Chapter 12
Prevention and Treatment of Major Complications After Cholecystectomy

Klaske A.C. Booij, Dirk J. Gouma, Thomas M. van Gulik, and Olivier R.C. Busch

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Introduction

Annually, over 19.000 patients undergo a cholecystectomy in the Netherlands, of which approximately 16.500 are performed laparoscopically [1]. The complication rate after laparoscopic cholecystectomy (LC) is 2–12 % and the mortality rate about 0.2 % [2, 3]. General complications include wound infection, intra-abdominal abscess formation, and postoperative bleeding from the cystic artery which occurs in about 0.05 % and usually presents within a few hours after surgery [4]. Laparoscopy-induced "access injuries" are visceral and vascular injuries that are mostly related to the puncture technique. Although the incidence of these complications is low, ranging from 0 to 0.05 % for the open technique versus 0.044 to 0.07 % for the closed technique [5], the overall mortality rate is high, ranging from 13 to 21 % [6, 7]. The most specific and devastating complication after cholecystectomy is bile duct injury (BDI). This complication is, especially in combination with vascular injury, accompanied by substantial morbidity, mortality, and a decrease in the life expectancy and long-term quality of life [2, 8, 9]. The incidence reported in literature is dependent on its definition, study design, and study population and ranges from 0.16 to 1.5 % after LC versus 0.0 to 0.9 % after open cholecystectomy (OC) [2, 10]. After the introduction of LC, initially there seemed to be

K.A.C. Booij • D.J. Gouma • T.M. van Gulik • O.R.C. Busch, MD, PhD (✉)
Department of Surgery, Academic Medical Center,
University of Amsterdam, Amsterdam, The Netherlands
e-mail: d.j.gouma@amc.uva.nl; o.r.busch@amc.uva.nl

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an increase in the number of BDI. Go et al. [2] evaluated the incidence of BDI after the introduction of LC in the Netherlands in 1990 until 1992 by using a written questionnaire which was sent to all 138 Dutch surgical institutions and reported an incidence of BDI of 0.86 %. Gouma et al. [11] studied the incidence of BDI in 1991 using a questionnaire to all Dutch surgical departments to analyze the number of surgical reconstructions for BDI and therefore the true incidence of severe BDI and reported an incidence of 1.09 % after LC and 0.51 % BDI after OC. The higher incidence of BDI after LC in those days was mostly related to technical difficulties, unfamiliarity with the procedure, and the "learning curve" effect. A Cochrane systematic review from Keus et al. [12] in 2006 suggests that the incidence of BDI has been stabilized since they found no difference in complications after LC or OC, with BDI occurring in 0.2 % in both groups. Nevertheless, annually 40–45 patients are still referred to the Academic Medical Center, without any sign of decrease in recent years [13]. This suggests a higher incidence of BDI in the Netherlands than reported in the literature [13]. As stated before, initially inexperience probably contributed to the high incidence of BDI, but other factors such as anatomical variation and techniques without using the critical view of safety (CVS) of Strasberg [14] as the standard of care seem to be responsible for the current incidence of BDI. Furthermore, there appears to be a lack of knowledge of escape techniques in difficult cholecystectomies to prevent BDI. Buddingh et al. [15] recently conducted a nationwide survey in which 97.6 % of Dutch surgeons reported to use the technique of CVS. Hereby the incidence of BDI in the Netherlands might decline in the future.

Even though the incidence of BDI may not be high and the results of treatment are excellent, especially when performed in a multidisciplinary team in a tertiary referral center [16, 17], the consequences of this injury have a negative impact on the life expectancy [9] and the quality of life (QoL) [18]. Therefore a thorough knowledge of the possibilities for prevention, early diagnosis, and treatment of this complication are mandatory for every surgeon and surgical resident performing cholecystectomies, either performed open or laparoscopically.

Prevention of BDI

The key issue in the management of BDI and other complications is prevention. Prevention of BDI is only possible with the thorough knowledge of pre- and intraoperative risk factors for BDI. Furthermore, the surgeon should be familiar with various escape techniques in difficult cases.

Risk Factors for BDI

Informed consent, in which the risk of BDI and its possible consequences are mentioned, should be obtained and registered in all cases, particularly in the presence of preoperative risk factors.

Risk factors and measures to prevent and recognize BDI are outlined in many publications [19–22]. Adverse outcome after LC is particularly associated with male gender, comorbidity, complexity and urgency of surgery, and conversion [23, 24]. Local risk factors are acute cholecystitis, aberrant anatomy, severe local fibrosis due to previous inflammation [10, 25], and bleeding in the Calot's triangle disturbing the operative view. Other risk factors are misuse of cautery, technical problems, and misidentification of the anatomy [21, 26]. Injuries due to misidentification usually occur when the surgeon interprets the common bile duct or an aberrant right hepatic duct for the cystic duct [21]. Way et al. [22] suggested that errors leading to laparoscopic bile duct injuries result principally from visual perceptual illusion, not from errors in skills, knowledge, or judgment. Lillemoe [20] stated that the concept of human error should not be used as an "excuse" for surgeons to avoid responsibility for complications. Knowledge of the anatomy and the mechanism of injury, an appropriate level of suspicion, the standard use of the CVS technique, and probably the use of an intraoperative cholangiogram (IOC) will prevent misperception errors that may occur during cholecystectomy.

