

## **RESEARCH ARTICLE**

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# Bile duct injury in laparoscopic cholecystectomy with a posterior infundibular approach

Joachim Geers, Joris Jaekers, Halit Topal, André Collignon, Baki Topal

## **ABSTRACT**

Aims: Bile duct injury (BDI) in laparoscopic cholecystectomy (LC) has a significant impact on morbidity and mortality. Although the critical view of safety (CVS) concept is the most widely supported approach to prevent BDI, alternative approaches are used as well. The aim was to evaluate the incidence, severity, and management of bile duct injury in LC, using a posterior infundibular approach.

Methods: This retrospective, monocentric cohort study includes patients who underwent LC for gallstone disease. Data were collected in a prospectively maintained database. Patients with BDI were identified and were analyzed in-depth.

Results: Between 1999 and 2018, 8389 consecutive patients were included (M/F 3288/5101; mean age 55 (standard deviation; SD ± 17) years). Mean length of postoperative hospital stay was two days (SD ± 4). Fourteen patients died after LC and 21 patients were identified with BDI. Seventeen BDI (81%) patients were managed minimally invasive (14 endoscopic, 3 laparoscopic), and 4 patients via laparotomy (3 hepaticojejunostomy, 1 primary suture). Severe complications (Clavien-Dindo ≥3) after BDI repair were observed in 6 patients. There was no BDI-related mortality. Median follow-up time was 113 months (range 5-238).

**Conclusion:** A posterior infundibular approach in LC was associated with a low incidence of BDI and no BDIrelated mortality.

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#### INTRODUCTION

Laparoscopic cholecystectomy (LC) is the standard treatment for symptomatic gallstone disease. Bile duct injury (BDI) in LC is a severe complication with significant impact on morbidity and mortality [1, 2]. In the early days of the LC, the incidence of BDI in LC was alarmingly high (0.5-0.7%), compared to open cholecystectomy (OC) (0.1–0.2%) [3–5]. Fortunately, recent data suggest that the rate of BDI in the advanced laparoscopic era reaches that of OC (0.2%) [6, 7]. One of the most common causes or mechanisms of BDI in LC is misidentification of the anatomic structures during the procedure [8-10]. The most widely supported approach to prevent BDI is the critical view of safety (CVS) concept, first described by Strasberg et al. in 1995 [11]. In the CVS concept both the cystic duct and cystic artery are identified, the lower third of the gallbladder is separated from the cystic plate, and the hepatocystic triangle is cleared of all tissue so that only two structures are visible before any transection takes place. Alternative surgical approaches and techniques, such as infudibulo-cystic or infundibular, fundus-down, subtotal cholecystectomy without visualization of the CVS, have been described but less adopted by surgeons [12-14]. Despite the fact that the CVS concept reduces BDI by misidentification, it does not eliminate BDI altogether, for example, by direct Int J Hepatobiliary Pancreat Dis 2022;12(2):5-13. www.ijhpd.com

(thermal) injury in severe inflammatory conditions [15]. In our tertiary teaching hospital, an adaptation of the socalled infundibular view method (ductal identification by exposing the infundibulo-cystic junction) is consistently used. However, great concerns have been raised using this method in severely inflamed gallbladders and/or in patients with an aberrant ductal anatomy [15]. Nonetheless, data on BDI using a standardized infundibular approach in a large cohort is missing. The aim of this retrospective single-center cohort study was to investigate the incidence, severity, and management of BDI, using a standardized posterior infundibular approach.

