Preoperative Biliary Drainage

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13.1 Effects of Biliary Drainage

13.1.1 Introduction

Obstructive jaundice, clinically evident by jaundiced skin, nausea, pruritus, dark urine and discoloration of stool, is the most prevalent presenting symptom of hilar cholangiocarcinoma (HCCA). Obstructive jaundice is associated with a proinflammatory state, resulting from portal and systemic endotoxemia, increased permeability of the intestinal mucosal barrier, an altered reticuloendothelial system function of Kupffer cells in the liver, and increased concentrations of proinflammatory cytokines [1–3]. The exact link between jaundice and the development of infectious complications remains yet to be elucidated, but jaundice has been largely recognized as a major risk factor for performing pancreatic and liver surgery [4–6]. The presence of toxic substances such as bilirubin and bile salts, impaired liver function, and altered nutritional status have been proposed as responsible factors for increased infectious complications.

13.1.2 History

Already in 1935, the increased risk of surgery in jaundiced patients was acknowledged by Dr. Whipple [7]. He was the first to introduce the concept of preoperative biliary drainage (PBD) by performing a staged pancreatoduodenectomy. After a cholecystogastrostomy to reduce jaundice, a resection was performed at a later stage. In the mid 1960s, a preoperative less invasive biliary drainage method was developed, namely percutaneous transhepatic cholangiography (PTC) [8]. This was followed by the introduction of endoscopic retrograde cholangiopancreatography (ERCP) in the 70s of the previous century, which allowed endoscopists to leave a stent in the bile duct via the duodenum [9]. A variation of this endoscopic approach—the endoscopic nasobiliary drainage (ENBD)—was introduced in the beginning of the 80s [10]. With this technique, instead of leaving a stent through the stenosis, a tube is retracted from beyond the stenosis to the nose, where it is taped to the patient's cheek and attached to a drainage bag. The indication of biliary drainage, either by ERCP or PTC for pancreatic and liver surgery and the preferred method has been a matter of debate since the introduction of these techniques.

13.1.3 Differences in Drainage of Distal and Proximal Bile Duct Tumours

Since its introduction, ERCP has been widely used in patients with obstructive jaundice due to a tumour in the pancreatic head region, as a diagnostic tool as well as to drain the obstructed bile duct. However, the indispensability of a preoperative ERCP has slowly vanished over the years. Firstly, because today, state of- the-art radiological techniques offer a higher diagnostic accuracy than ERCP, are noninvasive, and have the advantage of assessing local tumour extension, as well as distant metastases. Therefore, nowadays ERCP is considered obsolete as a diagnostic tool. Secondly, complications of ERCP have been better assessed over the years, and consequently, the net benefit of the procedure is questioned. A large RCT in the USA concluded that PBD does not reduce operative risk, and does increase hospital cost and, therefore, should not be performed routinely [11]. In addition, a systematic review from our department

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summarized all retrospective and prospective studies until 2001, comparing PBD in jaundiced patients with patients that underwent direct surgical treatment [12]. Meta-analysis of both level I and level II studies showed no differences in mortality between patients who had PBD and those who had surgery without PBD. However, overall complication rate was significantly adversely affected by PBD compared with surgery without PBD. Furthermore, overall hospital stay was prolonged after PBD. The conclusion was that the potential benefit of PBD, in terms of postoperative rates of death and complications, does not outweigh the disadvantage of the drainage procedure and therefore should not be performed routinely, unless further improved PBD techniques would become available [12]. Finally, we conducted a large RCT in the Netherlands, in which patients were randomized between preoperative drainage and direct surgery [13]. A higher rate of serious complications was found in the drainage group, while mortality and hospital stay did not differ between the groups. Based on these findings, we concluded that routine PBD increases the rate of complications and thus should not be routinely performed. However, there remains an indication for PBD, when early surgery is not possible, due to logistics in terms of (local) referral patterns, waiting lists, extended diagnostic workup with laparoscopy (on indication), or scheduled neo-adjuvant chemotherapy.