Especially in the presence of risk factors, adequate expertise in the operating room should be ensured [21], and familiarity with escape techniques should be present. In the case of acute cholecystitis, there is a higher conversion rate and a longer duration of surgery when operated by a surgeon without laparoscopic expertise [27]. In the presence of acute cholecystitis, the operation should therefore be upgraded to an advanced laparoscopic procedure [21]. Obviously, this will have consequences for on call shifts. In 2009 the Dutch Association on Endoscopic Surgery has already stated that surgeons who only incidentally operate laparoscopically are not allowed to perform laparoscopic procedures without supervision. Recently the Dutch Society of General Surgery has confirmed this by formulating specific agreements and certifications concerning this problem. During shifts, a surgeon on call should not perform procedures that he or she is not familiar with, i.e., that are not regularly performed during daytime shifts, without consulting or help from an experienced surgeon. For on call shifts certain procedures, such as small bowel obstruction due to adhesions, appendicitis, and rupture of a spleen, can still be performed by the general surgeon. For other acute procedures such as gastric, pancreatic, colon, and rectal resections and also cholecystectomy, specific expertise is mandatory. Thereby these procedures will be exclusively performed by experienced surgeons. A clear shift schedule should be available and well known by surgeons on call within a hospital or region. In some cases consultation of or even referral to a tertiary center may be the best option.

Critical View of Safety

Already in 1995 Strasberg described the guidelines for a critical view of safety (CVS) [28]. This technique is generally adopted by the Dutch Society of Surgery in the guidelines on gallstone disease and best practice of cholecystectomy in 2007 [10] and introduced as the standard of care in all training programs. The objective

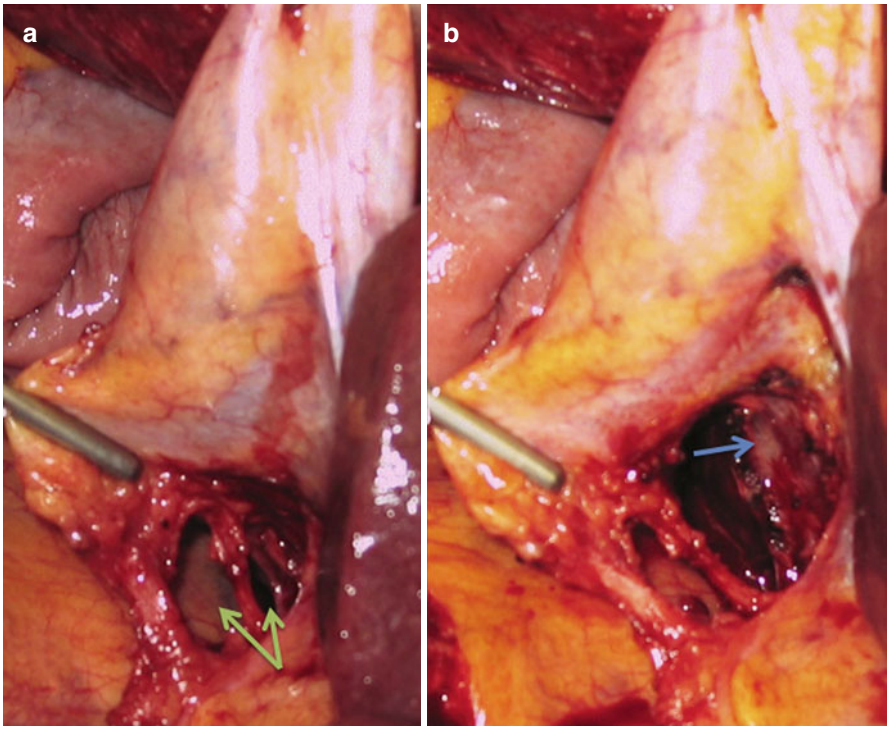

Fig. 12.1 Difference between two "windows" and CVS. (**a**) After dissection, two windows are created, one between the cystic duct and cystic artery and one between the artery and the liver bed (*arrows*). Because the cystic plate is not fully cleared of tissue, CVS has not been reached. (**b**) Here the cystic plate (*white, arrow*) is clearly identified and hence CVS is reached. (Published with permission of Elsevier. *J Am Coll Surg* [29])

