

Intraoperative Cholangiography and Risk of Common Bile Duct Injury During Cholecystectomy

David R. Flum, MD, MPH

E. Patchen Dellinger, MD

Allen Cheadle, PhD

Leighton Chan, MD, MPH

Thomas Koepsell, MD, MPH

CHOLECYSTECTOMY IS THE MOST commonly performed elective abdominal surgical procedure in the United States with more than 750 000 performed yearly.¹ Injury to the common bile duct (CBD) during cholecystectomy occurs infrequently, but it is an important source of patient morbidity. Serious injuries often require at least 1 surgical repair, and these repairs have variable long-term outcomes.² Furthermore, CBD injury is the leading cause of medical malpractice claims against general surgeons.^{3,4}

The use of intraoperative cholangiography (IOC), the injection of radiographic contrast material into the cystic duct to evaluate the CBD, may prevent a CBD injury during cholecystectomy. Since Mirizzi⁵ introduced IOC in the 1930s, its benefit has been extensively debated. Some surgeons advocate routine IOC use^{6,7} while others advise selective^{8,9} or no use. Intraoperative cholangiography can provide information about the presence of CBD stones and show a surgical road map of the CBD. It can provide an early warning¹⁰ for the most seri-

For editorial comment see p 1691.

Context Intraoperative cholangiography (IOC) may decrease the risk of common bile duct (CBD) injury during cholecystectomy by helping to avoid misidentification of the CBD.

Objective To characterize the relationship of IOC use and CBD injury while controlling for patient and surgeon characteristics.

Design, Setting, and Patients Retrospective nationwide cohort analysis of Medicare patients undergoing cholecystectomy from January 1, 1992, to December 31, 1999. Patients were identified using Current Procedural Terminology codes from the Medicare Part B depository. Common bile duct injury was defined by a second surgical procedure to repair the CBD injury within 1 year of cholecystectomy. Surgeon demographic features were obtained from matching the Medicare Part B data to the American Medical Association Physician Masterfile database.

Main Outcome Measure Frequency of CBD injury in patients who did and did not have IOC performed during cholecystectomy, controlling for patient-level (age, sex, race, and case complexity) and surgeon-level (surgeon's age, sex, race, year of surgical procedure, case order, percentage of IOC use in prior surgical procedures, years in medical practice, board certification, and specialization) factors.

Results The database search identified 1 570 361 cholecystectomies and 7911 CBD injuries (0.5%). Common bile duct injury was found in 2380 (0.39%) of 613 706 patients undergoing cholecystectomy with IOC and in 5531 (0.58%) of 956 655 patients undergoing cholecystectomy without IOC (unadjusted relative risk, 1.49; 95% confidence interval, 1.42-1.57). After controlling for patient-level factors and surgeon-level factors, the risk of injury was increased when IOC was not used (adjusted relative risk, 1.71; 95% confidence interval, 1.38-2.28). While surgeons performing IOCs routinely had a lower rate of CBD injuries than those who did not, this difference disappeared when IOC was not used.

Conclusions In this study of Medicare patients undergoing cholecystectomy in the 1990s, the risk of CBD injury was significantly higher when IOC was not used. Although IOCs may not prevent all CBD injuries, this study suggests that the routine use of IOC may decrease the rate of CBD injury.

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ous type of surgical misperception, the misidentification of the CBD as the cystic duct.^{11,12} Thus, the informa-

tion obtained from the IOC may prevent and decrease the severity of CBD injuries.¹²

Author Affiliations: The Robert Wood Johnson Clinical Scholars Program (Drs Flum and Koepsell), the Departments of Surgery (Drs Flum and Dellinger), Health Services (Dr Cheadle), and Rehabilitation Medicine (Dr Chan), University of Washington; and the Division of Clinical Standards and

Quality, Centers for Medicare and Medicaid Services Region 10 (Dr Chan), Seattle, Wash.

Corresponding Author and Reprints: David R. Flum, MD, MPH, University of Washington, Department of Surgery, BB 431, 1959 N E Pacific St, Box 356410, Seattle, WA 98195-6410 (e-mail: daveflum@u.washington.edu).

