

Iatrogenic Bile Duct Injury

A Population-Based Study of 152 776 Cholecystectomies in the Swedish Inpatient Registry

Anne Waage, MD, PhD; Magnus Nilsson, MD, PhD

Hypothesis: Older age, male sex, and low yearly hospital volume of cholecystectomy may increase the risk of bile duct injury (BDI), whereas the use of intraoperative cholangiography may decrease the risk. The incidence of BDI at cholecystectomy may have increased after the introduction of laparoscopic cholecystectomy.

Design: Nationwide population-based study of all cholecystectomies registered in the Swedish Inpatient Registry from 1987 through 2001.

Setting: All hospitals performing inpatient cholecystectomies in Sweden.

Patients: Cholecystectomies were identified using *International Classification of Diseases, Ninth and 10th Revisions* surgical procedure codes. After exclusion of patients with hepatobiliary and pancreatic malignancies, patients with codes indicating reconstructive bile duct operations within 1 year after cholecystectomy were considered BDI cases. Risk factors for BDI were analyzed using multivariate logistic regression. The inci-

dence proportion of BDI was calculated by dividing the number of cases by the number of cholecystectomies.

Main Outcome Measures: Relative risks were estimated using odds ratios with 95% confidence intervals, and incidence proportion was used to describe incidence.

Results: Among 152 776 cholecystectomies, 613 reconstructed BDIs (0.40%) were identified. Older age and male sex were positively associated with BDI, whereas intraoperative cholangiography was negatively associated with BDI. The incidence proportion of BDI was 0.40% from 1987 to 1990, decreased to 0.32% from 1991 to 1995, and increased to 0.47% from 1996 to 2001. The mean yearly hospital volume did not affect the risk of BDI.

Conclusions: Older age and male sex increased the risk of BDI, whereas intraoperative cholangiography was protective. There was a small to moderate long-term increase in the risk of BDI after the introduction of laparoscopic cholecystectomy compared with the prelaparoscopic era.

Arch Surg. 2006;141:1207-1213

BILE DUCT INJURY (BDI) DURING cholecystectomy may have a severe effect on the health of patients, including mortality and considerable disability, and can be costly for the individual patient and for the health care system.¹⁻⁴ After the introduction of laparoscopic cholecystectomy (LC), the rate of BDI was reported to be significantly higher than in previous investigations concerning open cholecystectomy.⁵⁻⁹ The highest rates were reported in the early 1990s when LC was introduced, suggesting a learning curve effect.⁹⁻¹²

Several factors affect the occurrence of BDI during cholecystectomy. Authors of some previous studies^{9,13-16} claim that the use of intraoperative cholangiography (IOC) could decrease the incidence and severity of BDI. Age, sex, severity of the disease, and characteristics of hospitals and

surgeons are also believed to influence the risk of BDI.¹⁷⁻²⁴

In the present large population-based study, we examined risk factors for iatrogenic BDI requiring operative reconstruction in 152 776 LCs and open cholecystectomies in Sweden between 1987 and 2001. Several proposed risk factors were analyzed, with the aim of testing the hypotheses that older age, male sex, and low yearly hospital volume of cholecystectomy may increase the risk of BDI, whereas the use of IOC may decrease it. Moreover, the incidence proportion of surgically reconstructed BDI was assessed before, during, and after the introduction of LC. Using objectively collected registry data, the population-based design served to reduce selection bias and differential misclassification of the studied exposures or BDI outcome, ensuring the validity of the study findings.

Author Affiliations:
Department of Surgery,
Karolinska University Hospital,
Stockholm, Sweden.

Table 1. International Classification of Diseases (ICD) Codes Identifying Cholecystectomies and Bile Duct Reconstructions