of this technique is to conclusively identify the cystic duct (CD) and cystic artery (CA) before they are clipped and cut. Calot's triangle cannot always be clearly identified due to retraction of the gallbladder against the liver. The principle of CVS is therefore to fully unfold Calot's triangle. First traction on the fundus and infundibulum of the gallbladder is applied in cranial and ventrocaudal direction, respectively. The peritoneal envelope is then opened bilaterally up to the liver bed. Using blunt meticulous dissection with limited and cautious use of cautery, the gallbladder is dissected for at least one third of its length out of the liver bed to ensure that no other structures besides the CA and CD are present between the gallbladder and the liver. Mobilization of the infundibulum is the essence of CVS. Hereby a two-window view is created between respectively the CD and CA and between the CA and liver bed (see Fig. 12.1a and b [29]). Thereby a definitive 360° identification of the cystic duct and cystic artery is achieved. CVS is captured photographically or by video and recorded together with the operation report [29]. Only after CVS is definitively reached, the cystic duct and artery can be clipped and divided safely.

Escape Techniques

If mobilization of the infundibulum is not possible and therefore CVS cannot be reached, the Dutch guidelines on gallstone disease and best practice on laparoscopic cholecystectomy propagate conversion to OC [10]. However, this advice is not sufficient because conversion is not a solution for the situation per se. The main question is whether conversion will give a better overview on the anatomy and thereby make the operation easier or is it better to change the operation strategy to other escape procedures. In the current laparoscopic era, surgical residents have little experience with OC [30]. Nevertheless, as stated before, this procedure is used in those cases when LC cannot be performed at all. Paradoxically, there is progressively less experience with the technique that is necessary for the most challenging cases [30]. Recently, psychological factors were described that play a role in the decision making of either continuing a difficult procedure laparoscopically or to convert to OC [31]. As mentioned before, the underestimation of the risk of visual misperception and therefore misinterpretation of the anatomical relationships seems to be crucial in the occurrence of BDI. This means that despite conversion and persisting indistinct visualization, local dissection is continued. A stopping rule, such as using a different operative strategy or consulting a surgeon that is experienced in OC and different escape techniques in those cases when CVS cannot be reached, may be much more important than conversion per se.

In the preoperative planning of cholecystectomy, the presence of preoperative risk factors for difficult cholecystectomy and conversion such as acute cholecystitis should be considered in choosing the right surgical team. Another option is to plan a primary open procedure [23]. In that way, patients with a suspected difficult cholecystectomy according to preoperative risk factors play an important role in the surgical training of young residents with the open procedure and alternative techniques. Recently primary percutaneous gallbladder drainage has been shown to be a safe and successful treatment option in high-risk patients less eligible for surgery [32].

Several techniques are suggested to prevent BDI [21, 33, 34]. The infundibular technique, which depends on observing the cystic duct flare as it becomes the infundibulum, can be misleading especially in case of acute inflammation [21]. This technique should therefore not be used for the identification of the ducts. Another error trap is the fundus-down cholecystectomy in the case of severe inflammation, the failure to perceive the presence of an aberrant right hepatic duct on cholangiography, and injury to the CBD in the case of a “parallel union” of the cystic duct [26]. Loss of the dissection plane between the liver and gallbladder might even lead to injury of the right portal vein.

An alternative strategy is the antegrade technique, also called the fundus-first technique, where the gallbladder is dissected from the liver bed starting at the fundus. This technique is used for difficult procedures and is a frequently used technique in OC. It can also be used laparoscopically and will, in the hands of an experienced surgeon, reduce the chance of BDI in the same manner [35].

An additional technique that may be used instead is leaving the infundibulum in situ. This principle is used in the method of Terblanche, or subtotal cholecystectomy, which can be performed open or laparoscopically [30, 36, 37]. Excision of the gallbladder is performed using cautery at the gallbladder-liver bed junction leaving a small rim of the posterior gallbladder wall. After that, the residual gallbladder mucosa must be destructed with electrocoagulation to prevent mucus production [36].

Another option, for example, in case of severe local inflammation, is to terminate the procedure and convert to percutaneous gallbladder drainage with delayed cholecystectomy or referral to a tertiary center.

It is unclear if intraoperative cholangiography (IOC), in difficult cases, can truly reduce the risk of BDI [10]. Flum et al. [9] and more recently Buddingh et al. [38] showed a lower rate of major BDI after implementation of routine IOC compared to selective use of cholangiography. This may partly be related to the fact that the interpretation of IOC might be difficult in inexperienced hands and should be learned adequately. When IOC is not frequently used, misinterpretation in the presence of injury has been described [21, 22], in particular with segmental lesions. If bile leakage occurs during dissection, cholangiography should be performed by inserting a catheter in the lesion.

Diagnosis of BDI

Inadequate management of BDI may lead to severe deterioration with biliary peritonitis, sepsis, multiple organ failure, and even death. Therefore, early recognition is of utmost importance. Early symptoms are abdominal pain, anorexia, nausea, vomiting, and ileus. As a matter of fact, in any patient who fails to recover within 24–48 h after LC or has persistent abdominal complaints after LC, BDI should be considered. Jaundice is usually a symptom that occurs in a later postoperative phase after several days. There seems to be no relation between the severity of the injury and the presenting symptoms [4].

