Indian College of Radiology and Imaging Evidence-Based Guidelines for Percutaneous Image-Guided Biliary Procedures

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Abstract

Percutaneous biliary interventions are among the commonly performed nonvascular radiological interventions. Most common of these interventions is the percutaneous transhepatic biliary drainage for malignant biliary obstruction. Other biliary procedures performed include percutaneous cholecystostomy, biliary stenting, drainage for bile leaks, and various procedures like balloon dilatation, stenting, and large-bore catheter drainage for bilioenteric or post-transplant anastomotic strictures. Although these procedures are being performed for ages, no standard guidelines have been formulated. This article attempts at preparing guidelines for performing various percutaneous image-guided biliary procedures along with discussion on the published evidence in this field.

Keywords
- biliary drainage
- percutaneous transhepatic biliary drainage
- malignant biliary strictures
- benign biliary stricture
- guidelines

Introduction

Percutaneous image-guided biliary procedures are the common nonvascular radiological interventions performed in the management of various benign and malignant pathologies of the biliary system. The commonly performed biliary interventions are percutaneous transhepatic biliary drainage (PTBD), biliary stenting (BS), and percutaneous cholecystostomy (PC). Other procedures include performing PTBD in postoperative bile leaks and various treatment procedures in benign postoperative biliary strictures, like bilioenteric and post-liver transplant anastomotic strictures. These procedures are safe and effective, particularly if appropriate steps are followed while performing them. Hence, formulating suitable guidelines based on the current published evidence and recommending them accordingly is necessary.

Methods

The Indian College of Radiology and Imaging (ICRI), after recognizing the necessity of framing these guidelines, adhered to the following process. The Interventional Radiology subspecialty head of the ICRI along with the committee identified an expert in the field to serve as the principal author. The principal author was allowed to assign other experts in the field as deemed necessary. The prospective authors performed extensive literature search and framed the guidelines in the form of statements and assigned the grade of recommendation (1 = strong, 2 = weak) and quality of evidence (A = high, B = moderate, C = low) as defined by UpToDate grading guide [https://www.uptodate.com/home/grading-guide].

The guidelines with the grade of recommendations were then reviewed by the committee of ICRI along with the interventional radiology subspecialty head. The draft was finalized after incorporating the comments of the committee. The statements and discussions have been broadly divided into two parts: Part 1 discussing the preprocedure evaluation and Part 2 discussing the details of various biliary procedures.

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Guidelines

Summary

Part 1: Preprocedure evaluation
1.1. Clinical presentation of patients requiring biliary drainage
1. The common presenting symptoms are jaundice and pruritus, recurrent fever due to cholangitis, and abdominal pain (IA).
2. Patients with post-traumatic bile leak present with increasing bile output in the drain (1B).
3. Patients with benign biliary strictures, may be asymptomatic with altered liver function tests and /or present with episodes of suspected cholangitis (1A).
1.2. Investigations required prior to performing biliary drainage
4. Laboratory investigations needed before biliary drainage include liver function tests, renal function tests, hemoglobin, prothrombin time, international normalized ratio (INR), and platelet count (1A).
5. Imaging is necessary with either computed tomography (CT) scan or magnetic resonance imaging (MRI) (1A).
6. Ultrasonography alone may be sufficient in cases of biliary stone disease (1B).
1.3. Management options of patients requiring biliary drainage
7. The approaches commonly used for biliary drainage are endoscopic and percutaneous. Endoscopic drainage is performed for mid and lower bile duct obstructions and PTBD is performed for high or hilar obstruction. PC is an option in nondilated bile ducts with lower bile duct obstruction. Surgical drainage is rarely performed, especially during a definitive treatment procedure for the cause of obstruction (1A).
8. Antibiotics are necessary in patients with cholangitis (1A).
Part 2: Interventional radiology management
2.1. Indications and contraindications
9. Common indications for PTBD include (a) Malignant hilar biliary obstruction; (b) Clinical features of cholangitis; (c) Postoperative bile leak; (d) Benign biliary strictures; (e) Failed endoscopic drainage; (f) Removal of calculi; (g) Cases where endoscopy is not possible due to altered anatomy after surgery (1A).
10. There are no absolute contraindications for biliary drainage. The relative contraindications for biliary drainage are (a) Deranged coagulation parameters; (b) Ascites; (c) Poor performance status; (d) Stage IV malignant disease (1A).
11. Indications for PC are: (a) Acute cholecystitis with sepsis or with surgical comorbidities; (b) obstructive jaundice with cholangitis due to common duct block where ERCP or PTBD is not feasible; (c) as an access route for biliary interventions (1A).
12. Contraindications for PC are relative and include deranged coagulation parameters and ascites (1A).
2.2. Patient preparation prior to biliary procedures
13. Patients should be fasting for 4–6 h prior to the procedure (1A).
14. Adequate hydration should be maintained (1C).
15. Broad spectrum antibiotics should be administered prior to the procedure and continued for 3–5 d (1A).
16. Ascites, when present, should be drained (1A).
2.3. Procedure of PTBD
17. Initial puncture of the bile duct should be preferably performed under ultrasonography (USG) guidance (1A).
18. Subsequent steps follow Seldinger technique under fluoroscopy (1A). Bedside PTBD is performed completely under USG guidance with external drainage (1B).
19. Unilobar drainage is usually adequate. Other lobe is drained if the bilirubin is persistently high or when there is cholangitis (1B).
20. Either right- or left-sided approach may be chosen if there are no contraindications to drain a lobe (1B).
21. Biliary stent is preferred over catheter in malignancies for palliation (1A).
2.4. Procedure of percutaneous cholecystostomy
22. PC should be performed under ultrasonography guidance, either through direct peritoneal or transhepatic routes, bed side or in interventional suite (1A).
23. Both Seldinger and trocar techniques may be used (1B).
2.5. Expected outcomes of PTBD
24. There is decrease in serum bilirubin values, thereby preparing the patient for surgery or chemotherapy whichever is appropriate; reduction or resolution of cholangitis, pain and pruritus (1A).
25. There is decrease in the bile output in the surgical drainage catheter (1B).