Code	Description
Identifying Cholecystectomies	
<i>ICD-9</i>	
5351	Cholecystectomy plus choledochotomy
5352	Cholecystectomy plus choledocholithotomy
5350	Cholecystectomy
5353	Laparoscopic cholecystectomy
5356	Cholecystectomy plus choledochotomy plus sphincterotomy
5357	Cholecystectomy plus choledocholithotomy plus sphincterotomy
5359	Other similar operations
<i>ICD-10</i>	
JKA 20	Open cholecystectomy
JKA 21	Laparoscopic cholecystectomy
Identifying Bile Duct Reconstructions	
<i>ICD-9</i>	
5330	Suture of common bile duct
5331	Biliary reconstruction with bili jejunostomy
5339	Other reconstructive surgery of biliary tract
5365	Choledochojejunostomy
5368	Hepaticojejunostomy
<i>ICD-10</i>	
JKB 40	Suture of common bile duct
JKC 10	Resection and anastomosis of bile duct
JKC 30	Resection of bile duct with cholangioenterostomy
JKC 40	Resection of bile duct with hepaticenterostomy
JKD 20	Cholangiojejunostomy
JKD 30	Extrahepatic hepaticojejunostomy
JKD 40	Intrahepatic hepaticojejunostomy

Table 2. International Classification of Diseases (ICD) Codes for 66 Exclusions of Benign Diagnoses

Diagnosis	ICD-9	ICD-10	No. of Exclusions
Obstruction of the bile duct*	576C	K83.1	29
Chronic pancreatitis*	577B	K86.0, K86.1	22
Cyst of the biliary tract	...	K83.5	4
Cysts and pseudocysts of the pancreas*	577C	K86.2, K86.3	1
Cholangitis without gallstone disease*	576B	K83.0	10

* Patient excluded only if it was the main diagnosis at the time of cholecystectomy with simultaneous reconstruction.

scopic cholecystectomy was first introduced in Sweden in 1990,²⁸ but until 1994 (when LC was first assigned an ICD-9 procedure code [code 5353]), registry data did not distinguish between laparoscopic, open, or converted procedures. However, even after the introduction of this code, it was not widely used at first, and a large proportion of the cholecystectomies coded as open procedures are likely to have been performed by laparoscopy. For this reason, analyses stratified for laparoscopic and open technique have not been conducted.

From 1987 through 2001, we identified 153 368 valid and unique national registration numbers indicating any type of cholecystectomy. To define BDI cases, we first selected patients in this population who during the index procedure or within 1 year after it had also undergone any reconstructive biliary procedures registered using ICD-9 and ICD-10 procedure codes (Table 1). To exclude all patients who underwent reconstruction for biliary malignant neoplasm, we identified and excluded 526 subjects who previously or within 1 year after the cholecystectomy had been diagnosed as having cancer of the liver, bile ducts, gallbladder, or pancreas, as indicated by ICD codes. Identification of these patients was based on linkage with the 98% complete Swedish National Cancer Registry²⁹ and on cancer diagnoses registered in the Swedish Inpatient Registry. Moreover, 66 additional reconstructions referring to benign biliary diagnoses that are listed in **Table 2** and are unlikely to be a result of BDI were excluded. From the remaining population of 152 776 patients who had undergone any sort of cholecystectomy, we identified 613 patients who had had reconstructive biliary procedures within 1 year after cholecystectomy, without a diagnosis of any of the named cancers or benign conditions, and classified them as having reconstructed iatrogenic BDIs.

STATISTICAL ANALYSIS

To study risk factors for BDI, cross-sectional case-control analyses were performed. Variables under study were categorized to facilitate unconditional logistic regression analysis. Age was categorized into 6 groups (15-30, >30 to 40, >40 to 50, >50 to 60, >60 to 70, and >70 years). The use of IOC was recorded as yes or no. The mean yearly number of cholecystectomies performed during the study period at each hospital, hereafter referred to as the hospital volume, was categorized as fewer than 100 operations, 100 to 200 operations, or more than 200 operations.

Odds ratios (ORs) with 95% confidence intervals (CIs), derived from unconditional logistic regression analysis, were used to assess the association between the risk of BDI and the potential risk factors under study. Any possible confounding effects of the individual variables under study were tested by introducing them one by one into the multivariate logistic

METHODS

SWEDISH INPATIENT REGISTRY

Beginning in 1964, the Swedish National Board of Health and Welfare started collecting data on individual hospital discharges in the Swedish Inpatient Registry. Reporting data to the registry is required by Swedish law, securing completeness and avoiding selection bias. To ensure the accuracy of the data, regular validation of information such as patient identification and hospital codes is performed by the registry administration. This registry is event based, and when a patient is discharged from a clinic, some 20 variables (including patient demographics, dates of admission and discharge, hospital identification codes, and procedure and diagnosis codes according to the 9th and 10th revisions of the *International Classification of Diseases [ICD]*) are registered. The number of hospitals that provide data to the registry has steadily increased, covering 60% of the Swedish population in 1969, 75% in 1978, and 85% by the end of 1983. The registry contains nationwide coverage of all admissions to public and private health care in Sweden from 1987 onward. The registry has previously been described in greater detail.²⁵⁻²⁷