#### MATERIAL AND METHODS

#### **Patients**

A retrospective analysis of a prospectively maintained database was performed. All patients who underwent LC with or without bile duct exploration between January 1999 and December 2018 were included. Patients who had LC simultaneously during another operation or for oncologic reasons were excluded. Comorbidities were registered according to the International Classification of Diseases and Related Health Problems (ICD-9 and ICD-10), using the Elixhauser Comorbidity Index [16]. In order to identify patients with BDI within the database, all patients who had hepatobiliary surgery or an endoscopic retrograde cholangiopancreatography (ERCP) after cholecystectomy were identified using a surgery- and procedure-specific code, and further analyzed in-depth. A subgroup-analysis of these patients was performed. The type of BDI was defined according to the Strasberg classification [11]. Patients with BDI referred from other centers were excluded from this study. The severity of complications after BDI repair was classified according to the Clavien-Dindo grading scale, with severe complications as grade 3 or higher [17]. All procedures performed in this study involving the patients were in accordance with the ethical standards of the institutional, the national research committee and with the 1964 Helsinki declaration (as revised in Brazil 2013) and its later amendments or comparable ethical standards. The medical ethics committee of our institution (University Hospitals Leuven, Leuven, Belgium) waived the need for review of the study due to its observational and retrospective nature. Due to the observational and retrospective nature, the need for a written or verbal informed consent to analyze the patients' data was also waived by the medical ethics committee of our institution (University Hospitals Leuven, Leuven, Belgium).

## **Surgical technique (Figure 1)**

The patient is positioned in supine position, with the legs in abduction. The surgeon is positioned between the patients' legs. A CO<sub>2</sub>-pneumoperitoneum is established

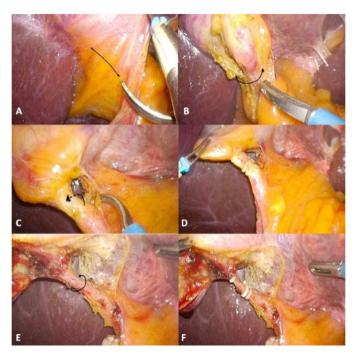
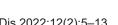


Figure 1: Key steps of a laparoscopic cholecystectomy using a posterior infundibular approach. (A) Incision of the posterior peritoneum at the level of the infundibulo-cystic connection. (B) Circumferential continuation of the peritoneal incision towards the anterior leaflet. (C) 360° complete isolation of the cystic duct. (D) Clipping and ligation of the cystic duct. (E) 360° complete isolation of the cystic artery. (F) Clipping and ligation of the cystic artery.

using a Veres needle at Palmer's point, until an intraabdominal pressure of 15 mmHg is achieved. A total of four trocars is placed: a 12 mm trocar at the umbilicus, a 5 mm in the left hypochondrium at the midclavicular line, a 5 mm in the right subcostal region at the midclavicular line, and a 5 mm at the right flank more laterally. After trocar placement, intra-abdominal pressure is reduced to 8-12 mmHg for the rest of the procedure, to enable sufficient space for laparoscopic view. The gallbladder is retracted cephalad at the fundus and the infundibulum pulled medially, thus creating an optimal exposure of the posterior hepatocystic triangle. The dissection of the hepatocystic triangle is performed using monopolar electrocautery and the peritoneal envelope is first incised posteriorly, keeping as close as possible to the infundibulo-cystic connection, which is the lowest border of the gallbladder infundibulum connecting with the upper border of the cystic duct. Once the posterior infundibulo-cystic connection is visualized, the cystic duct is freed from its peritoneum at this level onto the anterior and medial site of the infundibulo-cystic connection, creating a dissected area circumferentially around the infundibulo-cystic connection. The cystic duct is clipped with 1 Hem-O-Lok clip (Weck Surgical Instruments, Teleflex medical, Durham, NC, USA) toward the gallbladder. An intra-operative transcystic cholangiography is performed on a selective basis; i.e., in



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case of suspicion of bile duct stones preoperatively (bile duct distention on ultrasound, deranged liver function tests), during the procedure (diameter of the cystic duct measuring at least 5 mm), or in case of intra-operative unclear biliary anatomy or suspicion of bile duct injury. In case of confirmed bile duct stones on cholangiogram, a stone extraction is performed by transcystic approach, using a flexible cholangioscope. Next, the cystic duct is clipped with 2 Hem-O-Lok clips toward the main bile duct and transected. After transection of the cystic duct, the dissection is carried on anteriorly on the gallbladder where it is freed from the peritoneal envelope to visualize and dissect the cystic artery. The cystic artery is clipped with 1 Hem-O-Lok clip distally and 2 clips proximally, and transected. Finally, cholecystectomy is completed from the infundibulum toward the fundus, taking care the dissection is kept at all times as close as possible to the gallbladder. After extraction of the specimen through the umbilical trocar site, the hemostasis is controlled, the pneumoperitoneum deflated and trocars removed, without routine placement of a drain.

