Common Bile Duct Injury During Laparoscopic Cholecystectomy and the Use of Intraoperative Cholangiography

Adverse Outcome or Preventable Error?

David R. Flum, MD; Thomas Koepsell, MD; Patrick Heagerty, PhD; Mika Sinanan, MD; E. Patchen Dellinger, MD

**Background:** Common bile duct (CBD) injury is a serious complication of laparoscopic cholecystectomy (LC). Predictors of this adverse outcome have not been well documented.

**Hypothesis:** Surgeon experience and the use of intraoperative cholangiography (IOC) are associated with a decreased rate of major CBD injury during LC.

**Design:** A retrospective population-based cohort study.

**Setting:** Washington State hospital discharge database reports from 1991 through 1998.

**Patients:** Discharge reports were searched for International Classification of Diseases, Ninth Revision, procedure codes consistent with LC and then evaluated for procedure codes for CBD repair and reconstruction within 90 days of LC.

**Main Outcome Measure:** The rate of CBD injury in patients undergoing LC based on the surgeon’s experience and IOC use.

**Results:** In all, 30630 LCs and 76 major CBD injuries (2.5/1000 operations) were identified in this analysis. There were no significant differences between injured and non-injured patients in demographics, disease, payer status, or hospital variables. A CBD injury occurred in 3.2 of 1000 LCs in the early case order of surgeons compared with 1.7 per 1000 at later points (P = .01) (relative risk, 1.81; 95% confidence interval, 1.44-2.88). The rate of injury in LCs performed without IOC was 3.3 per 1000 compared with 2.0 per 1000 in LCs with IOC (P = .02) (relative risk, 1.7; 95% confidence interval, 1.1-2.6). Surgeon’s experience and IOC use were independent predictors of injury.

**Conclusions:** The rate of CBD injury is significantly lower when IOC is used. This effect is magnified during the early experience of surgeons. Systematic use of IOC may significantly reduce the rate of CBD injury.

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The widespread acceptance of laparoscopy as the preferred approach to cholecystectomy was based on anticipated reductions in postoperative pain and recuperative time associated with "minimal access." Soon after its introduction, however, it became clear that laparoscopic cholecystectomy (LC) was associated with unique complications compared with the "open" approach. Early reported rates of common bile duct (CBD) injury were 2 to 15 times greater than those identified in historic series. The incidence of CBD injury appeared to be highest during the introduction of LC and was related to early experience with LC, the so-called learning curve. As the procedure has become increasingly common, surgeons have tended to cite a rate of injury of 1:300. However, despite the broad experience of surgeons with LC during the past decade, rates of injury as high as 1.4% have recently been reported.

The impact of a major CBD injury is staggering to both the patient and the health care system. Major CBD injury is associated with 11% case fatality and almost always requires a technically demanding, expensive, operative reconstruction of the biliary tree. Depending on the expertise of the surgeon reconstructing the bile ducts, reoperations may be common. For example, of 57 injuries resulting in litigation, an average of 2 procedures (range, 1-8) were required to definitively repair the ducts. It is the third most commonly litigated general surgical complication, with median jury awards of $500000. Despite its relative infrequency, CBD injury is by far the most important possible complication of LC.

Cholecystectomy requires the ligation and division of the cystic duct at a
METHODS

STUDY DESIGN

A retrospective cohort study was conducted with the use of a statewide hospital administrative discharge database to determine the effects of IOC and surgeon's experience on CBD injury after LC.

SETTING

Data were taken from the Washington State Comprehensive Hospital Abstract Reporting System database. This data set is derived from all public and private hospitals in Washington State (Veterans Affairs and US military hospitals excluded). It contains demographic variables, admission and discharge administrative details, payer status, International Classification of Diseases, Ninth Revision (ICD-9) procedure and diagnosis codes, and coded surgeon and hospital identifiers. This study was granted an exception by agreement of the University of Washington Human Subject Review Committee and the Washington State Department of Health. The data set includes only anonymous data and is considered within the public domain.

SUBJECTS

All Comprehensive Hospital Abstract Reporting System reports from January 1, 1991, through December 31, 1998, were searched for ICD-9 procedure codes pertaining to LC. This group was further evaluated for ICD-9 procedures codes that describe CBD injury and repair subsequent to LC. Exclusion criteria included records with ICD-9 diagnosis codes consistent with biliary tract malignancy and repairs of biliary tract fistulas. The LCs with major CBD injuries were therefore defined as LCs necessitating either “major repair” of the CBD or anastomosis of bile duct to intestine within 90 days of LC (Table 1). The 90-day period for bile duct repair after LC was selected because, in one large survey of CBD injuries, this corresponded to the mean time until bile duct reconstruction.

