Original communications

Survival in bile duct injury patients after laparoscopic cholecystectomy: a multidisciplinary approach of gastroenterologists, radiologists, and surgeons

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Background: *Bile duct injury (BDI) after laparoscopic cholecystectomy (LC) has an enormous socioeconomic impact on patients. BDI has been associated with severe morbidity, impaired survival, and poor long-term quality of life. This study was performed to analyze the impact of a multidisciplinary approach in BDI patients on survival.*
Methods: *A prospective cohort study was performed in a tertiary referral center to determine the effect of a multidisciplinary treatment on survival in 500 bile duct injury patients. Referral pattern and patient survival after bile duct injury are analyzed, and a survey was performed on the prevalence of medical litigation in bile duct injury patients.*
Results: *The number of patients referred to the Amsterdam Medical Center increased to 0.3% of the total number of patients, yearly undergoing laparoscopic cholecystectomy in the Netherlands. The referral rate to the departments of gastroenterology (n = 329), surgery (n = 146), and radiology (n = 25) was, respectively, 66%, 29%, and 5%. After referral to the tertiary center, 150 patients (30%) were internally referred to a different department to optimize treatment. The 10-year survival rate in bile duct injury patients is not significantly worse compared with the age-matched general Dutch population (89% vs 88%,* P = .7*). Overall, 19% of the patients submitted a medical litigation claim against the initial surgeon or hospital. In total, 40% of these claims were resolved in the favor of the patients through settlement or verdict.*
Conclusions: *BDI is a severe complication in modern surgical practice. BDI is associated with major morbidity and high rates of litigation claims. The detrimental effect of BDI on survival can be prevented if gastroenterologists, radiologists, and surgeons work together in a multidisciplinary team. (Surgery 2007;142:1-9.)*

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Symptomatic gallstone disease is 1 of the most common medical conditions leading to surgical intervention. In the United States, more than 750,000 laparoscopic cholecystectomies (LCs) are performed each year for gallbladder removal.[1] Bile duct injury (BDI) occurs in 1 of 200 LCs and is a feared surgical complication associated with increased morbidity and poor long-term quality of life.[1-3] Measures to prevent and recognize BDI are outlined in many publications, and the optimal treatment strategy and outcome has been published extensively.[4-11] Flum et al.[12] demonstrated in a population-based study the detrimental effect of

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BDI on survival in the United States. In a nationwide cohort of nearly 1.6 million Medicare beneficiaries, BDI patients are nearly 3 times more likely to die during the first few years after a cholecystectomy compared with patients without BDI. Although the poor outcome can be explained by selection of elderly patients, more bias was introduced by selecting only patients who underwent surgical treatment. Although it was previously suggested that a multidisciplinary approach by gastroenterologists, radiologists, and surgeons is beneficial for BDI patients, the survival after a combined approach is unreported.[13-16] Because the Netherlands is a relative small and defined country, Dutch specialists and generalists are aware of the treatment possibilities for BDI patients in our center.[2,13,17,18] Centralization of a large cohort of BDI patients made it possible to analyze the role of different specialists in the detection and treatment of BDI patients.

The socioeconomic impact of BDI is shown in American studies in which a strong relation between BDI and increased rates of malpractice litigation claims are reported.[3,19,20] Although malpractice litigation is less common in Europe, the prevalence among BDI patients is unknown.

The purpose of this study was to analyze the referral pattern of BDI patients to a tertiary center and to determine the impact of a multidisciplinary treatment of BDI on survival. To assess the prevalence of medical litigation in BDI patients, a survey was performed.

METHODS

Patients and injury classification. Between January 1990 and December 2005, 500 consecutive patients referred to the Academic Medical Center in Amsterdam for management of BDI were included into a prospective database. Clinical data obtained from the referring centers included indication for cholecystectomy, type of operation, and type of injury. The type of injury was classified according the Amsterdam Classification and the McMahon classification.[21,22] The Amsterdam classification categorizes 4 types of injury: type A, cystic duct leakage; B, common bile duct leakage; C, stricture of common bile duct; and D, complete transection of common bile duct.[21] The McMahon classification defines 2 categories: minor injury, cystic duct leakage, and major injury, any type of more severe injury.[22] BDI in segmental biliary branches was not separately classified.