## Statistical analysis

Categorical variables are reported with frequency (n) and percentage (%). Continuous variables are described with mean (standard deviation; SD) or median (range). Patients with BDI were followed up until death or until the date of study closure in December 2019. Median follow-up time in patients with BDI in LC was 113 months (range 5-238 months). Statistical analyses were done using the software package JMP for Mac, version 14 (SAS Institute Inc., Cary, NC, USA).

## RESULTS

## **Patients**

During the study period, a total of 8389 consecutive patients underwent a laparoscopic cholecystectomy for symptomatic cholelithiasis. Male-to-female ratio was 3288/5101, and the mean age was 55 (SD  $\pm$  17) years. Indications for LC and patients' comorbidities are shown in Table 1. In 2197 (26%) patients LC was performed in an emergency setting. In 1440 (17%) patients, an intraoperative cholangiography was obtained and in 324 (4%) a laparoscopic common bile duct exploration was performed. Mean length of hospital stay was two days (SD  $\pm$  4). 4894 patients (58%) were operated in an outpatient clinic setting.

Among all patients who underwent LC the postoperative mortality rate was 0.17% (n=14). Causes of postoperative mortality were: preoperative-existing septic shock (n=1), small bowel ischemia (n=2), multiorgan failure following spontaneous hematoma of the abdominal rectus muscle (n=1), respiratory insufficiency (n=2), cardiac arrest (n=3), hypoglycemic coma (n=1), end-stage chronic renal failure (n=1), septic shock following duodenal perforation (n=1), progressive underlying oncologic disease (metastasized breast cancer, n=1), and hemorrhagic shock (n=1).

Table 1: Patients' characteristics

**EDORIUM** Journals

Variable Variable	n=8389	Missing
	(100%)	data n (%)
Indication for LC		676 (8.1)
1. Cholecystolithiasis	1316 (17.1)	
2. Chronic cholecystitis	4302 (55.8)	
3. Acute cholecystitis	1717 (22.3)	
4. Choledocholithiasis	246 (3.2)	
5. Pancreatitis	56 (0.7)	
6. Cholangitis	3 (0.04)	
<ol><li>Acute cholecystits and choledocholithiasis</li></ol>	73 (0.9)	
Comorbidity (ICD-9 or ICD-10)		6 (0.07)
8. Acquired immune deficiency syndrome	14 (0.2)	
9. Alcohol abuse	114 (1.4)	
10. Deficiency anemia	87 (1.0)	
11. Rheumatoid arthritis/ collagen vascular diseases	137 (1.6)	
12. Chronic blood loss anemia	4 (0.05)	
13. Congestive heart failure	67 (0.8)	
14. Chronic pulmonary disease	392 (4.7)	
15. Coagulopathy	50 (0.6)	
16. Depression	44 (0.5)	
17. Diabetes, uncomplicated	531 (6.3)	
18. Diabetes with chronic complications	154 (1.8)	
19. Drug abuse	28 (0.3)	
20. Hypertension, uncomplicated	1956 (23.3)	
21. Hypertension, complicated	178 (2.1)	
22. Hypothyroidism	215 (2.6)	
23. Liver disease	329 (3.9)	
24. Lymphoma	36 (0.4)	
25. Fluid and electrolyte disorders	174 (2.1)	
26. Metastatic cancer	68 (0.8)	
27. Other neurological disorders	156 (1.9)	
28. Obesity	1342 (16)	
29. Paralysis	56 (0.7)	
30. Peripheral vascular disorders	199 (2.4)	
31. Psychoses	30 (0.4)	
32. Pulmonary circulation disorders	39 (0.5)	

Table 1: (Continued)

Variable	n=8389 (100%)	Missing data n (%)
33. Renal failure	218 (0.3)	
34. Solid tumor without metastasis	112 (1.3)	
35. Peptic ulcer disease excluding bleeding	6 (0.07)	
36. Valvular disease	259 (3.1)	
37. Weight loss	61 (0.7)	

Abbreviations: LC, laparoscopic cholecystectomy; ICD-9/10, International Statistical Classification of Diseases and Related Health Problems