In general there are three different groups of patients that can be identified according to the moment of recognition of the BDI, all with different symptoms and a different treatment strategy.

In the first group of patients, the injury is detected during initial operation, usually by biliary leakage and sometimes by intraoperative cholangiography. This appears to be only the case in 15–30 % of the patients [4, 13].

In the second group there is a delayed identification of BDI in the direct postoperative period (34 % of cases [13]). However, the time interval between LC and diagnosis of the BDI varies widely with a median interval of 7 days and the mean interval of approximately 4 weeks [13]. These patients are frequently discharged on the second postoperative day and readmitted a few days later with a biloma, biliary peritonitis, obstructive jaundice, or sepsis due to abdominal leakage of infected bile.

In the last group of patients, there is a long symptom-free interval of several months up to more than a year after the initial injury. The cause is usually an ischemic stricture of the CBD, presenting with obstructive jaundice rather than cholangitis. A few patients present with intermittent obstruction and cholangitis, due to a spontaneous enteric fistula [4].

The type of diagnostic procedure to be performed is dependent on the presenting symptoms. In the case of sepsis, the first diagnostic procedure should be ultrasound or CT scanning for the detection of fluid collections. The next step is visualization of the biliary tree by endoscopic retrograde cholangiopancreatography (ERCP), magnetic resonance cholangiopancreatography (MRCP), percutaneous transhepatic cholangiography (PTC), or sometimes drainography to establish the diagnosis and classify the injury. In the case of jaundice without sepsis, visualizing the biliary tree should be the first step. The diversity in the types of injury demands a multidisciplinary approach in which treatment options are discussed in a team of surgeons, gastroenterologists, and radiologists, all familiar with these patients [13]. Interpretation of completeness of the biliary tree before any intervention is undertaken is of utmost importance to exclude segmental injury and anatomical variation (see Fig. 12.2).

Classification of BDI

Before proceeding with the actual treatment of BDI, the type of injury should first be classified or staged. Several classifications of BDI exist. The oldest one is the Bismuth classification [39] which classifies the injury in terms of the level of the lesion in the biliary tree. The classification of McMahon [40] classifies the injury into major and minor injuries, and the Strasberg classification [28] classifies the injury in terms of level and severity. In 1996 the Amsterdam classification was developed which links the type of injury directly to the further clinical management of BDI and is in our opinion therefore of practical use [41]. Type A injury (see Fig. 12.3) involves cystic duct leakage. Type B injury (see Fig. 12.4) is bile duct leakage. Type C injury (see Fig. 12.5) is a bile duct stricture. Type D injury (see Fig. 12.6) is a bile duct transection [41].

Vasculo-biliary Injury

Unfortunately, it is not uncommon that a BDI is combined with a vascular injury. The most common type of vasculo-biliary injury (VBI), also called the "classical injury," is injury to the right hepatic artery (RHA) and common bile duct (CBD), with an incidence around 25 % of all the BDIs [14]. The cause of the misidentification is frequently a combination of adverse operative conditions and the use of suboptimal identification techniques, such as the infundibular technique [42]. In the operative report, the division of a so-called second cystic duct or accessory duct may