Referral pattern. To describe the referral pattern in BDI patients, the interval between the moment of diagnosis and the referral to a tertiary center was analyzed. The number of patients who were discharged from hospital without BDI being detected was evaluated. Surgical, endoscopic, and radiologic interventions performed in the initial hospital were recorded. The department of the tertiary center to which patients were referred was determined. Initial referral to our center was performed by specialists in the initial center or general practitioners. Based on medical history, clinical findings, and diagnostic imaging, referring physicians determined the department to which BDI patients were referred. After referral to our center, injury classification and location was performed generally by means of cholangiography (magnetic resonance cholangiopancreatography, endoscopic retrograde cholangiopancreatography, or percutaneous transhepatic cholangiography). Subsequently, patients were internally referred to optimize treatment: endoscopic stenting, percutaneous catherization, or surgery if indicated.[21] Patients with complicated injuries or indications for combined treatments were discussed in a multidisciplinary setting of surgeons, gastroenterologists, and intervention radiologists.

To describe the multidisciplinary approach of BDI patients in a tertiary center, all therapeutic interventions were recorded and the department to which the patient was finally referred for definitive treatment was determined. Treatment outcome was analyzed by the type of final treatment, number of hospital admissions, total duration of hospital stay, in-hospital mortality, and BDI-related mortality during follow-up.

Survival. Patient survival was measured as time from initial operation until death or February 1, 2006, as censoring date. To compare survival between BDI patients and the general Dutch population standardized mortality rates were calculated.[23] In addition, the standardized mortality ratio was computed as the number of observed deaths divided by the expected number of deaths, based on age, gender, and year-specific mortality rates at the Dutch Bureau of Statistics.

Malpractice litigation. To evaluate malpractice litigation among BDI patients, a questionnaire was sent in March 2005. At that time, 462 patients were referred for treatment of BDI. Four hundred and three patients were eligible for a mailed questionnaire. Deceased patients (n = 39), patients lost in follow-up (n = 14), and patients who returned to the country of origin (n = 6) were excluded from participation. The questionnaire enquired whether the patient was currently involved in a legal procedure or had been involved in the past and whether the claim was sustained by settlement or verdict.

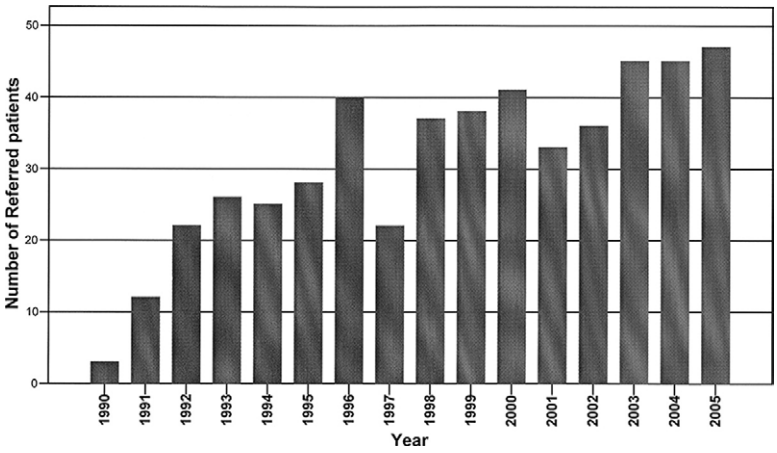

Fig 1. Number of bile duct injury patients referred to the Amsterdam Medical Center. In 2005, 15,000 LCs were performed in the Netherlands.

The questionnaires were sent by mail, and a reminder was sent to patients who did not respond. After 4 weeks, patients were contacted by phone, if they had not responded. The AMC Medical Ethical Committee approved the study, and all subjects were informed as to the nature and purpose of the study and gave their consent to participate.

Data and statistical analysis. Patient characteristics, referral pattern, management, outcome, and legal activity are summarized by descriptive statistics in numbers and percentages. Mean values with standard deviation or median values with minimum and maximum are given if appropriate.

Cumulative patient survival in different patient groups was analyzed by means of the Kaplan-Meier method and compared statistically using the log-rank test. To detect whether age, gender, injury, moment of diagnosis, therapeutic interventions before referral, and final treatment influenced survival in BDI patients, univariate analysis was used to detect an effect of these factors on survival by means of a log-rank test. A Cox proportional hazard regression analysis was used to identify factors that independently influenced survival. The multivariable analysis was performed by a stepwise selection of variables through backward modeling. A $P < .05$ was considered statically significant.

