

Preoperative biliary drainage for biliary tract and ampullary carcinomas

MASATO NAGINO¹, TADAHIRO TAKADA², MASARU MIYAZAKI³, SHUICHI MIYAKAWA⁴, KAZUHIRO TSUKADA⁵, SATOSHI KONDO⁶, JUNJI FURUSE⁷, HIROYA SAITO⁸, TOSHIO TSUYUGUCHI⁹, TATSUYA YOSHIKAWA¹⁰, TETSUO OHTA¹¹, FUMIO KIMURA³, TAKEHIRO OHTA¹², HIDEYUKI YOSHITOMI³, SATOSHI NOZAWA³, MASAHIRO YOSHIDA², KEITA WADA², HODAKA AMANO², and FUMIHIKO MIURA²

¹Division of Surgical Oncology, Department of Surgery, Nagoya University Graduate School of Medicine, 65 Tsurumai-cho, Showa-ku, Nagoya 466-8550, Japan

²Department of Surgery, Teikyo University School of Medicine, Tokyo, Japan

³Department of General Surgery, Chiba University Graduate School of Medicine, Chiba, Japan

⁴Department of Gastroenterological Surgery, Fujita Health University, Toyoake, Japan

⁵Department of Surgery and Science, Graduate School of Medicine and Pharmaceutical Science for Research, University of Toyama, Toyama, Japan

⁶Department of Surgical Oncology, Hokkaido University Graduate School of Medicine, Sapporo, Japan

⁷Hepatobiliary and Pancreatic Oncology Division, National Cancer Center Hospital East, Chiba, Japan

⁸Department of Radiology, Asahikawa Kosei General Hospital, Asahikawa, Japan

⁹Department of Medicine and Clinical Oncology, Chiba University Graduate School of Medicine, Chiba, Japan

¹⁰Tokyo Metropolitan Health and Medical Treatment Corporation, Ebara Hospital, Tokyo, Japan

¹¹Department of Gastroenterologic Surgery, School of Medicine, Kanazawa University, Kanazawa, Japan

¹²Department of Surgery, Institute of Gastroenterology, Tokyo Women's Medical University, Tokyo, Japan

Abstract

We posed six clinical questions (CQ) on preoperative biliary drainage and organized all pertinent evidence regarding these questions. CQ 1. Is preoperative biliary drainage necessary for patients with jaundice? The indications for preoperative drainage for jaundiced patients are changing greatly. Many reports state that, excluding conditions such as cholangitis and liver dysfunction, biliary drainage is not necessary before pancreatoduodenectomy or less invasive surgery. However, the morbidity and mortality of extended hepatectomy for biliary cancer is still high, and the most common cause of death is hepatic failure; therefore, preoperative biliary drainage is desirable in patients who are to undergo extended hepatectomy. CQ 2. What procedures are appropriate for preoperative biliary drainage? There are three methods of biliary drainage: percutaneous transhepatic biliary drainage (PTBD), endoscopic nasobiliary drainage (ENBD) or endoscopic retrograde biliary drainage (ERBD), and surgical drainage. ERBD is an internal drainage method, and PTBD and ENBD are external methods. However, there are no reports of comparisons of preoperative biliary drainage methods using randomized controlled trials (RCTs). Thus, at this point, a method should be used that can be safely performed with the equipment and techniques available at each facility. CQ 3. Which is better, unilateral or bilateral biliary drainage, in malignant hilar obstruction? Unilateral biliary drainage of the future remnant hepatic lobe is usually enough even when intrahepatic bile

ducts are separated into multiple units due to hilar malignancy. Bilateral biliary drainage should be considered in the following cases: those in which the operative procedure is difficult to determine before biliary drainage; those in which cholangitis has developed after unilateral drainage; and those in which the decrease in serum bilirubin after unilateral drainage is very slow. CQ 4. What is the best treatment for post-drainage fever? The most likely cause of high fever in patients with biliary drainage is cholangitis due to problems with the existing drainage catheter or segmental cholangitis if an undrained segment is left. In the latter case, urgent drainage is required. CQ 5. Is bile culture necessary in patients with biliary drainage who are to undergo surgery? Monitoring of bile cultures is necessary for patients with biliary drainage to determine the appropriate use of antibiotics during the perioperative period. CQ 6. Is bile replacement useful for patients with external biliary drainage? Maintenance of the enterohepatic bile circulation is vitally important. Thus, preoperative bile replacement in patients with external biliary drainage is very likely to be effective when highly invasive surgery (e.g., extended hepatectomy for hilar cholangiocarcinoma) is planned.