VARIABLE DEFINITIONS AND ANALYSIS

Univariate analysis was used to compare groups of patients undergoing LC with and without CBD injury by means of Stata (Stata Corp, College Station, Tex). Variables were compared with Pearson χ², Fisher exact test, and unpaired, 2-tailed t test. We calculated the number of LCs performed by each surgeon before any given operation and created the variable “case order” as a marker of surgical experience at that point in time. Case order rather than total experience with LC was considered the more relevant marker of surgical experience, because it represents experience at the time of the index LC within the surgeon's total experience curve. The lowest quartile of case orders was considered “early” case order (defined as the surgeon's first 20 procedures). Relative risk (RR) of CBD injury was calculated in relation to the use of IOC and whether the operation occurred early in the sequence of a surgeon's LC experience. Case order was considered as both a continuous variable and a categorical variable on the basis of quartiles. To examine variation among surgeon's use of IOC, a second, surgeon-level variable (percentage of IOC use) was created. This variable was defined as the proportion of LCs in which a given surgeon used IOC. The percentage of IOC use was further categorized in relation to the frequency of IOC use among all surgeons and divided into 4 groups (<15%, 15%-45%, 46%-75%, and >75% IOC use). Surgeons in the greater than 75% IOC use group were considered to be “routine” users of cholangiography. The Mantel extension test for trend was used to examine overall odds ratios of CBD injury among different percentage of IOC use groups, adjusting for LCs in which an IOC was or was not used.

Other analysis variables included age and sex, payer status, source of admission (emergency department, transfer, clinic), diagnoses and history of previous admissions for biliary tract disease (evidenced by ICD-9 diagnostic codes consistent with cholecystitis and/or cholecystitis with choledochal disease, during previous hospitalizations), and hospital type (rural and nonprofit status as defined by State of Washington definition, teaching if surgical training programs were known to work at the hospital).

A multivariable logistic regression model was constructed that included the primary variables of early surgeon experience with LC (1st through 20th operation) and the use of IOC. Models were constructed in 4 steps. Model 1 (unadjusted) included only the primary covariates, IOC use, and “less experienced” (case order, 1-20) variables. Model 2 included the primary covariates and demographic variables (sex and age). Model 3 further included payer variables (Medicare, Medicaid, health maintenance organization, and private). Finally, model 4 included the primary covariates, demographics, payer variables, and patient acuity variables (admission from emergency department, total previous admissions for biliary disease based on ICD-9 diagnosis codes, and ICD-9 diagnosis code for acute cholecystitis and/or concurrent choledochal disease at the time of admission). Separate analyses using hospital-level variables (teaching, for-profit, and rural status) and surgeon-level variables (percentage of IOC use as a continuous variable) were also performed. This model accounted for clustering by surgeon, and all results are presented with robust SEs. Unadjusted and adjusted odds ratios and predicted probabilities were obtained by means of these logistic regression models. Because of the infrequency of CBD injury, odds ratios approximate RR.
Table 1. ICD-9 Procedure and Diagnostic Codes Used as Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial procedure code</td>
<td>Laparoscopic cholecystectomy</td>
</tr>
<tr>
<td>Subsequent procedure code†</td>
<td>Cholecdochenterostomy</td>
</tr>
<tr>
<td>Procedure code 51.72 Repair of fistula of common bile duct</td>
<td></td>
</tr>
<tr>
<td>Diagnosis codes 155.1, 156.1, 156.8, and 156.9 Biliary tract and/or gallbladder cancer</td>
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*ICD-9 indicates International Classification of Diseases, Ninth Revision.
†Within 90 days of initial procedure code.