Table I. Characteristics of BDI patients

Characteristics	*n = 500*	*%*
Female	334	66.8
Age, mean (SD), years	50.6 ± 15.7	
Indication for cholecystectomy		
Symptomatic cholelithiasis	377	75.4
Chronic cholecystitis	13	2.6
Acute cholecystitis	50	10.0
Cholecystectomy after cholecystitis	36	7.2
Unknown	24	4.8
Initial procedure		
Laparoscopic cholecystectomy	288	57.6
Laparoscopic cholecystectomy with conversion	153	30.6
Open cholecystectomy	45	9.0
Unknown procedure	14	2.8
Type of injury		
Amsterdam classification*		
Type A, cystic duct leakage	136	27.2
Type B, bile duct leakage	87	17.4
Type C, bile duct stricture without leakage	63	12.6
Type D, bile duct transsection	214	42.8
McMahon classification†		
Minor injury, cystic duct leakage	136	27.2
Major injury, all other injuries	364	72.8

*From Bergman et al.[21]
†From McMahon et al.[22]

RESULTS

Patients. There is an increase in the number of referred BDI patients to our hospital over the last 15 years (Fig 1). Two thirds of the patients is female and underwent a cholecystectomy at the mean age of 51 years (Table 1). Cystic bile duct leakage was an indication for referral in 136 patients (27%). In 364 patients (73%), injury was classified as a major injury, of which 214 patients (43%) were referred after a complete transection of the common bile duct.

Referral pattern and multidisciplinary approach. In 103 patients (21%), BDI is detected during LC (Table 2). In 172 patients (34%), BDI is detected

Table II. Diagnose and therapeutic interventions in patients with BDI before referral to a tertiary center

Characteristics	*n = 500*	*%*
Time of diagnosis		
During initial operation	103	20.6
In hospital	198	39.6
After discharge/readmission	172	34.4
Unknown	27	5.4
Time interval between LC and diagnosis, median (range), days	7 (0–1688)	
Number of patients who underwent a therapeutic intervention before referral	319	63.8
Surgical interventions		
Repair during initial LC	85	17.0
Relaparotomy	136	27.2
With repair	56	11.2
Without repair	80	16.0
Percutaneous drainage	80	16.0
Nonsurgical interventions		
ERCP stent/papillotomy	104	20.8
PTC/D	24	4.8
Time from injury to referral to a tertiary center, median (range), days	19 (0–4612)	

ERCP, endoscopic retrograde cholangiopancreatography; *PTC/D*, percutaneous transhepatic cholangiography/dilatation.

after discharge from hospital. The mean interval between LC and the diagnosis BDI was 4 weeks (range 0–1688). One or more therapeutic interventions were performed in 310 patients (64%) in the initial hospital before referral. A surgical repair was performed in 141 patients (28.2%); 85 patients (85/141) underwent a repair during the initial operation and 56 (56/141) patients during a relaparotomy. In 80 patients (16%), a relaparotomy was performed without performing a reconstruction, as 31 (31/80) of these patients only had a minor injury. BDI patients were referred after a mean interval of 112 days (range 0–4612) after the initial cholecystectomy. The referral pattern of BDI patients from the initial hospital to the tertiary center is summarized in Fig 2. The initial referral rate to the departments of gastroenterology, surgery, and radiology was, respectively, 66%, 29%, and 5% (Fig 2). One hundred fifty patients (30%) were referred to a different department after initial referral to optimize treatment. The referral rate within the tertiary center, between different departments, ranged from 7% (from gastroenterology to radiology) to 40% (from radiology to surgery). One hundred sixty patients (32%) underwent a definitive surgical treatment, whereas endoscopy was the definitive treatment in 264 patients (53%) and a radiologic intervention in 58 patients (12%). Eighteen patients (4%) did not receive additional treatment after referral.