Two prior population-based, retrospective studies have suggested a reduction in the risk of CBD injury with IOC use.^{13,14} Unfortunately, these studies had a relatively small population size and could not adjust for important surgeon-level factors. The purpose of this study was to characterize the relationship of IOC use and CBD injury while controlling for patient and surgeon characteristics; specifically, to distinguish the effect of a surgeon performing IOCs routinely from the effect of the IOC itself on the rate of CBD injury.

METHODS

Study Design

We used a retrospective cohort design, using complete, nationwide Medicare Part B data (January 1, 1992, to December 31, 1999) that contained *Current Procedural Terminology (CPT)* codes pertaining to cholecystectomy and/or biliary tract disease. This study was exempted from University of Washington human subjects review.

Data Sources and Setting

Medicare's Part B files consist of a series of line items, with each line representing a discrete service for which a payment claim was made to Medicare for an individual patient. These data, generated from the medical claims depository, include all billing information for Medicare inpatients and outpatients seen in the fee-for-service arena during the study years. Each billing line has information regarding the physician providing the care, the CPT code for the service performed, associated *International Classification of Diseases, Ninth Revision (ICD-9)*¹⁵ diagnostic codes, and demographic information about the patient. Medicare's unique physician identification number was used to match Medicare Part B data to the American Medical Association (AMA) Physician Masterfile database, as previously described.¹⁶ The AMA Physician Masterfile includes information on physicians/surgeons, such as age, race, sex, specialty in surgery, board certification status during the year of the surgical procedure, and year of graduation from medical

school. Of the surgeons identified in the Medicare Part B depository, 2% could not be matched to the AMA Physician Masterfile. A complete-case analysis was performed on all surgeons identified in the AMA Physician Masterfile.

Subjects

Patients were defined as having likely CBD injuries if they had undergone a cholecystectomy with IOC (CPT codes 49311, 56341, 47563, 47605, 74300, and/or 74301) or without IOC (CPT codes 49310, 56340, 56342, 47562, 47600, 47610, 47612, or 47620 without codes for IOC) followed by surgical repair of the CBD (CPT codes 47701, 47720, 47721, 47740, 47760, 47765, or 47780) within the subsequent 12 months of cholecystectomy. We excluded patients with diagnoses of hepatobiliary malignancies or choledochal cysts (ICD-9 diagnostic codes 155.1, 156, 156.1, 156.8, and/or 156.9).

Definition of Variables

Patient-Level Covariates. The modified Charlson comorbidity index (0-3, with 3 indicating greatest comorbidity)¹⁷ was calculated for each patient based on ICD-9 diagnostic codes from all index and all prior medical records that contained an ICD-9 diagnostic code for biliary tract disease. Medical records with associated ICD-9 diagnostic codes of pancreatitis, CBD stone, cholangitis, sepsis, acute cholecystitis, or CPT codes for CBD exploration, were defined as *complex biliary tract disease*.

Surgeon-Level Covariates. The number of cholecystectomies performed by each surgeon prior to a given cholecystectomy was defined as *case order*, and this number was used as a marker of surgical experience at that point in time. *Early case order* was defined as the lowest quartile of case orders, that is, the surgeon's first 20 cholecystectomies. Case order also was considered as a continuous variable. *Routine* and *selective* IOC were defined by the percentage of prior cholecystectomies performed with an IOC. This percentage was considered a marker for the surgeon's frequency of IOC use. Surgeons who perform rou-

tine IOCs were defined as those using IOCs in at least 75% of surgical procedures. Frequency of IOC use also was considered as a continuous variable.

Statistical Analysis

Descriptive statistics on patient-level and surgeon-level variables were compared for patients with and without CBD injury and for patients who did or did not undergo IOC (SAS version 7; SAS Institute, Cary, NC). A multivariate logistic regression model was used to analyze the relationship of IOC use and CBD injuries while controlling for clinically relevant covariates (patient-level and surgeon-level variables). Because of the infrequency of CBD injury, the odds ratios approximated the relative risks (RRs). In the first unadjusted model, the sole predictor variable was IOC and the outcome variable was CBD injury. Then this model was augmented to adjust for patient-level covariates (age group, sex, race, and case complexity) and then for both patient-level and surgeon-level covariates (surgeon's age, race, and sex, year of the surgical procedure, case order, frequency of IOC use in other cholecystectomy cases, specialty in surgery, board certification status, and years in practice since medical school).

