ORIGINAL ARTICLE

Post cholecystectomy bile duct injury: early, intermediate or late repair with hepaticojejunostomy – an E-AHPBA multi-center study[1]

A European-African HepatoPancreatoBiliary Association (E-AHPBA) Research Collaborative Study management group, Other members of the European-African HepatoPancreatoBiliary Association Research Collaborative*

Abstract

Background: Treatment of bile duct injuries (BDI) during cholecystectomy depends on the severity of injury and the timing of diagnosis. Standard of care for severe BDIs is hepaticojejunostomy. The aim of this retrospective multi-center study was to assess the optimal timing for repair of BDI with hepaticojejunostomy.

Methods: Members of the European-African HepatoPancreatoBiliary Association were invited to report all consecutive patients with hepaticojejunostomy after BDI from January 2000 to June 2016. Patients were stratified according to the timing of biliary reconstruction with hepaticojejunostomy: early (day 0–7), intermediate (1–6 weeks) and late (6 weeks–6 months). Primary endpoint was re-intervention >90 days after the hepaticojejunostomy and secondary endpoints were severe 90-day complications and liver-related mortality.

Results: In total 913 patients from 48 centers were included in the analysis. In 401 patients (44%) the bile duct injury was diagnosed intraoperatively, and 126 patients (14%) suffered from concomitant vascular injury. In multivariable analysis the timing of hepaticojejunostomy had no impact on post-operative complications, the need for re-intervention after 90 days nor liver-related mortality. The rate of re-intervention more than 90 days after the hepaticojejunostomy was significantly increased in male patients but decreased in older patients. Severe co-morbidity increased the risk for liver-related mortality (HR 3.439; CI 1.37–8.65; p = 0.009).

Conclusion: After BDI occurring during cholecystectomy, the timing of biliary reconstruction with hepaticojejunostomy did not have any impact on severe postoperative complications, the need for re-intervention or liver-related mortality. Individualised treatment after iatrogenic bile duct injury is still advisable.

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Introduction

The incidence of bile duct injury (BDI) after cholecystectomy is reported to be between 0.3 and 1.5%.[1–4] Risk factors for BDI include anatomical variants, difficult pathology, visual misperception and surgeon dependent factors such as surgical technique and learning curve.[5–7] Treatment of BDI after cholecystectomy depends on the severity of the injury, the timing of diagnosis and the general condition of the patient. Late detection of BDI has been shown to be associated with reduced survival.[2] Gold standard for treatment of severe BDI and complete transection is hepaticojejunostomy.[8–10]

The timing of hepaticojejunostomy after BDI is however still under debate. Immediate reconstruction is only possible when the injury is detected intraoperatively during cholecystectomy. In

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* See Appendix for group authorship.

case of early postoperative diagnosis of the BDI, the timing of repair depends on several factors like sepsis, the general condition of the patient and the surgeon's preference. When the biliary reconstruction is performed by hepatopancreaticobiliary (HPB) surgeons, comparable results have been shown between immediate/early versus delayed/late repair.[11–14] However, in the presence of sepsis, reconstruction is generally advocated after sepsis control to mitigate local and systemic inflammation.[15] Finally most publications that focus on the impact of timing come from high-volume single centers, which could introduce a bias on reported outcomes.[15,16]

The aim of this retrospective multicenter study was to assess the optimal timing for repair of BDI with hepaticojejunostomy in terms of postoperative complications, re-interventions after 90 days and liver-related mortality.

Methods

Members of the European-African HepatoPancreatoBiliary Association (E-AHPBA) were invited to participate and report all consecutive patients operated with a hepaticojejunostomy after BDI from January 2000 to June 2016. Participants reported their data either through an on-line questionnaire (SurveyMonkey®) containing predefined case report forms (CRF) or by a CRF-file (Excel®). BDI was reported according to the Strasberg classification.[4]

Primary endpoint was surgery or interventional procedures aimed for the biliary tree more than 90 days after reconstruction with hepaticojejunostomy, representing failure of the hepaticojejunostomy.[17] Secondary endpoints were severe complications and re-interventions within the first 90-days after the reconstruction, Clavien-Dindo $\geq$3,[18] and liver-related mortality.

