Long-Term Impact of Iatrogenic Bile Duct Injury

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Keywords

Bile duct injury · Bile leakage · Cholecystectomy · Long-term outcome · Anastomotic stricture

Abstract

Background: Bile duct injury (BDI) is a devastating complication following cholecystectomy. After initial management of BDI, patients stay at risk for late complications including anastomotic strictures, recurrent cholangitis, and secondary biliary cirrhosis. **Methods:** We provide a comprehensive overview of current literature on the long-term outcome of BDI. Considering the availability of only limited data regarding treatment of anastomotic strictures in literature, we also retrospectively analyzed patients with anastomotic strictures following a hepaticojejunostomy (HJ) from a prospectively maintained database of 836 BDI patients. **Results:** Although clinical outcomes of endoscopic, radiologic, and surgical treatment of BDI are good with success rates of around 90%, quality of life (QoL) may be impaired even after “clinically successful” treatment. Following surgical treatment, the incidence of anastomotic strictures varies from 5 to 69%, with most studies reporting incidences around 10–20%. The median time to stricture formation varies between 11 and 30 months. Long-term BDI-related mortality varies between 1.8 and 4.6%. Of 91 patients treated in our center for anasto-

motric strictures after HJ, 81 (89%) were treated by percutaneous balloon dilatation, with a long-term success rate of 77%. Twenty-four patients primarily or secondarily underwent surgical revision, with recurrent strictures occurring in 21%. **Conclusions:** The long-term impact of BDI is considerable, both in terms of clinical outcomes and QoL. Treatment should be performed in tertiary expert centers to optimize outcomes. Patients require a long-term follow-up to detect anastomotic strictures. Strictures should initially be managed by percutaneous dilatation, with surgical revision as a next step in treatment.

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Introduction

Bile duct injury (BDI) is still a much feared complication following gallbladder surgery. After the introduction of laparoscopy, the initial learning curve resulted in a rise in the incidence of major BDI up to around 1–1.5% [1]. More recently reported incidences of major

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BDI vary between 0.08 and 0.3% [2–4]. When including “minor” BDI, reported incidences range from 0.3 to 1.5% [5, 6]. Although the risk of sustaining BDI is low, cholecystectomy is one of the most performed procedures worldwide. Resulting from this, the total number of BDI patients is still considerable. With approximately 750,000 cholecystectomies being performed in the United States annually, an estimated 2,500 patients per year are expected to be affected by a BDI [7].

The severity of BDI ranges from relatively simple leakage of the cystic duct or liver surface to complete transection or even resection of one or more bile ducts, sometimes accompanied by vascular injuries, mainly involving the right hepatic artery and right portal vein. Several classification systems exist for BDI, with the Strasberg classification with Bismuth modification being generally accepted (Table 1) [8, 9]. Treatment is often highly individualized as not only the type of injury, but also the time to detection of the injury, comorbidity, clinical condition of the patient (e.g., the presence of sepsis or peritonitis) and location of (re)admission and diagnosis confine treatment [10]. A multidisciplinary approach including hepato-pancreato-biliary surgeons, gastroenterologists, and interventional radiologists is essential in order to achieve optimal outcomes [11–13]. Preferably the patient should be referred to a center with expertise in BDI [12, 14, 15].

For a patient undergoing an elective cholecystectomy, BDI is an unexpected and devastating complication. It is associated with high morbidity and even mortality, and generally requires invasive treatment. Even type A injury, which is often classified as “minor injury,” may still lead to considerable morbidity due to persistent bile leakage and biliary sepsis [6]. For major injuries, short-term morbidity of up to 40–50% and mortality rates of 2–4% have been reported [16–19]. Late complications include biliary strictures, anastomotic strictures, recurrent cholangitis, and biliary cirrhosis, which increase the burden for the patient even more. Furthermore, BDI patients show impaired quality of life (QoL), even years after cholecystectomy [20]. A BDI not only causes a major impact for the individual patient, it also is associated with increased health care demands and costs, and litigation claims [21–23].