Key words Biliary · Drainage · Endoscopy · Percutaneous · Bile replacement · Guidelines

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Introduction

In the 1980s, several randomized controlled trials (RCTs) were conducted in Western countries to determine the clinical value of percutaneous transhepatic biliary drainage (PTBD). These RCTs concluded that

“preoperative biliary decompression using PTBD did not improve surgical outcomes.” However, there were many concerns regarding these RCTs: first, most of the surgeries performed in these studies were bypass or palliative small resections, and few major surgeries such as pancreatoduodenectomy or hepatectomy were included; second, PTBD-related complications were very high; and the drainage period was insufficient. Thus, most Japanese surgeons were skeptical about the results of these RCTs, yet they were motivated to reevaluate preoperative biliary drainage in the treatment of obstructive jaundice.

Subsequently, the view of preoperative biliary drainage has changed dramatically, and a consensus has started to form that, in many cases, preoperative biliary drainage is unnecessary, even before pancreatoduodenectomy. Recently, a surprising study was reported suggesting that preoperative biliary drainage is unnecessary even before extended hepatectomy for jaundiced patients.

In this article, we have posed six clinical questions (CQs) on preoperative biliary drainage and organized all pertinent evidence regarding the questions. In the responses to the CQs, recommendations for treatment are noted (grades of these recommendations are defined in Table 1¹). Also, levels of evidence are given (in parentheses) for findings in reference citations (see definitions of levels in Table 2¹).

Table 1. Strength of recommendations¹

A, Strongly recommend performing the clinical action
B, Recommend performing the clinical action
C1, The clinical action may be considered although there is a lack of high-level scientific evidence for its use. May be useful
C2, Clinical action not definitively recommended because of insufficient scientific evidence. Evidence insufficient to support or deny usefulness
D, Recommend not performing the clinical action

Table 2. Levels of evidence¹

Level I	Systematic review/meta-analysis
Level II	One or more randomized clinical trials
Level III	Nonrandomized controlled trials
Level IV	Analytic epidemiology (cohort studies and case-control studies)
Level V	Descriptive study (case reports and case-series studies)
Level VI	Opinions of expert panels and individual experts not based on patient's data

CQ 1 Is preoperative biliary drainage necessary for patients with jaundice?

Preoperative biliary drainage is necessary for patients with cholangitis or patients scheduled to undergo extended hepatectomy (recommendation B).

The proper approach to obstructive jaundice has been debated for a long time. Although research on the pathology of the disease is progressing with time, it is still not well understood. As obstructive jaundice affects the liver, kidneys, gastric mucosa, coagulation, the immune system, and other systems, biliary drainage has been a routine preoperative management for jaundiced patients in Japan. However, RCTs conducted in Western countries raised questions about the effectiveness of preoperative biliary drainage. The results of these trials showed no significant difference in postoperative morbidity and mortality between patients who received preoperative biliary drainage and those who did not. These RCTs concluded that, considering the potential risk related to PTBD, preoperative biliary drainage had no advantage, and was unnecessary²⁻⁴ (level II). These RCT studies included mostly bypass surgeries and palliative small resections, involving few major procedures such as hepatectomy for jaundiced liver. In addition, the incidence of PTBD-related complications was extremely high. These flaws made it difficult to accept the conclusions of these RCTs.

There was a time when nationwide RCTs were being considered in Japan as well, but they never came about, for various reasons. Recently, several reports from Western countries have clearly shown that preoperative biliary drainage is unnecessary, except for patients with cholangitis or poor hepatic function, before pancreatoduodenectomy or less invasive surgery, although these studies were retrospective, not RCTs⁵⁻⁹ (level IV). However, mortality after extended hepatectomy for jaundiced patients is still high, near 10%, and the cause of death is mainly hepatic failure¹⁰ (level IV). These observations indicate that preoperative biliary drainage should be recommended before extended hepatectomy, in spite of a lack of clear evidence based on RCTs.

CQ 2 What procedures are appropriate for preoperative biliary drainage?