Table 2. Similarity of Patients Within Study Group, Based on Presence of Injury

<table>
<thead>
<tr>
<th>Variables</th>
<th>CBD Injury (n = 76)</th>
<th>No CBD Injury (n = 30,630)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD, y</td>
<td>48.7 ± 2.2</td>
<td>50.9 ± 0.1</td>
<td>.29</td>
</tr>
<tr>
<td>Sex, % F</td>
<td>78.9</td>
<td>74.4</td>
<td>.80</td>
</tr>
<tr>
<td>Payer, %</td>
<td>Medicare 33.3</td>
<td>37.1</td>
<td>.69</td>
</tr>
<tr>
<td>Medicaid</td>
<td>19.7</td>
<td>15.4</td>
<td>.31</td>
</tr>
<tr>
<td>Private</td>
<td>36.8</td>
<td>37.9</td>
<td>.85</td>
</tr>
<tr>
<td>Disease severity, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED admission</td>
<td>30.3</td>
<td>37.4</td>
<td>.19</td>
</tr>
<tr>
<td>Acute cholecystitis†</td>
<td>35.5</td>
<td>37.5</td>
<td>.73</td>
</tr>
<tr>
<td>CBD stone†</td>
<td>3.9</td>
<td>6.2</td>
<td>.42</td>
</tr>
<tr>
<td>Hospital, %</td>
<td>Teaching 18.4</td>
<td>13</td>
<td>.16</td>
</tr>
<tr>
<td>Rural</td>
<td>9.7</td>
<td>9.5</td>
<td>.95</td>
</tr>
<tr>
<td>For-profit</td>
<td>4.9</td>
<td>4.3</td>
<td>.78</td>
</tr>
</tbody>
</table>

*CBD indicates common bile duct; ED, emergency department. There were no significant differences between groups.
†Diagnosis codes according to International Classification of Diseases, Ninth Revision.

RESULTS

A total of 30,630 LCs were identified from 1991 through 1998. The LCs were performed by 3447 attending physicians at 138 hospitals. The number of patients undergoing LC increased substantially from 1991 to 1992 and remained relatively stable from 1992 to 1998 (Figure 1). Seventy-six major CBD injuries (2.5/1000 or 1/400) by 66 surgeons (range of injury per surgeon, 0-4) were identified. The incidence of injury decreased slightly during the study period. A test for trend indicates that there was a significant overall decrease in the rate of injury over time (P = .05). After 1991, the incidence of CBD injury declined by approximately 10% per year.

Patients undergoing LC with subsequent CBD injury were compared with patients undergoing LC without injury (Table 2). There were no significant differences between groups on the basis of demographics, previous hospitalizations for biliary tract diagnoses, payer status, or hospital variables.

SURGEON’S EXPERIENCE

Surgeon’s total experience (number of LCs performed during an 8-year period) varied widely (mean, 68.7; median, 56; range, 1-256). Twenty-five percent of surgeons performed fewer than 20 LCs during the study period, while 25% performed more than 100 LCs. The LCs were analyzed on the basis of whether the surgeon performing the LC was in the early (<20 cases preceding), middle (21-36), high (37-75), or highest (>75) experience level group (based on quartile). The LCs performed in the early portion of a surgeon’s experience were at significantly higher risk for injury than those performed at later points in the case order. Injury to the CBD occurred in 3.2 per 1000 of LCs in this early case order, compared with 1.7 per 1000 at later points in case order (RR, 1.81; 95% confidence interval, 1.44-2.88). Despite this finding, no significant differences in the rate of CBD injury were identified between later points in the experience curve, and an overall test of trend failed to identify significant differences in injury based on case order for case orders greater than 20 (P = .80). For example, the rate of injury in LCs performed after surgeons’ 100th LC was 1.6 per 1000 compared with 1.4 per 1000 after the 150th LC (P = .90).
INTROPERATIVE CHOLANGIOGRAM

Intraoperative cholangiography was performed in 63.7% of LCs. The rate of CBD injury was significantly lower when IOC was used. The rate of injury in LCs performed without IOC was 3.3 per 1000, compared with 2.0 per 1000 in LCs with IOC (P = .02) (RR, 1.7; 95% confidence interval, 1.1-2.6). Case order and IOC use were independent predictors of injury.

When the effect of IOC use on injury rate during the early portion of the learning curve was examined, significant differences were identified (Table 3). For example, during the first 36 LCs of surgeons (median case order of LCs in survey was 36), the risk of CBD injury was significantly higher if no IOC was obtained (RR, 2.2; 95% confidence interval, 1.31-3.74). The difference in CBD injury rates between LCs done with and without IOC appeared somewhat larger at lower case orders, but a regression model showed no significant interaction between IOC and case order.