2.6. Complications of PTBD and their management
26. Most common major complication is cholangitis. It is treated with antibiotics, uncapping the internal/external drainage catheter, repositioning the displaced catheter, exchange or upgradation of the drainage catheter and /or draining the undrained system (1A).
27. Abdominal pain is another common complication, managed by analgesics (1A).
28. Pericatheter leak is managed by repositioning a displaced catheter, upgrading the catheter, draining ascites when present, and placing a stoma bag (1B).
29. Catheter-related complications include partial or complete displacement or fracture of catheter. They are managed by repositioning the catheter, replacing the catheter through the previous tract or performing a new procedure immediately or later depending on the extent of biliary dilatation and urgency of the drainage (1B).
30. Hemorrhagic complications present in the form of bleeding from or around the catheter, hematemesis or melena or hypotension and shock. They are managed, depending on the severity, by capping the catheter for tamponade, doing cholangiogram or CT angiography followed by digital subtraction angiography (DSA) and embolization wherever necessary (1A).
31. Pancreatitis is an uncommon complication. It is managed similar to acute pancreatitis occurring due to other etiologies (1B).
2.7. Follow-up of patients of PTBD
32A. Regular clinical evaluation should be done by evaluating patient's performance status, jaundice, and fever (1B).
32B. Laboratory parameters like serum bilirubin and alkaline phosphatase should be regularly done (1B).
32C. Ultrasonography and/or cholangiogram, should be performed whenever necessary (1B).
32D. Catheter exchanges must be done at regular intervals (1B).
2.8. Complications and outcomes of percutaneous cholecystostomy
33. Common complications include catheter displacement, bile leak, biliary peritonitis, and hemorrhage. Management is by repeat procedure, catheter replacement, drainage, and embolization. (1B)
34. The aim of PC is relief of acute symptoms and infrequently, biliary obstruction (1B).
2.9. Indications for biliary stenting
35. Malignant biliary obstruction is the most common indication, particularly in the palliative setting (1A).
36. The role of stents in benign biliary strictures is not well established (1B).
2.10. Types of biliary stents and their indications
37. The widely used stent for malignant biliary obstruction is uncovered self-expandable metallic stent; covered stents are still not routinely recommended for malignant biliary obstruction (1A).
38. Metallic stents are always better than plastic stents for malignant strictures (1B).
39. Retrievable covered stents are promising in benign biliary strictures (1B).
40. Bioabsorbable stents are used in research settings, particularly in benign strictures (1B).
41. The role of drug eluting stents is not established (1C).
2.11. Biliary stenting technique in malignant biliary obstruction
42. Both one-stage and two-stage deployment of the stents can be done (1B).
43. Between suprapapillary and transpapillary stent placement neither has distinctly shown benefit over the other (1B).
44. Bilobar stents may be stent-in-stent or parallel stent and in T or Y configuration (1B).
2.12. Technique for PTBD in benign strictures or bile leaks
45. Benign strictures and bile leaks are associated with minimally dilated or nondilated bile ducts which increase the difficulty of the procedure and complications; there is no difference in the procedural steps of PTBD (1B).
46. Benign strictures are managed by balloon dilatation, serial upgradation to large bore catheters and stents (1B).
47. Endoscopic stenting is the preferred option in case of biliary strictures or bile leaks in post-transplant patients; if endoscopic attempt is unsuccessful or there is altered anatomy (bilioenteric anastomosis), percutaneous biliary drainage is the next option (1B).
2.13. Brush cytology or brush biopsy in malignant biliary strictures
48. Intrabiliary brush cytology or biopsy should be obtained whenever possible, particularly when other methods of tissue sampling are not possible or fail (1B).
2.14 Current status of intrabiliary treatment techniques for malignant strictures
49. Intrabiliary radiofrequency ablation (RFA) has been shown to increase patency rates of biliary stent and may be used (1B).
50. Intrabiliary radiation therapy improves patency of the stent and patient survival (1C).

2.15. Other methods of biliary drainage and their indications
51. Other methods of biliary drainage include endoscopic drainage, surgical drainage, and endoscopic ultrasound-assisted drainage (1A).
52. Endoscopic drainage is suggested as the initial choice in cases of mid and lower bile duct obstruction with normal upper gastrointestinal anatomy (1A).
53. Endoscopic ultrasound-assisted drainage is increasingly being used, but its role is yet to be established (1B).
54. Surgical drainage is indicated in patients who fail minimally invasive procedures or who need definitive treatment (1A).

Detailed Guidelines

1. Part 1: Preprocedure Evaluation

1.1. Clinical presentation (signs/symptoms/when to suspect)

Q1. What are the common clinical presentation of patients requiring biliary drainage?

The most common symptoms are obstructive jaundice and pruritus, recurrent fever due to cholangitis, and abdominal pain (**1A**).

Remarks

Jaundice is the most common presentation of biliary obstruction. Even though most causes of obstructive jaundice are benign in nature, the common indications for biliary drainage procedure are due to malignant lesions producing biliary obstruction.[1] In malignant causes, periampullary carcinoma is the most common, followed by hilar cholangiocarcinoma.[1,2] In addition to jaundice, patients may present with pruritus which occurs in 50 to 80% of malignant cases.[3] Abdominal pain occurs in majority of benign cases, while in malignancy it is seen in 50 to 60% and occurs late.[1,3] Cholangitis occurs in both benign and malignant cases and presents with fever and can complicate into sepsis and multiorgan failure.

Q2. How do patients of post-traumatic bile leak manifest?

Patients with post-traumatic bile leak present with increasing bile output in the drain (**1B**).

Remarks

Post traumatic bile leak occurs after laparoscopic cholecystectomy (0.3–0.5%), open cholecystectomy, liver resection (3–11%), and liver transplantation (LT) (4–5%).[4] It should be suspected when there is persistent bile in drainage catheter, abdominal distention or with features of biliary peritonitis, in the postoperative period.[5] Liver transplant recipients may present with early and delayed biliary leak due to biliary ductal injury and also due to hepatic arterial thrombosis. Patients with grades 3 to 5 blunt liver injury frequently present with biliary leak after 5 to 6 days of trauma which require a drainage procedure.

Q3. What are the symptoms of patients with benign biliary strictures?

Patients with benign biliary strictures, may be asymptomatic with altered liver function tests and /or present with episodes of suspected cholangitis (**1A**).

Remarks

In patients with benign biliary strictures, other than the obstructive symptoms, the patients may be asymptomatic with altered liver function tests in the form of elevated alkaline phosphatase and gamma-glutamyl transferase.[6] The causes include post cholecystectomy or post LT biliary stricture or bilioenteric anastomotic stricture. They can also present with recurrent episodes of cholangitis and may progress to biliary cirrhosis if not diagnosed early.[7]

1.2. Investigations required (laboratory and imaging)

Q4. What laboratory investigations are required from patients prior to performing biliary drainage?

Laboratory investigations needed before biliary drainage include liver function tests, renal function tests, hemoglobin, prothrombin time, INR, and platelet count (**1A**).

Remarks

Liver function tests with prothrombin time and INR are required in all cases prior to any hepatic interventional procedure. Like in a general surgical procedure, hemoglobin needs to be ideally above 10 g/dL, and hemoglobin levels below 6 g/dL require packed red-blood cell transfusion.[8,9] In patients with hemoglobin levels between 6 and 10 g/dL, the decision of transfusion depends on hemodynamic condition of the patient.[9] Platelet count is required in all patients and counts below 50,000/mL require platelet transfusion.[10,11]

Q5. What imaging modalities are necessary before biliary drainage?

Imaging is necessary with either CT scan or MRI (**1A**).

Remarks

The main aims of imaging are to assess the cause and level of obstruction, and stage the disease. Imaging with either CT scan or MRI is necessary in almost all patients prior to biliary drainage.[12,13] In the diagnosis of malignant hilar stricture, accuracy of CT scan and MRI is comparable, although, CT scan shows the vascular involvement better while MRI better depicts biliary tree.[14] Magnetic resonance cholangiopancreatography (MRCP) provides a better delineation of the bile ducts than CT, and is comparable to ERCP.[15] A study comparing MRI with MRCP and CT in periampullary tumors showed that MRI with MRCP is better than CT scan with AUROC of 0.96 and 0.81,

respectively.[16] The MRI is better than CT or ultrasonography (USG) in cases of bilioenteric anastomosis stricture, benign inflammatory strictures like primary sclerosing cholangitis, and recurrent pyogenic cholangitis.[17-19]

Q6. How does ultrasonography assist in preprocedure diagnosis?

Ultrasonography alone may be sufficient in cases of biliary stone disease (**1B**).