The aim of this article is to give a comprehensive literature review of long-term outcomes and impact of BDI, in terms of clinical outcomes, QoL and medico-legal aspects. As there appeared to be limited data in literature regarding management of anastomotic strictures follow-

ing Roux-en-Y hepaticojejunostomy (HJ), we assessed the management and outcomes of anastomotic strictures using a large cohort of BDI patients from Amsterdam, the Netherlands.

Methods

Literature Review

We provided a comprehensive overview of current literature on the long-term outcome of BDI following cholecystectomy. For this, we searched Pubmed, Embase and the Cochrane library using the following key words and Medical Subject Headings (MeSH) terms: “Bile Ducts/injuries” Medical Subject Headings, “BDI”, “HJ”, “biliodigestive anastomosis”, “surgical repair/reconstruction”, “long-term outcome”.

To assess reported long-term outcomes of BDI patients, we included articles reporting outcomes after endoscopic, radiologic and surgical treatment, published between 1995 and 2018. Articles reporting on less than 30 patients, articles only reporting short-term outcomes, and reviews and articles in languages other than English were excluded. For overlapping publications on the same patient cohort, the largest or most recent publication was included. Outcomes of interest were the overall long-term morbidity/mortality, incidence of anastomotic strictures, cholangitis, secondary biliary cirrhosis, incisional hernias. Records were screened in 2 phases by one author (A.M.S.), Figure 1.

Retrospective Analysis

As there appeared to be limited data in literature regarding the management of anastomotic strictures following HJ, we also retrospectively analyzed all patients with anastomotic strictures following a biliodigestive anastomosis from a prospectively maintained database containing a consecutive series of 836 BDI patients from the Amsterdam UMC, location AMC. All patients who developed an anastomotic stricture after Roux-en-Y HJ were identified from this database. Data of patients who developed a stricture following HJ performed in the AMC have been published before [24]. We complemented these data with (previously unpublished) information on patients referred to the AMC for the treatment of anastomotic strictures following HJ performed elsewhere.

We collected data on management of anastomotic stricture (surgically or radiologically, number of percutaneous transhepatic biliary drainage [PTBD] procedures, duration of treatment) and outcomes of this treatment (recurrence of strictures and/or cholangitis, time to recurrence, development of biliary cirrhosis, long-term BDI related mortality).

Our treatment protocol has been described previously. All patients referred with a BDI were discussed in a multidisciplinary meeting including hepato-pancreato-biliary surgeons, endoscopists, and interventional radiologists to determine a treatment policy. Endoscopic, radiological, and surgical interventions were performed as previously described [25–27].

Data are presented in numbers and percentages. Means (SD) or median values with range or interquartile range are presented, when appropriate. Data analyses were performed using IBM SPSS statistics, version 24.0 (SPSS, Chicago, IL, USA).

Table 1. The Strasberg-Bismuth classification for BDI

Type	Description
A	Cystic duct leak or leak from small ducts in the liver bed
B	Occlusion of an aberrant right hepatic duct
C	Transection without ligation of an aberrant right hepatic duct
D	Lateral injury to a major bile duct
E	Circumferential injury to a major bile duct:
E1	Transection or stricture >2 cm from the hilum
E2	Transection or stricture <2 cm from the hilum
E3	Transection at the level of the bifurcation, without loss of contact between the left and right hepatic duct
E4	Transection at the level of the bifurcation with loss of communication between the left and right hepatic duct
E5	An injury of a right segmental duct combined with an E3 or E4 injury

BDI, bile duct injury.

Fig. 1. Flow diagram of the study selection process. HJ, hepaticojejunostomy.