ROUTINE IOC USE

Because surgeons who use IOC more frequently might have a lower rate of CBD injury independent of IOC use, we considered the percentage of time that a surgeon performed IOC as a separate, surgeon-level covariate. Fifty percent of surgeons performed IOC less than 18% of the time. Ten percent of surgeons performed IOC more than 75% of the time, and only 5% used IOC in more than 92% of their LCs. When surgeon percentage of IOC use was examined as a categorical variable (<15%, 15%-45%, 46%-75%, >75%) CBD injury rates were not significantly different among LCs performed by surgeons in any of the percentage of IOC categories (Table 4). For example, surgeons using IOCs in more than 75% of LCs had an injury rate of 2.2 per 1000 compared with 2.8 of 1000 among those who used IOC less than 15% of the time (P = .33). Furthermore, when the subgroup of surgeons who performed IOC in nearly all LCs (>90%) was evaluated separately, no significant benefit was identified (rate of injury, 1.8/1000) when compared with surgeons using IOC less than 15% of the time (P = .25). Interestingly, among surgeons who used IOC in greater than 75% of LCs, there was a significantly lower rate of injury in LCs that included the IOC compared with LCs that did not include the IOC (1.6/1000 compared with 6.3/1000, respectively; P < .001, Fisher exact test). No similar effect was identified in surgeons groups with other frequencies of IOC use. The Mantel extension test showed no significant trends in CBD injury rates across percentage of IOC use groups, adjusting for IOC use (P = .52).

MULTIVARIATE ANALYSIS

A logistic regression model was constructed to determine whether the effect of case order and IOC use was altered by the addition of possible confounding variables (Table 5). The unadjusted model and 3 adjusted models all identified the negative association of IOC use and CBD injury. The magnitude of the association remained largely unchanged in all models. Hospital-level variables, including rural location, teaching, and/or for-profit status, were also tested and were found to have essentially no effect on odds ratios (data not shown).

PREDICTED PROBABILITY OF CBD INJURY

Case order and the use of IOC were incorporated into a predictive model for CBD injury. Figure 2 graphically
represents the predicted probability of CBD injury at the full range of possible case orders considered in this survey (1-256) and based on IOC use. Although the 2 fitted curves appear to have different slopes, there was no statistically significant interactive effect between IOC use and case order (P = 0.09).

The wide acceptance of LC in the early 1990s was based on several case series rather than randomized controlled trials. Community awareness that a minimally invasive procedure could dramatically reduce postoperative pain and improve recuperation made it impractical to conduct trials that might have better refined the technique. As a result, even though IOC has been offered by some6,16,17 as an approach to prevent CBD injury during LC, testing its efficacy has not proved practical because of the relative infrequency of the complication. Testing for a difference in injury rate of 1:400 to 1:200 related to IOC use would require more than 6000 patients in each limb of a hypothetical prospective, randomized trial.

Although CBD injury occurs more commonly in the early portion of a surgeon’s learning curve,6,8 recent reports9 suggest that even surgeons with a great deal of experience with LC have high rates of CBD injury. Technical modifications to decrease injury rates have been suggested.10 These include proper angulation of the cystic duct and the CBD during initial dissection, use of an angled laparoscope, and a lowered threshold for conversion to an open procedure.11,17,24 These technical recommendations and proctoring of surgeons during their first LCs have been incorporated into the “modern” era of laparoscopy, yet the reported rate of CBD injury remains high.4,5

In the era when IOC was applied strictly for CBD stone detection, surgeons used it either routinely or selectively on the basis of their confidence in the preoperative diagnostic modalities related to CBD stones. As a result, a debate in the surgical community has continued for the past 30 years9 regarding the benefits and drawbacks of routine IOC use. The debate continues today, even though the benefit of IOC in the era of LC has been expanded by also providing a road map of the biliary system. Some surgeons use IOC routinely for CBD stone identification, confirmation of assumptions made during operative dissection, and/or training purposes. Selective cholangiographers tend to use the IOC when they are unsure of the anatomy or when CBD stones are suspected. Others choose to obtain a pre-LC or post-LC endoscopic cholangiogram if a CBD stone is suspected. These surgeons believe that IOC does not offer significant advantages in operative dissection sufficient to justify the associated operative time and cost of IOC.

The results of this retrospective cohort evaluation indicate that the rate of CBD injury after LC is significantly lower—about 40%—when IOC is used. As expected, surgical experience was also associated with the rate of CBD injury. Significantly higher injury risk was identified in LCs performed early in a surgeon’s case series. The relative risk of CBD injury based on IOC use did not vary according to case order. However, more CBD injuries occurred at earlier parts of the learning curve, and, therefore, more CBD injuries have the potential to be prevented by using IOC early in a surgeon’s experience.