While there is now evidence showing that PBD for distal (peripancreatic) tumours should not be routinely performed, this is not the case for the more proximal cholangiocarcinomas, i.e. HCCA. An important difference between distal tumours as compared with hilar tumours lies in the need for an (extended) liver resection in most patients with HCCA. Liver resections in jaundiced patients are associated with significantly increased rates of mortality and morbidity, resulting mainly from the development of postoperative complications such as sepsis, bleeding, and most importantly, liver failure [5]. Another important difference lies in the complexity of the procedure required to relieve jaundice. In distal tumours involving the common bile duct, complete drainage of the entire biliary tree can usually be accomplished by a single, well-placed catheter or stent because the obstruction is below the confluence of right and left bile ducts. In HCCA however, several segmental bile ducts are usually affected, rendering a single drainage catheter ineffective to completely drain the biliary tree.

13.2 Methods of Biliary Drainage

13.2.1 Endoscopic Biliary Drainage (ERCP)

13.2.1.1 Technique

Prior to stent insertion, crossectional studies such as CT or MRI, or ultrasound examinations are performed to assess biliary anatomy and to plan the most appropriate approach for intervention. In view of the high incidence of bacterial colonization of the obstructed biliary tree, broad-spectrum antibiotics are administered intravenously prior to the procedure to minimize the incidence of cholangitis. After a retrograde cholangiography is performed to localize the site of obstruction, the guidewire is maneuvered through and above the biliary stenosis followed by a catheter. The endoprosthesis is then pushed in position over the catheter (Fig. 13.1). It is important to reduce the risks of cholangitis by minimizing the amount of contrast injected and always draining ducts that have been opacified with significant amounts of contrast.

In addition to achieving imaging of the biliary system and adequate biliary drainage, ERCP is also used for tissue diagnosis. Tissue sampling during ERCP is however difficult and in case of using brush cytology, fine needle aspiration (FNA),

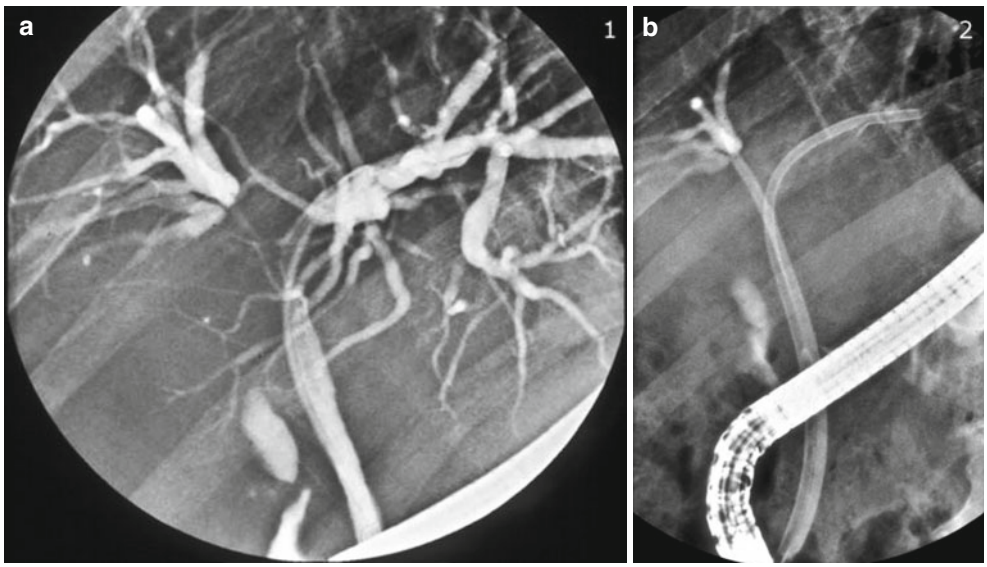

Fig. 13.1 ERCP in a patient with a Bismuth-Corlette type IIIa HCCA planned for hilar resection in combination with extended right hemihepatectomy. Cholangiography shows the anterior and posterior sectional obstruction on the *right side* and obstruction of the left hepatic duct (**a**); Stents are inserted in the right and left biliary systems (**b**)

fluoroscopically directed biopsy, or a combination of the above, a definitive diagnosis is only made in approximately 50 % of cases in most series [14, 15]. In a large study, ERCP brushings in 498 consecutive patients with pancreaticobiliary strictures were evaluated and compared with regard to diagnostic yield of routine cytology, addition of digital image analysis (DIA), and fluorescence in situ hybridization (FISH). None of the evaluated tests achieved a sensitivity above 43 % for detecting malignancy. Hence, clinical presentation and imaging studies (CT, PET-CT, MRCP, or ultrasound) remained the mainstay of diagnosis of HCCA.