Remarks

Ultrasonography alone may be sufficient in cases of biliary stone disease. It is used as screening modality in suspected malignant biliary lesions which later require a cross sectional imaging for staging and operability.[1] USG is used to assess biliary dilatation, ascites, liver volume, and patency of biliary confluence, all of which are critical in planning the drainage procedure.[13,20]

1.3. Management (Medical/IR/other)

Q7. What are the management options of patients requiring biliary drainage?

The approaches commonly used for biliary drainage are endoscopic and percutaneous. Endoscopic drainage is performed for mid and lower bile duct obstructions and PTBD is performed for high or hilar obstruction. Percutaneous cholecystostomy is an option in nondilated bile ducts with lower bile duct obstruction. Surgical drainage is rarely performed especially during a definitive treatment procedure for the cause of obstruction (**1A**).

Remarks

Endoscopic biliary drainage (EBD) is attempted for mid and distal obstruction. A systematic review and meta-analysis comparing EBD and PTBD in periampullary carcinoma found that EBD is safer and has lesser tumor seeding rate compared with PTBD.[21] However, in cases of failure of the endoscopic approach, PTBD should be performed as an emergency since endoscopy, not being an aseptic procedure, is likely to increase the risk for cholangitis. In hilar masses, EBD needs more expertise and has higher risk of cholangitis due to contamination from duodenal contents. The DRAINAGE trial, meta-analysis by Moole et al, and by Tang et al, have shown higher technical success and lower incidence of cholangitis with PTBD for hilar cholangiocarcinoma; however, there was more patient discomfort and catheter-related complications.[22-24] In another meta-analysis by Liu et al, in resectable hilar masses, PTBD had better success rates with less infection rate compared with EBD and so PTBD was recommended in hilar lesions.[25] In lower bile duct obstruction, the peripheral intrahepatic biliary radicals may not be dilated and percutaneous puncture of biliary radical may come difficult even with repeated attempts.[26] In such cases PC may be attempted.[27]

Q8. What is the role of antibiotics in cholangitis?

Antibiotics are necessary in patients with cholangitis (**1A**).

Remarks

Patients in cholangitis have an increased mortality rate, with a 30 day "all-cause mortality rate" of approximately 10%.[28] Hence, such patients should be treated with antibiotics within one hour of onset of fever and hypotension in cases of septic shock and within six hours of diagnosis in others.[29,30] Empirical antibiotics like ampicillin/sulbactam can be used as initial therapy.[28]

Part II: IR Management

2.1. Indications and contraindications

Q9. What are the indications for PTBD?

a. Malignant hilar biliary obstruction.
b. Clinical features of cholangitis.
c. Postoperative bile leak.
d. Benign biliary strictures.
e. Failed endoscopic drainage.
f. Removal of calculi.
g. Cases where endoscopy is not possible due to altered anatomy after surgery.
Level of evidence—**1A**

Remarks

Biliary drainage in malignant resectable cases is performed to reduce the bilirubin levels and improve liver function. PTBD is usually not recommended in operable, noncomplicated periampullary mass, if the bilirubin is below 10 mg/dL in view of procedure-related complications which reduce a good surgical outcome.[31,32] If neoadjuvant chemotherapy is required, the bilirubin levels need to be decreased to less than 2 to 5 mg/dL for adequate functioning of the various chemotherapeutic drugs.[33] Biliary drainage in unresectable malignancies is mainly performed to prepare patient for palliative chemotherapy, reduce intractable pruritus, cholangitis, access for brachytherapy, and improve the quality of life.[12,34-36] In perihilar mass, since there is partial hepatectomy involved, the target bilirubin threshold is lower and so presurgical PTBD is indicated to reduce bilirubin levels to 2 to 3 mg/dL.[37,38] Cholangitis warrants urgent biliary decompression.[28,35,39-41] Elevated bilirubin with signs of systemic toxicity should be treated as cholangitis unless proven otherwise. In elderly and malnourished, fever may not be prominent and so elevated total leucocyte counts, erythrocyte sedimentation rate, and C-reactive protein are taken as markers of sepsis.[42] In postoperative biliary leak, the preferred approach is endoscopic or surgical after the drainage of symptomatic biloma, if present.[5,43,44] Percutaneous biliary drainage is performed if endoscopy fails or is contraindicated or in cases of intrahepatic biliary injury with biloma.[44,45] The biliary system is nondilated in a majority of such cases and PTBD needs expert hands. In bilioenteric anastomotic strictures, higher adhesions around the anastomotic site make the field hostile for surgeons, and hence PTBD with balloon dilatation is the preferred option to prevent recurrent cholangitis and late liver atrophy.[46,47] In surgeries

which alter the upper gastrointestinal tract anatomy, like Roux-en-Y anastomosis and Billroth procedure, standard endoscopic access to the bile ducts is limited, unless surgeon deliberately places an anterior abdominal pouch.[48] In such cases, percutaneous or enteroscopy or EUS-guided options assist in biliary access.

Q10. What are the contraindications of PTBD?

a Absolute contraindications—none.
b. Relative contraindications:
i. Deranged coagulation parameters
ii. Ascites
iii. Poor performance status
iv. Stage IV malignant disease

Level of evidence—**1A**

Remarks

PTBD is a procedure with "significant risk" of bleeding.[11] There are no absolute contraindications for PTBD.[49] However, there are multiple precautions which need to be taken while performing a safe procedure. The coagulation profile should be reasonably good. The INR should be ideally below 1.5.[12,50] There are new recommendations suggesting an INR of below 1.7 as cut-off for a safe biliary procedure.[3,10] Gupta et al, has shown less complication rates with PTBD in cases with deranged INR.[51] In elective cases with deranged INR, oral vitamin K (5–10 mg) should be administered for 3 days in adults and then reviewed.[11,12] In emergency cases, fresh frozen plasma (FFP) is infused for immediate correction. The FFP infusion should be started prior to the procedure and continued through the procedure.[4,52] Prothrombin concentrates are also recommended to restore coagulopathy in acute cases.[52,53] Platelet count should be above 50,000/mL.[39,40,54-56] Platelet rich plasma transfusion should be done if counts are less than 50,000.[5] One unit of random donor platelet increases platelet count by around 6,000/mL and one unit of single donor platelet, by around 30,000/mL.[57] Ascites is a relative contraindication.[12,40,50] Ascites increases the risk of hemoperitoneum, and causes difficulty in tracking the dilators and catheters with increased chance of catheter malposition. Patel et al, showed higher rate of complications in the presence of diffuse ascites (26%) compared with the presence of perihepatic fluid (7.3%) only.[58] Ascites needs to be drained completely prior to the procedure. However, Sofue et al, successfully placed percutaneous biliary stents in 16 patients with massive ascites with coil embolization of the track.[59] There are studies showing that ascites is not a contraindication in case of cholecystostomy.[60]

Q11. What are the indications for PC?

Acute cholecystitis with sepsis or with surgical comorbidities; obstructive jaundice with cholangitis due to common duct block where ERCP or PTBD are not feasible; as an access route for biliary interventions (**1A**).