Results

Clinical Outcomes after Endoscopic and Radiologic Treatment

Bile leakage due to minor injuries was usually treated endoscopically by endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy and/or inser-

tion of plastic stents, which yielded success rates of 90–97% [25, 28–30]. Endoscopic treatment of more severe BDI, for example, lateral defects of major bile ducts, showed a slightly lower success rate of 85–89% [25, 29]. For biliary strictures, progressive endoscopic stenting by inserting an increasing number of plastic stents every 3–4 months was usually performed [28, 31]. The long-term success rate of

Table 2. Overview of reports on long-term outcomes after surgical repair of BDI by HJ

Author	Number of HJs	Overall longterm morbidity, %	HJ stricture, %	Cholangitis, %	Intrahepatic stones, %	cirrhosis, %	Incisional hernia, %	Late BDI-related mortality, %	Time to stricture formation	Follow-up time
AbdelRafee et al. [95], 2015	120		11.6	14.2	2.5	6.7	3.3			
Bansal et al. [96], 2015	138		8							54 months (6–83)
Booij et al. [24], 2018	281		13.2				7.5	1.8	30 months (IQR 9.5–51.7)	10.5 years (IQR 6.7–14.8)
Cho et al. [97], 2015	122		4.1	3.3			9			Mean 4.6 years SD $\pm$ 4.1
de Santibanes et al. [74], 2006	90		15							78 months (4–168)
Dominguez-Rosado et al. [50], 2016	586		22.5			3		2.1		Mean 40.5 months
Felekouras et al. [52], 2015	74	40.5	29.7	14.9						
Frilling et al. [98], 2004	33		17.5	5						16 months (1–42.7)
Gazzaniga et al. [99], 2001	54		9.3		1.9					Mean 5.9 years, SD $\pm$ 0.3
Gomes and Doctor [100], 2015	57		7			3.5		1.8		84 months (36–84)
Hajjar et al. [101], 2014	36		12						18 months	34 months (12–68)
Holte et al. [102], 2010	42		23.8			2.4			11 months (2–51)	110 months (0–172)
Huang et al. [70], 2014	94		18			0				65.5 months (6–120)
Iannelli et al. [49], 2013	325		29							
Jablonska et al. [103], 2009	38		21							
Jayasundara et al. [104], 2011	35		9							37 months (1–90)
Kaman et al. [69], 2006	48		20.8							
Kazibudzki et al. [105], 2006	30		10		6.6		10			(2 months – 10 years)
Lillemoe et al. [38], 2000	142		9.2							55 months (11–119)
Lubikowski et al. [106], 2011	32		6							59 months (6–102)
Martinez-Lopez et al. [15], 2017	63		19	21						
Mishra et al. [107], 2007	137					5.6		2.8		30 months (18–80)
Nuzzo et al. [13], 2008	41		12							
Patrono et al. [108], 2015	32		21.9							81 months (12–182)

Table 2. (continued)

Author	Number of HJs	Overall longterm morbidity, %	HJ stricture, %	Cholangitis, %	Intrahepatic stones, %	cirrhosis, %	Incisional hernia, %	Late BDI-related mortality, %	Time to stricture formation	Follow-up time
Perera et al. [48], 2011*	112	25	17	11						60 months (12–212)
	45	82	69	33						
Pottakkat et al. [47], 2010	30		63	37						
Rystedt et al. [4], 2016	30		20							37 months (9–69)
Sahajpal et al. [109], 2010	69	16	14			0	3			71.5 months (0–120)
Schmidt et al. [110], 2004	46		19.6			10.9		4.6		44.6 months (2–143.5)
Stilling et al. [111], 2014	139	42	30	23	6	5	6	2.2	12 months (2–141)	102 months (0–182)
Sulpice et al. [112], 2014	36		13			5		3		93 months (26–204)
Thomson et al. [113], 2005	47		11							33 months (6–201)
Walsh et al. [19], 2007	84	30	13			2.4	2.4	4	13 months	Mean 67 months
Winslow et al. [63], 2009	112		5							4.3 years
Wu et al. [114], 2007	176		12.5	1.7						3.7 years (0.25–10)

Values are presented as proportions or medians (range), unless specified otherwise.

* The study by Perera et al. [48] compared outcomes of patients treated by HPB specialists ($n = 112$) to those of patients treated by general surgeons ($n = 45$). Differences between outcomes were all statistically significant ($p < 0.001$).