PATIENTS

The study was approved by the Regional Research Ethics Committee of Stockholm, Sweden. The study was limited to persons who were 15 years or older at the time of cholecystectomy. All cholecystectomies registered from 1987 through 2001 were identified. The procedure codes pertaining to cholecystectomy were from ICD-9 and ICD-10 (**Table 1**). Laparo-

Table 3. Univariate and Multivariate Logistic Regression Models of Risk Factors for Bile Duct Injury During Cholecystectomy*

Variable	No. of Cases	No. of Controls	Univariate OR (95% CI)	Multivariate OR (95% CI)	P Value for Linear Trend
Age, y					<.001
15-30	41	15 984	1.00	1.00	
>30-40	62	20 968	1.02 (0.63-1.64)	0.99 (0.61-1.59)	
>40-50	76	26 022	1.15 (0.74-1.79)	1.10 (0.70-1.70)	
>50-60	92	29 286	1.22 (0.79-1.87)	1.14 (0.74-1.77)	
>60-70	137	29 918	1.70 (1.13-2.56)	1.57 (1.04-2.38)	
>70	205	29 985	2.71 (1.84-4.01)	2.46 (1.65-3.66)	
Sex					<.001
Female	353	101 728	1.00	1.00	
Male	260	50 435	1.44 (1.20-1.74)	1.26 (1.04-1.53)	
Intraoperative cholangiography					<.001
No	280	57 594	1.00	1.00	
Yes	333	94 569	0.65 (0.54-0.78)	0.66 (0.54-0.79)	
Hospital volume					.35
>200	103	28 474	1.00	1.00	
100-200	178	46 954	1.03 (0.78-1.36)	0.98 (0.74-1.30)	
<100	332	76 735	1.17 (0.90-1.51)	1.14 (0.88-1.47)	

Abbreviations: CI, confidence interval; OR, odds ratio.

*No collinearity, overfitting, or interactions between variables were found in the multivariate logistic regression models.

regression model. Collinearity was assessed by calculating the degree of correlation between the exposure variables using Spearman rank correlation coefficients. The fitting of the used models was assessed by dividing the Pearson product moment correlation χ^2 value by the degrees of freedom. Interactions between the studied exposure variables were tested by entering interaction terms into the models. *P* values for linear trend tests were derived from Wald tests by treating categorical variables as continuous integers where applicable. Given 613 cases of reconstructed BDI among 152 776 cholecystectomies with an exposure rate of 30%, the power to detect an OR of 1.3 was 0.88.

To calculate BDI incidence proportion over time, the cholecystectomies were categorized by procedure date into periods (1987-1990, 1991-1995, and 1996-2001) corresponding to the time immediately before, during, and after the introduction of LC in Sweden. For each period, the incidence proportion was calculated by dividing the number of BDIs by the number of cholecystectomies during that specific period.

RESULTS

STUDY SUBJECTS

A total of 152 776 cholecystectomies, identified from 1987 through 2001, were analyzed. Among these, 613 cases of iatrogenic BDI requiring operative reconstruction were identified. The mean age at the time of cholecystectomy for all study subjects was 54.1 years and for BDI cases was 60.1 years. Of all 152 776 cholecystectomies, 102 081 (66.8%) were performed in women, while 353 (57.6%) of the BDIs occurred in women.

RISK FACTORS FOR BDI DURING CHOLECYSTECTOMY

Age and Sex

There was a strong and dose-dependent increase in the risk of BDI with older age (*P*<.001 for linear trend). In the mul-

tivariate analysis, patients older than 70 years had a risk of BDI at cholecystectomy that was almost 2½ times higher than that of patients younger than 30 years (OR, 2.46; 95% CI, 1.65-3.66) (**Table 3**). Male sex also significantly increased the risk of BDI by 26% compared with female sex (OR, 1.26; 95% CI, 1.04-1.53). For age and sex, the multivariately adjusted ORs were not markedly different from the unadjusted estimates, indicating a lack of strong confounding effects of the other variables under study.