Remarks

The most common indication for PC is acute calculous cholecystitis, occurring in individuals with high surgical risk.[61-63] A study by Akyürek et al, found that PC followed by early cholecystectomy resulted in significantly early improvement and shorter hospital stay compared with conservative management and delayed cholecystectomy.[64] The authors concluded that PC assists in resolution of sepsis and prepares patient for early cholecystectomy. Similar results were found by another study by Narayanan et al.[65] In a randomized controlled trial (RCT) by Hatzidakis et al, in 2002, the authors found that, in high-risk patients, PC was not better than conservative management in terms of clinical improvement and 30-day mortality.[66] However, they suggested to perform PC in patients who fail to respond to conservative treatment within 3 days. Interestingly, a recent multicenter RCT from Netherlands (CHOCOLATE trial), comparing PC with laparoscopic cholecystectomy in high-risk patients with acute calculous cholecystitis, showed that PC was associated with significantly higher rate of major complications (65 vs. 12%).[67] Ito et al, found that PC is significantly better than gallbladder aspiration in patients of acute cholecystitis in terms of technical success and clinical response with no difference in complications.[68] Two large retrospective studies also found that PC was associated with higher mortality and did not offer any advantage over emergent cholecystectomy in acute cholecystitis.[69,70] Hence, they suggested that PC should not be routinely used. Other indications include acute cholangitis, gallbladder mucocele, or biliary obstruction and biliary interventions (stenting or stone removal) when ERCP or PTBD is not possible or has failed.[26,27] It is important to understand that PC benefits the patients with obstruction below the level of cystic duct insertion. Li et al, found that PC for acute cholangitis in high-risk patients significantly improved the clinical symptoms in 91% and had a 30-day mortality of 9%.[71] Gallstone removal through transcholecystic route is technically successful in 85 to 94% cases with low rate of complications.[72,73]

Q12. What are the contraindications for PC?

There are no absolute contraindications. Relative contraindications include deranged coagulation parameters and ascites (**1A**).

Remarks

There are no absolute contraindications for PC.[74] Relative contraindications include coagulopathy, ascites, and gallbladder filled with calculi.[60,61,74] Duncan et al, in their study, did not find any significant difference in complications after PC between patients with and without ascites.[61] Similarly, another study comparing PC in patients without and with coagulopathy (INR >1.5; platelet count < $50x10^9$/L) found that there was no significant difference in the incidence of complications.[75]

2.2. Patient preparation prior to the procedure.

Q13. How long should the patients fast prior to biliary procedures?

Patients should be fasting for 4 to 6 hours prior to the procedure (**1A**).

Remarks

Patient should be kept fasting for 4 to 6 hours prior to the procedure.[40] Since some of the patients may require conscious sedation, American Society of Anaesthesiology recommends at least 2 hours of fasting for clear fluids and 6 hours for light meal prior to the procedure to avoid the risk of aspiration during sedation.[76,77]

Q14. How should hydration be maintained?

Adequate hydration should be maintained (**1C**). No data are available on the protocol.

Remarks

Adequate hydration needs to be maintained by intravenous fluids since patients often suffer from inadequate nutrition and fluid imbalance resulting in low intravascular volume making them vulnerable to any episode of pain-induced vasovagal shock or inadvertent bleeding during procedure.[12] Although no data are available, patients are usually infused with approximately 500 mL of fluids intravenously prior to the procedure.

Q15. What is the protocol for the administration of antibiotics?

Broad spectrum antibiotics should be administered prior to the procedure and continued for 3 to 5 days (**1A**).

Remarks

Prophylactic antibiotics should be given 1 hour prior to the procedure in patients without cholangitis.[78] The SIR guidelines recommend prophylaxis with ceftriaxone 1 g or ampicillin/sulbactam intravenously prior to fresh puncture and catheter exchanges.[79] In patients with cholangitis, broad spectrum antibiotics should be administered during the complete episode of cholangitis as mentioned vide supra.[29]

Q16. Should ascites be drained prior to the procedure?

Ascites, when present, should be drained to reduce the incidence of complications (**1A**).

Remarks

As mentioned previously, ascites is a relative contraindication due to the increased risks of bleeding and difficulties in catheter manipulation and warrants complete drainage prior to the procedure.[12,50,58] Antiplatelet drugs like aspirin and clopidogrel preferably need to be withheld for at least 5 days prior to the procedure since it doubles the bleeding risk.[80]

2.3. Basic procedure of PTBD

Q17. Under what imaging guidance should the bile duct be punctured?

Initial puncture of the bile duct should preferably be performed under USG guidance (**1A**).

Remarks

The initial puncture can be done under USG or fluoroscopic guidance depending on the individual's preference and institute protocol.[12,81] USG guided puncture is suggested to reduce procedure time, radiation dose, and the amount of use of contrast agent.[82] However, in a recent study by Nennstiel et al, comparing fluoroscopic and USG-guided PTBD, the authors found that overall procedure success, complication rates, fluoroscopy times, and procedure times were not significantly different between the groups.[83] However, in this study, fluoroscopic PTBD (n = 207) was mostly done on the right side and USG guidance (n = 44) was mostly used for the left. Further, the numbers were not comparable. Wagner et al, found that USG-guided PTBD resulted in lower incidence of complications compared with fluoroscopic PTBD.[84] The EFSUMB guidelines in 2016, recommended the use of USG for initial duct puncture with 100% consensus.[85] After initial puncture, remaining steps are performed under fluoroscopy. However, when the procedure is performed bedside, it is done completely under USG guidance.

Q18. What technique should be followed for steps after puncture?

Subsequent steps should follow Seldinger technique under fluoroscopy (**1A**). Bedside PTBD is done completely under USG guidance with external drainage (**1B**).

Remarks

The procedure is performed using the standard Seldinger technique after the initial puncture under fluoroscopy.[12,81] If the obstruction is crossed, an 8F-sized ring biliary catheter for combined internal and external drainage is placed. If not, an 8F external biliary catheter is placed and manipulation is tried few days later. When performing a bedside procedure, fluoroscopy and internalization are not possible and hence the procedure is performed under USG guidance and an external drainage catheter is placed.[51]

Q19. Should the drainage of one or both lobes be performed?

Unilobar drainage is usually adequate. Other lobe is drained if the bilirubin is persistently high or when there is cholangitis (**1B**).

Remarks

In patients with hilar obstruction, unilobar drainage is adequate to improve the liver functions. It has been suggested that drainage of 25% of the liver is sufficient to relieve symptoms of biliary obstruction, improve biochemical parameters, and reduce biliary dilatation on USG.[86] Hence, it is reasonable to perform unilobar drainage in cases of Bismuth II and III strictures.[87,88] Inal et al, found that the clinical response, complications, and stent patency were similar in unilobar and bilobar drainage groups in cases of Bismuth II and III strictures.[88] However, in type IV strictures, they suggested bilobar drainage only to improve patency of stents. Longer patency by using bilateral stents

was also shown in other studies.[89,90] Bilobar drainage has been suggested in cases of cholangitis developing after unilobar drainage and when serum bilirubin does not decrease adequately after unilobar drainage.[91]

Q20. Is left-sided approach better than right-sided one?

Either right- or left-sided approach may be chosen if there are no contraindications to drain a lobe (**1B**).

Remarks

In a patient with patent primary biliary confluence, either right or left lobe of the liver can be used to access the biliary system without any significant difference in radiation dose, procedure time, or complications.[92,93] Even in cases with blocked primary confluence, absence of lobar atrophy or cholangitis and vascular invasion by the malignancy, either right- or left-sided drainage can be performed.

Q21. Is biliary stent better than placement of catheter?

Biliary stent is preferred over catheter in malignancies for palliation (**1A**).

