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ORIGINAL ARTICLE

Long-term outcome after early repair of iatrogenic bile duct injury. A national Danish multicentre study

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Abstract

Background: The aim of this retrospective study was to evaluate the peri-operative and long-term outcome after early repair with a hepaticojejunostomy (HJ).

Methods: Between 1995 and 2010, a nationwide, retrospective multi-centre study was conducted. All iatrogenic bile duct injury (BDI) sustained during a cholecystectomy and repaired with HJ in the five Hepato-Pancreatico-Biliary centres in Denmark were included.

Results: In total, 139 patients had an HJ repair. The median time from the BDI to reconstruction was 5 days. A concomitant vascular injury was identified in 26 cases (19%). Post-operative morbidity was 36% and mortality was 4%. Forty-two patients (30%) had a stricture of the HJ. The median follow-up time without stricture was 102 months. Nineteen out of the 42 patients with post-reconstruction biliary strictures had a re-HJ. Twenty-three patients were managed with percutaneous transhepatic cholangiography and dilation. The overall success rate of re-establishing the biliodigestive flow approached 93%. No association was found between timing of repair, concomitant vascular injury, level of injury and stricture formation.

Conclusion: In this national, unselected and consecutive cohort of patients with BDI repaired by early HJ we found a considerable risk of long-term complications (e.g. 30% stricture rate) and mortality in both the short- and the long-term perspective.

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Introduction

Since the first laparoscopic cholecystectomy (LC) was performed in 1985¹ LC has evolved as the treatment of choice for symptomatic gallbladder stones. Around 7000 cholecystectomies are performed each year in Denmark within a total population of 5.6 million. The majority of cholecystectomies (96%) are performed as a laparoscopic procedure and with a conversion rate of 7.6%,² thus confirming the worldwide decline in the number of open cholecystectomies (OC). Iatrogenic bile duct injury (BDI) after a

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cholecystectomy is a serious complication and treatment options may vary from simple stenting of minor lesions to complex surgical reconstruction of major bile duct injuries. The Roux-en-Y hepaticojejunostomy (HJ) is generally accepted as the standard of care for complex bile duct injury.^{3–5} The timing of bile duct repair after BDIs is still a matter of debate.^{6–8} In the pre-laparoscopic era the incidence of major BDI was in the range of 0.1–0.3%,^{9,10} but this number has at least doubled after LC became the gold standard. A national database monitoring cholecystectomies in Denmark found a major BDI incidence of 0.74% in the period 1991–1994 although less than half of these needed a reconstruction.¹¹ Another Danish study observed a decline to 0.2% in major bile duct injuries requiring reconstruction in the years 2006 to

2009,² and a similar decrease has been observed worldwide where the reported incidence of major of BDI seems to have stabilized between 0.3% and 0.55%.¹²

Iatrogenic BDI may be associated with severe morbidity and even mortality even after being reconstructed with an HJ. Thus, an otherwise healthy patient undergoing a simple operation for gall bladder stones may turn into a liver transplantation candidate owing to recurring strictures resulting in secondary biliary liver cirrhosis.¹³

The aim of this retrospective study was to evaluate the perioperative and long-term outcome in all Danish patients who sustained a major BDI during a cholecystectomy and who had an HJ reconstruction.

Patients and methods

The study was designed as a nationwide, retrospective multicentre study. All patients undergoing HJ reconstruction after iatrogenic BDI sustained during a cholecystectomy between January 1995 and January 2010 were identified in local and national registers associated with the five Hepato-Pancreatico-Biliary (HPB) centres located at University Hospitals in Denmark (Herlev Hospital, Rigshospitalet, Aarhus Hospital, Aalborg Hospital and Odense University Hospital). Patients with bile duct injury owing to trauma, or stricture as a result of chronic pancreatitis, duodenal ulcer or similar, and patients with malignant causes, were excluded.

In Denmark, all confirmed major bile duct injuries requiring reconstruction with HJ or other complex surgical procedures are treated in one of the aforementioned HPB centres or by a HPB surgeon travelling to the referring hospital. This principle combined with a nationwide database covering all patients undergoing a cholecystectomy made it possible to perform this study within the entire Danish population.