Regardless of the location of the biliary obstruction, percutaneous transhepatic, endoscopic, or surgical drainage can be used. However, a method should be used that can be safely performed with the equipment and techniques available at each facility (recommendation B).

There are three different kinds of biliary drainage methods: percutaneous transhepatic biliary drainage (PTBD), endoscopic drainage (endoscopic nasobiliary drainage [ENBD] or endoscopic retrograde biliary drainage [ERBD]), or surgical drainage. There are no RCTs that compare PTBD, ENBD, and ERBD as the most appropriate method for preoperative biliary drainage. Two RCTs on stent therapy for unresectable cases concluded that an endoscopic procedure was superior to percutaneous stents and bypass operations, especially in patients with lower bile duct obstruction^{11,12} (level II). In hilar malignancies in which multiple biliary drainages are required, endoscopic drainage is often difficult and is closely associated with cholangitis, while percutaneous drainage is effective and recommended^{13–15} (level IV).

CQ 3 Which is better, unilateral or bilateral biliary drainage, in malignant hilar obstruction?

In principle, unilateral drainage in the future remnant lobe is enough (recommendation C1).

It is well known that a sufficient decrease in serum bilirubin can be achieved through unilateral drainage (drainage of either the left or right lobe), as the hepatic reservoir for the excretion of bilirubin is quite large.

The strategy for biliary drainage, i.e., right-side drainage, left-side drainage, or both, is directly linked to the selection of the operative procedure. The advent of Multidetector row computed tomography (MDCT) has made it possible to determine the surgical procedure for jaundiced patients before biliary drainage^{16,17} (level IV). In addition, the types of hepatectomy have changed since the introduction of portal vein embolization; the performance of central hepatectomies, including S1 resection, S1 + 4 resection, S1 + 5 + 8 resection, and S1 + 4 + 5 + 8 resection, has become uncommon, while typical major hepatectomies including right or left hepatectomy, and right or left trisectionectomy have been increasingly performed^{18–20} (level IV). Overall, unilat-

eral drainage of the future remnant lobe is enough in many patients.

Bilateral biliary drainage should be considered in the following cases: those in which the operative procedure is difficult to determine before biliary drainage; those in which cholangitis has developed after unilateral drainage; and those in which the decrease in serum bilirubin after unilateral drainage is very slow. Unilateral or bilateral drainage should be determined on a case-by-case basis considering the operative procedure, liver function, and/or the presence or absence of cholangitis.

CQ 4 What is the best treatment for post-drainage fever?

Treat with antibiotics and confirm whether the biliary drainage is effective. If the drainage is effective, suspect cholangitis in the undrained segment (segmental cholangitis; recommendation B).

Segmental cholangitis may occur when an undrained segment is left despite the performance of biliary drainage using PTBD, ERBD, or another procedure. Thus, segmental cholangitis never develops in middle or lower bile duct obstruction and is seen only when there is hilar obstruction such as Bismuth type III and IV²¹ hilar cholangiocarcinomas or advanced gallbladder carcinoma involving the hepatic hilus. Segmental cholangitis is a potential cause of posthepatectomy liver failure²² (level IV) and may worsen the surgical outcome^{23,24} (level IV); thus, segmental cholangitis must be treated immediately.

When a patient with hilar cholangiocarcinoma who has already undergone biliary drainage suddenly presents with high fever, the most probable cause of the fever is cholangitis due to drainage catheter obstruction or catheter dislodgement, or segmental cholangitis in the undrained segment (Fig. 1). If cholangiography demonstrates no problem with the existing catheter, segmental cholangitis should be suspected. After giving antibiotics and identifying the undrained bile duct by computed tomography (CT) or ultrasonography (US), drainage must be urgently performed in the undrained segment^{24,25} (level V). Even with a wait-and-see approach when using antibiotics, drainage should be considered if the fever does not come down within 1 or 2 days. Drainage can become effective either through the additional insertion of a new PTBD catheter or, if possible, through inserting the existing catheter into the undrained bile tract.^{23,25,26} The latter method is less invasive and less painful for the patient. If drainage is done properly, the fever comes down by the following day in most patients, and administration of antibiotics for 2 or 3 days is sufficient²⁷ (level IV).