Only patients with BDI treated with hepaticojejunostomy within six months from the cholecystectomy were included in the analysis to obtain a homogenous cohort. Patients were stratified according to the timing of biliary reconstruction with hepaticojejunostomy: early (day 0–7 days), intermediate (1–6 weeks) and late (6 weeks–6 months).[15]

Statistical analysis

Data was analyzed using SPSS 22.0 (IBM Corp., New York, US). Categorical data are presented as proportion, and continuous data as either mean with standard deviation or median with inter-quartile-range (IQR) as appropriate. Student's t, Mann Whitney U, Chi-square, or Fisher's exact tests were used as appropriate. Multivariable analysis was performed using logistic regression except for mortality analysis where Cox-regression analysis was applied. A crude limit of $p < 0.3$ for inclusion in the multivariable analysis was applied. Parameters with a high frequency of missing values were excluded in the multivariable analysis and clinically significant parameters, like vascular injury, were included even if the univariable analysis showed a $p > 0.3$. A $p < 0.05$ was considered statistically significant.

Ethics

The study protocol was approved by the regional ethics board in Lund, Sweden (2017/4). All participating centers were individually responsible to obtain adequate ethical approval according to national/local legislation before inclusion of patients.

Results

In total 913 patients with BDI were subject to hepaticojejunostomy within six months from the cholecystectomy and were included in the analysis. Time to hepaticojejunostomy was median 15 days (IQR 2–72) after the cholecystectomy with a skewed and not clearly bi-modal distribution, Fig. 1. Median follow-up was two years (IQR 6–62 months), Fig. 2.

Median age at cholecystectomy was 55 years (42–67) and 63% were women. Twenty percent of patients underwent emergency cholecystectomy and 64% suffered from complicated gallstone disease like acute or chronic cholecystitis, acute or previous pancreatitis. In 401 patients (44%) the bile duct injury was diagnosed intraoperatively, 126 patients (14%) suffered from concomitant vascular injury and the right hepatic artery was involved in 103 patients (82%). No information if the artery was reconstructed at the time of injury was collected. In 240 patients (27%) where the injury was diagnosed during cholecystectomy, an immediate attempt at repair was made. Of these, 152 patients were reconstructed with a hepaticojejunostomy by a tertiary HPB-team, either as an outreach team or at the tertiary center site. The remaining 88 patients had attempted intraoperative repair with some other technique including suturing with or without internal drain and end-to-end anastomosis. The median time from cholecystectomy to hepaticojejunostomy in patients with vascular injury was 35 days (IQR 1–63). The median referral time to hepatobiliary center was 8 days (IQR 1–24 days). Eighty-three percent of the injuries were classified as Strasberg E and only 7/913 (0.8%) injuries were unclassified. Eight patients (0.9%) underwent a concomitant liver-resection at the time of the hepaticojejunostomy. Descriptive data for all patients stratified according to the timing of hepaticojejunostomy are presented in Table 1.

Severe postoperative complications and interventions within 90 days (Clavien 3–4)

Hepaticojejunostomy at any time after the first week after the cholecystectomy showed a decreased risk for severe postoperative complications in univariable analysis, $p = 0.041$. This impact of timing of reconstruction on postoperative complications and the need for intervention within 90 days was not reproduced in multi variable analysis, $p = 0.080$. Vascular injury was not associated with a higher risk of complications, $p = 0.302$, Table 2. In multivariable analysis no statistically significant difference on postoperative complications and early interventions could be demonstrated for any, modifiable or non-modifiable, parameter.