Treatment outcome and survival. Three hundred thirty-nine patients (67.8%) were admitted for treatment, whereas the remaining patients could be treated by multiple day-care interventions. The mean hospital stay was 10.4 days (Table 3). One third of the patients (n = 160) underwent a surgical procedure as definitive treatment, of which 151 underwent a surgical reconstruction and in 9 patients a laparotomy to control bile leakage or to drain abscesses. During the study period, an increase was found in the number of performed surgical interventions (30% in 1990–1995 vs 39% in 2000–2005, $P < .05$). However, during the same period, an increasingly number of patients with major injury, without previous repair, were referred for treatment (41% in 1990–1995 vs 52% in 2000–2005, $P < .05$). Patients with a type B injury (n = 87) were generally treated by endoscopic stent therapy (n = 61), whereas 15 of the 87 patients required subsequent surgical repair. In-hospital mortality was 0.4% (n = 2), and after a mean follow-up of 6.7 ± 4.1 years, 42 patients had died (8.4%). In 10 of 42 patients who died, death was related to the biliary injury. Six patients died from biliary peritonitis and related conditions. In the remaining 4 patients, death was attributed to persistent biliary obstruction and cirrhosis (n = 2), duodenal perforation after stent insertion (n = 1), and severe cholangitis combined with pulmonary comorbidity (n = 1).

Ten-year survival rate in BDI patients in comparison with the age-matched general Dutch population is plotted in Fig 3. The standardized mortality ratio is 1.06 (standard error = 0.16) and not significantly different from the Dutch population ($P = .7$). When survival between different groups of BDI patients is compared, no significant differences were found between patients with different types of injury, or between patients with different treatment modalities (Figs 4, *A* and *B*).

Risk factors for worse survival after BDI are shown in Table 4. The unadjusted hazard ratio (HR) for death in BDI patients increased significantly with advancing age (HR = 1.1, 95% confidence interval = 1.1–1.2) and male gender (HR = 3.1, CI = 1.7–5.8). A nonsurgical, definitive treatment did have a significant trend for worse survival (HR = 2.3, CI = 1.0–5.2). In the adjusted analysis,

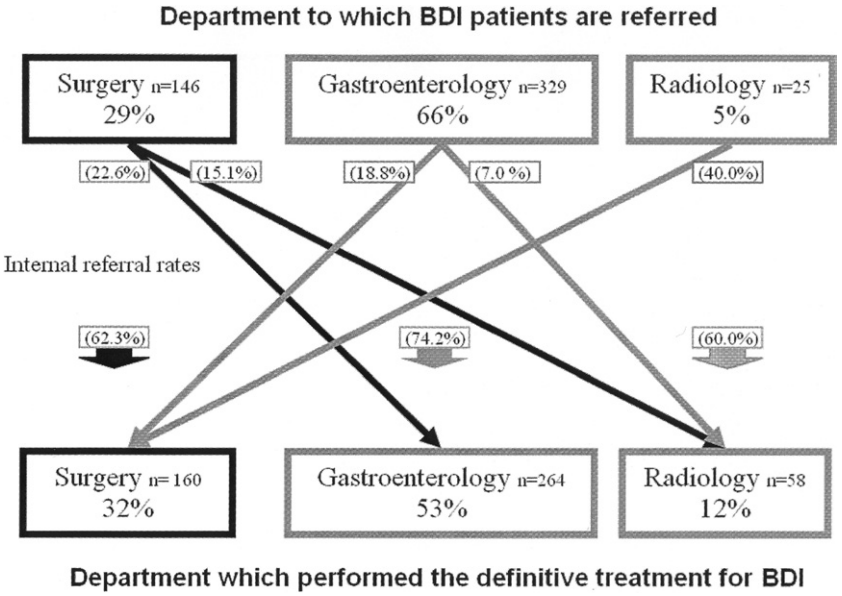

Fig 2. Referral pattern of bile duct injury patients within a tertiary center. A multidisciplinary approach by surgeons, gastroenterologists, and radiologists. Percentages are given from the total cohort of 500 patients. Percentages between brackets represent referral rate from the referring department to the department of final treatment. Eighteen patients (3.6%) were referred for a second opinion and received no additional treatment.

Table III. Outcome of a multidisciplinary treatment in BDI patients

Outcome Variable	*n = 500*	*%*
Final treatment modality		
Surgery	160	32.0
Endoscopy	264	52.8
Radiologic intervention	58	11.6
Hospital admissions per patient, median (range), days	1 (0–20)	
Hospital stay, median (range), days	2.5 (0–249)	
Mortality		
In hospital	2	0.4
During follow-up, related to BDI	10	2.0

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).

Malpractice litigation. From the 403 patients surveyed for the prevalence of legal activity, 278 patients (69%) returned the questionnaire. Fifty-three BDI patients (19%) reported medical litigation after BDI. In 21 of 53 patients (40%), the claim was resolved in the favor of the patient through settlement or verdict, whereas for 17 patients, the claim was not sustained. In 15 patients, the case was not settled at the time of the survey.