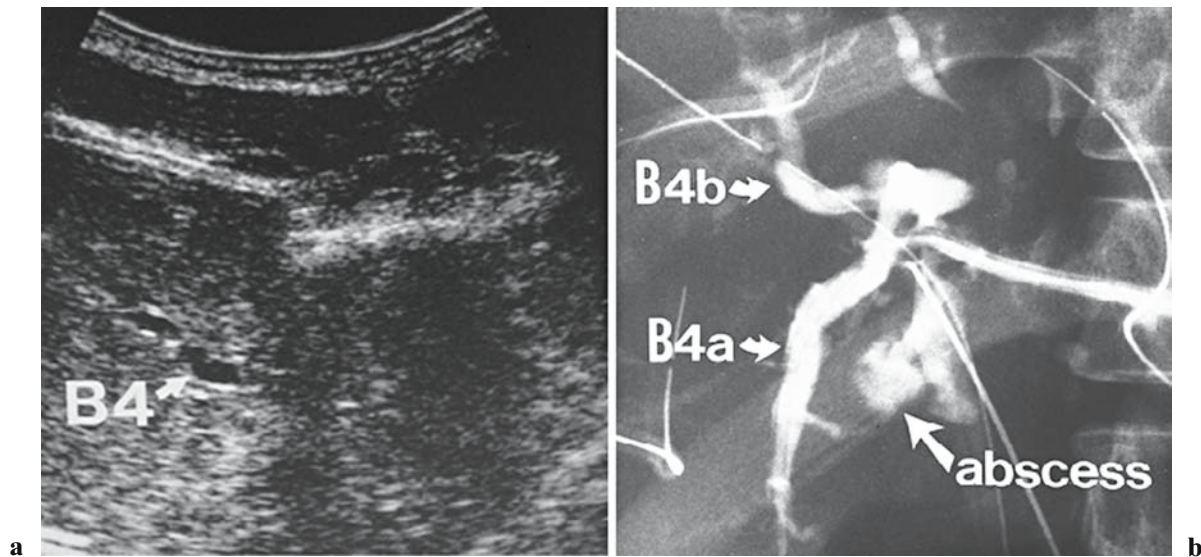


Fig. 1a,b. A patient who had undergone percutaneous transhepatic biliary drainage (PTBD) suddenly presented with high fever. **a** Abdominal ultrasound demonstrated dilation of the left medial segmental bile duct (*B4*). A diagnosis of seg-

mental cholangitis of this undrained segment was made, and additional PTBD was performed urgently. **b** Cholangiogram through the PTBD catheter shows typical findings of liver abscess

CQ 5 Is bile culture necessary in patients with biliary drainage who are to undergo surgery?

Monitoring of bile culture is necessary to select appropriate antibiotics in the perioperative period (recommendation B).

Once biliary drainage has been performed, the bile is contaminated with microorganisms. In recent studies involving patients who underwent pancreatoduodenectomy, the incidence of postoperative infections was significantly higher in patients with biliary infection before surgery than in those without.^{28,29} Furthermore, in 30% to 50% of cases, the microorganisms isolated from postoperative infections were identical to those found in the preoperative bile cultures^{13,28,29} (level IV). Therefore, identification of microorganisms in bile before surgery is necessary to enable selection of the appropriate prophylactic antibiotics after surgery.

CQ 6 Is bile replacement useful for patients with external biliary drainage?

Bile replacement may be useful (recommendation C1).

Maintenance of the enterohepatic circulation of bile is important for host defense function. In humans, it is

well known that the increased intestinal permeability caused by obstructive jaundice is recovered after internal biliary drainage^{30,31} (level IV). A recent study has shown that bile replacement by oral intake during external drainage helps restore intestinal barrier function in patients with biliary obstruction, similar to findings that have been documented in studies of internal drainage³² (level IV). Internal drainage (ERBD) is more physiological than external drainage (PTBD and ENBD), as the enterohepatic circulation of bile is maintained. Several experimental studies have demonstrated that internal drainage is superior to external drainage, from the viewpoints of intestinal immunity, prevention of bacterial translocation, and liver regeneration.

Preoperative bile replacement is recommended for patients scheduled to undergo hepatectomy for biliary cancer, as this type of hepatectomy is still a high-risk procedure. However, further studies are required to assess whether bile replacement can prevent gut-derived bacterial translocation and, in turn, reduce the incidence of postoperative septic complications.

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