Hospital Volume

Of 152 776 cholecystectomies, 76 735 (50.2%) were performed at hospitals that registered a mean number of procedures of fewer than 100 per year. The mean yearly hospital volume of cholecystectomies did not significantly affect the risk of reconstructed BDI (Table 3).

Intraoperative Cholangiography

Among 94 569 patients (61.9%) in whom IOC was performed, the multivariate analyses showed a 34% decrease in the risk of BDI compared with patients who did not undergo IOC during cholecystectomy (OR, 0.66; 95% CI, 0.54-0.79) (Table 3). Univariate data did not markedly differ from the multivariate analyses, indicating limited effects of examined confounding factors.

RISK FACTOR ANALYSIS, EXCLUDING PATIENTS WITH A DIAGNOSIS OF COMMON BILE DUCT STONES

After excluding 16 449 patients (10.8%) with a diagnosis of common bile duct stones at the time of cholecystectomy, stratified risk factor analyses were performed. This multivariate analysis gave results similar to those concerning all study subjects (**Table 4**).

Table 4. Multivariate Logistic Regression Model of Risk Factors for Bile Duct Injury During 136 327 Cholecystectomies, After Omitting Patients Having Common Bile Duct Stones

Variable	Univariate Odds Ratio (95% Confidence Interval)
Age, y	
15-30	1.00
>30-40	1.19 (0.71-1.98)
>40-50	1.11 (0.67-1.18)
>50-60	1.09 (0.67-1.78)
>60-70	1.40 (0.87-2.25)
>70	2.18 (1.39-3.43)
Sex	
Female	1.00
Male	1.27 (1.01-1.59)
Intraoperative cholangiography	
No	1.00
Yes	0.75 (0.59-0.92)
Hospital volume	
>200	1.00
100-200	0.98 (0.70-1.35)
<100	1.10 (0.81-1.49)

Table 5. Incidence Proportion of Bile Duct Injury During Cholecystectomy in Different Periods

Period	No. of Cholecystectomies	No. of Bile Duct Injuries	Incidence Proportion (95% Confidence Interval)
1987-1990	36 278	145	0.40 (0.34-0.46)
1991-1995	53 563	172	0.32 (0.27-0.37)
1996-2001	62 935	296	0.47 (0.42-0.52)
Total	152 776	613	0.40 (0.37-0.43)

INCIDENCE OF BDI DURING CHOLECYSTECTOMY

From 1987 through 2001, 152 776 cholecystectomies were registered, yielding 613 reconstructed BDIs, resulting in an estimated incidence proportion of BDI of 0.40% (95% CI, 0.37%-0.43%) (Table 5). From 1987 to 1990, the period immediately preceding the introduction of LC, the incidence proportion was 0.40% (95% CI, 0.34%-0.46%). From 1991 to 1995, the period when LC was introduced, the incidence proportion of BDI dropped significantly to 0.32% (95% CI, 0.27%-0.37%). From 1996 to 2001, the period when LC was widely in use, the incidence proportion of reconstructed BDI increased significantly (compared with the first and second periods) to 0.47% (95% CI, 0.42%-0.52%). The increase during this last period was gradual from 1996 to 1999 and leveled off in 2000 and 2001 (Figure).

COMMENT

Findings from this study indicate that older age and male sex are associated with an increased risk of iatrogenic BDI requiring biliary reconstruction, while the use of IOC

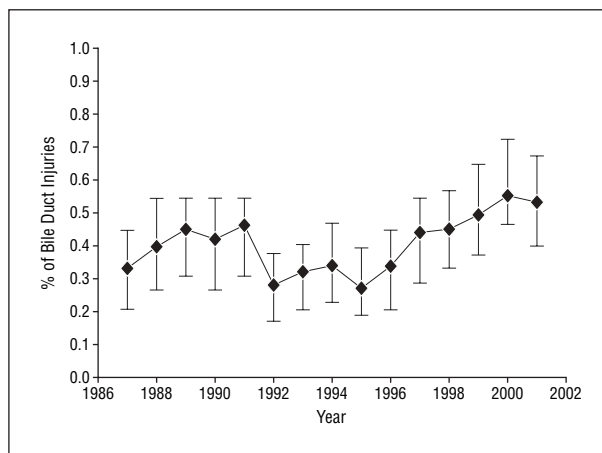


Figure. Incidence proportion (with 95% confidence intervals) of bile duct injuries in Sweden from 1987 to 2001.