We accounted for the potential correlation of data from patients treated by the same surgeon using mixed-model estimating techniques (SAS, PROC GENMOD, SAS Institute, Cary, NC).¹⁸ Because of the large number of medical records involved in the study, the mixed-model analysis was performed on a 10% random sample. While this analysis did not affect the point estimate, it did modestly widen the confidence intervals (CIs), and the final reported estimates are based on this 10% sample.

RESULTS

A total of 1570361 Medicare patients underwent cholecystectomy performed by 40210 physicians between 1992 and 1999. Of the cholecystectomies performed, 76% were classified as laparoscopic cholecystectomy, but this

percentage may not include surgical procedures that started out as laparoscopic cholecystectomies and then were converted to open cholecystectomies. For this reason, the study results did not distinguish between laparoscopic and open cholecystectomies.

Common bile duct injury was identified in 7911 (0.5%) cholecystectomies. Patients who had a CBD injury, compared with patients without CBD injury, had a higher mean (SD) age (73.5 [9.5] years vs 71.4 [10.5] years), were less likely to be female (53.9% vs 62.9%), were more commonly operated on by surgeons performing 1 of their first 20 recorded cholecystectomies (35.1% vs 24.8%), had a higher mean (SD) comorbidity index (0.76 [0.96] vs 0.06 [0.22]), and were more likely to have complex biliary tract disease (14.2% vs 10.9%) (TABLE 1).

Intraoperative cholangiograms were performed in 39% (n=613 706) of all patients who underwent a cholecystectomy. Patients who did and did not have an IOC had similar features (TABLE 2) with clinically minor (although statistically significant [$P<.001$]) differences in age, sex, and case order.

Nonuse of IOC was associated with an increased risk of CBD injury when an IOC was performed. Common bile duct injury was found in 2380 (0.39%) of 613 706 patients undergoing cholecystectomy with IOC and in 5531 (0.58%) of 956 655 patients undergoing cholecystectomy without IOC (unadjusted RR, 1.49; 95% CI, 1.42-1.57). After adjusting for patient-level factors, the RR of CBD injury when IOC was not used was 1.51 (95% CI, 1.44-1.58). After adjusting for patient-level and surgeon-level factors, the RR of CBD injury when IOC was not used was 1.71 (95% CI, 1.61-1.81). After accounting for the potential correlation of observations for any given surgeon, the RR was 1.71 but the CI widened (95% CI, 1.38-2.28).

Only 1 in 5 surgeons (21.5%) routinely performed IOC (>75% of cholecystectomies performed). In general, surgeons who performed IOCs in a lower percentage of cases had a higher rate of patients with CBD injury than those who

routinely performed IOC (FIGURE). The effect of using IOC in a given patient was different among surgeons in different IOC frequency of use categories (TABLE 3). When surgeons infrequently performed IOCs (<25%), the rate of CBD injury was actually higher than when they did not perform IOC (0.78% vs 0.49%, respectively). When surgeons more commonly performed IOCs (25%-75%), the rate of CBD injury was lower than when they did not perform IOC. This association be-

tween frequency of IOC use and CBD injury increased in surgeons who performed IOCs routinely (>75%), for whom the rate of CBD injury was approximately 6 times higher than if IOC was not performed (0.26% vs 1.50%).

Use of IOC decreased over time with 44.9% of patients in 1992 but only 35.8% of patients in 1999 having an IOC. Controlling for case order, cholecystectomies after 1997 were 26% less likely to have had an IOC than those before 1997 (odds ratio, 0.74; 95% CI, 0.72-0.77).

Table 1. Characteristics of Patients With and Without Common Bile Duct (CBD) Injury

Variable	Without CBD Injury (n = 1 562 450)	With CBD Injury (n = 7911)
Patient-level variables		
Age, mean (SD), y	71.4 (10.5)	73.5 (9.5)
Sex, % female*	62.9	53.9
Race, % white/non-Hispanic	88.8	88.2
Complex biliary tract disease, %*	10.9	14.2
Comorbidity index, mean (SD)*	0.06 (0.22)	0.76 (0.96)
Surgeon-level variables		
Age, mean (SD), y*	48.4 (9.5)	47.7 (9.6)
Sex, % male	96.7	96.6
Percent performed in the surgeon's first 20 cholecystectomies*†	24.8	35.1
Case order, mean No. (SD)*†	64.3 (59.2)	62.9 (61.5)
General surgeon/surgical specialist, %‡	95.6	95.5
Surgeon board certified, %*	80.8	82.4
Years since surgeon graduated from medical school, mean (SD)*	22.1 (9.8)	21.5 (9.6)

*Differences were statistically significant ($P<.001$).