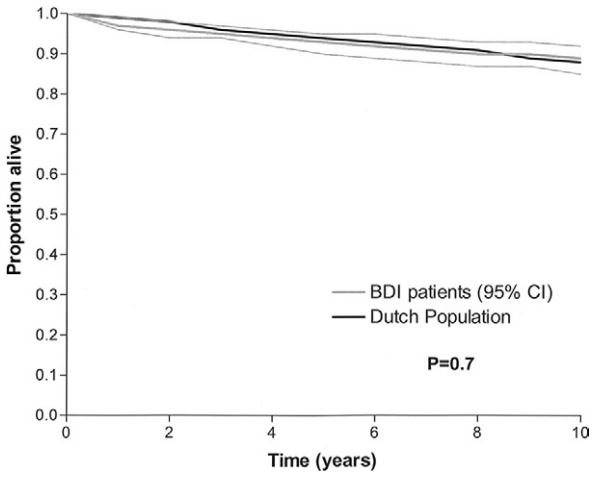

Fig 3. Survival in bile duct injury patients after treatment in a tertiary center compared with the age, gender, and year of birth-matched Dutch population. The 2 light red lines reflect the confidence interval of survival in BDI patients.

DISCUSSION

The number of referred patients with BDI to our center increased significantly over the last 15 years. Around 40 to 45 BDI patients are referred annually, with most patients suffering from major injury after an elective LC. Considering 15,000 LCs per year in the Netherlands, 0.3% of the LC patients are referred to our center for the treatment of BDI.

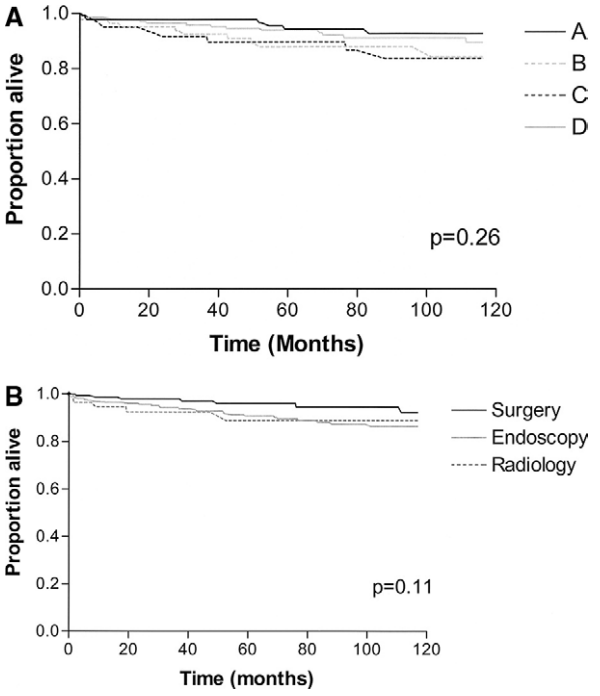

Fig 4. A, Survival in BDI patients with type A injury; cystic duct leakage, type B; bile duct leakage, type C; bile duct stricture, type D; bile duct transsection. **B,** Survival in BDI patients with different definitive treatment modalities.

This rate shows that the minimum incidence of BDI in the Netherlands is 0.3%, which suggests a higher incidence of BDI in the Netherlands than the 0.3% to 0.5% reported in previous studies.[24-26] BDI is a health-wise and monetary burden as illustrated by the severe long-term morbidity in BDI patients and high rates of litigation claims.[2,19,20] The long-term detrimental effect of BDI on quality of life is illustrated by studies from Europe and the United States.[2,3] The current study shows that the detection and treatment of BDI patients is a concern for generalists and specialists. The detrimental effect of BDI on survival can be decreased if BDI patients are referred to a specialized center and are treated by a multidisciplinary team.