seems to significantly reduce this risk. Hospital volume did not affect the risk of BDI. Moreover, the present study yields an incidence proportion of reconstructed BDI during cholecystectomy of 0.40% from 1987 through 2001. This incidence is estimated from the total population of patients who had undergone any cholecystectomy (open or laparoscopic) and decreased during the period when LC was first introduced (1991-1995) compared with the prelaparoscopic years (1987-1990). From 1996 to 2001 (ie, immediately following the introduction of LC), the incidence of BDI in the study population increased to a level that was slightly but significantly higher than the prelaparoscopic incidence (Table 5).

A major strength of our study is the population-based design that included most of the cholecystectomies performed in Sweden during the study period, thereby minimizing errors from selection bias and ensuring the internal and external validity of our results. Selection bias has introduced flaws in many previous hospital-based case series, including those from single institutions and multicenter studies with voluntary prospective registration of cholecystectomies, as well as nationwide series in which case registration has been voluntary (generally with low inclusion rates).^{6,12,17,24,30-34} Apart from a recent study by Dolan et al³⁵ in which the study population was drawn from the Nationwide Inpatient Sample, previous population-based reports may be limited regarding the generalizability of some findings because of the use of particular subpopulations such as Medicare patients as the study base.^{3,13} Furthermore, given the relative rareness of the BDI outcome, the large sample size of our present study enhances the precision and reduces the risk of random error. Another strength of the present study is that (to our knowledge) it is the first large population-based study to assess the incidence of BDI before, during, and after the introduction of LC in the same study population.

A potential weakness of the study is misclassification of data in the Swedish Inpatient Registry, which may have affected the exposure data, the selection of cholecystectomies for inclusion in the study, and the ICD codes for classification of the procedures used to determine outcome. However, the degree of misclassification in the registry is low, and a previous comparison of the informa-

tion in this database with manual reviews of patient medical records demonstrates 94% agreement concerning ICD procedure codes.³⁶ Although the accuracy is high, the lack of completeness before 1987 motivated the exclusion of cholecystectomies performed from 1964 through 1986 from the analyses.

Another possible source of misclassification is that minor BDI may have been treated by endoscopic procedures or by ultrasonographically assisted percutaneous interventions and was unidentified by ICD codes for biliary reconstruction. Consequently, the true incidence of BDI in our population may be underestimated because minor injuries may have been overlooked.

Some concern may be raised that our method of classifying cases of reconstructed BDI may include disorders of the biliary tract other than BDI. Alternative indications, other than BDI, are rare for having a reconstructive biliary procedure within 1 year of cholecystectomy in the absence of a malignant disease of the liver, biliary tract, or pancreas or a benign biliary diagnosis as excluded (Table 2). However, there is a potential risk of differential misclassification if one includes biliodigestive anastomosis resulting from impacted common bile duct stones as cases, although we would expect hepaticoduodenal anastomosis (which was not used for our case classification) to be performed most frequently in this situation. Moreover, previous studies^{3,13,35,37} have validated the present method used for identifying injuries. Furthermore, risk factor analyses stratified to exclude all cholecystectomies with a diagnosis of common bile duct stones gave results almost identical to those already described (Table 4). In contrast to self-reported case series, misclassification in the present study is likely to be nondifferential, meaning that misclassification of exposures is not linked to BDI outcome and vice versa, limiting the amount of bias introduced.

Outpatients are excluded from our database, which may potentially affect the completeness of our registration. However, outpatient cholecystectomy has not yet gained wide acceptance in Sweden and until recently was rare. Furthermore, only the generalizability of the study, not the internal validity, would have been affected even if the proportion of outpatient procedures had ever been large during the study period.

Because the ICD code for LC was introduced late in Sweden and only gradually came to be widely used, it was impossible to reliably distinguish between LCs and open cholecystectomies in the study. For this reason, we could not stratify our risk factor analyses by open or laparoscopic procedure. Given our inability to distinguish laparoscopic from open procedures in this study, we chose to study the effect of the introduction of laparoscopic technique on the incidence of reconstructed BDI in a total population of patients who had undergone cholecystectomy by analyzing the time trend of the incidence of BDI in relation to the introduction of laparoscopy.

