotic prophylaxis for patients undergoing EUS-FNA of mediastinal lesions and in those who are at high risk for infection. Antibiotic prophylaxis is not required for patients undergoing EUS-FNA of solid lesions.

† Patients at high risk for postprocedural infections may also include those with decreased gastric acidity and motility resulting from malignancy or acid suppression.

** In patients with cirrhosis and upper gastrointestinal bleeding, antibiotics are indicated even if endoscopy is not planned.

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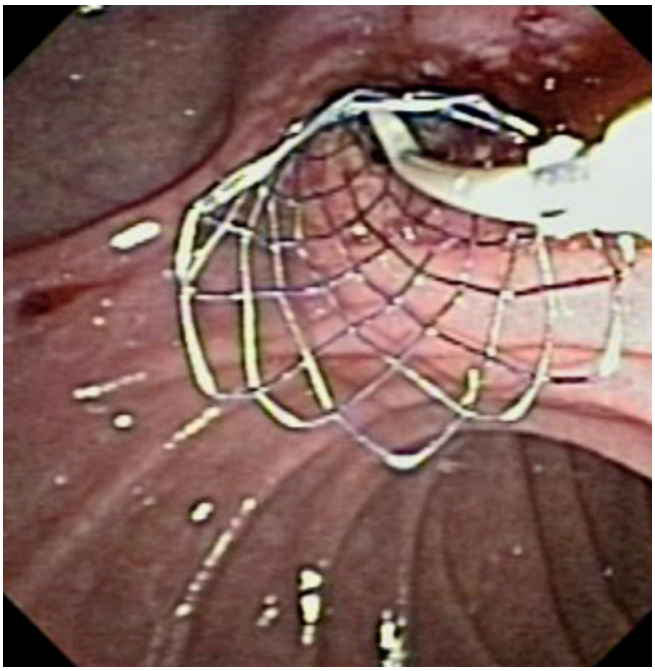
2. *Bratzler DW, Dellinger EP, Olsen KM, et al. Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery. Am J Health Syst Pharm 2013; 70:195.*
3. *Allison MC, Sandoe JA, Tighe R, et al. Antibiotic prophylaxis in gastrointestinal endoscopy. Gut 2009; 58:868.*

Additional data from:

1. *Red Book: 2012 Report of the Committee on Infectious Diseases, 29th ed, Pickering LK, ed, Elk Grove Village, IL: American Academy of Pediatrics, 2012, p.808.*

Graphic 54121 Version 9.0

Endoscopic image of a transampullary uncovered metal stent

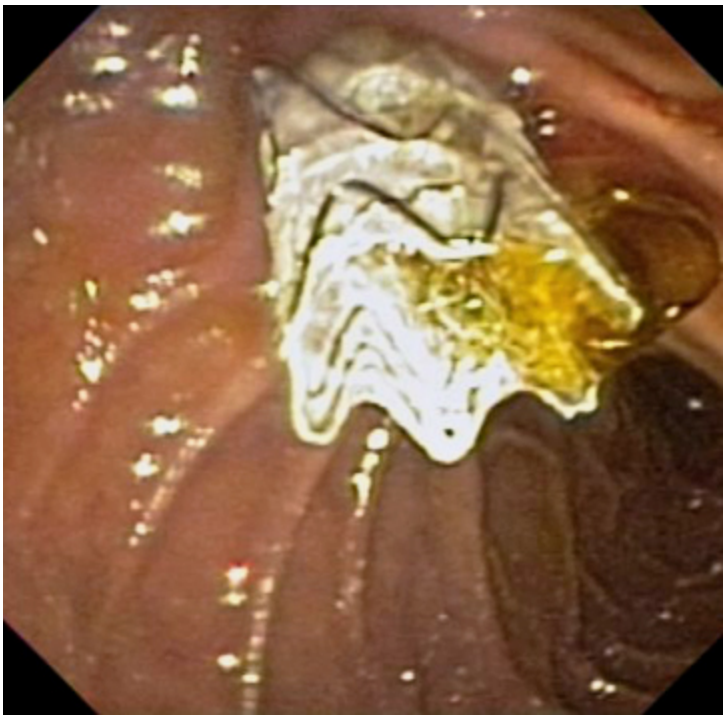


Endoscopic post-deployment image of an uncovered metal stent.

Courtesy of Douglas G. Adler, MD, FACG, FASGE.