Bile duct injury occurred in 21 (0.25%) patients (M/F 8/13; median (range) age 57 (30-83) years). Patient characteristics are summarized in Table 2. In 1 patient a concomitant vascular injury was reported, and in 1 patient laparoscopy was converted to an open procedure to perform a hepaticojejunostomy for the repair of the BDI. The suspected mechanism or pathophysiology of the BDI is also reported in Table 2. The majority of the BDIs were bile leaks of the cystic stump (n=6) and thermal injury (n=7). In 4 patients there was a misidentification of the ductal anatomy, of which 1 patient had an aberrant anatomy and in 1 patient there was a vascular injury during the LC. In 17 patients (81%), BDI was visualized with postoperative ERCP. Characteristics of BDI management and its outcome are summarized in Table 3. Fourteen patients (67%) were managed endoscopically and 4 (19%) via laparotomy. Severe complications were observed in 3 patients (duodenal perforation n=2; bile duct perforation n=1) after endoscopic and in 2 after surgical (primary repair) management of BDI. The former 3 patients were finally treated via surgical reintervention, while the latter 2 patients were managed via endoscopic biliary stenting. One of the duodenal perforations was due to a duodenal ulcer, which was managed with an open duodenoraphy and omentoplasty. One patient was admitted to the intensive care unit (ICU) due to post-ERCP bleeding, which was managed via interventional radiology. None of the patients died after management of BDI. Median length of hospital stay in the BDI-subgroup was 12 days (range 2-57).

Table 2: Patients' characteristics of BDI-subgroup

Variable	n=21 (100%)	Missing data n (%)
Age (years, median, range)	57 (30-83)	0 (0)
Sex		0 (0)
1. Female	13 (62)	
2. Male	8 (38)	
BMI (kg/m², median, range)	26.5 (16.8– 35)	4 (19)

Table 2: (Continued)