Little evidence exists regarding the use of ERCP in preoperative drainage in potentially resectable patients with HCCA, while much more has been published about the results of ERCP in a palliative setting. Although in palliative drainage, different aspects are important as compared to the preoperative setting, several conclusions from studies in unresectable patients may also apply in resectable patients.

The major debate when using stent-directed biliary decompression has been the need for unilateral or bilateral drainage for anything more advanced than a Bismuth type II HCCA [16]. Bilateral stenting is technically challenging. The left system should be drained preferentially as a stent placed into the left main duct will usually produce more effective drainage than a stent in the right system. This is due to the longer length of the left main duct before branching leading to a larger volume of the liver being drained. The right system is more variable with earlier branching of the right hepatic duct; multiple segmental obstruction is more likely on the right side while a right sided stent more likely drains only a limited portion of the right system. Drainage of 25 % of the liver volume can achieve adequate palliation with improvement in biochemical parameters and relief of symptoms, with consequently improved quality of life [17]. No study comparing bilateral versus unilateral stenting for patients with resectable HCCA has been published. One RCT in unresectable patients showed a higher technical success rate of stent insertion and a significantly lower incidence of complications in patients who underwent unilateral drainage [18]. However, another study showed that mean survival, 30-day mortality, and deaths from sepsis were all significantly less with bilateral versus unilateral drainage [19]. In addition, a different group also found a better survival in patients who were drained bilaterally [20]. How this data should be extrapolated to the preoperative setting with curative intent remains to be determined. One additional factor should be acknowledged in the preoperative setting. Biliary drainage of the future remnant liver (FRL) promoted hypertrophy of the FRL after portal vein embolization, by which extended hemihepatectomy could be performed more safely [21].

Several studies have compared plastic with metal stents [22–24], and concluded that the patency rate of metal stents is superior. In order to further improve patency rates of the metal stents, covered metal stents were introduced. In contrast to patients with distal obstructions, patency rates did not improve with the use of covered stents in patients with proximal obstruction [25–27]. Due to the relatively short time to surgery, long patency is not essential for resectable patients, and metal stents may hamper hilar dissection and resection. Hence, although metal stents have advantages over plastic stents, this is not the case for resectable patients, and plastic stents are recommended in the preoperative work-up of patients with HCCA.

Finally, considering the difficulties in endoscopic management encountered in patients with HCCA, ERCP for hilar obstruction should only be undertaken in specialized centres with high success rates for endoscopic drainage of hilar obstruction. This is also supported by a study that evaluated 5,264 ERCP's in 66 centers, concluding that careful patient selection combined with skilled cannulation minimizes complications, while higher risk procedures should be performed in specialist centers [28].

13.2.1.2 Advantages and Complication

A major disadvantage of an endoscopic approach is contamination of the sterile environment of the biliary tree. This can lead to severe cholangitis, biliary sepsis, and even mortality of the procedure has been described. Several other complications of ERCP that have been reported include: cholangitis, acute cholecystitis, pancreatitis, duodenal perforation, post-papillotomy bleeding, biliary perforation, tube occlusion requiring re-intervention. A technical success rate of 81 % was found in a study including 90 patients who underwent ERCP for HCCA. The ERCP was accompanied by infectious complications in 43 patients, dislocation of the stent in 21 patients, pancreatitis in seven patients, duodenal perforation in one patient, and biliary perforation in another patient. Hence, complications or unsuccessful drainage attempts are encountered in the majority of patients.

Another disadvantage is that ERCP usually does not offer the possibility to perform selective biliary drainage, and typically, only part of the biliary system can be drained adequately. Lastly, ERCP is not feasible, or eventually not successful in a substantial part of patients with HCCA. Conversion of ERCP to PTBD or ENBD has been reported in 30–95 % of patients undergoing biliary drainage [29–32].

13.2.2 Percutaneous Transhepatic Biliary Drainage (PTBD)

13.2.2.1 Technique

Pre-procedural, broad spectrum antibiotic prophylaxis is given to all patients undergoing biliary drainage because transient bacteremia commonly occurs during the procedure, even in the absence of signs of infection. Biliary drainage is