Graphic 66141 Version 1.0

Endoscopic image of a transampullary covered metal stent

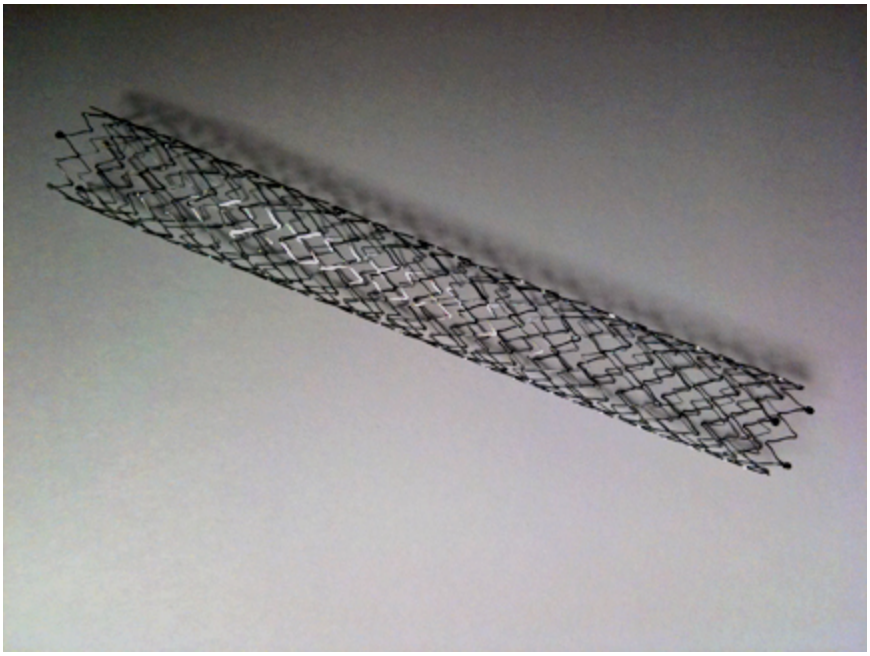


Endoscopic post-deployment image of a fully covered metal stent.

Courtesy of Douglas G. Adler, MD, FACS, FASGE.

Graphic 77951 Version 1.0

Uncovered biliary stent



Representative photo of an uncovered biliary self-expanding metal stent.

Courtesy of Douglas G. Adler, MD.

Graphic 50214 Version 2.0

Biliary stents

Stent (manufacturer)	Covering	Material	Diameter (mm)	Length (mm)	Delivery system
Wallflex (Boston Scientific)	Uncovered	Platinol	8, 10	40, 60, 80, 100	8.0 Fr
	Partially covered	Platinol	8, 10	40(30)*, 60(50), 80(70)	8.5 Fr
	Fully covered	Platinol	8, 10	40*, 60, 80	8.5 Fr
Wallstent (Boston Scientific)	Uncovered	Nitinol	8, 10	40, 60 ,80, 100	8.0 Fr
	Partially covered	Nitinol	8, 10	40(30), 60(50), 80(70)	8.0 Fr
Zilver (Cook Medical)	Uncovered	Nitinol	6, 8, 10	40, 60, 80	7.0 Fr
Zilver 635 (Cook Medical)	Uncovered	Nitinol	6, 8, 10	40, 60, 80	6.0 Fr
Viabil (Gore)	Fully covered with sideholes	Nitinol	8, 10	60, 80, 100	8.5 Fr
	Fully covered without sideholes	Nitinol	8, 10	40, 60, 80, 100	8.5 Fr
FLEXXUS (ConMed)	Uncovered	Nitinol	8, 10	40, 60, 80, 100	7.5 Fr
ALIMAXX-B (MeritMedical)	Uncovered	Nitinol	8, 10	40, 60, 80	6.5 Fr
X-Suit NIR (Olympus)	Uncovered	Nitinol	8, 10	40, 60, 80, 100	7.5 Fr
Bonastent (EndoChoice)	Uncovered	Nitinol	10	Range, 60 to 90	7.0 Fr
	Covered	Nitinol	10	Range, 60 to 90	8.0 Fr
Protege Everflex (Medtronic)	Uncovered	Nitinol	5	Range, 20 to 120	6.0 Fr

Parentheses () indicate the covered length of the stent.