Name	Table 2: (Continued)		
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15. No  LCBDE at index operation  16. Yes  2 (10)  17. No  19 (90)  Iatrogenic gallbladder perforation  18. Yes  10 (48)  19. No  Vascular injury at index operation  20. Yes  1 (5)  21. No  19 (90)  Cholecystitis present at index operation  22. Yes  12 (57)  23. No  Conversion to laparotomy during index operation  24. Yes  25. No  Type of BDI according to Strasberg Classification  26. A  10 (48)  27. C  4 (19)  28. D  19 (90)  14 (66)  14 (66)  14 (66)  0 (0)  15 (10)  16 (48)  17 (10)  18 (10)  19 (90)  10 (48)  10 (48)  2 (10)  10 (48)  2 (10)	IOC at index operation		0 (0)
LCBDE at index operation       0 (0)         16. Yes       2 (10)         17. No       19 (90)         Iatrogenic gallbladder perforation       2 (10)         18. Yes       10 (48)         19. No       9 (43)         Vascular injury at index operation       1 (5)         20. Yes       1 (5)         21. No       19 (90)         Cholecystitis present at index operation       0 (0)         22. Yes       12 (57)         23. No       9 (43)         Conversion to laparotomy during index operation       0 (0)         24. Yes       1 (5)         25. No       20 (95)         Type of BDI according to Strasberg Classification       0 (0)         26. A       10 (48)         27. C       4 (19)         28. D       2 (10)	14. Yes	7 (33)	
16. Yes       2 (10)         17. No       19 (90)         Iatrogenic gallbladder perforation       2 (10)         18. Yes       10 (48)         19. No       9 (43)         Vascular injury at index operation       1 (5)         20. Yes       1 (5)         21. No       19 (90)         Cholecystitis present at index operation       0 (0)         22. Yes       12 (57)         23. No       9 (43)         Conversion to laparotomy during index operation       0 (0)         24. Yes       1 (5)         25. No       20 (95)         Type of BDI according to Strasberg Classification       0 (0)         26. A       10 (48)         27. C       4 (19)         28. D       2 (10)	15. No	14 (66)	
17. No 19 (90)  Iatrogenic gallbladder perforation  18. Yes 10 (48)  19. No 9 (43)  Vascular injury at index operation  20. Yes 1 (5)  21. No 19 (90)  Cholecystitis present at index operation  22. Yes 12 (57)  23. No 9 (43)  Conversion to laparotomy during index operation  24. Yes 1 (5)  25. No 20 (95)  Type of BDI according to Strasberg Classification  26. A 10 (48)  27. C 4 (19)  28. D 2 (10)	LCBDE at index operation		0 (0)
Iatrogenic gallbladder perforation       2 (10)         18. Yes       10 (48)         19. No       9 (43)         Vascular injury at index operation       1 (5)         20. Yes       1 (5)         21. No       19 (90)         Cholecystitis present at index operation       0 (0)         22. Yes       12 (57)         23. No       9 (43)         Conversion to laparotomy during index operation       0 (0)         24. Yes       1 (5)         25. No       20 (95)         Type of BDI according to Strasberg Classification       0 (0)         26. A       10 (48)         27. C       4 (19)         28. D       2 (10)	16. Yes	2 (10)	
perforation  18. Yes	17. No	19 (90)	
19. No 9 (43)  Vascular injury at index operation  20. Yes 1 (5)  21. No 19 (90)  Cholecystitis present at index operation  22. Yes 12 (57)  23. No 9 (43)  Conversion to laparotomy of uring index operation  24. Yes 1 (5)  25. No 20 (95)  Type of BDI according to Strasberg Classification  26. A 10 (48)  27. C 4 (19)  28. D 2 (10)			2 (10)
Vascular injury at index operation  20. Yes 1 (5)  21. No 19 (90)  Cholecystitis present at index operation  22. Yes 12 (57)  23. No 9 (43)  Conversion to laparotomy during index operation  24. Yes 1 (5)  25. No 20 (95)  Type of BDI according to Strasberg Classification  26. A 10 (48)  27. C 4 (19)  28. D 2 (10)	18. Yes	10 (48)	
operation  20. Yes  1 (5)  21. No  19 (90)  Cholecystitis present at index operation  22. Yes  12 (57)  23. No  9 (43)  Conversion to laparotomy during index operation  24. Yes  1 (5)  25. No  20 (95)  Type of BDI according to Strasberg Classification  26. A  10 (48)  27. C  4 (19)  28. D  20 (95)	19. No	9 (43)	
21. No 19 (90)  Cholecystitis present at index operation  22. Yes 12 (57)  23. No 9 (43)  Conversion to laparotomy of (0) during index operation  24. Yes 1 (5)  25. No 20 (95)  Type of BDI according to Strasberg Classification  26. A 10 (48)  27. C 4 (19)  28. D 2 (10)			1 (5)
Cholecystitis present at index operation  22. Yes 12 (57)  23. No 9 (43)  Conversion to laparotomy 0 (0) during index operation  24. Yes 1 (5)  25. No 20 (95)  Type of BDI according to 5 (0) Strasberg Classification  26. A 10 (48)  27. C 4 (19)  28. D 2 (10)	20. Yes	1 (5)	
operation  22. Yes  12 (57)  23. No  9 (43)  Conversion to laparotomy of (0)  during index operation  24. Yes  1 (5)  25. No  20 (95)  Type of BDI according to Strasberg Classification  26. A  10 (48)  27. C  4 (19)  28. D  2 (10)	21. No	19 (90)	
23. No 9 (43)  Conversion to laparotomy o (0) during index operation  24. Yes 1 (5) 25. No 20 (95)  Type of BDI according to Strasberg Classification  26. A 10 (48)  27. C 4 (19) 28. D 2 (10)			0 (0)
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during index operation  24. Yes  1 (5)  25. No  20 (95)  Type of BDI according to Strasberg Classification  26. A  10 (48)  27. C  4 (19)  28. D  2 (10)	23. No	9 (43)	
25. No 20 (95)  Type of BDI according to 0 (0)  Strasberg Classification  26. A 10 (48)  27. C 4 (19)  28. D 2 (10)			0 (0)
Type of BDI according to 0 (0) Strasberg Classification  26. A 10 (48)  27. C 4 (19)  28. D 2 (10)	24. Yes	1 (5)	
Strasberg Classification  26. A	25. No	20 (95)	
26. A 10 (48) 27. C 4 (19) 28. D 2 (10)			0 (0)
27. C 4 (19) 28. D 2 (10)		10 (48)	
28. D 2 (10)	27. C		
	,		
	29. E1		