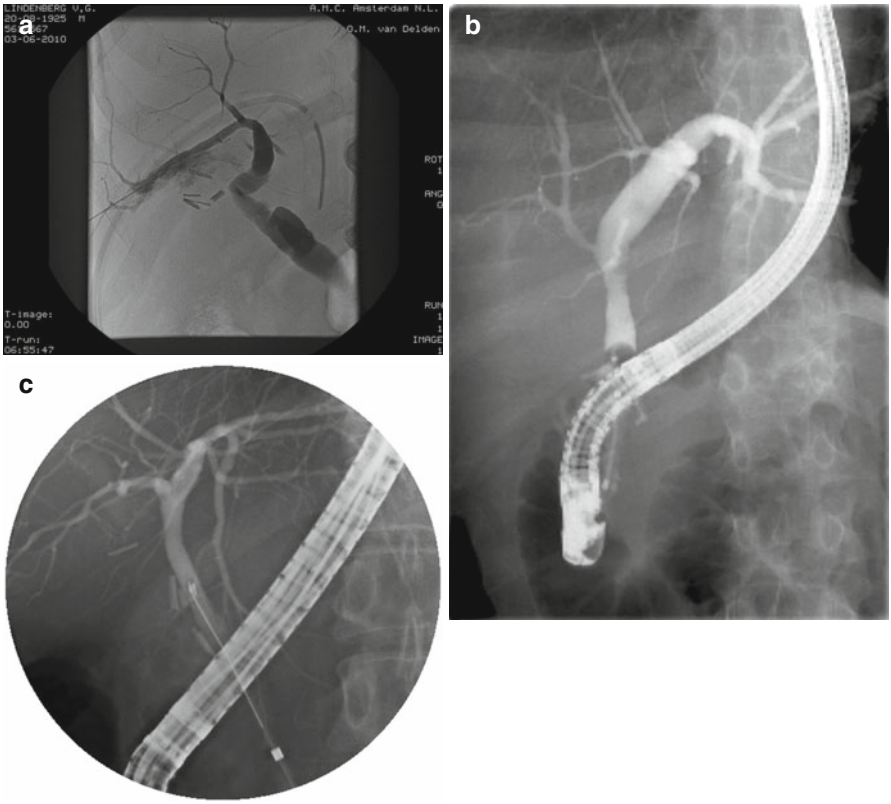

Fig. 12.2 Segmental injury. (**a**) Cholangiogram. Leakage from the RHD near an operation clip. (**b**) ERCP. Occlusion RHD. (**c**) ERCP. Occlusion of the anterior segment of the RHD due to an operation clip (later confirmed by MRCP)

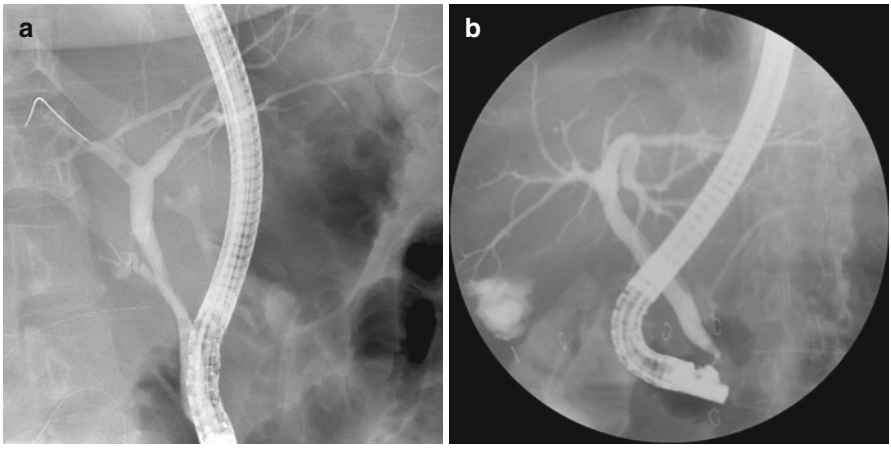

Fig. 12.3 Type A injury. (**a**) ERCP. Leakage from the cystic stump near the operation clips (*red arrow*). The tip of a PTC drain is shown (*black arrow*). (**b**) ERCP. Leakage from a duct of Luschka (*arrow*)