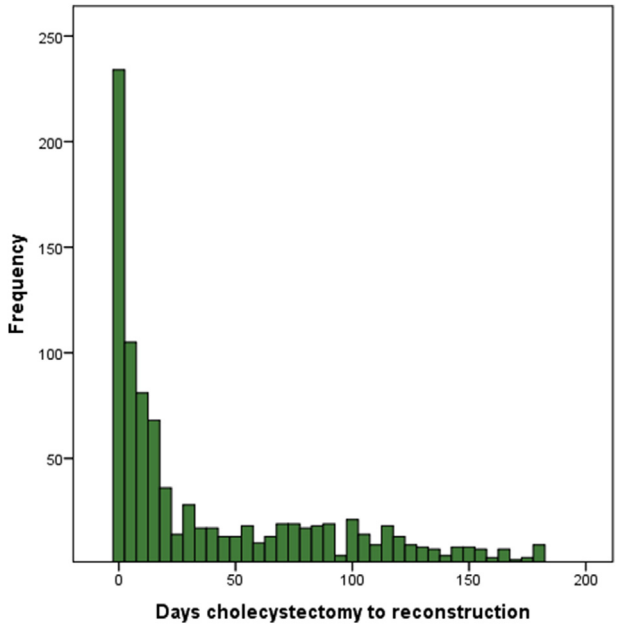

Figure 1 Time from cholecystectomy to hepaticojejunostomy, median 15 days (IQR 2–72), n = 913

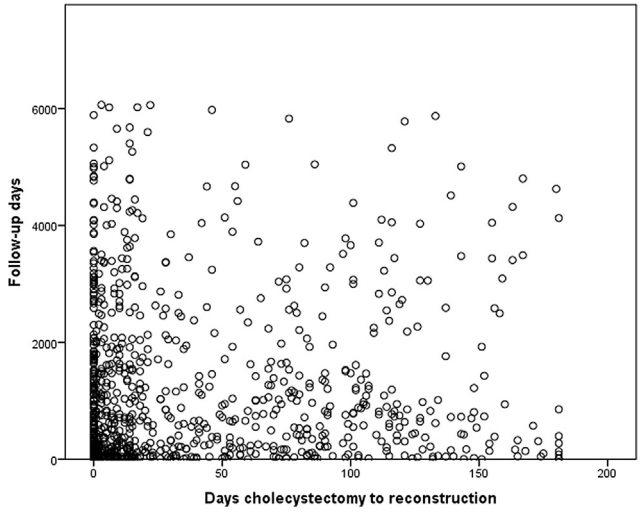

Figure 2 Follow-up time in relation to timing of biliary reconstruction (days from cholecystectomy to hepaticojejunostomy). Follow-up time median 24 months (IQR 6–62), n = 882 (31 missing)

Re-intervention after 90 days

The timing of hepaticojejunostomy after bile duct injury had no influence on patency and the need for re-intervention more than 90 days after the reconstruction. Among 101 re-interventions, 35 were re-do hepaticojejunostomy, 51 patients had one or several percutaneous biliary interventions, 6 patients were treated endoscopically and five needed liver-resection. The rate of re-intervention more than 90 days after the hepaticojejunostomy was significantly increased in male patients while it was significantly decreased in older patients, Table 3.

Mortality

Vascular injury increased the risk for liver-related mortality more than three times in univariable analysis (p = 0.003) while late reconstruction was associated with less mortality (p = 0.040). In multivariable analysis the risk for liver-related mortality after BDI repair was not associated with the timing of hepaticojejunostomy, nor with vascular injury, Table 4. The only factor influencing liver-related mortality was severe co-morbidity (ASA 3–4) (HR 3.439; CI 1.37–8.65; p = 0.009).

