Laparoscopic bile duct injury: consequences, quality of life and claims

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SUMMARY AND CONCLUSIONS

Bile duct injury (BDI) is a feared surgical complication of laparoscopic cholecystectomy with an estimated incidence of 0.5%. BDI is associated with increased morbidity, mortality, high rates of litigation claims, and poor long-term quality of life. Until recently, the multidisciplinary approach by a team of gastroenterologists, radiologists, and surgeons was given scant attention. Although groups with different expertise have reported good outcomes after treatment, no reliable predictors of success in reconstructive surgery and endoscopic therapy were known. Therefore, improvement of BDI patient management is essential. Currently, more than 500 patients have been referred to the AMC for treatment of BDI. This thesis evaluated the experience in treatment, outcome, and malpractice litigation in the largest series of BDI patients to date.

Part I of this thesis is entitled ‘Consequences and treatment after bile duct injury’ and describes studies that evaluate the clinical consequences of BDI for surgeons and patients. This part shows the available therapeutic modalities for BDI patients and provides reliable predictors of success in reconstructive surgery and endoscopic therapy.

In contrast with the reported good functional outcome after treatment is the poor patient-reported outcome by BDI patients after long-term follow-up. In part II, entitled ‘Quality of life after bile duct injury’, the effect of BDI on patients is evaluated in terms of mental and physical wellbeing. The two studies in this part determined predicting factors for poor quality of life and show the association between malpractice litigation and quality of life outcome.

In part III, entitled ‘Claims’, the Dutch malpractice litigation system is evaluated based on the experience of BDI patients. Predicting factors for litigation are determined and the outcome of the litigation process in the Netherlands is evaluated. Finally a study among experts in gastrointestinal surgery shows that expert witness testimonies in BDI litigation cases are of little value as the agreement among experts is poor, and judgements on negligence of care vary widely.

PART I - CONSEQUENCES AND TREATMENT AFTER BILE DUCT INJURY

The Netherlands Healthcare Inspectorate assesses quality of care in Dutch hospitals based on performance indicators. One of these indicators is bile leakage after cholecystectomy. The majority of bile duct injuries are Type A injuries, bile leakages from the cystic duct remnant. Type A is generally considered to be a minor injury. It could be argued that this indicator is not appropriate for determining differences in quality of care between hospitals as the indicator does not assess quality of care but merely signals the frequency of a post-operative complication with a wide variation in causes and consequences. In CHAPTER 1 the various consequences
of post-cholecystectomy bile leakage and injury are described. Three patient histories illustrate the wide variation in consequences of bile leakage for patients, surgeons, and insurers. Chapter 1 summarizes the drawbacks of using post-operative bile leakage as a performance indicator for quality of care among general hospitals.

In 20 - 40% of the BDI patients, injury is detected during initial surgery. Controversy exists however about the management of intraoperative-detected BDI. The peroperative management ranges from simple drainage and referral to a tertiary centre to an end-to-end anastomosis (EEA) (duct-to duct, with or without T-tube drainage), or a hepaticojejunostomy (HJ). It has been suggested that EEA is associated with a relatively high stricture rate of up to 70-80%, and consequently a high incidence of secondary repair. **Chapter 2** describes the outcome of patients (n=56) who underwent an EEA elsewhere and were referred because of complications. Even in this negatively selected group of patients, 68% could be successfully treated without surgical reconstruction after referral. Reconstructive surgery after complicated EEA is a procedure with a relatively low morbidity (8%) and no mortality. Based on these results, EEA has to be considered as a good alternative as a primary treatment for peroperative-detected transection of the bile duct without extensive tissue loss.

Segmental bile duct injury, solitary lesions to the anterior or posterior segmental duct, or right hepatic duct are a distinct type of BDI, and treatment of these specific patients should be carried out in an expert centre. **Chapter 3** shows that the prevalence of segmental injury is 8% (42/500) in the present series. The interval between referral and accurate diagnosis was relatively long, 126 days. Surgical treatment (n=18) and endoscopic stent therapy (n=16) are associated with higher morbidity compared to bile duct injury patients (post-operative abscesses 22% vs. 8%, p=0.044; endoscopic failure 25% vs. 4%, p=0.057). Chapter 3 shows that segmental duct injury is a rare complication, difficult to diagnose, and associated with more treatment-related morbidity compared to general bile duct injury patients.