BDI, bile duct injury; HJ, hepaticojejunostomy; HPB, hepato-pancreato-biliary; IQR, interquartile range.

this strategy is reported to be between 74 and 89% [25, 31, 32]. More proximally located injuries (Bismuth type III and IV) had a lower success rate, while the insertion of more than 1 stent increased chances of success [25].

Radiological intervention for BDI by means of PTBD is increasingly used as the availability of this technique grows. This approach is especially useful for patients with a complete transection of the bile duct (loss of continuity) but also in case of a surgically altered (upper) abdominal anatomy. PTBD may be used as a solitary treatment of BDI in patients with minor injuries, or as a bridge to definitive surgical treatment in order to optimize the clinical condition of the patient preoperatively (major injuries) [33]. PTBD in the presence of bile leakage may be more difficult as a result of non-dilated bile ducts [34] but still leads to a technical success of 90% and a (short-term) clinical success of 70–80% in expertise centers [35, 36]. PTBD in addition to surgical recon-

struction yields high success rates of 98% [37, 38]. However, data on long-term outcomes of PTBD as a solitary treatment for bile leakage are very limited.

For major injuries (complete transection or resection of a bile duct) in which ERCP and PTBD fail to overcome the defect in the bile duct, a percutaneous-endoscopic rendezvous procedure can be considered before moving on to surgical reconstruction [39–41]. In a series of 47 patients from our institution, the rendezvous procedure was the final treatment with long-term success for 55% of patients, while for another 30%, the rendezvous procedure provided internal biliary drainage as a bridge to definitive surgical treatment [41].

Clinical Outcomes after Surgical Treatment

In case of a complete transection of the bile duct, surgical reconstruction is generally indicated despite the availability of the rendezvous procedure. Preferably, sur-

gical reconstruction is performed by specialized HPB surgeons in a tertiary referral center [13, 42–44]. Perera et al. [42] compared outcomes of 45 patients treated by non-specialized surgeons to 112 patients treated by hepatobiliary specialists, showing significantly better long-term outcomes and less overall morbidity in patients treated by hepatobiliary specialists (Table 2). Stewart and Way reported that only 13% of repairs performed by the index surgeon without HPB expertise were successful [43]. Of note, this was based on a selected population of patients referred to a tertiary center after undergoing HJ by the index surgeon; it was unknown how many HJs were performed by non-HPB specialists in the community. Inadequate repair of an intraoperatively detected BDI by the index surgeon may complicate the injury and lead to a worse clinical condition of the patient; several reports show that a previous attempted repair is negatively correlated with postoperative morbidity and long-term outcome [45–47]. In a few centers in the United Kingdom, the HPB surgeon travels toward the index surgeon to perform an immediate repair with excellent outcome [48].

The timing of surgical reconstruction has been suggested to be of influence of long-term outcomes; however, this topic is currently still under debate. Several studies have concluded that an overall delay in surgical repair has a lower risk of postoperative complications compared to early repair [10, 18, 27, 49, 50]. In contrast, publications by Barauskas et al. [30], Booij et al. [24], Kirks et al. [51], and Felekouras et al. [52] all showed similar short- and long-term results for early and delayed repair. The rationale of delayed surgical repair is that it allows for adequate sepsis control, restoration of vascular damage, and optimization of the clinical condition of the patient. Deviation of bile through a PTBD (with bile replacement via a nasogastric feeding tube) in this period will stop intra-abdominal bile leakage and reduce inflammation. Furthermore, delaying surgery may allow ischemia of the bile duct to reach its final state, making sure that the anastomosis is made on an adequate level to serve as definitive repair (generally higher up to the bifurcation). On the other hand, early repair may preclude the patient from clinical deterioration in the first place. Early repair also leads to a shorter hospitalization period and lower costs [53]. An individualized approach, taking into account the type of injury, patient characteristics but in particular the clinical condition of the patient may be most advisable. Moreover, as only 20–40% of BDIs are recognized during the initial cholecystectomy, it is not always possible to choose for an early repair.