†Case order among Medicare patients from January 1, 1992, to December 31, 1999.

‡Specialty code designated as general surgeon or other specialist.

Table 2. Characteristics of Patients With and Without Intraoperative Cholangiography (IOC)

Variables	With IOC (n = 613 706)	Without IOC (n = 956 655)
Patient-level variables		
Age, mean (SD), y*	71.7 (10.3)	71.2 (10.7)
Sex, % female*	62.6	63.2
Race, % white/non-Hispanic	88.9	88.8
Complex biliary tract disease, %	10.9	11.0
Comorbidity index, mean (SD)*	0.04 (0.22)	0.08 (0.24)
Surgeon-level variables		
Age, mean (SD), y*	48.1 (9.3)	48.6 (9.6)
Sex, % male*	96.8	96.7
Percent performed in the surgeon's first 20 cholecystectomies*†	24.6	25.0
Case order, mean No. (SD)*†	70.5 (61.3)	66.6 (57.7)
General surgeon/surgical specialist, %‡	95.6	95.6
Surgeon board certified, %*	82.6	79.6
Years since surgeon graduated from medical school, mean (SD), y*	21.8 (9.6)	22.3 (9.6)

*Differences were statistically significant ($P<.001$).

†Case order among Medicare patients from January 1, 1992, to December 31, 1999.

‡Specialty code designated as general surgeon or other specialist.

COMMENT

The results of our study indicated that not using an IOC during cholecystectomy was associated with a 50% to 70% increase in the risk of CBD injury. Even after controlling for important patient-level and surgeon-level factors, we found that the adjusted RR of CBD injury during cholecystectomy was 71% higher when IOC was not used. Surgeons who routinely performed IOCs had a lower rate of patient CBD injuries than those who performed IOCs less than routinely, but only when IOC was used. This study suggests that routine use of IOC during cholecystectomy may decrease the rate of CBD injury.

For years, some surgeons have speculated that IOC use can decrease both the absolute rate and the seriousness of CBD injuries,^{11,12} but because of the infrequent nature of CBD injury, no properly conducted controlled trials have evaluated this hypothesis. Because of the large sample size required for such a trial, conducting large observational studies may be the only feasible way to address the relationship of CBD in-

jury and IOC use. The Medicare Part B depository was an attractive way to obtain information about a large number of individuals, and because IOC has a unique surgical CPT code, the information was readily available.

Previous observational studies have addressed the issue of CBD injury and IOC use. For example, Fletcher et al¹⁴ demonstrated a 50% reduction in the rate of CBD injury when IOC was used among a cohort of patients in Western Australia during the early 1990s. Our group examined the frequency of CBD injury in Washington State from 1991 to 1997 and found that for laparoscopic cholecystectomies, the risk of CBD injury was 67% higher when an IOC was not used.¹³ Surgeon experience modified the effect of the IOC on CBD injury, and among surgeons performing their first 20 laparoscopic cholecystectomies, the risk of CBD injury was 2.2 times higher when IOC was not used.

Our findings in this study extend our previous work in that we have examined the largest cohort to date and we have controlled for important patient-level and surgeon-level variables. Another important distinction of our current analysis from previous observational studies is that we have evaluated a surgeon's previous use of IOC and its relationship to CBD injury. Surgeons who routinely use IOC may be different in other ways that offer protection from CBD injury. For example, if surgeons who routinely use IOC are generally more cautious or more protective of the CBD and have a lower rate of CBD injury than those

who infrequently use IOC, observational studies, such as these cited herein, might ascribe this lower rate to the increased use of IOC.