Patient charts were reviewed regarding peri-operative complications (within 30 days after the HJ reconstruction) as well as long-term outcomes (morbidity and mortality beyond 30 days). In addition to standard demographics, the type of cholecystectomy, the rate of intra-operative BDI recognition, previous repair attempts, time to referral and reconstruction, the severity of BDI (Bismuth classification) and concomitant vascular injury were also recorded. The immediate peri-operative complications were described with regard to 30-day mortality and morbidity including cardiopulmonary complications, thromboembolic complications, multiple organ dysfunction syndrome, wound infection (requiring surgical intervention), intra-abdominal abscess/biloma (requiring radiological/surgical intervention), anastomotic dehiscence of the HJ (requiring radiological/surgical intervention), peri-operative bleeding and reoperations. The length of stay (LOS) in the HPB centre was recorded from the day of surgery. The long-term complications were described with regard to mortality (related to the long-term complications), cholangitis (requiring antibiotics), gall stones, incisional hernia (only patients

who underwent surgery for this), mechanical bowel obstruction, bleeding, patients needing liver surgery/transplantation and stricture of the HJ. Strictures of the HJ and thereby failure of the index reconstruction was defined as a clinically relevant stricture leading to either jaundice, significant alterations of the liver function tests, cirrhosis or reoccurring cholangitis requiring radiological/ surgical intervention or a liver failure-related death. The time from reconstruction to stricture formation and stricture-free observation were recorded as well.

Patients not currently treated in the outpatient clinic were followed up through national registers.

The observation period ended on the 25th of November 2011.

Clinical management

All patients treated with HJ were operated by an experienced HPB surgeon from one of the participating centres. The overall approach was to reconstruct the patient as soon as possible after referral. The surgical reconstruction was performed with a Rouxen-Y HJ at the level of injury, with one or two end-to-side anastomoses sewn with interrupted one-layer mono- or polyfilament absorbable sutures. All patients had at least one intra-abdominal drain placed behind the biliodigestive anastomosis. No access loop was constructed. Transhepatic- and trans-Roux limb stents were placed in a few selected cases, primarily depending on the level of injury and/or the presence of biliary peritonitis as well as in the case of extensive tissue necrosis or a narrow anastomosis. Routine cholangiography was performed before removal of stents typically within 3 months. Percutaneous transhepatic cholangiography (PTC) catheters in place during surgery were occasionally left in situ but not through the anastomosis. Cholangiography was also performed before removal of the PTC catheters.

Statistical analysis

Data are presented as the median (range). Comparison between groups were made using Fisher's exact test. Kaplan–Meier estimates were used for the analysis of a stricture-free period (Stata 9.0; Stata Corp., College Station, TX, USA). P < 0.05 was considered statistically significant.

Ethics

There were no special ethical issues related to this retrospective study, and according to law it was not submitted to the Danish National Committee on Biomedical Research Ethics. The study was submitted to ClinicalTrials.gov (Identifier: NCT01447030) and approved by the Danish Data Protection Agency (no. 2008-58-0035).

Results

Demography

One-hundred and thirty-nine patients had a HJ repair as a result of an iatrogenic BDI. Patient demographics are listed in Table 1. One-hundred and thirty-two patients (95%) had a LC, and 47 (36%) were converted to open surgery. The BDI was recognized in

Table 1	Patient	demographics
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3 4	
N	139
Female/Male	102/37
Median age at cholecystectomy (range)	46 (20–85)
ASA Score 1/2/3/4/5	80/19/38/2/0
Distribution of cases between HPB centres, Aalborg/Aarhus/Odense/Herlev/Rigshospitalet	14/36/38/8/43
Overall recognition of BDI during surgery (%)	58 (42)
Recognition of BDI when not converted to OC (%)	22 (16)
Recognition of BDI when converted to OC (%)	33 (70)
Recognition of BDI when primary OC (%)	3 (43)
Attempted repair by primary surgeon (%)	5 (4)
Time from injury to referral, median, days (range)	3 (0–5690)
Time from injury to HJ, median, days, (range)	5 (0–5690)
Level of BDI, Bismuth classification, 1/2/3/4/5/x ^a	20/78/12/18/5/6
Injury to the right hepatic artery, yes/no, (%)	26 ^b /113 (19)

^aBismuth level insufficiently described in the medical records.

^b2 patients had injury to the proper hepatic artery.

ASA, American Society of Anesthesiologists' classification of patient condition (modified); BDI, bile duct injury; HAI, Hepatic artery injury; HJ, hepaticojejunostomy; HPB, hepatopancreaticobiliary; LC, laparoscopic cholecystectomy; OC, open cholecystectomy.