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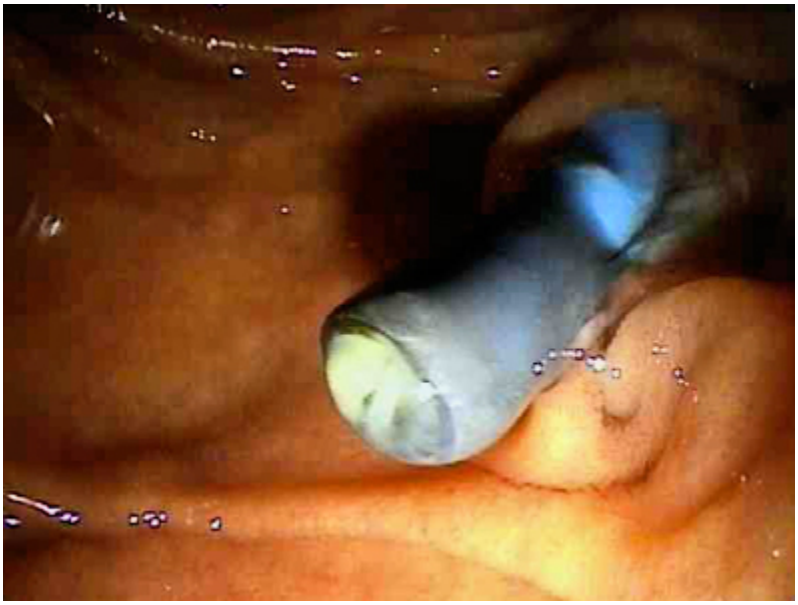
* Only available in 10 mm diameter.

Courtesy of Douglas G. Adler, MD, FACG, FASGE.

Graphic 71470 Version 2.0

Endoscopic image of a transampullary plastic stent

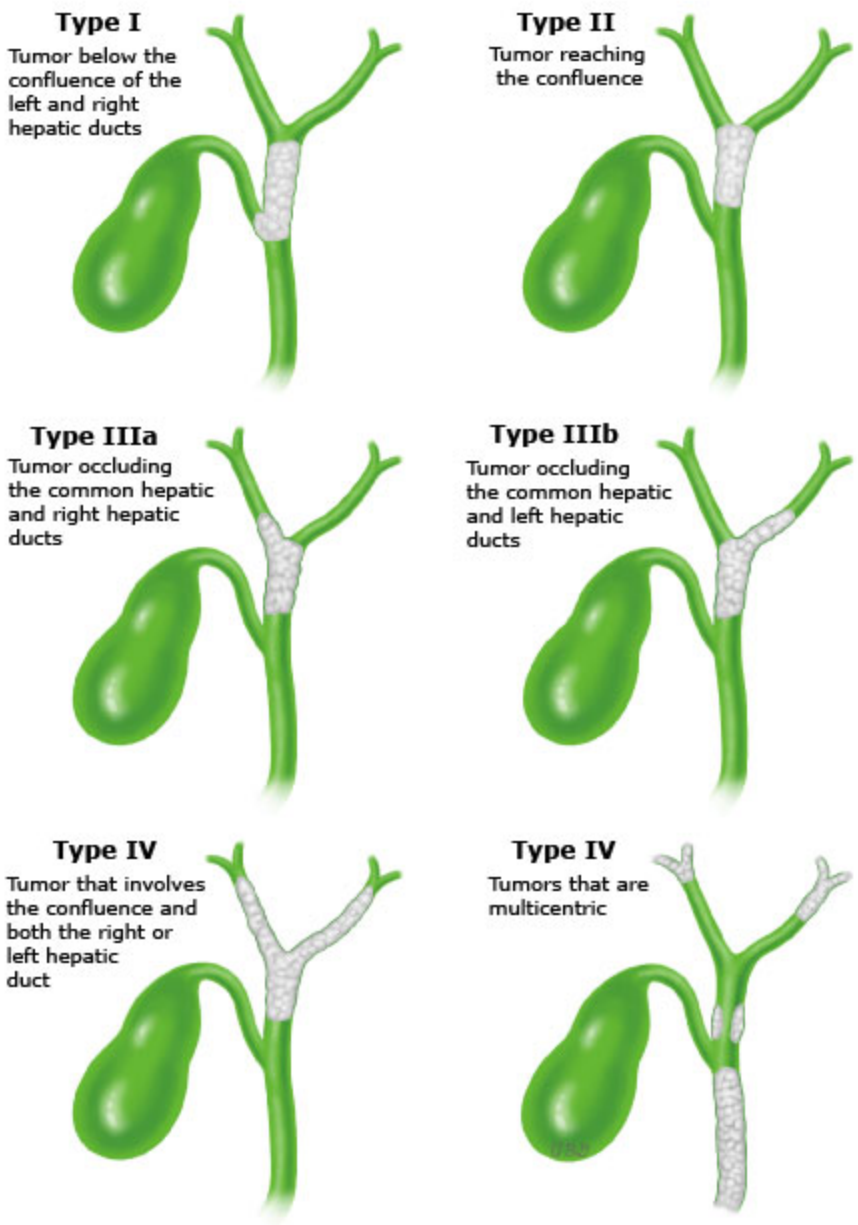


Endoscopic image of a transampullary straight (Amsterdam) plastic stent.