This study describes the referral pattern of 500 BDI patients treated in our center. Two thirds of the patients underwent a therapeutic intervention in the initial hospital. From the 136 patients suffering from a minor injury (cystic duct leakage), 32 patients (24%) still underwent a relaparotomy in the referring center only for drainage. Adequate assessment before surgery by means of cholangiography (magnetic resonance cholangiopancreatography, endoscopic retrograde cholangiopancreatography, or percutaneous transhepatic cholangiography) could have prevented relaparotomy as cystic duct leakage can successfully managed by endoscopic stenting in more than 97% of the patients.[18] Of interest in the referral pattern of BDI patients is the difference in referral rate to the departments of surgery, gastroenterology, and radiology, and the definitive treatment by these departments. This study is the first to illustrate that in a relatively high percentage of patients, therapeutic strategy changes as a result of a multidisciplinary approach. The diversity in types of injury demands a multidisciplinary approach in which treatment modalities are discussed by a team of surgeons, gastroenterologists, and radiologists. Referral rates between departments ranging from 7% to 40% result in an optimal treatment strategy with a definitive nonsurgical treatment in two thirds of the BDI patients.

In the current series, the 10-year survival rate in BDI patients is 88%. Survival in BDI patients treated in a tertiary center is not significantly worse compared with the general Dutch population. Remarkable is the fact that no significant difference was found in survival between patients with minor and major injury, probably because patients referred for treatment of a minor injury are a selected group of patients who sustained severe morbidity from persistent bile leakage. Multivariate analysis showed that male patients and patients who underwent a repair during the initial cholecystectomy have a nearly 2-fold higher risk of dying within 10 years after the occurrence of BDI compared with the other BDI patients. These findings correspond to the previously mentioned study by Flum et al.[12] This outcome might be explained by the fact that comorbidity is generally higher in male patients undergoing cholecystectomy and that initial repair is generally performed by inexperienced hands. The initial repair in acute setting, with possible inflammation and operating on nondilated bile ducts, complicate the procedure.

The study by Flum et al. demonstrated the dramatic impact of BDI on survival in the United States. In a patient cohort of 576 BDI patients with an age less than 65 years old, the 10-year survival rate was less than 50%. This rate is in sharp contrast with the 10-year survival rate in the current series. Although it is known that survival is worse in population-based studies compared with single institution studies, these discrepant findings in survival of BDI patients are of interest. The limitation of the current study is the selection of patients who were referred for specialized treatment; therefore, patients who died before referral were automatically excluded. However, Flum et al. defined BDI pa-

Table IV. Cox proportional hazard analysis of survival in patients with BDI

Factors	*n*	*Unadjusted Hazard Ratio (95% CI)*	P *value**	*Adjusted Hazard Ratio† (95% CI)*	P *value*
Patient factors					
Age per yearly increase	500	1.13 (1.09−1.16)	<.01	1.12 (1.09−1.16)	<.01
Gender: male‡	166	3.13 (1.70−5.78)	<.01	2.01 (1.08−3.76)	.03
Injury					
Minor	136	—			
Major	364	1.89 (0.84−4.27)	.12		
Characteristics at referral					
Moment of diagnose					
In hospital	301	—			
After discharge	172	0.52 (0.25−1.06)	.07		
Interventions in referring hospital					
Surgical and nonsurgical interventions‡	319	1.51 (0.76−3.00)	.24		
Surgical interventions					
Repair during initial LC‡	85	1.84 (0.94−3.59)	.07	2.12 (1.07−4.21)	.03
Relaparotomy‡	136	1.41 (0.75−2.65)	.29		
With repair‡	56	0.90 (0.35−2.29)	.83		
Without repair‡	80	1.49 (0.59−3.79)	.40		
Nonsurgical interventions					
ERCP stent/papillotomy‡	104	0.75 (0.34−1.69)	.49		
PTC/D‡	24	1.76 (0.54−5.68)	.35		
Definitive treatment					
Surgical	160	—			
Nonsurgical	340	2.28 (1.01−5.15)	.05		

CI, confidence interval; *ERCP*, endoscopic retrograde cholangiopancreatography; *PTC/D*, percutaneous transhepatic cholangiography/dilatation.
**P* value of log rank test.
†*P* value of remaining significant independent variables after multivariate Cox regression analysis.
‡The hazard ratio for this variable was compared with patients who were negative for this variable.

tients as patients who underwent LC and a repair procedure within 1 year and excluded BDI patients treated by gastroenterologists and interventional radiologists. As BDI requires a multidisciplinary approach, the selected patients in Flum's study did not represent a general population of BDI patients. Secondly, the study showed an 11% death increase in patients who underwent a repair procedure by the same surgeon who performed the initial cholecystectomy. In their series, the repair was performed in 75% by the initial surgeon. If general practitioners would refer BDI patients directly to a tertiary center, this increased mortality could be prevented. The current study suggests a positive effect of a multidisciplinary approach in treating BDI by different specialists in the hepatobiliary field.