58 (42%) of the primary operations, but only in 22 (26%) of the during the operations which were completed laparoscopically. Converting 47 operations from LC to OC resulted in the intra-operative recognition of 33 (70%) of the BDI's. Primary surgical repair (i.e. performed by the surgeon doing the cholecystectomy) was attempted in five (4%) patients before referral to one of the five HPB centres: primary anastomosis in one patient and suture over a T-tube in four patients. The median time interval from the BDI to referral was 3 days (range 0-5690) and the time to reconstruction was 5 days (range 0-5690). Only 12 patients were reconstructed more than 2 months after the primary bile duct injury, and this included the five aforementioned patients with primary surgical repair attempts. The seven remaining patients presented with delayed stricture formation apparently as a result of lateral thermal injury to the bile duct (e.g. one patient presenting with a stricture more than 15 years after primary surgery). Endoscopic or PTC-guided attempts to treat the stricture had been tried with these 12 patients before referral. Overall, 49 patients (36%) were reconstructed within 2 days and 115 patients (83%) within 2 weeks from the BDI. Only 12 patients were not reconstructed with a HJ within 1 week of referral. In these cases endoscopic treatment had been attempted prior to definitive surgical biliary reconstruction.

Type of BDI

Ninety-eight patients (71%) had a Bismuth type 1 or type 2 BDI, whereas 35 patients (25%) were classified as type 3–5. The BDI was insufficiently described and could not be classified in six patients (4%). A concomitant vascular injury was described by the

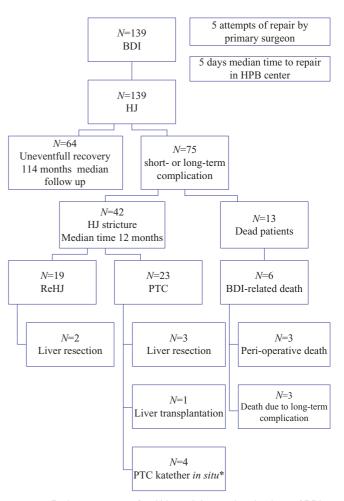


Figure 1 Patient outcome after HJ repair in a national cohort of BDIs. BDI, bile duct injury; HJ, hepaticojejunostomy; PTC, percutaneous transhepatic cholangiography. *One patient died with a PTC catheter *in situ*

surgeon performing the reconstruction in 26 cases (19%). All were hepatic artery injuries (HAI). Twenty-four of these were injuries to the right hepatic artery (RHAI), whereas two patients suffered a complete transection of the proper hepatic artery. No patients had vascular reconstruction or liver resection performed in conjunction with the primary reconstructive operation.

Outcome

Morbidity and mortality

The median LOS after the reconstruction at the HPB centre was 11 days (range 3–69). A total of 64 patients (46%) had an entirely uneventful follow-up (median 114 months) with neither perioperative nor long-term complications (Fig. 1). Post-operative morbidity was 36% and the 30-day mortality was 2% (Table 2). One patient died from a pulmonary embolism on the third post-operative day (POD), another had intra-abdominal bleeding from an unnamed mesentery artery in close proximity to the HJ and

Table 2 30-day morbidity and mortality and long-term outcome after a HJ

Peri-operative (<30 days) complications	N (%)
Hospital stay in HPB centre after HJ, days, median, (range)	11 (3–69)
Morbidity (patients with at least one peri-operative complication)	50 (36)
Type of complication	
Cardiopulmonary	17 (12)
Thromboembolic	2 (1)
MODS	4 (3)
Wound infection	17 (12)
Intra-abdominal abscess/biloma	20 (14)
Anastomotic dehiscence (HJ)	7 (5)
Bleeding	7 (5)
Reoperation	15 (11)
Mortality (<30 days)	3 (2)
Long-term complications	
Morbidity (patients with at least one long-term complication	58 (42)
Type of complication	
Cholangitis	32 (23)
Intrahepatic stones	9 (6)
Incisional hernia	8 (6)
Mechanical bowl obstruction	4 (3)
Bleeding	2 (1)
Patients with liver resection	5 (4)
Patients with liver transplantation	1 (1)
Patients with stricture of the HJ	42 (30)
Time from HJ to stricture, months median, (range)	12 (2–141)
Follow-up without stricture, months median, (range)	102 (0–182)
Patients with no peri-operative or long-term complication	64 (46)
Mortality >30 days	3 (2)
Overall biliary specific mortality	6 (4)

HJ, hepaticojejunostomy; MODS, multiple organ dysfunction syndrome.

was operated but died the following day apparently from upper gastrointestinal bleeding (POD 13), and the last patient suffered multiple organ dysfunction syndrome (MODS) due to sepsis (POD 19). A total of 15 patients (11%) were re-operated within 30 days of the HJ operation. Seven of these had a dehiscence of the HJ anastomosis, and another 7 patients had bleeding. The last one had an abscess close to the HJ. No patients were re-operated due to biloma formation.