Besides the timing of surgery, a delayed referral to a tertiary center may negatively influence patient outcomes. In a series of 63 BDI patients, Martinez-Lopez et al. [54] showed that a delayed referral was associated with a higher incidence of postoperative complications, requiring more invasive procedures and prolonging recovery. Similar results have been reported by Fischer et al. [55]. A possible explanation for this may be that pre-reconstructive optimization of the patient may be better in a center with expertise in BDI and a multidisciplinary approach, in particular by experience in endoscopic and radiological drainage procedures [56].

Surgical Techniques

The Roux-en-Y HJ is considered the optimal technique for surgical repair of BDI. Although an end-to-end bile duct anastomosis is technically simple (it may be performed by the initial surgeon) and is associated with lower rates of postoperative complications compared to HJ, it almost always requires additional endoscopic dilatation or surgical treatment. In a series of 54 patients who underwent end-to-end repair (mostly in the initial hospital), 66% of patients underwent subsequent endoscopic stenting and 32% underwent an HJ [57]. Similar results have been reported by others [58, 59].

A high-level bile duct anastomosis is recommended in order to prevent anastomotic leakages and biliary strictures due to ischemia [60, 61]. Several techniques have been described to conduct this biliary-enteric anastomosis: an end-to-side anastomosis, the Hepp-Couinaud technique, incorporating both the biliary confluence and the left hepatic duct in a side-to-side anastomosis [62], and a similar side-to-side anastomosis to the right hepatic duct as proposed by Winslow et al. [63] No direct comparison has been made between these techniques; however, a side-to-side anastomosis theoretically spares more of the vascularization of the bile duct itself, also providing a wide and tension-free anastomosis.

Outcomes

Of 1,607 records screened, 35 studies reporting on long-term outcomes following HJ for BDI were identified (Fig. 1). In Table 2, we provide an overview of reported incidences of long-term outcomes after HJ. Reported incidences of anastomotic strictures vary between 4.1 and 69%, with most studies reporting incidences around 10–20%. The median time to stricture formation varied between 11 and 30 months. This means that patients who underwent HJ for BDI require a long follow-up period. In

our experience, these patients should be followed-up for 3–5 years, with the assessment of cholestatic parameters every 6 months.

Results of these studies are difficult to compare due to different definitions of outcome across studies. For that purpose, an international working group of surgeons, endoscopists, and interventional radiologists recently proposed a standardized procedure of reporting outcome of BDI using outcome grades [64]. These outcome grades, ranging from A to D, are defined for surgical and non-surgical treatment and take into account the invasiveness and duration of treatment required for complications (e.g., the period of subsequent stenting after stricture formation of a HJ) as well as the final outcome. They also propose to take into account “disease-free survival” by reporting the duration of bile duct patency according to the Kaplan-Meier method (“actuarial primary patency rate”). This grading system will not only allow for adequate comparison of results between future studies but also between different treatment modalities, recognizing the different indications for those treatment options.

Several factors have been reported to be associated with worse outcomes. Vascular injury [65–67], level of injury [19, 65, 68–70], sepsis or peritonitis [24, 50, 70], postoperative bile leakage [24], and overall postoperative complications [24] are thought to be risk factors for stricture formation.

Anastomotic strictures may eventually lead to secondary biliary cirrhosis, portal hypertension, end-stage liver disease, and death. The reported incidences of biliary cirrhosis in literature are relatively low varying between 2.4 and 10.9% (Table 2); however, this is a disastrous complication. Liver transplantation is a last-resort option for patients with secondary biliary cirrhosis. Parrilla et al. [71] reported that of 7 patients who required emergency liver transplantation for acute liver failure, 2 patients died while on the waiting list, and only one patient survived past 30 days. Of a further 13 patients who underwent elective liver transplantation for secondary biliary cirrhosis, the 5-year survival rate was 68%.