Remarks

In palliative setting, biliary stent is preferred as it provides better long-term patency than catheter or plastic stents. Studies comparing plastic stents and metallic stents have shown that metallic stents have significantly longer patency rates and significantly lesser reintervention rates, but similar procedure-related complication rates.[94,95] The PTBD catheter is associated with problems like early occlusion, pericatheter leakage, and partial or complete dislocation of the catheter.[96] Stents are not associated with these complications. Occasionally, the percutaneous catheter may be replaced by a plastic stent over the wire.[97]

2.4. Procedure of PC

Q22. What image guidance and technique are used for PC?

PC should be done under ultrasonography guidance, either through direct peritoneal or transhepatic routes, bed side or in interventional suite (**1A**).

Remarks

Ultrasound guidance should be used for puncturing the gallbladder. USG is the best modality to perform PC safely and comfortably.[98] Although other modalities like CT scan and fluoroscopy are occasionally used, they cannot be done bedside, are associated with radiation and increase the cost. Infrequently, after puncture under USG guidance, subsequent steps can be performed under fluoroscopy.[99] CT guidance has been used in cases when gallbladder is poorly visualized on USG.[100] Either transhepatic or transperitoneal route can be used to perform PC. A recent large study by Beland et al showed that there are no differences between transhepatic and transperitoneal routes in terms of pain, procedure-related complications, catheter occlusion, and catheter replacement.[99] Another study comparing these techniques also found no difference in complication rate.[101] It has been suggested that transhepatic route be preferred in patients with ascites and transperitoneal route in patients with liver disease or coagulopathy.[98,102] Some have suggested the use of a subcostal route than an intercostal route to avoid injury to the pleura and neurovascular bundle.[63]

Q23. What technique should be used for PC?

Either trocar or Seldinger technique can be used for PC (**1B**).

Remarks

The technique used can either be trocar or Seldinger technique. No studies are available comparing the two techniques for PC. Both techniques are considered safe although Seldinger technique reduces the chances of injury due to the use of thin initial needle and trocar technique is associated with lesser steps.[63,98] Many authors have suggested the use of Seldinger technique although there is no evidence to prefer one over the other.[27,63,98] However, with trocar technique there is a tendency to use smaller catheter.[99] Either 8F or 10F catheters are used for biliary drainage. Larger catheters can be used to improve drainage of thick material.[99]

2.5. Expected outcomes of PTBD

Q24. What are the expected clinical and laboratory outcomes of PTBD?

There is decrease in serum bilirubin values, thereby preparing the patient for surgery or chemotherapy whichever is appropriate; reduction or resolution of cholangitis, pain and pruritus (**1A**).

Remarks

The outcome of PTBD depends on the indication for which biliary drainage is performed. Most of the procedures are performed for biliary obstruction and thus to relieve jaundice and pruritus and to improve liver function tests. Clinical success is defined as reduction of the bilirubin levels by 20% of the baseline value at the end of 1 week or by 75% at the end of 1 month after PTBD.[87,103] The clinical success after PTBD ranges from 75 to 98% in the studies published.[36,104] Studies have shown that the bilirubin reaches below 1 mg/dL in one-third of patients and below 2 mg/dL in up to 60% of the patients requiring chemotherapy.[105,106] The decreasing bilirubin relieves the symptoms like jaundice and pruritus. The survival of the patients depends on the type and stage of the malignancy and PTBD prepares the patient for subsequent step of treatment and thus indirectly improves survival.[104] In patients with cholangitis, after PTBD, success is defined when there is resolution of fever, with or without reduction in the serum bilirubin levels.[107]

Q25. How do patients of bile leak respond after PTBD?

There is decrease in the bile output in the surgical drainage catheter (**1B**).

Remarks

There is limited data on the evaluation of the outcomes of PTBD performed in the setting of bile leak. When PTBD

is performed for bile leak, clinical success is defined as reduction of bile in the surgical drain and absence of contrast leak in the follow-up cholangiograms.[108] There is no clear evidence that biliary drainage improves quality of life in patients with malignancies or biliary injury.[106,109,110]

2.6. Complications of PTBD and their management

Q26. Which is the most common complication and how is it managed?

The most common major complication is cholangitis. It is treated with antibiotics, uncapping the internal/external drainage catheter, repositioning the displaced catheter, exchange or upgradation of the drainage catheter and/or draining the undrained system (**1A**).

Remarks

Cholangitis is a common major complication of PTBD. The incidence of cholangitis ranges from 3 to 9%.[92,111-114] Earlier studies have shown the incidence to be 28 to 30%.[115,116] The Society of Interventional Radiology has recommended a threshold of 10% for all major complications.[117] It is said that up to 85% of the patients have their bile contaminated with bacteria after initial PTBD, which increases to 100% during later catheter exchanges.[116] The diagnosis of cholangitis is based on the presence of fever and elevated total leucocyte counts.[118] A definition of post-PTBD raise in temperature above 38.5 degrees for 24 hours and elevation of total leucocyte count by 20% in the absence of other evidence of sepsis has been suggested.[119,120] Lucatelli et al, suggested that age, previous cholecystectomy and bilioenteric anastomotic surgery, mildly dilated or nondilated bile ducts, malignancy and unsatisfactory drainage on imaging are predictors for the development of cholangitis after PTBD.[118]

Management of cholangitis is initially similar to other types of cholangitis, which involves patient resuscitation, intravenous fluid supplements, and antibiotics.[121] Next step is to assess the status of the biliary system and catheter to identify catheter or stent occlusion, biliary dilatation, undrained lobes or segments, displaced catheter and liver abscesses. This is done with a combination of USG or CT scan and cholangiogram.[91] Occluded catheters should be exchanged, displaced catheters may be repositioned or repeat PTBD may be performed; undrained segments require drainage through PTBD, and liver abscesses need to be aspirated or drained.[84,85,119,121,122] Unclamping of the internal–external drainage catheter temporarily is also helpful.[81,123] The incidence of cholangitis can be reduced by prophylactic dose of antibiotics whenever biliary procedure is performed and by regular exchange of catheters (every 2–3 months) under antibiotic cover.[84,112,124]

Q27. How is abdominal pain managed?

Abdominal pain is another common complication, managed by analgesics (**1A**).

Remarks

Pain is a minor complication of PTBD. Procedure-related pain is a common complication of PTBD, seen in up to 55% of patients.[125,126] This occurs due to stretching of the liver capsule during initial puncture or dilatation of the tract, due to stricture dilatation and due to the presence of the catheter. The intraprocedure pain can be reduced or avoided by adequate sedation and occasionally by general anesthesia.[127] A combination of midazolam and fentanyl has been shown to be effective in controlling procedure-related pain.[128] Thoracic paravertebral block has also been shown to be beneficial in controlling pain during PTBD.[129]

Management of post procedure pain is usually by analgesics.[125] They are adequate in most of the cases. Occasionally, the catheter may need to be replaced by stent or moved to a newer access location with repeat procedure.

Q28. How is pericatheter leak managed?

Pericatheter leak is managed by repositioning a displaced catheter, upgrading the catheter, draining ascites when present, and placing a stoma bag (**1B**).

Remarks

Pericatheter leak is a morbid complication of PTBD. It is seen in up to 33% of patients of PTBD.[96,112,122] The causes of leak include occlusion of the catheter due to sludge, clots or tumor, displacement of the catheter, pericatheter tissue necrosis and ascites.[123] Management includes flushing of the catheter forcefully with warm saline, probing the catheter with hydrophilic guidewire, upgrading and/or repositioning the catheter, and replacement with internal stent and stoma bag to collect leaked bile.[122,126] Bile leak may also result in perihepatic collection which requires drainage.