Table 2: (Continued)

Variable	n=21 (100%)	Missing data n (%)
30. E2	1 (5)	
31. E3	2 (10)	
Timing of BDI diagnosis		0 (0)
32. Intraoperatively	2 (10)	
33. Postoperatively	19 (90)	
Presentation at postoperative diagnosis		0 (0)
34. Bile leakage in drain	7 (37)	
35. Jaundice	5 (26)	
36. Pain, peritonitis, fever	7 (37)	
Diagnostic modality		0 (0)
37. ERCP	17 (81)	
38. Laparoscopy	4 (19)	
Time between LC and diagnosis of BDI (days, median, range)	7 (0 – 1324)	0 (0)
Mechanism of BDI		
39. Misidentification 1. With aberrant	4	
anatomy	1 1	
2. With vascular injury	6	
40. Cystic stump leakage	7	
41. Thermal injury 42. Luschka's duct leakage	1 2	
43. Stenosing clip	1	
44. Bile duct suture leakage		

Abbreviations: BDI, bile duct injury; LC, laparoscopic cholecystectomy; BMI, body mass index; ASA, American Society of Anesthesiologists classification; IOC, intraoperative cholangiography; LCBDE, laparoscopic common bile duct exploration; ERCP, endoscopic retrograde cholangiopancreatography

Table 3: Characteristics of BDI management and outcome

Variable	n=21 (100%)	Missing data n (%)
Time between BDI diagnosis and repair (days, median, range)	0 (0-45)	0 (0)
Time between LC and BDI repair (days, median, range)	7 (0–1324)	0 (0)
Type of repair		0(0)
1. Endoscopic:	14 (67)	
<ol> <li>ERCP: sphincterotomy without stenting</li> </ol>	1 (5)	
2. ERCP: sphincterotomy with stenting	13 (62)	
2. Laparoscopic:	3 (14)	
1. Primary suture	1 (5)	

Table 3: (Continued)

Variable	n=21 (100%)	Missing data n (%)
2. Suture duct of Luschka	1 (5)	
3. Removal clips	1 (5)	
3. Laparotomy:	4 (19)	
1. Primary suture on Kehr drain	1 (5)	
<ol> <li>Intrahepatic hepaticojejunostomy</li> </ol>	3 (14)	
Complication after BDI repair		0 (0)
4. Bleeding	1 (5)	
5. Duodenal perforation	2 (10)	
6. Biliary tract perforation after ERCP	1 (5)	
7. Biliary stenosis	3 (14)	
Complication grade after BDI repair		o (o)
8. Clavien-Dindo classification > 3	6 (29)	
ICU stay		o (o)
9. No	20 (95)	
10. Yes	1 (5)	
Postoperative mortality	o (o)	o (o)
Length of hospital stay (days, median, range)	12 (2 – 57)	0 (0)
Readmission within 30 days of discharge, after BDI repair		0 (0)
11. No	16 (76)	
12. Yes	5 (24)	
Readmission beyond 30 days of discharge, after BDI repair		
13. No	18 (86)	
14. Yes	3 (14)	
Reason for readmission		0 (0)
15. Cholangitis	2 (10)	
16. Biliary stenosis	3 (14)	
17. Intra-abdominal abscess	1 (5)	
18. Ileus	1 (5)	
19. Bile stone ileus	1 (5)	
Length of readmission (days, median, range)	7 (3- 15)	0 (0)
Length of follow-up (months, median, range)	113 (5 – 238)	0 (0)

Abbreviations: LC, laparoscopic cholecystectomy; ERCP, endoscopic retrograde cholangiopancreatography; BDI, bile duct injury; ICU, intensive care unit

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#### **DISCUSSION**

The posterior infundibular approach in LC appears to be a safe and reproducible technique, and was associated with a BDI rate of 0.25% at our center. This observed BDI rate is comparable with the literature [6, 7]. Avgerinos et al. [18] published their results of more than 1000 LC and state to routinely use the CVS-method in order to perform a LC. They report a 0% BDI rate, however in contrast to our study, they did not consider bile leaks as a BDI, which occurred in 5 out of 1046 patients (0.48%). Moreover, in 48 patients a CVS could not be obtained and in 19 of those patients, the authors used an infundibular technique. A similar infundibular approach has been recently described by Iskandar et al. [14]. They postulate that such a posterior infundibular approach avoids the need to an extensive dissection in the hepatocystic triangle. Thereby this reduces the potential injury to the common hepatic duct, the right hepatic duct and the right hepatic artery. They report an impressive zero percentage of BDI in 1402 LC. However, they also did not consider bile leaks of the cystic stump as a BDI, in contrast to this study.