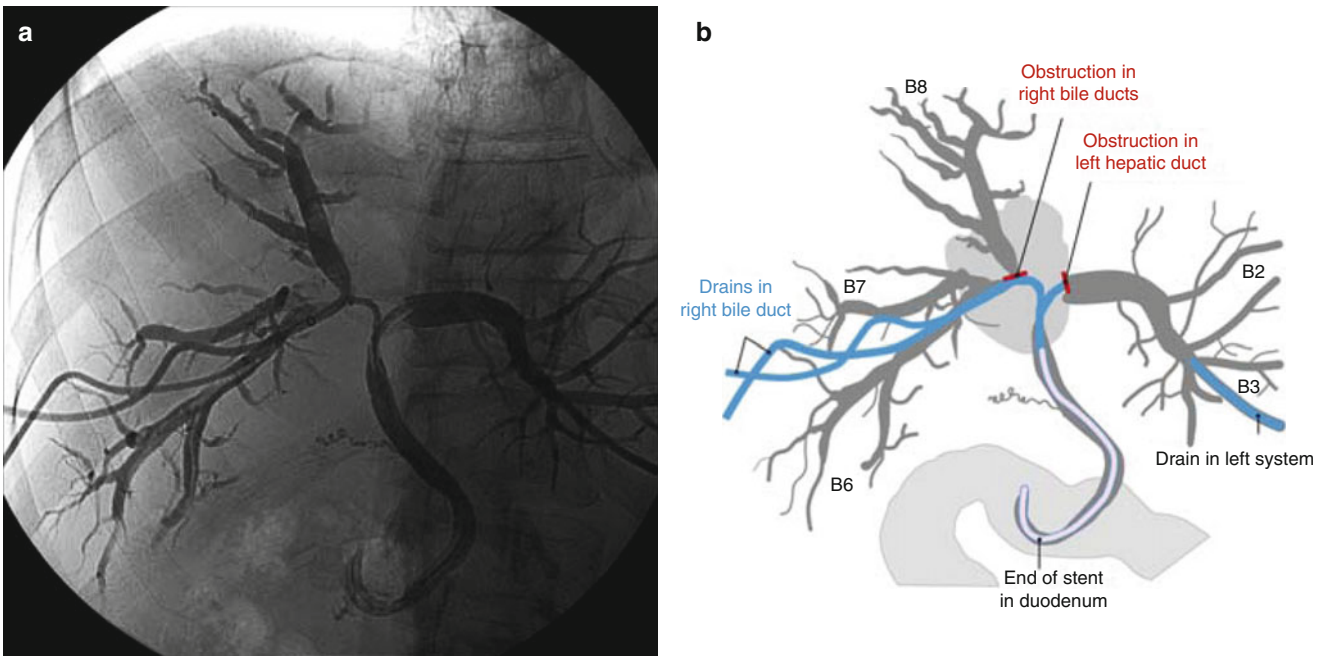

Fig. 13.2 Percutaneous cholangiogram of patient with a Bismuth-Corlette type IV tumour, in whom the right as well as the left bile duct system were drained separately. There is an obstruction of the first segmental bile ducts of the right system (B6, B7 and B8; B5 is not filled with contrast, due to obstruction), and an obstruction of the left hepatic duct, in which the segmental ducts (B2, B3, and B4) end. The B4 segmental duct has no connection with B2 and B3, and is therefore not filled with contrast. This patient underwent hilar resection in combination with extended right hemihepatectomy and resection of segment 1

performed with conscious sedation, often with short-acting benzodiazepines and narcotics. As with an endoscopic approach, PTCD is more challenging for a HCCA than for a distal bile duct tumour. Pre-procedural planning should involve evaluation of the exact level and extension of the stenosis or stenoses, selection of the most appropriate liver segments for drainage, and assessment of an appropriate access route, mostly by ultrasound guidance. This is particularly important when segmental bile duct obstruction is suspected, and every attempt should be made to avoid contaminating regions of the biliary tree that will not be drained.

Biliary drainage is most often performed using fluoroscopic guidance as shown in Fig. 13.2, after initial puncture of a bile duct using ultrasound guidance. Adequate drainage and stenting of one complete liver lobe is usually sufficient to relief the jaundice, but drainage of only one or two segments within one lobe is usually not enough. There is no consensus as to whether stents should be placed from the hilum all the way down the common bile duct through the papilla of Vater into the duodenum. Theoretically, preservation of function of the sphincter should lower the chance of developing ascending cholangitis. Although many authors advocate to stent through the papilla in distal obstructions, there is no evidence that this improves patency in proximal bile duct strictures. When one lobe is severely atrophied as a result of longstanding occlusion of the ipsilateral portal vein, it is usually not useful to stent the atrophied lobe, unless cholangitis is suspected to originate from this lobe. As hilar cholangiocarcinomas are often very rigid, it may in some cases be useful to pre-dilate the stricture to facilitate insertion of a stent. Dilating a self-expanding stent after insertion may also be required in selected cases.