Long-term complications

One-hundred and twenty-six patients were alive at the end of the observation period. Thirteen patients (9%) had died, seven of these of causes unrelated to the reconstruction. The long-term

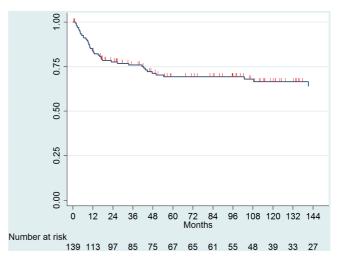


Figure 2 Kaplan-Meier estimate of stricture-free follow-up (months)

outcomes are listed in Table 2. Fifty-eight patients (42%) had at least one long-term complication. Forty-two patients (30%) had a stricture of the HJ. The biliary strictures were diagnosed a median of 12 months (range 2–141) after the HJ reconstruction, and 71% of the strictures evolved within 2 years after reconstruction. The median follow-up of patients without a stricture was 102 months (range 0-182). A Kaplan-Meier estimate of stricture-free follow-up is shown in Fig. 2. Nineteen of the 42 patients with post-reconstruction biliary strictures were treated with a re-hepaticojejunostomy. Among these, two patients ended up developing localized cirrhosis and were treated with either liver segment resection or hemihepatectomy. The remaining 23 patients with stricture of the HJ were managed with PTC and dilation. Among these, three patients ended up with a liver resection and one patient was treated with orthotopic liver transplantation as a result of secondary biliary liver cirrhosis.

By the end of the observation period 3 patients still had a PTC stent *in situ* for a median of 8 years as they were unable to endure further surgery. One patient died with the stent *in situ* (death unrelated to biliary disease). Apart from the three patients dying within 30 days of reconstruction an additional three patients (2%) died from long-term complications: one due to complications 47 months after liver transplantation, one after bleeding related to a PTC procedure and one as a result of cholangitis.

No significant effect on the stricture rate was observed in relation to timing of reconstruction (within versus after 2 weeks of injury, P = 0.48), concomitant vascular injury (P = 0.07), level of injury (Bismuth 1–2 versus 3–5, P = 0.44), place of reconstruction (between the 5 HPB centres, P = 0.17), the presence of perioperative complications (P = 0.08) or ASA group (P = 0.33).

Discussion

Iatrogenic BDI remains a severe complication related to LC and may result in both immediate and long-term morbidity and mor-

tality. The management of the most complicated BDIs with HJ has been described in several previous reports and often presented as a single HPB center's consecutive case series. Two of the largest HJ reconstruction series evaluated 156 and 175 patients, respectively,^{3,14} with the latter also including other but iatrogenic BDIs. No previous study has, to our knowledge, included all BDIs sustained during a cholecystectomy and reconstructed with early HJ in an entire country population over a longer period of time. Thus, this study presents the short- and long-term outcome after reconstruction of iatrogenic BDI in an entire national cohort. The strength of this consecutive case series lies within a prospective and national register on gallstone surgery in Denmark as well as in the complete long-term follow-up based on both local and national databases. These prospective databases allowed extraction of patients with BDI sustained during OC or LC who all were reconstructed with an HJ over a 15-year period. In addition, the median follow-up period for the patients without a stricture (102 months) was long compared with other studies which ranged from 12 to 57.5 months. 12,14

The timing of the repair surgery has been debated and some major series have argued for a late repair in order to let infection, inflammation and ischaemia settle before reconstruction. In contrast, immediate repair has been suggested if the BDI is recognized during primary surgery.^{3,14} The median time interval from injury to referral (3 days) in the present study was much different from the studies by Lillemoe¹⁴ and Sicklick³ who presented a median of 3 months and 3 weeks, respectively. The same applied to the median time from BDI to final repair: Five days in our study and 10.3 weeks in the study by Sicklick. Only 4% of our patients had undergone a previous attempt on repair outside the HPB centre, whereas 41.4% was reported by Lillemoe.14 This indicates that the treatment of severe BDI is well organized in Denmark, but the higher stricture rate could also indicate that too many HPB centres are dealing with these patients - and/or that the early repair should not be performed as a general rule. It is plausible that the extent of the primary BDI may increase as a result of inflammation, infection and disrupted blood supply during the first days and maybe weeks. However, we were unable to detect any significant difference comparing stricture formation between early or late repair (within versus after 2 weeks of injury, P = 0.48). Bearing in mind that the best short- and long-term results are achieved in tertiary HPB centres, 3,15 the referral of patients to these institutions should be sought in any case. We observed an overall 30% biliary stricture rate which was somewhat higher than reported by others. Schmidt¹⁶ and Holte¹⁷ found stricture rates of 19.6% and 24%, respectively, whereas the reported stricture rates varied between 0 and 19% in other dedicated HPB centres. 12,14,18,19 As an example, Strasberg's group¹⁹had a stricture/failure rate of only 5% during a median follow-up period of 4.9 years in 113 patients. They advocate for the Hepp-Couinaud technique with side-to-side HJ to the left hepatic duct when possible and a late repair, if ischaemia is suspected due to vascular injury to the liver arteries. This may allow for the ischaemic part to demarcate, and then reconstruction is typically