Q29. What are the catheter-related complications and how are they managed?

Catheter-related complications include partial or complete displacement or fracture of catheter. They are managed by repositioning the catheter, replacing the catheter through the previous tract or performing a new procedure immediately or later depending on the extent of biliary dilatation and urgency of the drainage (**1B**).

Remarks

Catheter displacement is an important complication, often associated with long-term indwelling.[122] Partially displaced catheters should be replaced over the wire. If the catheter is fully displaced, management depends on the duration after the initial PTBD. If the catheter dislocates after approximately 10 days, a mature tract is usually formed, and it can be cannulated using a catheter and hydrophilic wire. Subsequently, a larger catheter may be inserted.[123,126] If catheter dislocates earlier, then repeat procedure may be necessary. Sometimes, displacement may result in biloma formation which may need drainage if large and symptomatic. Catheter fracture is an uncommon complication, which occurs particularly when it is connected to a bag for a long time. If the fracture site is external, then the catheter should be replaced over a wire. If it is deep, then steps should be taken to remove or push the fracture fragment and replace it with new catheter.[130]

Q30. What are the manifestations and management options for hemorrhagic complications?

Hemorrhagic complications present in the form of bleeding from or around the catheter, hematemesis or melena or hypotension and shock. They are managed, depending on the severity, by capping the catheter for tamponade, doing cholangiogram or CT angiography followed by DSA and embolization wherever necessary (**1A**).

Remarks

Hemorrhagic complications after PTBD are uncommon but are potentially lethal. The incidence of these complications ranges from 2 to 3%.[131] In a large study involving 3,110 patients by Choi et al, the incidence of severe hemorrhage was 1.9%.[132] Most common presentation is bleeding in the catheter or blood mixed with bile. Other presentations include pericatheter bleeding, gastrointestinal bleeding like hematemesis or melena, hemodynamic instability and shock.[133] Delayed bleeding (after 3–7 days of PTBD) is usually due to arterial injury.[133,134] Bleeding may occur into the perihepatic space and peritoneal cavity. Since PTBD is an invasive procedure, some amount of blood in the drain is normal during the initial 24 to 48 hours.[122]

Management of minor hemorrhage, in a hemodynamically stable patient is conservative.[113] If the bleeding is persistent, cholangiogram without or with CT angiogram is necessary to identify any bleeding source.[126] Venous communication on cholangiogram can be managed by temporary clamping of the catheter or upgrading the catheter.[126] Occasionally, coil embolization of the vein or placement of stent graft may be necessary.[135,136] Sometimes, bleeding may occur due to a malpositioned catheter with holes communicating with portal vein branches and hence may need repositioning.[123] Arterial communication or arteriobiliary fistula and any pseudoaneurysm (hepatic, intercostal, or abdominal wall arteries) are treated by embolization. Angiography should be performed, preferably with the catheter removed over a wire, for better demonstration of the site of bleeding.[137] The standard "sandwich technique," i.e., closure of distal and proximal openings, is used for embolization, usually with coils.[126] If this is not possible, *n*-butyl cyanoacrylate glue may be used, either endovascularly or by direct percutaneous route, if the pseudoaneurysm is seen on USG.[138]

Q31. How common is pancreatitis after PTBD and how is it managed?

Pancreatitis is an uncommon complication. It is managed similar to acute pancreatitis occurring due to other etiologies (**1B**).

Remarks

Acute pancreatitis occurring after biliary intervention is an uncommon complication with a prevalence ranging from 0.48 to 6%.[119,126,139] It is defined as new onset of epigastric pain after PTBD with the elevation of serum amylase or lipase more than three times normal within 24 hours of the procedure.[119] Asymptomatic hyperamylasemia is common after PTBD and is seen in up to one-fifth of the patients.[139] The risk is higher whenever the distal bile duct or ampulla is manipulated as with placement of internal–external drainage catheter or stent.[126,139] Majority of them will develop mild pancreatitis. Management is similar to acute pancreatitis developing due to other etiologies.

2.7. Follow-up of patients of PTBD

Q32. How are patients of PTBD followed up?

- Regular clinical evaluation should be done by evaluating patient's performance status, jaundice and fever.
- Laboratory parameters like serum bilirubin and alkaline phosphatase should be regularly done.
- Ultrasonography and/or cholangiogram, should be performed whenever necessary.
- Catheter exchanges must be done at regular intervals.

Level of evidence: **1B.**

Remarks

No standard follow-up protocol has been recommended after PTBD. However, many studies have suggested that the patients with internal–external drainage catheters be reviewed every 2 to 3 months for any delayed complications and perform check of cholangiogram and catheter exchange.[84,112] Patients should be evaluated clinically for improvement in jaundice and fever. Liver function tests should be evaluated once in 1 to 2 weeks to assess the clinical response of PTBD or stenting, more frequently in the initial 2 weeks.[140] If the serum bilirubin is stagnant or increasing, then repeat evaluation should be done to look for any undrained segments and procedure should be performed to drain them. The patients should be advised to flush the catheters with 20 mL of sterile saline two to three times every day to prevent clogging of the catheter.[112,122] In patients who are on external drainage, adequate hydration should be advised. In the event of any symptoms related to the procedure like fever, pericatheter leak, catheter displacement, abdominal distension or bleeding, they should be advised to visit the hospital for further evaluation according to the symptoms. If an imaging becomes necessary, USG or CT scan should be performed. MRI is occasionally necessary.

2.8. Complications and outcomes of PC.

Q33. What are the complications of PC?

Common complications include catheter displacement, bile leak, biliary peritonitis, and hemorrhage; management is by repeat procedure, catheter replacement, drainage, and embolization (**1B**).

Remarks

The incidence of complications after PC ranges from 2.4 to 16%.[100,141] The complications associated with transhepatic route of PC include pain, sepsis, bleeding from the liver, biliary fistula, and pneumothorax.[142] Pain can be managed by parenteral analgesics. Biliary infection is managed

mostly with antibiotics.[143] Mild bleeding usually settles on conservative management.[27] Severe bleeding may need CT angiogram and embolization. Catheter dislodgement, occurring in up to 9% of the patients, may be asymptomatic or may result in bile leak which requires repeat procedure or drainage of biloma or both.[142,144] Procedure-related mortality is seen in <1% cases.[100,145]

Q34. What are the outcomes of PC?

The aim of PC is relief of acute symptoms and infrequently, biliary obstruction (**1B**).

Remarks

The response to PC, depending on the indication, is considered positive, when the symptoms resolve, the body temperature decreases to below 37.5 degrees and there is decrease in total leucocyte count by 25% within 72 hours of the procedure.[146] Follow-up is done by clinical and laboratory parameters and if necessary, by imaging, usually USG. After PC, the catheter should be left in situ for at least 4 to 6 weeks to allow maturation of the tract.[98,147] The catheter should be flushed with sterile saline twice a day to prevent clogging. Clogged catheters can be cleared by passing a guide wire through them or they may be replaced with newer catheters.[98]

2.9. Indications for BS.

Q35. What are the indications for BS?

Malignant biliary obstruction is the most common indication, particularly in the palliative setting (**1A**).

Remarks

Metallic stents are the standard palliative forms of treatment of malignant biliary strictures.[148] Metallic stents provide better long-term patency rates compared with plastic stents in inoperable malignant strictures.[149] The median patency rates are in the range of 7 to 9 months.[150,151] Stenting may be unilobar or bilobar, but the former is usually adequate as described earlier for unilobar biliary drainage.[13,87,134] A recent randomized controlled trial also confirmed that bilobar drainage does not offer benefit over unilobar drainage.[152] Similarly, a recent meta-analysis also found that efficacy and safety of unilobar and bilobar endoscopic stenting are comparable.[153]

Q36. What is the role of biliary stents in benign biliary strictures?