Of all surgeons, we found that those who routinely used IOC had the lowest rates of CBD injury, but only in those cases in which they actually used IOC. In fact, among surgeons who routinely used IOC, when a decision was made not to use IOC (or when an IOC could not be obtained) we saw a significantly higher rate of CBD injury. This increased rate may indicate that in certain clinical situations, both a higher risk of CBD injury and a greater likelihood of not having an IOC performed exist. In Mirizzi syndrome^{19,20} in which the gall bladder is inflamed and adjoined to the CBD or when anatomic variants are present, an IOC may be difficult to perform and the patient may be at a higher risk for injury. Interestingly, surgeons who infrequently use IOC were shown to have a higher rate of CBD injury when using the IOC. This higher rate may be because they used IOC at later points in the surgical procedure, specifically when a CBD injury was already suspected. Alternatively, the performance of the IOC may cause damage to the CBD in certain situations encountered by surgeons who infrequently perform IOC.

While observational studies cannot show that IOC use prevents CBD injury, several components to this association are compelling. The rate of CBD injury was higher when IOC was not used. This association persisted when controlling for many important patient-level and surgeon-level factors and showed a stronger association when these factors were accounted for. In addition, this study is the third population-based analysis that has shown this effect, and all 3 studies have demonstrated a similar magnitude of effect.^{13,14} If this association is causal, then a change in surgeon behavior to more frequently perform IOC could potentially decrease the rate of CBD injury.

It may be argued that the absolute risk reduction associated with IOC (ap-

Figure. Frequency of Use of Intraoperative Cholangiography (IOC) by Surgeons and the Rate of Common Bile Duct Injury (CBD)

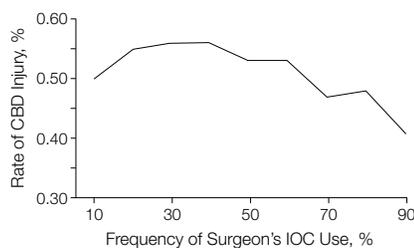


Table 3. Rate of Common Bile Duct (CBD) Injury Based on the Surgeon's Frequency of Intraoperative Cholangiogram (IOC) Use With and Without IOC Use

IOC Use Categories	Rate of CBD Injury, %		
	Overall*	Without IOC	With IOC†
<25% (n = 741 742)	0.52	0.49	0.78
25%-49% (n = 279 270)	0.54	0.56	0.50
50%-75% (n = 211 880)	0.51	0.85	0.31
>75% (n = 337 469)	0.43	1.50	0.26
All (N = 1 570 361)	0.50	0.58	0.39

*Differences between the overall rate in the greater than 75% IOC use group compared with all other levels of IOC use were statistically significant ($P < .001$).

†Differences between CBD rates with and without IOC were all statistically significant ($P < .001$).

proximately 0.2%) does not warrant the added time and cost. However recent cost analyses^{21,22} suggest significant gross savings, and in a modeled analysis, IOC routinely performed was associated with a cost/life-year saved of approximately \$13 000.²² Routine application of IOC might be considered unnecessary because only certain patients are at high risk for CBD injury, and in this group, selective use of IOC has been advocated.^{8,9} However, until there is accurate prediction of which patients are more likely to have CBD injury, the recommendation for routine IOC application may remain the best approach.

A final argument against routine use of IOC deals with the rarity of CBD injury, and that many surgeons practice their entire careers without using IOC and without resulting in CBD injuries.⁸ Because of the relative infrequency of CBD injury, the benefit of IOC use may not be detectable within the case series of an individual surgeon. Nonetheless, when considering CBD injury from a public health perspective, the experience of the community at large is more important than the experience of individual surgeons.

The routine use of IOCs will not prevent all CBD injuries. An IOC has to be correctly performed and interpreted to assist the surgeon in identifying the CBD, and injuries can occur after an IOC has been performed. Furthermore, the rate of other types of injuries, such as those caused by cautery and excessive traction on the bile duct, may not be affected by increased use of IOC. Use of IOC also is not without risk, although the risk is quite small. For example, a case of an allergic reaction to the contrast used in IOC has been reported.²³

Other less-invasive approaches to evaluating the biliary tract tree aimed at decreasing the rate of CBD injury exist. For example, intraoperative ultrasonography of the biliary tract tree may be used to obtain images of the bile duct, and in limited series, this imaging procedure has been helpful in evaluating biliary tract anatomy.^{24,25} Other technical interventions that may reduce the

risk of CBD injury include beginning the dissection on the laterally retracted gallbladder rather than the cystic duct/CBD junction,^{26,27} avoiding blood in the surgical field, early identification of a surgical safety zone,²⁸ using a 30° angled laparoscope,²⁹ and having a low threshold for conversion to open cholecystectomy.³⁰ All these interventions should be considered, but because of the infrequent nature of CBD injury none of these approaches has been shown, in an appropriately powered study, to reduce the rate of CBD injury.