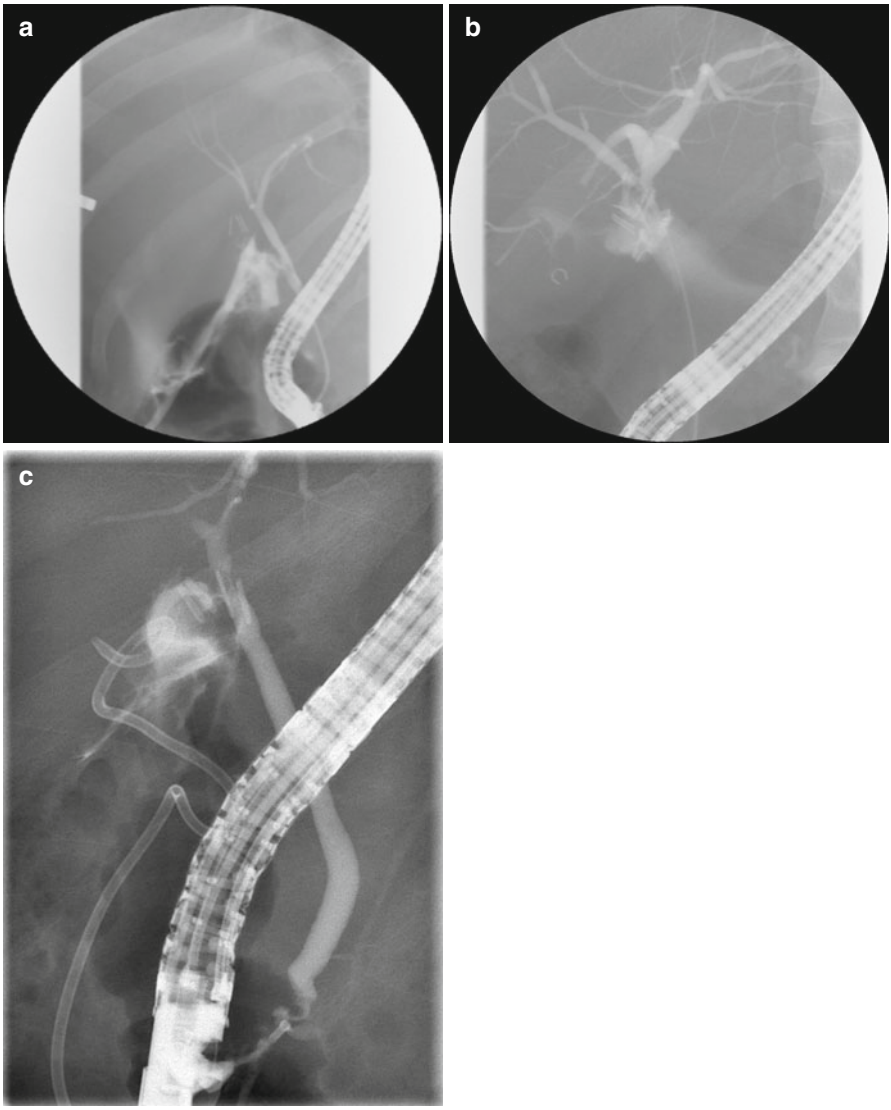

Fig. 12.4 Type B injury. (**a**) ERCP. Leakage of the CBD (*red arrow*). Part of the right hepatic system is missing (*black arrow*). MRCP showed aberrant anatomy with the posterior segment of the RHD originating from the LHD (not shown). (**b** and **c**) ERCP shows diffuse leakage of the CBD around multiple operation clips (*arrows*)

undeserved be described. The cause of this may be the tendency to persist in the anatomic frame of reference. This seems to be caused by the complexity of the human brain in which strongly held assumptions, i.e., being convinced of operating in the correct anatomical plane, cause that peroperative complications are attributed to behavioral factors, e.g., an "accessory duct," instead of leading to corrective feedback, i.e., considering the anatomical plane may not be correctly chosen [14, 22, 33].

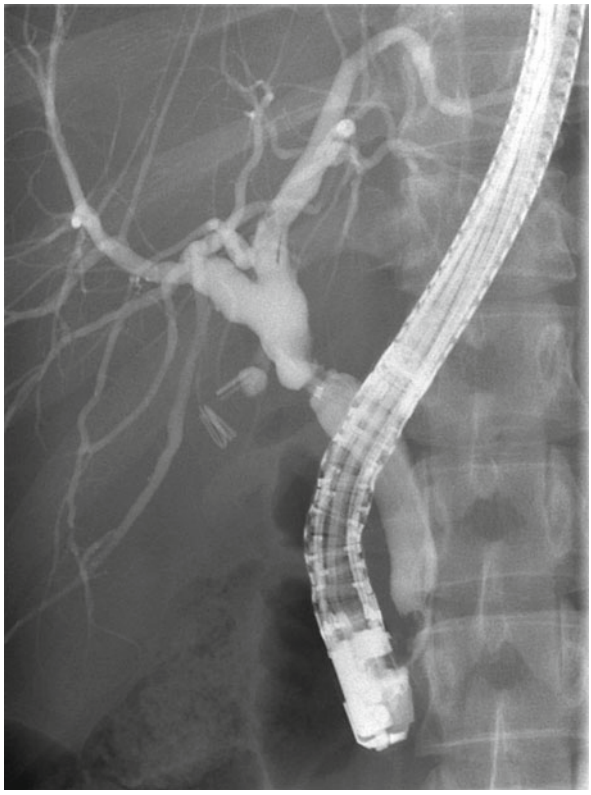

Fig. 12.5 Type C injury ERCP. Stenosis of the proximal CBD, approximately 1 cm below the bifurcation of the left and right hepatic duct (*red arrow*). The biliary tree is intact

Clinically, isolated RHA injury is rarely noticed due to compensatory collateral flow, but in combination with BDI part of the collateral blood supply is damaged as well. Therefore in combination with BDI the actual injury tends to be more complex and higher up in the biliary tree than the primary observed injury [14]. This process may also be responsible for stenosis after early biliary reconstruction due to ischemia of the bile duct [14]. Repair of the artery is rarely possible and the benefit of such a reconstruction is not proven [14]. Injuries to the portal vein or proper or common hepatic artery are uncommon but much more complex. These patients should immediately be referred to a tertiary center and considered to have vascular reconstruction or partial hepatectomy [14].

Treatment of BDI

As mentioned earlier, the treatment of BDI requires a multidisciplinary approach by surgeons, gastroenterologists, and interventional radiologists, all experienced in this field [13]. BDI can only be treated adequately after a thorough classification of the type of injury. In discussing the treatment of BDI, we routinely use the Amsterdam classification and consider the timing of diagnosis as well [10, 41].