For complex vasculobiliary injuries or high intrahepatic BDI, a partial liver resection may be indicated in rare situations [72]. Only 0.8–1.4% of patients require a liver resection [73, 74]. Postoperative morbidity of this procedure is considerable [73, 75], with a short-term mortality of up to 18% [73].

The rate of incisional hernias is not reported in many studies, although this late complication contributes substantially to the overall long-term morbidity. The long-term mortality after BDI is considerable: BDI-related

mortality varied between 1.8 and 4.6%. Regarding all-cause mortality, Halbert et al. [76] reported an increase of 8.8% in BDI patients compared to the expected age-adjusted death rate after 20 years.

Management of Anastomotic Strictures

Following Roux-en-Y HJ, ERCP is often not possible due to the altered anatomy. Therefore, for a non-surgical approach, PTBD with balloon dilatation and internal drainage is generally applied. This usually requires 1–4 repeat dilatations and a period of biliary drainage of approximately 3 months [26]. Overall success rates of 66–76% and low procedural morbidity of 11–13% have been reported [26, 38, 77], making PTBD with balloon dilatation a suitable first step in treatment before moving on to surgical revision. Surgical revision of an HJ shows a slightly higher operative morbidity of 30–40%, but long-term results are good in approximately 90% of cases [24, 78]. A step-up approach starting with PTBD dilatation and moving on to surgical revision when PTBD fails seems advisable; however, only a few reports exist on this topic.

The AMC Experience

Of 281 patients who underwent an HJ in our institution between 1991 and 2016, 37 patients (13%) developed an anastomotic stricture [24]. Of these, 33 patients (89%) were treated by PTBD dilatation, which initially was successful in all patients. Fourteen of these 33 patients (42%) developed a recurrent stricture, requiring another PTBD treatment and finally only 4 patients (11%) eventually underwent surgical revision of their HJ.

Furthermore, 54 patients who underwent HJ at their referring hospital were referred to us for treatment of an anastomotic stricture, at a median of 29 months after HJ (range 1–261 months). Median follow-up was 13.6 years (range 2.8–25.3 years). Of these 54 patients, 5 patients directly underwent surgical revision. One patient chose conservative treatment and up to now received 5 courses of antibiotics for cholangitis. The other 48 patients underwent PTBD with balloon dilatation. In 2 patients, dilatation failed due to a tight stenosis and these patients underwent surgical revision; in 46 patients, the treatment was initially successful. Twenty-one patients developed a recurrent stricture, for which 16 patients underwent a second cycle of PTBD dilatations (5 patients underwent surgical revision). All 16 PTBD treatments were initially successful; however, 10 patients developed another recurrent stricture. A third cycle of PTBD dilatations was attempted in 5 patients, with success in 2. The

remaining 8 patients eventually underwent surgical revision of the HJ.

Combining all patients with an anastomotic stricture (both after HJ performed in our institution or in a referring hospital), 91 patients were analyzed, of whom 81 underwent PTBD treatment. PTBD treatment was eventually successful in 62 out of 81 patients (77%). Per PTBD treatment cycle, a median of 3 dilatations was performed (range from 1 to 8 dilatations). Median duration of treatment was 2 months, with a range from 1 week to 5 months.

Altogether, 24 patients underwent surgical revision of an HJ. Of these, re-structure of the anastomosis occurred in 5 patients (21%). Four of these patients underwent additional PTBD dilatation, which was successful in all; one patient who already developed secondary biliary cirrhosis underwent a second surgical revision.

Quality of Life

After the first study on QoL following BDI in 2001 by Boerma et al. [79], several reports have examined the long-term effect of BDI on health-related QoL. Although some authors claim that in the long term BDI does not affect QoL [80, 81], most studies show an impaired QoL even many years after treatment of the injury [79, 82–85]. A meta-analysis performed by Landman et al. [20] in 2013 showed a long-term detrimental effect on health-related QoL for patients with BDI when compared to patients undergoing uneventful cholecystectomy. More recent reports substantiate this finding [17, 86]. Furthermore, Booij et al. [17] assessed work-related limitations, finding a loss of productivity in paid and unpaid work and increased use of disability benefits.