Discussion

The present series is the largest cohort to date of post-cholecystectomy BDIs treated by reconstruction with hepaticojejunostomy. The timing of hepaticojejunostomy seems to have no influence on patency and the need for re-intervention following biliary reconstruction.[15–17]

If the BDI is diagnosed intraoperatively the timing of surgical repair can be chosen depending on the severity of the injury and the available expertise.[9,19] The reported frequency for intraoperative detection of BDI varies from 19% to 90%. In the present series 44% of injuries were diagnosed intraoperatively.[19–23] A high frequency of intraoperative detection is reported from centers performing intraoperative cholangiogram (IOC) on a routine basis.[3,20,24] Referral to specialised HPB-units is reported to be associated with better surgical outcomes for severe BDIs.[12–14] Results of immediate or early repair by a HPB surgeon are comparable to those after late repairs.[11] Immediate repairs include on-table repair performed by a hepatobiliary outreach team travelling to the anesthetised patient. The reasons for late repair are either due to delayed diagnosis or a scheduled delayed reconstruction. Patients with late diagnosis constitute a more heterogeneous cohort and there is a risk of patients dying before referral or reconstruction.

The definition of early, intermediate or late repair of BDI varies much in the literature.[14–16] Without any international definition it is difficult to make direct comparison to other studies. In the present study we chose three timeframes; 1 week, 1–6 weeks and 6 weeks-6 months. This was based on previous publications on time for diagnosis and referral.[15]

As definition of treatment failure any intervention on the biliary tract, either by interventional radiology, endoscopy or surgery, more than 90 days after reconstruction was chosen. Similar definitions have been used previously.[15,16] The median follow-up time was two years in the present study, which is somewhat short as compared to previous reports. The reason for which was loss of follow up. However, the median time to first anastomotic failure has been reported to be around 6 months after reconstruction and 75% of patients in the present study had six months or longer follow-up.[15] The re-intervention rate was 11% and is in the lower range of what has been previously reported.

Table 1 Total number of patients with hepaticojejunostomy (HJ) after bile duct injury (n = 913) stratified according to the timing of repair. Values expressed as median (IQR) or numbers (%)

	Early Day 0–7 (n = 339)	Intermediate Day 8–42 (n = 261)	Late Day 43–183 (n = 313)	p
Time from cholecystectomy (days)	1 (0–3)	15 (11–26)	91 (70–121)	*
Follow-up in months	24 (6–59)	23 (6–63)	25 (8–63)	0.304
Age in years	59 (45–72)	53 (40–65)	51 (41–65)	0.110
Male gender	144 (42)	88 (34)	108 (35)	0.044
BMI kg/m2	27.3 (24.6–29.4)	26.3 (23.5–30.2)	26.2 (23.2–29.7)	0.499
ASA≤2	202 (78)	168 (77)	246 (83)	0.200
Emergency cholecystectomy	82 (24)	47 (18)	55 (18)	0.004
Indication for cholecystectomy				<0.001
Acute cholecystitis	102 (30)	72 (28)	86 (28)	
Biliary pain	91 (27)	89 (34)	147 (47)	
Chronic cholecystitis	60 (18)	57 (22)	52 (17)	
Other	21 (6.2)	4 (1.5)	10 (3.2)	
Intraoperative cholangiogram	110 (32)	23 (9)	40 (13)	<0.001
Intraoperative diagnosis	267 (79)	55 (21)	79 (25)	<0.001
Vascular injury	57 (17)	33 (13)	36 (12)	0.168
Attempted intraoperative repair	173 (51)	23 (8.8)	44 (14)	<0.001
Clavien 3 & 4 within 90 d after HJ	74 (22)	40 (15)	54 (17)	0.102
Mortality within 90 days (Clavien 5)	8 (2.4)	7 (2.7)	2 (0.64)	0.137
Biliary intervention after 90 d	42 (12)	22 (8.4)	37 (12)	0.269
Revision HJ	12 (3.5)	14 (5.4)	9 (2.9)	0.284
Overall mortality	40 (12)	24 (9.2)	21 (6.7)	0.111
Cause of death; biliary	12 (3.5)	11 (4.2)	3 (1.0)	0.041

Table 2 Univariable and multivariable analysis to identify predictors for severe complications (Clavien-Dindo score 3 and 4) postoperative within 90 days after the hepaticojejunostomy (n = 168/913)