With the use of predicted probability based on the data from this survey, it may be possible to better define the risk of CBD injury for patients undergoing LC. Since many surgeons quote the general rate of injury (as reported in previous series) of 1:300 to 1:350 (0.33%-0.29%), these predictive models may be helpful in the informed consent process. For example, a surgeon who has performed more than 250 LCs and uses IOC has a predicted probability of CBD injury that is significantly lower (0.6/1000) than that of a surgeon in his or her first 20 LCs who does not use IOC (3.9/1000).

To distinguish the technology from the technologist, this analysis tried to separate the benefit of the IOC from other benefits that a surgeon who frequently uses IOC might offer. Surgeons who used IOC in a higher proportion of operations did not appear to have significantly lower rates of CBD injury. This may be because surgeons who performed IOC frequently (>75% of LCs) had a significantly higher rate of injury in situations when they did not obtain an IOC. This suggests that, when those who use IOC more routinely deviate from their typical practice pattern, they are more prone to CBD injury, or that the risk of CBD injury is higher in patients in whom no IOC was obtained or completed. This relationship was further evaluated in regression analysis using the surgeon-level variable of percentage of IOC use and controlling for whether an IOC was obtained. With this regression analysis, no additional effect of the more routine IOC user, separate from IOC use itself, was identified. However, a comprehensive evaluation to separate the effects of IOC use from IOC user (surgeon) would require a much larger dataset.

This issue highlights the limitations of this data set: important clinical and intraoperative variables, such as why an IOC was used or the timing of the IOC in the LC, are not included. This limits our conclusions about why rates of injury might be different in LCs when no IOC was obtained. For example, surgeons may have determined that there was complex, “high-risk” anatomy...
in a patient and obtained an IOC in operations that were more likely to have a CBD injury or after a CBD injury had already occurred. This, however, would result in a higher rate of injury found with IOC use and would diminish the effect of IOC demonstrated in this survey. Conversely, injuries that were detected after the fact by an IOC might be underrepresented in this sample because of an increased chance for misclassification as an open cholecystectomy if an open repair was undertaken at the time of injury recognition. However, this possibility is not relevant to the issue of injury prevention. An IOC performed for the purpose of injury prevention should be done before the complete division of any bile duct.

Another potential hazard of using administrative databases for research is that it is difficult to effectively identify operative complications. For example, although an ICD-9 code for “accidental puncture” during surgery (E870 series and 998.2) does exist, this method of case detection has been shown to dramatically overreport the rate of clinically relevant CBD injury.27 Our technique of CBD injury detection was devised to avoid this pitfall. However, by describing only “major CBD injury” (through selection of cases based on the ICD-9 procedure codes suggesting CBD repair or bile duct-to-bowel anastomosis), we have excluded the minor CBD injuries, cystic duct leaks, and accessory duct transections that also occurred during the study period. This study, by focusing on more clinically relevant injuries, underestimates the rate of all CBD injuries.

The data set is also limited in its inclusion and classification criteria: patients with CBD injury who died before reoperation or who left the state after being injured would not be included in this survey. Also, the first LC of a surgeon in Washington who had previously accumulated experience with LC elsewhere would be considered the first in his or her experience curve. Finally, while it is clear that IOC was negatively associated with CBD injury, it is less clear that all injuries would have been prevented had an IOC been performed. For example, a thermal injury to the CBD during dissection would go unrecognized by IOC and might present only days later. As well, in several anecdotal cases of CBD injury the IOC was misinterpreted or disregarded, or dissection followed a properly obtained and interpreted IOC that then resulted in injury. The finding that injury was nearly half as likely when IOC was used suggests that a randomized controlled trial should be conducted to prove the hypothesis that many CBD injuries are preventable with increased use of IOC.

The relationship of IOC and CBD injury should be further investigated to determine whether more routine use of IOC might act as a “system-level” modification in the prevention of surgical error. There are many issues that influence recommendations about routine IOC use. These include efficacy, cost (D.R.F., Christopher Flowers, MD, and David L. Veenstra, PhD, unpublished data, 2001), resource utilization, and reimbursement considerations. In the interim, this study suggests that surgeons should consider the increased use of IOC, especially in their early experience with LC.

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REFERENCES