13.2.2.2 Advantages, and Complications of PTBD

As for ERCP, most evidence regarding PTBD is available for application in a palliative setting, and large series reporting success rates and complications predominately deal with unresectable patients. PTBD has a distinct advantage over ERCP in that with ultrasound guidance one or more appropriate segments for drainage can be chosen and injection of contrast medium in segments that are too small to be drained can be prevented. Ultrasound guidance during PTBD is extremely useful in such patients. Furthermore, assessing hilar strictures and draining the appropriate segments can be very difficult with ERCP. Also, the extent of tumour infiltration into the proximal bile duct proximal to the obstruction is hardly assessable by ERCP, whereas proximal ductal extent can usually be precisely determined by PTCD.

Several complications after PTCD have been reported, including: occlusion, cholangitis, contralateral segmental cholangitis, portal vein injury and thrombosis, tube dislocation, cholecystitis, biliovenous fistula, biloma, hemobilia, and cancer dissemination.

Metastatic tumour seeding along the transhepatic biliary catheter was considered a very rare complication with only a few reported cases. But, recently several large series were reported on the incidence of catheter tract recurrence [30, 33]. The largest series containing 445 patients detected 23 patients (5 %) with catheter tract recurrence, and concluded that therefore, PTCD should no longer be performed in resectable patients. We use preoperative low dose radiation (3×3.5 Gy) to prevent this troublesome complication, and did not detect any recurrence after introduction of preoperative radiation [34]. In our department, standard preoperative low dose radiotherapy is instituted in all patients with HCCA planned for resection [34].

An additional advantage of the percutaneous route of biliary drainage is that the biliary tubes are an aid to locate the bile ducts proximal of the tumour in the liver parenchyma and that after the resection has taken place, the tubes can be used as transanastomotic drains to facilitate healing of the hepaticojejunostomies. The tubes are removed after control cholangiography via the tubes 3–6 weeks later.

Reported technical success of PTCD is more than 90 % in all series. Clinical success ranges from 80 to 100 %, procedure-related mortality ranges from 0 to 3 %, 30-day mortality ranges from 9 to 20 % and was usually related to the underlying disease. Procedure related complications range from 7 to 30 % and can be treated conservatively in the majority of cases. Recurrence of obstructive jaundice ranges from 15 to 25 % [29, 31, 35–39].

13.2.3 Endoscopic Nasobiliary Drainage (ENBD)

13.2.3.1 Technique

Although ENBD was introduced in the beginning of the 80s, very little information about this technique has been reported in literature. As was described already in 1984 [40], a guide wire is passed down the endoscope channel and through the stricture of the bile duct. The tip is advanced and looped high in the common hepatic duct or liver. A suitable drainage tube is then advanced through the endoscope to the tip of the wire. The guide wire is withdrawn, and the proximal end of the tube is rerouted from the mouth to the nose using temporary nasopharyngeal intubation. The tube is taped to the patient's cheek and attached to a drainage bag via a 3-way tap, so that the system can be closed, flushed, or aspirated as required. An anchorage system is necessary to avoid tube migration.

13.2.3.2 Advantages and Complications of ENBD

Advantages, disadvantages, and complications are similar to those of ERCP. Even though, due to the retrograde flow of duodenal fluid via the stent into the bile ducts, cholangitis occurs more frequently after ERCP. Furthermore, the availability of an external drain allows contrast cholangiography at any time via the nasobiliary tube. ENBD also permits evaluation of the volume and colour of biliary secretions. Enteral drainage in ERCP improves nutritional status and immune function by restoring enterohepatic recirculation to the digestive tract, and does not require a nasal tube. Clearly, internal drainage using a stent is a benefit for the patient as nasal intubation is a significant burden.

Until now, only three series have been published reporting the results of ENBD [29, 30, 41]. Complications were found in 13–38 % of patients who underwent ENBD, and included acute pancreatitis, segmental cholangitis, cholangitis with catheter obstruction, tube dislocation, and retroperitoneal perforation. Success rates of the initial procedure ranged from 74 to 78 % [29, 30].