Major BDI such as bile duct transection or recurrent strictures generally need reconstructive surgery. Controversy exists about the influence of previous interventions before referral and the timing of repair on outcome. In **Chapter 4** we describe our experience with 151 BDI patients who underwent a hepaticojejunostomy. In these series, hospital mortality was zero. A multivariate analysis revealed that referral after therapeutical interventions in the initial hospital (Odds ratio 4.35, 95% Confidence Interval 1.12- 16.76), repair in the acute phase (OR 5.44, CI 1.2-24.43), and extended injuries (OR 3.70, CI 1.32-10.34) have a negative effect on the short- and long-term outcome.

Several studies indicated that endoscopic stent therapy is associated with a good outcome in BDI patients with cystic duct leakage, common bile duct leakage, and common bile duct strictures. In **Chapter 5** a review of the literature was performed to retrieve best available data.
on the outcome of endoscopic stent therapy in BDI patients. The majority of biliary injuries can be treated successfully in 70-95% of the patients by means of endoscopic stenting. Some of the studies discussed in Chapter 5 suggest a more aggressive type of dilation therapy in patients with bile duct strictures, based on the sequential insertion of multiple stents. Therefore we analysed the short- and long-term outcome of stent therapy in BDI patients treated in the AMC in **Chapter 6**. In total, 67 patients underwent endoscopic stenting for cystic duct leakage, 26 patients for common bile duct leakage, and 110 patients for a bile duct stricture. Overall success in patients with cystic duct leakage was excellent (97%). The overall success of endoscopic stent therapy in patients with a bile duct stricture was good (74%). Predictors for success in patients treated for a bile duct stricture were the number of stents inserted during the first procedure (OR 3.2 per stent, CI 1.3-8.4), injuries classified as Bismuth III (OR 0.12, CI 0.02-0.91) and IV (OR 0.04 CI 0.003-0.52), and endoscopic stenting before referral (OR 0.24, CI 0.06-0.88). Interestingly, the introduction of sequential insertion of multiple stents did not improve the outcome (before 77% vs. after 66%, p=0.25).

Following a population-based study in the United States that showed the detrimental effect of BDI on survival in patients who only underwent surgical treatment, survival analysis was performed on the outcome of a multidisciplinary approach of 500 BDI patients treated in the AMC. **Chapter 7** shows that the referral rate to the department of gastroenterology (n=329), surgery (n=146) and to the department of radiology (n=25) was respectively 66%, 29% and 5%. After referral to our centre, 150 patients (30%) were internally referred to a different department to optimize treatment. The 10 years survival in bile duct injury patients is not significantly worse compared to the age-matched general Dutch population (89% versus 88%, P =0.7). Multivariate analysis showed that the hazard of death was twice as high in male patients (HR 1.9, CI 1.0-3.6) and in patients who underwent a repair during the initial cholecystectomy (HR 2.2, CI 1.1-4.3).

**PART II QUALITY OF LIFE**

Specific interest in quality of life in BDI patients was initiated at our outpatient clinic where patients who had been treated for BDI reported many undefined abdominal complaints, whereas objective symptoms of recurrent jaundice or cholangitis could be demonstrated in only a few patients. Even after long-term follow-up, patients were still preoccupied with the unexpected course of events after the removal of the gallbladder. Patients were disappointed by the prolonged hospital stay, and the occasionally delayed diagnosis. **Chapter 8** shows the results of a survey in 278 BDI patients, after a mean follow-up of 5.9 years. Quality of life of injured patients was significantly lower in 3 of the 8 domains compared to patients who underwent cholecystectomy without an injury (p<0.05). In 7 of the 8 QoL domains, injured
patients scored significantly worse than the healthy population norms (p<0.05). No improvement was found in a longitudinal study after 5.5 and 11 years of follow-up. Clinical characteristics such as the type of injury and type of treatment did not affect outcome. Nineteen percent of the patients (n=53) filed a malpractice claim after BDI. These patients reported better QoL (p = 0.02) if the claim was resolved in their favour compared to patients whose claim was rejected.