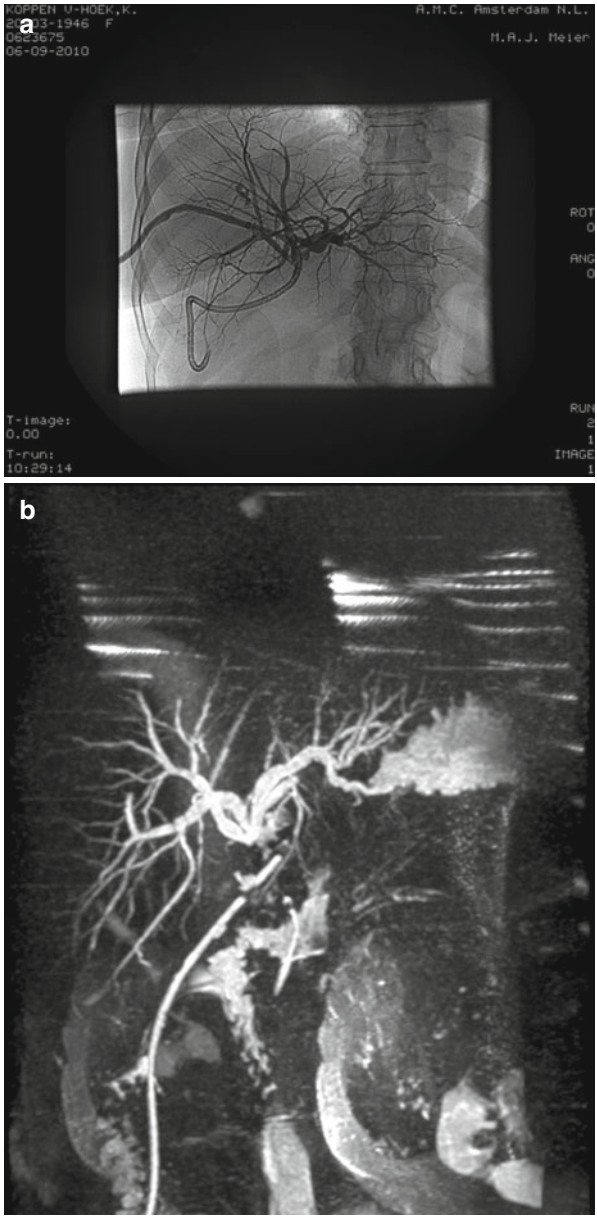

Fig. 12.6 Type D injury. (**a**) Cholangiogram via PTC drain (*black arrow*). The *red arrow* shows the bifurcation. Below the bifurcation the CBD is missing. Above this level, the biliary tree is intact. (**b**) MRCP. The *red arrow* shows a subhepatic drain. The red line shows the part of the CBD that is missing. The biliary tree is intact

Peroperatively Diagnosed Injury

In a study by de Reuver et al. [13], BDI was detected peroperatively in 21 % of the patients. In 17 % of the patients, a repair procedure was performed directly during the initial operation. However, it is known that patients in whom a repair procedure is performed during the initial cholecystectomy by the same surgeon who caused the BDI have a significantly worse prognosis than patients who were referred to a

tertiary center [9, 13]. When the choice for a direct repair of the injury still is made, the presence of an experienced surgical team is mandatory. If there is not enough experience present, the patient should be referred to a tertiary center or a surgeon from the referral center should visit the concerned hospital to perform a repair procedure.

Type A injuries can usually be secured primarily. The same is true for type B injuries, which can be closed over a T-drain. However, in both types of injury, care must be taken not to worsen the injury by occluding the CBD or one of the vascular structures. If sufficient surgical experience is lacking, a bailout technique is external drainage and subsequent referral to a tertiary center.

In type D lesions, peroperative classification of the injury is usually difficult. In these cases IOC may be helpful. As stated before, expertise in interpreting IOC is of great importance to avoid misinterpretation of the cholangiogram. In the presence of an experienced surgeon and when there are no signs of tissue loss, an end-to-end anastomosis using a T-drain can usually safely be constructed. After this type of reconstruction, there is a 68 % chance of stricture formation [43]. However, de Reuver et al. [43] showed that this complication can be adequately managed by endoscopic stenting or percutaneous drainage with a success rate of 66 % in these patients [43]. When the stricture is resistant to dilatation, reconstructive surgery by performing a hepaticojejunostomy (HJ) can still be performed with a relatively low morbidity [43]. However, when there is tissue loss of the CBD in the first place, hepaticojejunostomy should be performed, but especially for this procedure, adequate experience is mandatory, since this is the last resort operation. HJ in the acute setting without dilatation of the bile ducts is a difficult procedure, and one should be very careful not to further extend the injury into the intrahepatic ducts or subsequently damage the arterial supply [43]. In most cases there will not be enough experience present during the initial operation, and therefore the options are either to place a subhepatic drain and refer the patient to a tertiary center or let an experienced surgeon from the tertiary center perform a direct reconstruction in the referring hospital. The results of an early repair are actually good if performed by an experienced surgeon.