The role of stents in benign biliary strictures is not well established (**1B**).

Remarks

Although, stents are not usually advised for benign biliary strictures, retrievable covered self-expandable metallic stents (SEMS) are increasingly being used with clinical success rates ranging from 75 to 90%.[154-156] Stent migration rates were 14 to 20% in these patients. In addition, biodegradable stents, which spontaneously dissolve in 3 to 6 months, are finding place in the management of benign strictures with promising results.[157,158]

2.10. Types of biliary stents and their indications.

Q37. What is the type of stent used in malignant biliary obstruction?

The widely used stent for malignant biliary obstruction is uncovered self-expandable metallic stent. Covered stents are still not routinely recommended for malignant biliary obstruction (**1A**).

Remarks

Various types of biliary stents available include uncovered SEMS, covered stents which may or may not be retrievable, bioabsorbable stents, and drug eluting stents.[134,148] Uncovered SEMS are routinely recommended for malignant biliary strictures. Covered stents have been suggested to reduce tumor ingrowth and improve patency; however, they are associated with increased migration rates and possibility of isolation of biliary, cystic and pancreatic ducts.[148] Studies comparing uncovered and covered SEMS for malignant strictures have shown no distinct advantage of covered over uncovered stent.[151] This was shown in a meta-analysis of 20 randomized controlled trials.[159] Another large randomized controlled study by Kullman et al showed no difference in stent patency or survival of patients between covered and uncovered SEMS.[160] Absence of survival benefit with covered SEMS was also shown in a meta-analysis evaluating 2,239 patients.[161] Further, since covered SEMS are expensive, it is currently recommended to use uncovered SEMS routinely.

Q38. Are metallic stents better than plastic stents?

Metallic stents are always better than plastic stents for malignant strictures (**1B**).

Remarks

Metallic stents are associated with longer patency rates compared with plastic stents due to their larger calibre.[89,95,96,103,149] The recommended size of the metallic stent is 8 to 10 mm.[162] Plastic stents are typically placed endoscopically for benign conditions and preoperatively for malignant pathologies.[22,25] Although, plastic stents may be exchanged when necessary endoscopically, removing a metallic stent is challenging.

Q39. What types of stents are used in benign biliary strictures?

Retrievable covered stents are promising in benign biliary strictures (**1B**).

Remarks

Retrievable covered stents have been successfully used in the management of benign biliary strictures.[154-156] Covered stents have a larger diameter and maintain dilatation as long as they are in place.[148,155] With a mean indwelling period of 6 to 12 months, these stents provide a clinical success of 75 to 90% and mean duration patency of the stricture after stent removal of 36 months.[154-156] The covered stents offer significantly longer patency rates

of benign bilioenteric anastomotic strictures compared with balloon dilatation (3-year patency 85 vs. 53%).[163]

Q40. What is the current role of bioabsorbable stents?

Bioabsorbable stents are used in research settings, particularly in benign strictures (**1B**).

Remarks

Biodegradable stents, as described in the previous section, have shown promising results in the management of benign biliary strictures.[157,158] They have been used in cases which fail standard treatment. A recent meta-analysis comparing biodegradable stents and multiple plastic stents in benign biliary strictures showed that clinical success rate was similar in both groups (83 vs. 84%), but the incidence of cholangitis was higher in the plastic stent group.[164]

Q41. What is the status of drug eluting stents for malignant biliary strictures?

The role of drug eluting stents is not established (**1C**).

Remarks

Drug eluting stents, like paclitaxel coated stents, have been proposed to improve patency and survival in malignant strictures, but have not been proven in small studies evaluating its use.[165,166] Hence, its use is not established.

2.11. BS technique in malignant biliary obstruction

Q42. Should biliary stent be deployed in one stage or two stages?

Both one-stage and two-stage deployment of the stents can be performed (**1B**).

Remarks

Biliary stent placement may be performed either in a single stage (primary) or in two stages (PTBD followed by stent; secondary).[167,168] Both the techniques are effective. However, in view of shorter hospital stay and reduced cost, primary stenting is preferable.[167,168] Predilatation of the stricture prior to stenting is not advisable.[167] Although balloon dilatation prior to stenting is feasible, it has no effect on the long-term outcomes.[169]

Q43. Is suprapapillary stent placement better than transpapillary position?

Between suprapapillary and transpapillary stent placement neither has distinctly shown benefit over the other (**1B**).

Remarks

In cases with strictures involving the hila and proximal bile duct, it is not clear whether the distal end of the stent should be across the papilla or remain proximal to it.[134,170] Few studies have shown that suprapapillary stenting results in reduced incidence of pancreatitis and ascending cholangitis.[171,172] However, other studies have shown no significant difference between the two techniques in effectiveness and safety.[170,173]

Q44. How should bilobar stents be placed?

Bilobar stents may be placed as stent-in-stent or parallel stent and in T or Y configuration (**1B**).

Remarks

When draining both lobes, either T stent or Y stent may be deployed. T-stent allows drainage of both lobes through a single access site whereas Y-stent requires two separate access to the bile ducts.[151] Both techniques are safe and provide effective biliary drainage.[174-176] Deployment may be simultaneous or sequential and stent-in stent or parallel, with no difference between the techniques.[177-180]

2.12. Technique for PTBD in benign strictures or bile leaks

Q45. What is the difference in technique for PTBD in benign strictures or bile leaks?

Benign strictures and bile leaks are associated with minimally dilated or nondilated bile ducts which increase the difficulty of the procedure and complications. There is no difference in the procedural steps of PTBD (**1B**).

Remarks

The major group encompassing benign biliary strictures (BBS) includes postoperative anastomotic strictures, typically post LT bile duct stricture, and bilioenteric (hepaticojejunostomy) anastomotic stricture. In the presence of dilated ducts due to benign stricture, no additional challenges are encountered in performing PTBD. However, a good number of patients with benign strictures or and majority with bile leaks, do not show dilated intrahepatic bile ducts.[181,182] In view of this, obtaining access to the bile ducts requires more skill and experience. Studies have suggested a combination of USG and fluoroscopy as guidance to puncture the bile ducts.[183,184] The technical success rate of PTBD in nondilated system is in the range of 90 to 100%.[108,185,186]

Q46. What are the percutaneous methods of treating benign biliary strictures?

Benign strictures are managed by balloon dilatation, serial upgradation to large bore catheters and stents (**1B**).

Remarks

No standard protocol has been defined for the management of benign biliary strictures as these are frequently difficult to treat and require long-term and repeated interventions.[148,187] Percutaneous balloon dilatation is a simple, safe, and effective technique for the treatment of BBS.[188] A study by Janssen et al suggested that balloon dilatation with long-term drainage resulted in >85% clinical success.[189] Another study by Bonnel and Fingerhut, studying percutaneous balloon dilatation for bilioenteric (hepaticojejunostomy) anastomotic strictures showed a patency of 90.9% and recurrence rate of 15%.[190] Cutting balloons may be used for recalcitrant strictures.[191,192] Another technique of treatment in post-transplant bile duct strictures is serial upgradation of catheter from 8F to 18 to 20 F which is then left in situ for at least 3 to 6 months.[193] This

resulted in primary patency rates of 81 to 89%. Other techniques are the use of covered and biodegradable stents with good results. They have been described in the previous section (Q-39,40). The studies available are retrospective with no randomized controlled trials.