Another potential weakness is that we were unable to control for some potential confounding factors other than the studied variables in the risk factor analyses. Potential confounders excluded from the analyses in the present study include patient characteristics (such as body mass index and chronic and acute cholecystitis) and surgeon

characteristics (including level of experience), all of which have been highlighted in several articles.^{11,12,23,38}

The present study demonstrated a strong and dose-dependent association between older age and BDI, which is consistent with recent findings by Dolan et al.³⁵ The cause of this association may be confounding from chronic or acute cholecystitis. With older age, patients are more likely to have had long-lasting gallstone symptoms, and scarring and adhesions at the Calot triangle have been reported to increase the incidence proportion of BDI to as much as 3%.¹⁷ Reliable data concerning chronic or acute cholecystitis were unavailable in the present study, but these conditions might become more common with older age. Flum et al¹³ also reported age as a significant risk factor for BDI resulting from all types of cholecystectomies, but there was no such association when they analyzed risk factors separately for LC. This is in accord with other findings in which age does not seem to have an independent effect on the incidence of BDI in LC.³⁹

Male sex increased the risk of BDI in the present study, which has also been previously suggested.³⁵ In an Australian population-based study, BDI was found to be more than twice as common in men as in women.⁹ On the other hand, in an article specifically addressing this issue, Grönroos et al¹⁹ concluded that the risk of mild BDI was independent of sex and reported that women rather than men have a higher risk of severe BDI. However, this report is flawed by potential random error, given that it was based on only 32 cases of BDI. A possible mechanism behind male sex being a risk factor for BDI could be sex-dependent differences regarding the tissue around the Calot triangle, or the cause could be variations in bile duct anatomy, which may affect dissection and anatomical orientation in this particular area.

Although findings from prior studies^{24,40} suggest a relation between hospital volume and surgical mortality, we saw no effect of hospital caseload on the risk of BDI in our study. This is in line with the findings of Dolan et al,³⁵ who reported no association between the risk of BDI and institutional characteristics, although they did not explicitly analyze the effect of hospital volume. This is contradicted by a recent study⁴¹ that reported an association between low hospital volume of cholecystectomy and mortality and morbidity in general, without particular mention of BDI.

In contrast to more complex surgical procedures,⁴⁰ the surgical outcome in cholecystectomy may depend on how well the operation is performed rather than on the resources available at the hospital. If this is so, the operative complications would to a greater extent be affected by the case volume of the individual surgeon, which can be high even at low-volume hospitals. This hypothesis may be supported by the increased incidence of BDI reported during the learning curve periods in LC^{11,38} and in open cholecystectomy,²² but this cannot be addressed in the present study because the identity of the surgeon and characteristics are not registered in the registry. Nevertheless, data on the effect of hospital volume on the risk of iatrogenic BDI during cholecystectomy are scarce^{24,42} and need further study, including detailed exposure data concerning biliary disease severity and the experience level of the surgeon.

Our data suggest a protective effect of IOC against BDI, reducing the risk by 34%. The validity of this finding may be threatened by the risk of confounding by surgeon inexperience and by cholecystitis and other severe forms of gallstone disease, which may make IOC more difficult to perform and increase the risk of BDI. However, previous studies that have analyzed IOC, the risk of BDI, and the case order of surgeons have not reported strong confounding effects of surgeon inexperience on the association between IOC and BDI,^{13,15} and the findings of the present study are in line with previous data.^{9,13-15} A protective effect of IOC could be explained by an early warning for the most serious type of surgical misperception, namely, mistaking the common bile duct for the cystic duct. Therefore, the information obtained from IOC may decrease the severity of BDI, or prevent it altogether, which is in accord with prior reports. In a retrospective nationwide cohort analysis of more than 1½ million Medicare patients undergoing cholecystectomy in the United States, Flum et al¹³ demonstrated a 71% higher relative risk of BDI when IOC was not used. The same group examined the frequency of BDI in Washington State from 1991 to 1997 and found that the risk of BDI was 67% increased during LC without IOC.¹⁵ Furthermore, in an Australian study from the early 1990s, Fletcher et al⁹ observed a 50% increased risk of BDI without IOC among all cholecystectomies performed. However, no consensus exists concerning this issue, and selective use of IOC is advocated by some authors.^{43,44} Routine IOC will probably not prevent all BDI, as the injury is not always a consequence of anatomical misperception. Injuries caused by traction of the bile duct or tissue necrosis as an effect of cautery may not be reduced by increased use of IOC. In addition, injuries may occur after IOC has been performed. However, our data support the notion of IOC being a major protective factor against BDI.