Courtesy of Douglas G. Adler, MD, FACG, FASGE.

Graphic 50266 Version 1.0

Bismuth-Corlette classification of biliary tract cancers

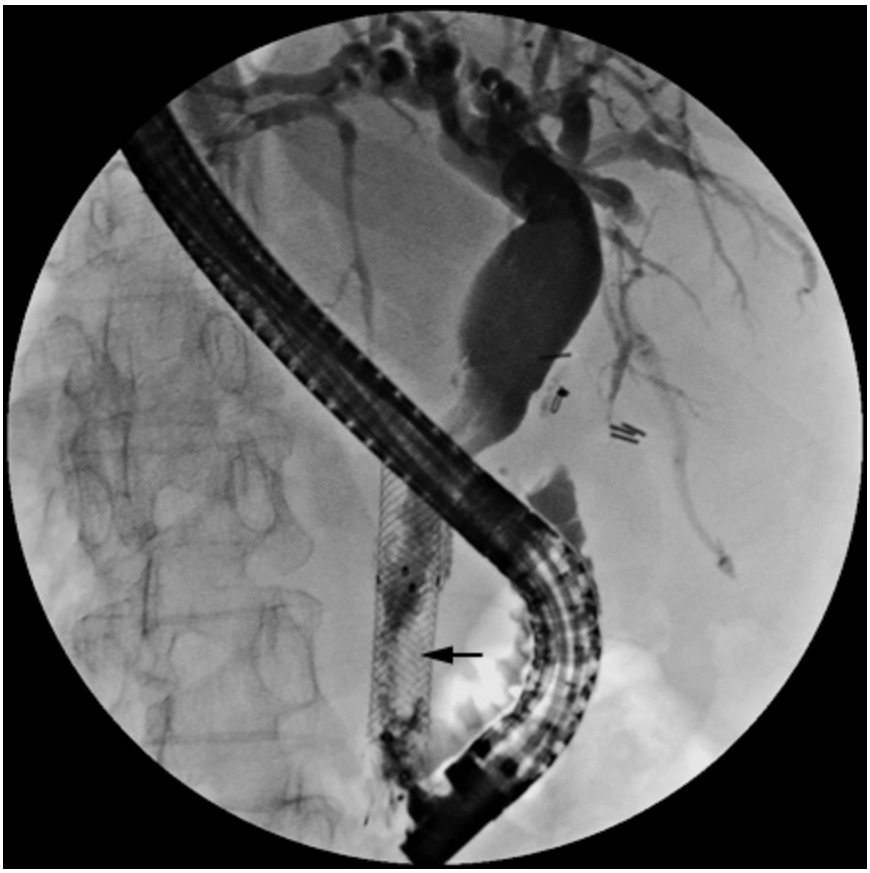


The Bismuth-Corlette classification of biliary tract. White areas represent tumor and green areas normal bile duct.

Modified from de Groen PC, Gores GJ, LaRusso NF, et al. N Engl J Med 1999; 341:1368.

Graphic 75886 Version 5.0

Fluoroscopic image of tumor ingrowth into a metal biliary stent



This image reveals a filling defect (arrow) within a metal biliary stent due to tumor ingrowth.

Courtesy of Douglas G. Adler, MD, FACS, FASGE.

Graphic 57138 Version 3.0

Contributor Disclosures

Douglas G Adler, MD, FACG, AGAF, FASGE Consultant/Advisory Boards: Abbvie [Endoscopy]; Boston Scientific [Endoscopy]; Endorotor [Endoscopy]; Merit [Endoscopy]; Olympus [Endoscopy]. Speaker's Bureau: Abbvie [Pancreatology, general GI]. All of the relevant financial relationships listed have been mitigated. **Kathryn R Byrne, MD** No relevant financial relationship(s) with ineligible companies to disclose. **John R Saltzman, MD, FACP, FACG, FASGE, AGAF** No relevant financial relationship(s) with ineligible companies to disclose. **Kristen M Robson, MD, MBA, FACG** No relevant financial relationship(s) with ineligible companies to disclose.

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