13.3 Efficacy of ENBD, ERCP, and PTCD

Currently, the preferred technique of biliary drainage prior to surgery for a proximal bile duct tumour depends mainly on local expertise [42]. Controversy exists regarding the preferred technique of PBD, either by ERCP, PTBD, or ENBD. This is also illustrated by the report of a recent Japanese consensus meeting, stating that: "*Regardless of the location of the biliary obstruction, percutaneous transhepatic, endoscopic, or surgical drainage can be used*" [43].

Internal drainage by ERCP, although a less invasive technique, carries increased risk of developing cholangitis due to bacterial contamination from the duodenum and increased risk of procedure related complications such as duodenal perforation and post-ERCP, acute pancreatitis [44, 45]. Drainage by means of PTBD is associated with hemobilia, portal vein thrombosis, cancer cell seeding and potentially more patient discomfort. And lastly, ENBD has some advantages over ERCP, in particular less complications like stent occlusion and cholangitis. On the other hand, the external drainage of ENBD impairs nutritional status and immune function by undermining enterohepatic recirculation, while the nasal tube is a considerable burden for the patient. All mentioned advantages, and disadvantages are summarised in Table 13.1.

Three prospective, randomized controlled trials (RCTs) have been published comparing ERCP versus PTBD [46–48]. These RCTs included patients with unresectable bile duct tumours or carcinoma of the gallbladder and pancreas showing conflicting results. These studies addressed palliative treatment and although important in the context of biliary drainage, no distinction was made between distal and proximal bile duct obstruction. To date, no RCT has been performed regarding the optimal route of drainage in patients with a potentially resectable HCCA. Two retrospective studies, compared ERCP and PTBD in patients eligible for resection of a suspected HCCA [30, 31], and in one of these, ENBD was assessed as well. The studies showed conflicting

results. The first study showed significantly less complications in the percutaneously treated patients, and advocated this technique for the future. The second study, found significantly more complications in the ERCP group, and comparable results for ENBD and PTCD. However, in the PTCD group as compared to the ENBD group, significantly more major complications (15 % vs. 2 %, $P<0.01$) were found, namely cancer dissemination and portal vein injury.

Table 13.1 Advantages and complications of ENBD, ERCP, and PTCD

	Advantages	Disadvantages and complications
PTCD	Allows selective drainage	Drainage tract metastases
	Allows combined external/internal drainage	Bleeding complications
	Allows post-drainage cholangiography	
	High success rate	
	Useful as transanastomotic drain postoperatively	
ENBD	Less invasive than PTCD	Patient discomfort due to nasal tube
	Less stent obstruction than ERCP	Selective drainage is not always possible
	Allows post-drainage cholangiography	
ERCP	Internal drainage	Failure of complete drainage
	Non invasive	Stent obstruction
		Post-ERCP pancreatitis
		Post-drainage cholangiography is not feasible
		Selective drainage is not always feasible

In conclusion the authors highly recommended ENBD as the preferred method for PBD. Hence, with these conflicting results, it remains difficult to conclude what the preferred drainage method is. Both studies suffered from limitations, and especially the retrospective nature of these studies precludes a definitive conclusion. The results of other studies reporting on PTCD, ERCP, or ENBD are summarized in Table 13.2.

PTBD used to be the preferred method in Japan for relief of obstructive jaundice due to HCCA [42, 49]. In Europe and the USA, ERCP is usually performed as primary intervention and is followed by PTBD only when ERCP has failed, as shown in Fig. 13.3. Yet recently, Japanese authors published

Table 13.2 Outcome of ENBD, ERCP, and PTCD in HCCA

Author (year)	Method	Patients	Success rate	Complications (%)	Additional drainage (%)
Nimura (2000)	PTCD	133	–	23	–
Mansfield (2005)	PTCD	65	–	–	–
	ERCP	41	71		36 (88)
Maguchi (2007)	PTCD	9	67	–	3 (33)
	ENBD	12	25		9 (75)
	ERCP	4	0		4 (100)
Arakura (2009)	ENBD	62	74	13	16 (26)
Paik[a] (2009)	PTCD	41	93	32	42
	ERCP	44	72	30	38
Kawakami (2010)	PTCD	48	96	31	2 (4)
	ENBD	60	78	38	13 (22)
	ERCP	20	5	65	19 (95)
Kloek (2010)	PTCD	11	100	9	0
	ERCP	90	81	48	39 (43)