This study illustrates the plausible involvement of general practitioners in the initial detection of BDI. In the current series, more than one third of the patients are discharged from hospital without BDI being noticed or suspected. Because of changes in health-care policy, LC procedures are more often performed in a day-care setting.[27] This setting might improve patient satisfaction and reduce costs; however, the detection of possible BDI has consequently become a matter of concern for surgeons as for other physicians. The detrimental effect caused by late diagnosis of BDI on patient morbidity and treatment outcome has been shown in previous studies.[20,28] Surgeons should always be aware of this potential harm when discharging patients after LC. Physicians confronted with patients after cholecystectomy with persistent vague abdominal symptoms lasting longer than 48 hours should always bear BDI in mind as a potential diagnosis. In a later phase, jaundice and persistent fever are more specific symptoms for BDI. Early referral to the initial hospital after physical examination is indicated as laboratory tests combined with an ultrasound scan can easily exclude biliary injury. Direct referral of BDI patients by a general practitioner to a tertiary center could improve early diagnoses, optimal treatment, and patient satisfac-

tion.[29] This setting could improve quality of life and might therefore prevent a malpractice litigation claim.

Malpractice litigation is less common in most European countries compared with the United States; nevertheless, the introduction of LC and the increase of BDI certainly influenced the number of litigation claims. This survey among BDI patients showed that 19% of the patients were involved in litigation. This rate probably is an underestimation because of deceased patients or patients afraid of affecting their case and therefore not reporting litigation. Nineteen percent is less than the 30% described in an American series of BDI patients who all underwent a surgical repair.[30] Nevertheless, a substantial number of BDI patients will demand legal justification for the experienced morbidity, in America as well as in Europe. Kern et al.[19] estimated that the costs from litigation in the United States may range from $40 million to $100 million annually. The economic impact of BDI on the health-care system was shown by Savader et al.[20] They estimated a 4-fold to 26-fold cost increase for American society when BDI patients are compared with patients without BDI. This estimation was performed on the basis of the complete departmental and hospital billing records of each patient treated for BDI. The additional costs made by general practitioners and by litigation were not included, whereas the current study emphasizes the impact of BDI on both.

In conclusion, the introduction of LC for gallbladder disease resulted in an increase in BDI. Because of changes in health-care policy, performance of LC in a short-stay setting, and changes in the treatment of BDI, specialists and general practitioners are potentially confronted with this severe surgical complication. BDI is a serious health-care problem with an important socioeconomic impact illustrated by increased morbidity, poor long-term quality of life, high costs, and high rates of litigation claims. However, the detrimental effect of BDI on survival can be prevented by a multidisciplinary approach of gastroenterologists, radiologists, and surgeons.

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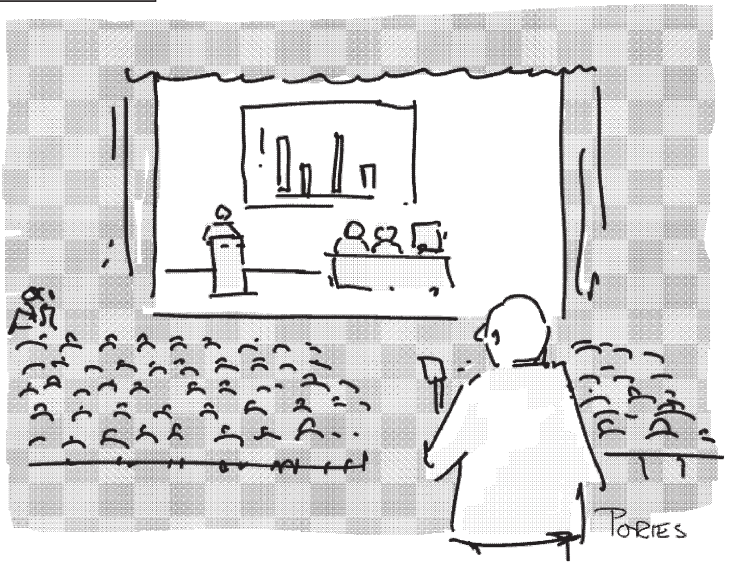
I.V. League



"Your results with those new medicines are certainly exciting. In surgery, however, we consider such results failures."