Of the 21 BDIs in our cohort, only 7 (0.08%) were major BDIs (Strasberg type D or E) including 1 vascular injury. The majority (81%) of BDIs were managed using a minimally invasive approach. Despite its minimally invasive treatment, severe complications after BDI management were noted in 6 patients, but without any BDI-related mortality. Strasberg et al. [10-12, 15] described an "infundibular technique" in LC, similar to our standardized technique, and considered this approach unreliable in comparison with the CVS concept, especially in cases with acute inflammation where the cystic duct might become "hidden" or in cases with a Mirizzi's syndrome. They state that using this technique in such cases would result into a misidentification of the cystic duct and the common bile duct. In our series, BDI due to misidentification only occurred in 4 patients (0.05%). The question whether the BDI in these cases could have been avoided using the CVS concept is impossible to answer. In more difficult cases, when the risk of biliary and vascular trauma is significantly higher, a reliable standardized approach seems crucial [7].

The CVS is advocated by many authors and recommended in most guidelines for a safe LC [19–23]. However, in patients with a severely inflamed gallbladder or chronic cholecystitis, it can be difficult to fulfill all 3 CVS criteria [11, 15]. Bail-out procedures or alternatives are therefore sometimes necessary [24]. This is also reflected in the recent "safe cholecystectomy" guidelines where subtotal cholecystectomy is advised in patients where CVS cannot be obtained [22, 23]. There also appears to be a significant discrepancy between theory and practice of the method used for bile duct identification during LC [25–27]. A Dutch study investigating complications after LC using video analysis revealed that the CVS was only attained in 10.8% of the investigated cases in a hospital where CVS was the preferred method for safe

cholecystectomy [25]. It is difficult to objectively study the mechanisms and factors related to BDI because of its low incidence, but remarkably, CVS has rarely been described as the method of hilar dissection in major BDI [1, 7, 25, 28]. Even more surprisingly, a substantial part of the surveyed surgeons fails to correctly describe the CVS altogether, again undermining the reliability of this concept and the current data supporting it [26].

Although some authors believe BDI is unavoidable in certain circumstances, prevention still remains key [29]. The question of how to effectively prevent BDI is still at large however. The most recent guidelines from five international HPB societies (SAGES, AHPBA, IHPBA, SSAT, EAES) for safe cholecystectomy have been published to address this issue [23]. However, many recommendations are still based on expert opinion because of the limited high-quality evidence available. Key risk factors for BDI in LC are bundled into training and inexperience (learning-curve effect), local risk factors (inflammation, scarring, operative bleeding, etc.), aberrant anatomy (aberrant right hepatic duct), and equipment failure (thermal injuries due to insulation malfunction) [10]. Experience and learning curve have been studied extensively as well in the past as possible cause of BDI. Some studies even report a BDI rate three times higher if LC is performed by young and inexperienced surgeons as compared to more experienced surgeons [19, 30, 31]. Griffiths et al. [31] compared the outcomes for LC and report that a higher operative difficult grade was associated with worse outcomes for both experienced and general surgeons. More interestingly, BDI in cases with a higher operative difficult grade remained low in the experienced groups, as compared to a high BDI-rate in the general surgeon group. However, the technique used for the LC in both groups is not mentioned. In our study, the vast majority of cholecystectomies are performed by junior surgeons, as this is a large teaching hospital. Nonetheless, the rate of BDI in our study is comparable with that in the literature suggesting that by using careful dissection based on a standardized technique, even less experienced surgeons are able to achieve a low BDI rate in LC.

In more recent data with a patient cohort of 217.774 cases, cholecystitis appeared to be the most evident risk factor for BDI during LC [7]. These findings imply that local factors such as inflammation and scarring play an important role in the occurrence of BDI, whatever the method of dissection is used [7, 22]. This is also reflected in our series: 10 out of 21 patients (47%) who suffered BDI had acute cholecystitis (n=2), chronic cholecystitis (n=4) or were operated on after conservative treatment of an episode of acute cholecystitis (n=4).