Q47. What is the role of percutaneous biliary intervention in liver transplant patients?

Endoscopic stenting is the preferred option in case of biliary strictures or bile leaks in post-transplant patients; if endoscopic attempt is unsuccessful or there is altered anatomy (bilioenteric anastomosis), percutaneous biliary drainage is the option **(1B).**

Remarks

Biliary complications are common (10–25%) after LT and more common with living donor LT compared with deceased donor LT.[194] Biliary leak comprises of the majority of post-transplant biliary complications (2–25%) and is due to anastomotic dehiscence, ischemia, and sphincter of Oddi hypertension.[195] Biliary strictures usually present late (after 3 months) and can be anastomotic or nonanastomotic. Endoscopic plastic stenting is the preferred treatment option in managing these complications.[195] However, in cases where bilioenteric anastomosis has been performed (LT in patients with biliary disease like primary sclerosing cholangitis) and in unsuccessful endoscopic attempts, percutaneous biliary drainage is attempted. PTBD is technically challenging as the bile ducts are either nondilated or minimally dilated. Mukund et al, described salvage PTBD in LT patients (n = 32) with failed endoscopic approach and showed complete and sustained clinical and biochemical improvement in 82% of the patients.[196] The technique failed to resolve sepsis in 18% of patients. Another study by Jegadeesan et al, evaluating 39 patients who underwent PTBD after failed ERCP for post LT biliary stricture, found PTBD successful in 87% cases with 15% morbidity.[197] Studies have shown that endoscopic stenting has a success rate of 75 to 80% in biliary complications after LT and PTBD is used as a second line option.[198]

2.13. Brush cytology or brush biopsy in malignant biliary strictures

Q48. What is the role of brush cytology or brush biopsy in cases of malignant biliary strictures?

Intrabiliary brush cytology or biopsy should be obtained whenever possible, particularly when other methods of tissue sampling are not possible or fail (**1B**).

Remarks

Sampling of the endobiliary tissue may be in the form of cytology or biopsy, which may be done by percutaneous or endoscopic route.[81] The standard fine needle aspiration cytology is less sensitive for small tumors of the biliary system.[199] Cytology with biopsy is more effective in diagnosis than cytology alone.[199] The technique involves insertion of a vascular sheath (6F) across the stricture over a wire and then inserting the cytology brush through the sheath followed by repeated movements of the brush at the level of stricture.[81] The diagnostic sensitivity and specificity of brush cytology are 68 and 100%, respectively.[200,201] Forceps biopsy is better than cytology in the diagnosis of malignancy.[202,203]

2.14. Current status of intrabiliary treatment techniques for malignant strictures

Q49. What is the current status of intrabiliary RFA for malignant strictures?

Intrabiliary RFA has been shown to increase the patency rates of biliary stent and may be used (**1B**).

Remarks

Biliary RFA uses an over-the-wire bipolar electrode which has been shown to create an ablation zone depth of 1.3 to 4.4 mm.[204] In a retrospective study of 50 patients of unresectable malignant biliary obstruction, percutaneous RFA and biliary stent placement were found to be a safe and feasible palliative option.[205] It has also been shown to improve stent patency.[206] In patients developing stent obstruction, few short series have shown the benefit of RFA and balloon sweep in recanalization.[207-209] One recent randomized controlled trial from China showed that endoscopic RFA with stenting significantly increases stent patency and survival in patients with extrahepatic cholangiocarcinoma.[210]

Q50. What is the role of intrabiliary radiation therapy for malignant biliary strictures?

Intrabiliary radiation therapy improves patency of the stent and patient survival (**1C**).

Remarks

Two recent retrospective studies have shown that biliary stent with intracavitary radiation with Iodine-125 particles improves the stent patency and patient survival.[211,212] Zhou et al showed that, in patients with malignant biliary strictures, stent with I-125 particles had significantly better patency (194d vs. 86d) and overall survival (194d vs. 96d) compared with the control group.[212] In another large multicenter study by Zhu et al, irradiation stents were associated with lower stent restenosis rate (21 vs. 33%) and longer survival (202d vs. 140d) when compared with standard uncovered SEMS.[213] However, no randomized controlled trials have proven their undisputable benefit.

2.15. Other methods of biliary drainage and their indications

Q51. What are the other methods of biliary drainage?

Other methods of biliary drainage include endoscopic drainage, surgical drainage, and endoscopic ultrasound-assisted drainage (**1A**).

Remarks

In patients requiring biliary drainage, various approaches include percutaneous, endoscopic, endoscopic ultrasound, and surgical approach.[214] Surgical method of drainage is associated with higher morbidity and mortality and

hence is used as a last resort, when other minimally invasive techniques have failed.[215]

Q52. What is the indication for endoscopic drainage and is it better than PTBD?

Endoscopic drainage is suggested as the initial choice in cases of mid and lower bile duct obstruction and with normal upper gastrointestinal anatomy (**1A**).

Remarks

Many studies have compared endoscopic and percutaneous biliary drainage in the treatment of malignant biliary strictures. A meta-analysis evaluating three RCTs and 11 retrospective studies compared 2,246 patients who underwent PTBD and 8,100 patients who underwent EBD for malignant obstructive jaundice.[216] They found no difference between PTBD and EBD in terms of clinical success, complication, and 30-day mortality and suggested that the choice of approach should depend on the level of obstruction, purpose of drainage, and level of expertise. Another meta-analysis comparing both techniques for preoperative drainage in operable hilar cholangiocarcinoma found that PTBD was associated with lower rate of complications (cholangitis and pancreatitis).[217] These results were also confirmed by another meta-analysis evaluating six trials.[25]

Q53. What is the role of endoscopic ultrasound-guided biliary drainage?

Endoscopic ultrasound-assisted drainage is increasingly being used, but its role is yet to be established (**1B**).

Remarks

Endoscopic ultrasound-guided biliary drainage (EUSBD) is increasingly being used in cases where standard endoscopic route fails.[218] Two recent meta-analysis comparing EUSBD with ERCP-BD found that EUSBD has similar efficacy and safety as ERCP-BD in cases of distal malignant biliary obstruction.[219,220] An RCT studying 125 patients also confirmed that EUSBD and ERCPBD provide comparable technical and clinical success rates.[221] However, EUSBD was associated with longer stent patency, lower complications, and more preserved quality of life. A retrospective study comparing EUSBD and PTBD for distal malignant biliary stricture showed that both have similar levels of efficacy.[222] But, EUSBD had fewer complications and reintervention rates. Similar results were found in another retrospective study by Sharaiha et al.[223] However, another recent study showed that EUSBD did not offer advantage over PTBD.[224] Thus EUSBD may be an option in patients with distal biliary obstruction, when ERCP fails, provided the expertise is available. Also, a study has shown that it is better in patients who have ascites.[225]

Q54. When is surgical biliary drainage indicated?

Surgical drainage is indicated in patients who fail minimally invasive procedures or who need definitive treatment (1A).

Remarks

Surgical method of drainage is associated with higher morbidity and mortality and hence is used as a last resort, when other minimally invasive techniques have failed, in the palliative setting.[215] However, in patients with resectable tumors, this is the curative treatment of choice.[25,217]

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Conflict of Interest

None declared.

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