This study has several limitations. Our study, as with all observational studies, was unable to control for other unmeasured variables, such as hospital characteristics, that may affect CBD injury. While a recent study demonstrated that low hospital volume was associated with adverse outcome,³¹ hospital factors have not been related to either the rate of CBD injury or the use of IOC.¹³ Another possible limitation of this study relates to the quality of the administrative coding. While the accuracy of clinical conclusions drawn from administrative data may be imperfect, our findings closely match those based on more clinical sources.³²⁻³⁴ For example, a rate of CBD injury of 0.5% matches that identified by a recently published review of more than 114 000 patients from 40 large case series.³⁵ Direct validation of the use of administrative codes for detection of CBD injury found this data source to be accurate³⁶ despite an earlier report that pointed out the pitfalls of using so-called "injury codes"³⁷ for the detection of these injuries. Furthermore, in a study³⁸ of patients in Maryland, there was a high level of agreement (96%-97%) between Part B Medicare data and physicians' office medical records regarding procedures.

Several unique features of this dataset also limit the conclusions of the study. Using administrative codes to evaluate cholecystectomy did not allow for the clear distinction of open and laparoscopic procedures, possibly resulting in inconsistent coding of converted laparoscopic procedures. A laparoscopic procedure in which a CBD injury was sus-

pected, prompting a change to an open procedure, might have been coded as an open procedure. This would spuriously increase the rate of CBD injury in open procedures and decrease this rate in laparoscopic procedures.

This study could not determine the intent of IOC use and could not distinguish among IOCs performed to prevent injury, used to detect injury when one was suspected, and intended to detect a CBD stone. Furthermore, this study focused on major CBD injuries by defining injury as a second surgical event within 12 months following cholecystectomy. In fact, many minor CBD injuries may be treated with endoscopic or percutaneous interventions. Therefore, the rate of CBD injury detailed in this study may underrepresent the actual rate of CBD injuries in this population and minor injuries were probably missed after IOC use.

We selected a follow-up interval extending to 1 year after cholecystectomy for surgical repair of CBD injury in determining CBD injury because in one of the larger case series of repairs of the CBD, all patients were operated on within 1 year after cholecystectomy.¹¹ By not including repairs that occurred after 1 year we may have undercounted actual CBD injuries.

Additionally, case order in this study was derived from all cholecystectomy procedures performed in patients covered by Medicare fee-for-service from 1992 to 1999. The case order variable likely undercounted surgeon experience by not including surgical procedures performed before 1992 and those performed in patients who were not covered through Medicare fee-for-service. Therefore, case order is likely defined on the basis of nonconsecutive cases and was considered a proxy marker of surgeon experience rather than a direct measure of this experience. Similarly, the frequency of IOC use by the surgeon should be considered a proxy for the frequency of IOC use performed by any given surgeon because it was determined by Medicare Part B data only. Lastly, some medical records may have been incomplete, for example, if the pa-

tient died before having a CBD injury repaired or if their health care coverage shifted to a health maintenance organization after the cholecystectomy was performed. The impact of these factors on the analysis is unclear.

In conclusion, among Medicare patients in the 1990s, the rate of CBD injury during cholecystectomy was significantly higher when IOC was not

used. This study suggests that the broader use of IOC may decrease the rate of CBD injury.

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Acquisition of the data: Chan.

Analysis and interpretation of the data: Flum, Dellinger, Cheadle, Chan, Koepsell.

Drafting of the manuscript: Flum, Dellinger, Cheadle, Chan, Koepsell.

Critical revision of the manuscript: Flum, Dellinger, Chan, Koepsell.

Statistical expertise: Flum, Chan, Koepsell.

Administrative, Technical or Material Support: Cheadle, Chan, Koepsell.

Study supervision: Dellinger, Chan.

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