Postoperatively Diagnosed Injury

When BDI is diagnosed postoperatively, at first sepsis should be controlled using fluid resuscitation, antibiotics, and percutaneous drainage of fluid collections. When the patient is treated in a hospital without sufficient experience in the treatment of BDI, the patient should be referred. Appropriate classification with visualization of the entire biliary tree is mandatory before the type of treatment can be determined. In the presence of local expertise in performing an ERCP, type A injuries can be directly treated by endoscopic stenting with an overall success of 97 % [44]. Even in type B and C injuries, when sepsis has subsided, the patients can be treated early by endoscopic dilatation and or stenting. In type B injuries the success rate is 89 %, and

stent-related complications occur in 3.8 % of the patients [44]. For type C injuries, the success rate of stenting is 74 %, with stent-related complications occurring in 33 % of the patients during a median duration of stenting of 11 months (range 1–69 months). Most complications were mild (19 % stent migration, 14 % stent occlusion) and managed by stent exchange. For type D injuries, hepaticojejunostomy should be constructed after sepsis is adequately treated and the patient is recovered from this period. The preferred timing of this procedure seems to be after about 6 weeks to 3 months after the initial procedure to prevent progressive ischemia and thereby postoperative leakage and stricture formation [14, 45]. Of the 500 patients referred to our tertiary center, 151 patients (30.2 %) underwent reconstructive surgery for BDI [45]. Surgery-related complications occurred in 29 patients (19 %). Severe complications include anastomotic leakage that occurred in 6 patients (4 %) and postoperative bleeding in 1 patient (1 %). Five patients with anastomotic leakage were successfully treated with a temporary percutaneous transhepatic stent. There was no hospital mortality. After a mean interval of 46 months (median 24, range 8–120) after surgical reconstruction, anastomotic strictures were diagnosed in 10 % of the patients. In 20 % of these patients, surgical reconstruction had to be performed, and most (80 %) of these patients could be adequately treated by percutaneous transhepatic dilatation. Independent negative predictive factors for outcome are extended injury in the biliary tree, secondary referral, and repair in the acute phase after the injury. Similar results after reconstruction have been published by others [46, 47]. Recently, it has been reported that the results of an early repair are as good when performed in the absence of sepsis and by an experienced team [48, 49].

Quality of Life and Litigation Claims

Although results after treatment of BDI in referral centers are fairly good, during follow-up of these patients, 62 % reported suffering from symptoms that are linked to the injury (De Reuver, unpublished data). Tiredness was reported by the majority of the patients (69 %), while more specific symptoms for BDI, such as fullness (59 %), periodical fever (22 %), and jaundice (9 %), were reported less frequently (De Reuver, unpublished data). These symptoms are in striking contrast with the functional outcome after treatment since the success rate of the nonoperative treatment of type A, B, and C injuries is 97 %, 89 %, and 74 %, respectively, and the success rate after surgical reconstruction in terms of strictures is 90 % [44]. The long-term QoL of patients after the treatment of BDI seems to be impaired [16, 17, 50], independent on the type of injury and type of treatment [16, 17]. The phenomenon of bias by response shift may also be responsible for the reported poor QoL, meaning that the patients do not accept a decline in daily health status after a surgical procedure that is perceived as relatively minor and was tremendously complicated [51].

The 10-year survival of BDI patients is 88 %, which is not significantly worse compared to the age-matched general population. The hazard of death is two times

as high in male patients and when the repair procedure was performed during the initial cholecystectomy [13]. Flum et al. [9] showed an 11 % death increase in patients who underwent a repair procedure by the same surgeon who performed the initial cholecystectomy. Furthermore, they reported a mortality rate after BDI almost three times as high compared to patients who underwent cholecystectomy without an injury [9].

The number of claim procedures in BDI patients in the Netherlands treated in a tertiary center is only 19 %. Factors associated with starting a claim procedure are younger age, severity of injury, employment, and the use of social securities. A complete transection of the CBD is an independent predictive factor for starting a claim procedure [52]. Most patients feel that they had not been taken seriously at the time of the first postoperative symptoms which has led to a delay in diagnosis of the injury. They were disappointed by the reluctance of the primary surgeon to admit to a procedural error and to give full information on the severity of the injury [51]. It has been suggested that settlement and liability payment can lead to a reduction of complaints related to QoL in patients after BDI.

Summary

The most devastating complication after cholecystectomy is BDI, with a reported incidence of 0–1.5 %. The key issue in the management of BDI is prevention. Prevention is only adequate with the awareness of pre- and intraoperative risk factors, the use of CVS, experience in performing cholecystectomy, and knowledge of the different escape strategies in the case of a difficult cholecystectomy. BDI can be diagnosed either peroperatively or in the direct or late postoperative phase. In case BDI occurs, the severity of the injury should be classified thoroughly before a proper treatment can be chosen. The treatment of BDI should be performed by a multidisciplinary team and only if sufficient experience in dealing with this complication is present. If not, the patients should be referred to a tertiary center. Even after an objectively excellent outcome of treatment, the reported QoL is still reduced.

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