We believe that the introduction of LC in Sweden during the early 1990s may have caused a small but statistically significant decrease in the incidence of reconstructed BDI among patients who had undergone cholecystectomy, a finding in contrast to previous reports⁹⁻¹² concerning the effect of LC on BDI incidence. In a study of more than 2.8 million LCs from 1990 to 2000, Dolan et al³⁵ reported rates of BDI requiring biliary reconstructions after cholecystectomy ranging from 0.25% in 1992 to 0.10% in 2000. However, the report by Dolan et al, like several previous studies,^{6,9,10,12} assesses the incidence based on a population of patients among whom cholecystectomy is completed or partially performed by laparoscopy. There is a risk of misclassification of the whole procedure as open, falsely lowering incidence figures for BDI in a purely laparoscopic data set. Moreover, no mention is made by Dolan et al³⁵ as to the validity of data from the Nationwide Inpatient Sample, especially concerning completeness of reporting (with regard to selection bias) and accuracy of coding (with regard to information bias).

A possible explanation for the decreased incidence of BDI that was observed in the present study when LC was introduced could be increased caution during laparoscopy, combined with wider indications for cholecystectomy (ie, a selection of easier cases for cholecystectomy

during this period, which is supported by the fact that the annual number of cholecystectomies performed in Sweden increased from <9000 in the late 1980s to >11 000 in the early to mid 1990s,⁴⁵ with approximately the same annual number of BDI cases). This notion is supported by Blomqvist et al,²⁷ who compared characteristics of patients undergoing cholecystectomy in Sweden in 1988 and in 1994 and found a higher proportion of patients with cholecystitis in the population of patients who had undergone cholecystectomy in the prelaparoscopic year compared with 1994. From 1996 to 2001, when the LC technique had matured and become routine, the incidence of reconstructed BDI in the present study was 0.47%. This is slightly but significantly higher than the prelaparoscopic level of 0.40%. Our results may be at least partly in agreement with the gradual decrease in BDI during the 1990s described by Dolan et al.³⁵ This may be because LCs were likely to represent a minority of procedures from 1991 to 1995, when BDI incidence dropped compared with the prelaparoscopic period, and the drop in incidence may actually have occurred among the open procedures as a result of the increased attention given to the risk of BDI when laparoscopy was introduced. The increased incidence of BDI that we then detected during the latter part of the 1990s may partly reflect the increasing proportion of laparoscopic procedures.

CONCLUSIONS

The findings of this nationwide population-based study suggest that older age and male sex increase the risk for BDI requiring reconstructive surgery, while the use of IOC seems to be protective against it. The operative case volume of hospitals does not seem to affect the risk of BDI. The present study (assessing the incidence in a population undergoing LCs and open cholecystectomies) demonstrates only a modest long-term increase in the incidence of iatrogenic BDI requiring reconstruction after the introduction of LC.

Accepted for Publication: October 21, 2005.

Correspondence: Anne Waage, MD, PhD, Department of Surgery, Karolinska University Hospital, Huddinge, 14186 Stockholm, Sweden (anne.waage@karolinska.se).

Author Contributions: *Study concept and design:* Waage and Nilsson. *Acquisition of data:* Waage and Nilsson. *Analysis and interpretation of data:* Waage and Nilsson. *Drafting of the manuscript:* Waage. *Critical revision of the manuscript for important intellectual content:* Waage and Nilsson. *Statistical analysis:* Waage and Nilsson. *Obtained funding:* Nilsson. *Administrative, technical, and material support:* Waage and Nilsson. *Study supervision:* Nilsson.

Financial Disclosure: None reported.

Funding/Support: This study was supported in part by a grant from Juhlin Fonder (Dr Nilsson).

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