Conflicting reports exist on whether QoL improves over time. De Reuver et al. [83] following up on a previous study, showed that QoL did not improve at follow-up 5.5 years later [79], while Dominguez-Rosado et al. [87] found an improvement of QoL at 5 years after the injury compared to the QoL at 1 year after the injury.

Several factors have been suggested to influence QoL in BDI patients – first, the time to detection of the injury. Surveying 107 BDI patients, Rystedt and Montgomery found that intraoperative detection and immediate intraoperative repair of an injury led to a QoL comparable to that of a matched control group of patients undergoing uneventful cholecystectomy [88]. Of note, the patients in this study mainly sustained minor injuries. Second, being involved in a malpractice litigation claim has been showed to negatively affect QoL [83–85]. In the study by de Reuver et al. [83] not only

the involvement in a malpractice litigation claim but also the outcome of this litigation claim showed to be correlated to QoL.

The effect of BDI on QoL is most evident in the psychological domain [20]. This may reflect the psychological impact an unexpected and severe complication after elective surgery can have. It may also explain why there seems to be no evident correlation between clinical outcomes and QoL [87]. Remarkably, the type of injury, type of treatment (surgical/endoscopic/radiological), and duration of treatment were also not correlated to QoL according to de Reuver et al. [83].

Medicolegal Aspects

Medical liability is often a concern of surgeons involved in BDI cases. In Europe, approximately 19–32% of BDI patients are involved in a litigation claim [42, 83]. Although in the majority of claims liability is rejected, payouts are high (especially in the United States) and increasing in recent years. Reported monetary compensation varies from 2,500 to 216,000 pound in the United Kingdom, EUR 9826–55,301 in the Netherlands, and USD 628,138–2,891,421 in the United States [89].

Death as a consequence of BDI and loss of workability are associated with increased acknowledgement of liability [90, 91]. Patients with more severe (vascular) injury, with (perceived) incomplete recovery and patients with a delayed recognition of BDI are more likely to file a claim [42, 92]. Two studies also reported treatment of BDI by the index surgeon as a risk factor for litigation [42, 90], which may be another argument for treatment of these patients in tertiary expert centers.

Although the risk of BDI during cholecystectomy is currently low (0.1–0.3%), the severity of this complication requires that it be part of preoperative informed consent. However, in a survey by McManus and Wheatley [93], almost half of surgeons in the United Kingdom discussed BDI rarely or never preoperatively, and in a study by de Reuver et al. [90] the possibility of BDI was noted only in 9.7% of patient files as part of an informed consent. In a study by Perera et al. [42], among patients with BDI, 70% of patients felt that they had been inadequately informed prior to the cholecystectomy. Straightforward and honest information/communication once the damage has been detected is at least as important. Disclosure of an iatrogenic injury may be the most challenging type of bad news to deliver to a patient, and physicians are often insufficiently trained in this kind of communication [94].

Key Messages

Although clinical outcomes of endoscopic, radiologic, and surgical treatment of BDI are good with success rates of around 90%, QoL may be impaired even after “clinically successful” treatment of BDI. Clear communication between patients and health care providers is key, both preoperatively during the informed consent procedure for cholecystectomy and postoperatively after detection of the DBI.

Patients should be referred to a tertiary referral center with expertise in BDI, and treatment policy should be decided in a multidisciplinary team before intervention. For patients requiring surgical treatment, a Roux-en-Y HJ is recommended. Timing of surgery is mainly dependent on the patient condition. HJ strictures will occur in 10–20% of patients. As most strictures develop after 1 year or

more, a long follow-up period or adequate instruction of patients is necessary; a follow-up period of 3–5 years, with assessment of cholestatic parameters every 6 months is recommended. Management of anastomotic strictures by PTBD yields reasonable results, with surgical revision as a next step in treatment.

Ethics Statement

The authors have no ethical conflicts to disclose.

Disclosure Statement

The authors declare that they have no conflicts of interest to disclose.

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