[a]RCT including unresectable HCCA patients

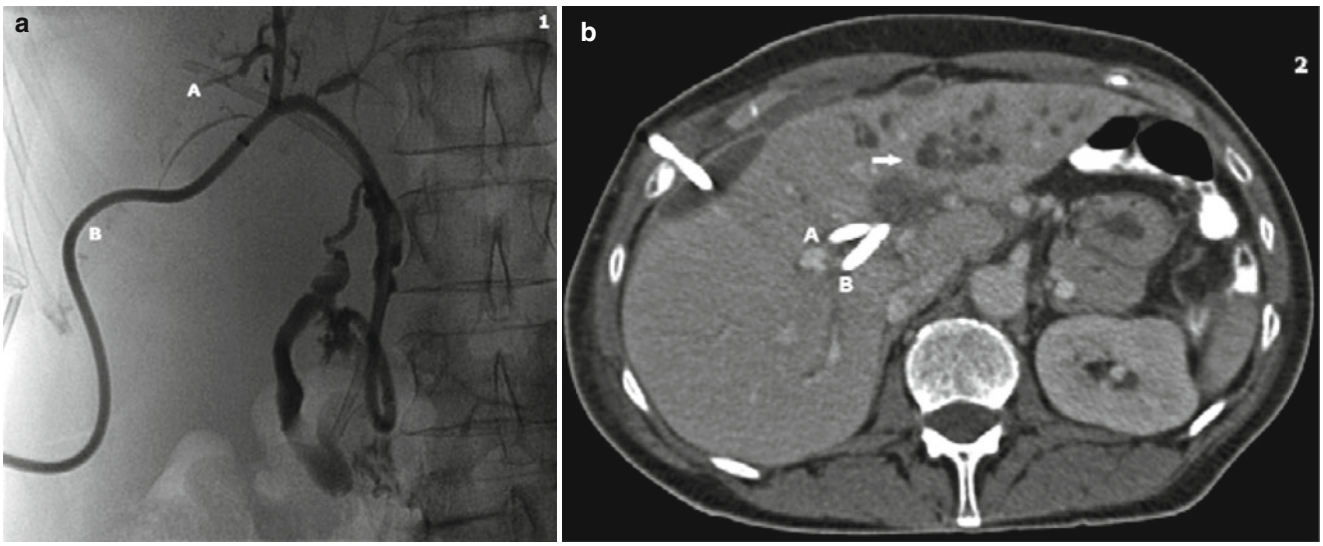

Fig. 13.3 Percutaneous transhepatic cholangiogram (**a**), and CT-scan (**b**) of a patient diagnosed with a Bismuth-Corlette type IV HCCA, referred with an ERCP-stent placed in the right anterior sectional bile duct. In preparation of hilar resection and extended left hemihepatectomy, the right posterior sectional ducts were drained using PTD. Only the future remnant liver is drained, and consequently the left bile duct system is still dilated (*arrow*). *A* ERCP-stent in right anterior sectional bile duct, *B* Percutaneous drain in right posterior sectional system

an article addressing the incidence of implantation metastases after PTCD and hereby pushed the pendulum back by recommending endoscopic drainage to prevent postoperative implantation metastases [33]. Hence, there is no evidence providing a clear-cut answer as to which method of PBD we should use.

Conclusions

The proper approach to jaundice in patients undergoing hepatobiliary and pancreatic surgery has been debated for several decades now. Although basic research on the mechanisms of the disease is progressing with time, the exact relation of jaundice and complications is still not fully understood. For distal bile duct tumours, evidence is nowadays fairly straight-forward, suggesting that PBD should not be routinely performed. For HCCA, high-quality evidence is still lacking, and consequently, the debate about the use of PBD for HCCA still continues. Nonetheless, mortality after extended liver resection in jaundiced patients is still highly significant, and therefore, most surgeons are in favour of PBD before undertaking extended hepatectomy, despite a lack of clear evidence based on RCTs.

The three usual drainage techniques, i.e. ERCP, ENBD and PTCD, all have their own pros, cons, and indications. These techniques are often used in combination with each other. Studies comparing PBD techniques, included different patient groups, are very outdated, or are retrospective in nature and are burdened by major methological flaws. In addition, these studies report conflicting results. Hence, solid advice regarding the recommended drainage technique to be used for PBD in HCCA cannot be given. Thus, until a well designed RCT proves otherwise, the preferred technique of biliary drainage prior to surgery for HCCA should mainly be contingent upon individual anatomy, and, in part, upon institutional expertise.

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