done after 3 months.¹⁹ Pitt *et al.*²⁰ surgically treated 104 patients with bile duct injury with a failure rate of 12% over a comparable 18-year period. Failure was defined as a further need for invasive intervention after the initial course of treatment or stenting beyond 15 months. They found a significant lower success rate by carrying out an early repair (2–4 weeks) compared with a late repair.^{4–8} They therefore advocate for waiting instead of repair at the peak of post-operative inflammation. No information of concomitant vascular injuries was reported in the study.²⁰

At the other end of the scale stricture rates up to 100% have been reported from non-HPB centres.²¹

We found that a sufficient biliodigestive flow was established in 129/139 patients (93%) by primary repair, or by re-intervention with a new hepaticojejunostomy or interventional PTC. Of the remaining 10 patients, six patients died from complications related to the BDI and reconstruction. One patient died with a PTC catheter *in situ*, and 3 patients alive were dependent on a PTC catheter

However, it is important to note that some of the patients were treated with interventional PTC more than 10 times before they eventually had an acceptable biliodigestive flow, and studies have shown that the quality-of-life (QOL) of BDI patients is significantly reduced when compared with patients who underwent cholecystectomy without an injury.²² In addition, Melton et al.²³ have shown that even patients who are successfully reconstructed have no reduction of the QOL assessment in the physical and social domains, but a significantly lower score in the psychological QOL domain, and a recent meta-analysis has confirmed the detriments in mental QOL.24 It is uncertain whether this is due to the unexpected, complicated and prolonged nature of LC injuries and their treatment.²³ Our approach of early reconstruction, without months of prior PTC drains, might reduce the overall mental stress felt by patients who afterwards did not develop a stricture. Owing the retrospective nature of this study no QOL assessments were performed.

Only one patient (0.7%) in our study had end-stage liver failure as a result of secondary biliary cirrhosis requiring liver transplantation, although five additional patients (3.6%) had a segment resection or a hemihepatectomy. The rate of liver resection and transplantation after BDI's ranges from 1% to 22%. ^{13,25,26} The numbers are probably biased by referral patterns but Schmidt¹⁶ reported a 10.9% incidence of biliary cirrhosis after reconstruction resulting in an overall liver transplantation rate of 4.3% and an additional 4.3% needing a hemihepatectomy among the patients treated with HJ.

Half of the patients in our study having a stricture were diagnosed within 12 months and 71% within 2 years. This was consistent with previous findings suggesting that 2/3 of the strictures evolved within the first 2 years after reconstruction. 14,26,27

Combined bile duct and vascular injury

Earlier studies have reported an association between RHAI and failure of the biliary repair (i.e. leading to stricture formation). ^{28–30}

A recent review³¹ could not confirm any association between RHAI and stricture formation in the largest studies, but concomitant RHAI were associated with liver necrosis and liver abscess formation. We did not find any association between hepatic artery injury (HAI) and a higher incidence of stricture formation, but there was a trend towards a poorer outcome in the HAI group (P = 0.07). However, no specific examinations were used to detect vascular injury. Thus, the only source in the present study has been the description of the reconstructive operation. This retrospective design might contribute to an underestimation of the rate.

Autopsy data³² have shown that 7% of patients who had undergone OC which did not contribute to the cause of death had a HAI. One may speculate whether this rate might be even higher for patients undergoing LC, owing to the more complex injuries generally inflicted during LC compared with OC.³³ In selected series the presence of concomitant HAI has been reported to be present in 12% to 47% of the cases.³¹ Stewart *et al.* analysed 261 cases of BDI sustained during laparoscopic cholecystectomy and found RHAI present in 32% of the patients by means of either surgeons observation, video review, angiography or contrast CT scan.³⁴

As mentioned above the BDIs sustained during LC tend to be more complex than during OC. As 95% of our BDI occurred after an intended LC, we are unable to comment on this tendency. Nor could we detect any correlation between stricture formation and a high Bismuth level. In this national, unselected and consecutive cohort of patients with BDI repaired by early HJ we found a considerable risk of long-term complications (e.g. 30% stricture rate) and mortality in both the short-and the long-term perspective.

Conflicts of interest

None declared.

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