	Event/Total	Missing (%)	Univariable analysis			Multivariable analysis		
			OR	95% CI	p	OR	95% CI	p
Early day 0–7	339/913	0	ref			ref		
Intermediate day 8–42	261/913	0	0.648	0.42–0.99	0.045	0.657	0.41–1.05	0.080
Late day 43–183	313/913	0	0.747	0.51–1.10	0.142	0.657	0.43–1.02	0.058
Age	907/913	6 (0.7)	1.010	1.00–1.02	0.059	1.005	0.99–1.02	0.460
Male gender	340/913	1 (0.1)	1.415	1.01–1.99	0.045	1.161	0.79–1.70	0.444
ASA 1&2	616/913	136 (15)	0.765	0.51–1.15	0.201	0.845	0.53–1.34	0.474
Emergency surgery	184/913	120 (13)	1.243	0.84–1.85	0.282	1.269	0.83–1.95	0.276
Acute cholecystitis	260/913	122 (13)	1.088	0.76–1.57	0.650			
IOC attempted or performed	173/913	29 (3.2)	1.410	0.94–2.11	0.095	1.001	0.64–1.57	0.998
Intraoperative diagnosis	401/913	4 (0.4)	1.155	0.83–1.62	0.400			
Attempted intraop repair	240/913	25 (2.7)	1.094	0.75–1.59	0.640			
Vascular injury	126/913	34 (3.7)	1.273	0.81–2.02	0.302	1.273	0.78–2.09	0.339

To proceed with treatment of any BDI, the injury needs to be well mapped anatomically and the patient in good condition.[9,17] Thomson *et al.* reported early repair, defined as within two weeks after the BDI, to be successful in selected patients.[23] Dominguez-Rosado *et al.* suggested that delayed reconstruction with hepaticojejunostomy should be considered for patients presenting late, if a previous repair had been attempted, to prevent complications.[15] While reconstruction of the bile ducts in the intermediate interval

Table 3 Univariable and multivariable analysis to identify predictors for re-intervention more than 90 days after the hepaticojejunostomy (n = 101/913)

	Event/Total	Missing (%)	Univariable analysis			Multivariable analysis		
			OR	95% CI	p	OR	95% CI	p
Early day 0–7	339/913	0	ref			ref		
Intermediate day 8–42	261/913	0	0.651	0.38–1.12	0.121	0.751	0.41–1.39	0.363
Late day 43–183	313/913	0	0.948	0.59–1.52	0.824	1.077	0.64–1.82	0.782
Age	907/913	6 (0.7)	0.990	0.98–1.00	0.117	0.984	0.97–1.00	0.027
Male gender	340/913	1 (0.1)	1.343	0.88–2.04	0.167	1.643	1.04–2.59	0.033
ASA 1&2	616/913	136 (15)	1.612	0.89–2.93	0.116			
Emergency surgery	184/913	120 (13)	0.751	0.44–1.27	0.288			
Acute cholecystitis	260/913	122 (13)	1.060	0.68–1.65	0.797			
IOC attempted or performed	173/913	29 (3.2)	0.973	0.57–1.65	0.920			
Intraoperative diagnosis	401/913	4 (0.4)	1.020	0.67–1.55	0.925			
Attempted intraop repair	240/913	25 (2.7)	1.455	0.93–2.27	0.097	1.433	0.86–2.40	0.171
Vascular injury	126/913	34 (3.7)	0.643	0.33–1.27	0.205	0.648	0.32–1.29	0.219

Table 4 Univariable and multivariable analysis to identify predictors for liver-related mortality (n = 913)