Parallel to chapter 8, in CHAPTER 9 we identified socio-demographic and psychosocial factors that explain quality of life in BDI patients. After a mean follow-up of almost 6 years, 62% of the BDI patients reported that they suffer from symptoms that they link to the injury. A multivariate analysis reveals that QoL is only partly explained by factors related to the injury, but more by older age, more self-reported symptomatology, increased co-morbidity, involvement in litigation, emotional instability, and a belief in loss of control over health.

Both studies on quality of life emphasize the impact of BDI on a patient’s mental and physical wellbeing. Surgeons and other physicians involved in the treatment of BDI patients should be aware of the patients’ characteristics and psychosocial profile.

PART III CLAIMS

Malpractice litigation among BDI patients is common. Nineteen percent of the patients in the present series filed a claim after occurrence of BDI. CHAPTER 10 shows that factors associated with starting a claim procedure are: younger age, the severity of the injury, surgical treatment, employment, and the use of social securities. A complete transection of the common bile duct is an independent predictive factor for starting a claim procedure (OR 7.53, CI 1.85-30.63).

To expand our knowledge about malpractice litigation after BDI, the largest Dutch hospital insurer for medical liability was consulted. The results of this study are presented in CHAPTER 11. This study shows that BDI litigation occurs in one out of 1250 laparoscopic cholecystectomies. Of the 133 filed claims between 1993 and 2005, 88 were closed after a median duration of 2 years. In 61 of the 88 cases (69%) liability was rejected and in 16 cases (18%) liability was acknowledged. The median compensation was €9,826.07. Rejection of liability increased from 50% in the period 1994-1998 vs. 72% in 2004-2006 (p=0.023). Factors associated with recognition were: patient employment and patient’s death. Factors associated with an increase in financial compensation are delay in imaging, delay in diagnosis, and relaparotomy with repair in the initial hospital.

The aim of the study described in CHAPTER 12 was to determine the inter-rater agreement of expert witness testimonies in surgical malpractice litigation. Thirteen independent experts reviewed 10 closed BDI litigation cases. In one out of 10 cases full agreement was observed. In seven of the 10 cases the highest percentage of agreeing experts was 53% or less. Judgements
on negligence of care were not associated with delay in diagnosis or the severity of injury. Chapter 12 illustrates the poor reliability of expert witnesses in BDI litigation claims. Raising consensus concerning the standards of surgical care may be required to improve agreement in judgements on negligence.

CONCLUSIONS
The present thesis illustrates the impact of a surgical complication and iatrogenic injury from a clinical, psychological, and socio-economic point of view. A multidisciplinary treatment of BDI patients by a team of gastroenterologists, radiologists and surgeons is shown to be beneficial for the long-term outcome. Several treatment-related factors improve functional outcome such as referral to a tertiary centre, delayed timing of surgical reconstruction, and insertion of multiple stents during the first endoscopic intervention in a patient with a bile duct stricture. However, the unexpected course after the cholecystectomy, the prolonged hospital stay, and the occasionally delayed diagnosis will probably remain, and form a patient’s physical and mental burden. Although an association between malpractice litigation and quality of life in BDI patients was found in the present thesis, the causality dilemma remains unanswered: what came first? Is it the poor quality of life that causes the patient to file a claim, or does the litigation process have a detrimental influence on a patient’s mental and physical wellbeing? Surgeons should be aware of the possibility of being sued after the occurrence of BDI. Honest and open communication with the patient and adequate documentation of clinical findings and therapeutical considerations might prevent a long and distressing litigation process. Finally, expert witnesses commonly disagree about negligent care during laparoscopic cholecystectomy. Defendants, plaintiffs, experts, and lawyers should be aware of the drawbacks of expert witness testimonies.