The use of intraoperative cholangiography (IOC) and its impact on BDI in LC is a matter of ongoing debate. At our center, IOC is used on a case-selective basis. Comparison of selective use of IOC between different study populations is once again difficult, as the indications for IOC are heterogeneous and study conclusions or recommendations are exposed to bias. The routine use of

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IOC does not protect against BDI, but it does result in a higher rate of intra-operative diagnosis of BDI, which might improve outcomes [23, 32, 33]. In our subgroup of BDI, IOC was used in a third of patients, while 90% of BDI was diagnosed postoperatively.

The timing of BDI diagnosis determines the further management, but the timing of surgical repair is still an ongoing debate. Regarding the reconstruction by hepaticojejunostomy, the timing of repair did not appear to impair or influence the outcome in a collaborative retrospective study from the EAHPBA comprising 913 patients [33]. However, this conclusion was based upon multicentric retrospective data with a relatively short follow-up period of two years. As some participating centers, which often have their own local policy, contributed large numbers of patients, this might have resulted in skewed data and thus might contain a potential bias. An even more recent systematic review and meta-analysis shows that early (<14 days) and delayed (>6 weeks) reconstruction after major BDI can decrease morbidity and risk of anastomotic stricture compared to intermediate reconstruction (between 2 and 6 weeks postoperatively) [34]. As the majority of BDI in our cohort was diagnosed postoperatively, an immediate primary repair was only possible in a small subset of cases. Generally, only 20-40% of BDIs are seen during the index case [7, 33]. In our cohort, median time between LC and BDI treatment was 7 days (range 0-1324 days). The outlier here was a patient with a late diagnosis of main bile duct stenosis (Strasberg type E2), which could be successfully managed by endoscopy (ERCP with stenting). This, together with the observation that most biliary strictures develop after one year or more, emphasizes the need for a long-term follow-up, especially in patients already treated for BDI [2]. In our patient cohort of BDI, there was a rather high 30-day readmission rate of 24% (n=5) and a readmission rate of 14% (n=3) for the period beyond the 30 days after discharge, reflecting the complexity and difficulty of BDI treatment and subsequent patient morbidity. It has well been documented in several studies that referral to a tertiary center with specialized HPB surgeons has positive impact on the outcomes of repair after BDI [30, 33].

The strength of our study is that it reviewed a large single-center patient cohort who underwent LC using a standardized surgical technique, often performed by junior surgeons in a teaching hospital setting, together with a long-term follow-up. Limitations of this study include its retrospective nature and the rather long study period, making it difficult to draw solid conclusions from an even in-depth analysis of this subgroup.

#### CONCLUSION

This study shows LC using the standardized posterior infundibular approach is associated with a low incidence of BDI. Although BDI has a relatively low incidence, it lays a heavy burden on both patients' quality of life and health economics. Surgeons need to be able to perform LC in the possible safest way by using a reliable technique that they're familiar with and that can be used in most circumstances, also during difficult LC with severe inflammation or fibrosis.

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Joris Jaekers — Acquisition of data, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Halit Topal – Acquisition of data, Analysis of data, Interpretation of data, Drafting the work, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

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#### **Guarantor of Submission**

The corresponding author is the guarantor of submission.

## **Source of Support**

None.

#### **Consent Statement**

The medical ethics committee of our institution (University Hospitals Leuven, Leuven, Belgium) waived the need for review of the study due to its observational and retrospective nature. Due to the observational and retrospective nature, the need for a written or verbal

informed consent to analyze the patients' data was also waived by the medical ethics committee of our institution (University Hospitals Leuven, Leuven, Belgium).

#### **Conflict of Interest**

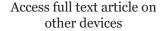
Authors declare no conflict of interest.

## **Data Availability**

All relevant data are within the paper and its Supporting Information files.

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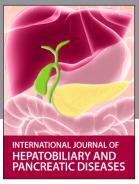
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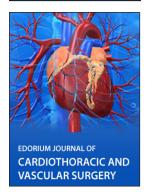














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