	Event/Total	Missing (%)	Univariable analysis			Multivariable analysis		
			OR	95% CI	p	OR	95% CI	p
Early day 0–7	339/913	0	ref			ref		
Intermediate days 8–42	261/913	0	1.199	0.52–2.76	0.670	1.321	0.44–4.00	0.623
Late days 43–183	313/913	0	0.264	0.07–0.94	0.040	0.373	0.09–1.54	0.173
Age	907/913	6 (0.7)	1.103	1.07–1.14	<0.001	1.080	1.04–1.13	<0.001
Male gender	340/913	1 (0.1)	3.510	1.56–7.89	0.002	1.962	0.75–5.14	0.170
ASA 1&2	616/913	136 (15)	0.161	0.07–0.35	<0.001	0.376	0.15–0.96	0.040
Emergency surgery	184/913	120 (13)	0.857	0.32–2.30	0.759			
Acute cholecystitis	260/913	122 (13)	0.956	0.41–2.21	0.915			
IOC attempted or performed	173/913	29 (3.2)	1.948	0.84–4.54	0.123	0.897	0.30–2.72	0.847
Intraoperative diagnosis	401/913	4 (0.4)	1.409	0.65–3.07	0.388			
Attempted intraop repair	240/913	25 (2.7)	1.676	0.75–3.74	0.207	1.084	0.39–3.01	0.877
Vascular injury	126/913	34 (3.7)	3.543	1.53–8.20	0.003	2.088	0.79–5.52	0.137

was expected to be associated with a higher risk of complications, there was a tendency towards a decreased morbidity when performing the hepaticojejunostomy at any time after the first week. Data does not allow for any analysis of the selection process for these patients. It can only be hypothesized that patients who underwent intermediate repair were well-drained, sepsis free and in good general condition. In addition, no data on if the patients presented with biliary fistula or jaundice were collected, which could have had an impact on the time for repair. Increased mortality has been associated with early repair, but no such association was found in the present study.[25]

Male gender has been shown by Booij *et al.* to be the only risk factor for stricture formation after hepaticojejunostomy.[16] This is in line with the results of this study showing that male gender increased the odds for re-intervention more than 90 days after hepaticojejunostomy. Other non-modifiable risk factors like age and severe co-morbidity (ASA 3–4), increased the risk for liver-related mortality.

Concomitant vascular injuries have been reported in 10–47% of BDIs, and most often (9 out of 10), the right hepatic artery is damaged.[11,14,26–28] In the presence of vascular injury it is still debated whether early repair of the BDI should be performed and revascularization to be attempted.[26,27,29] In this multicentre study 14% of the patients with BDI suffered a vascular injury, but no impact of vascular injury on the severe postoperative complications or the patency of the hepaticojejunostomy could be demonstrated. Previous studies have reported worse outcome after concomitant vascular injury.[29,30] It has been proposed that in case of injury to the right hepatic artery a reconstruction at the level of the biliary confluence using a Hepp-Couinaud approach avoids postoperative strictures.[26] Submitted data to the present study did not cover whether a reconstruction of the vascular

injury was performed or not nor with which technique the hepaticojejunostomy was performed. In multivariable analysis there was a tendency towards statistical significance but no increased risk for liver-related mortality in case of concomitant vascular injury could be proven ($p = 0.074$).

The strength of this study is that it evaluates repair by hepaticojejunostomy within six months from cholecystectomy only, excluding other techniques of repair, thus constituting a homogenous cohort. These conditions make the current study unique and increases the chance of making accurate conclusions. A limitation of this study is its retrospective design with the risk of selection bias and relative short follow-up. In addition, HPB-centers tend to have a local policy on treatment of BDI, either immediate, early, intermediate or late, with more impact on timing of repair than time of diagnosis and maybe also the co-morbidity of the individual patient. As some centers contributed with a large number of patients their policy and tradition may have skewed the data. On the other hand, the anonymity of a large multi-center study may reduce selection bias and may give a picture of practiced medicine.

In conclusion, this large retrospective multi-center study, shows that the timing of hepaticojejunostomy after iatrogenic BDI during cholecystectomy have no impact on postoperative complications, anastomotic patency or liver-related mortality when performed in tertiary HPB-units. Good clinical judgement and individualized treatment is still advisable.

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Conflict of interest

None.

Appendix.

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