Bile Duct Injury During Cholecystectomy and Survival in Medicare Beneficiaries

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Context Common bile duct (CBD) injury during cholecystectomy is a significant source of patient morbidity, but its impact on survival is unclear.

Objective To demonstrate the relation between CBD injury and survival and to identify the factors associated with improved survival among Medicare beneficiaries.

Design, Setting, and Patients Retrospective study using Medicare National Claims History Part B data (January 1, 1992, through December 31, 1999) linked to death records and to the American Medical Association's (AMA's) Physician Masterfile. Records with a procedure code for cholecystectomy were reviewed and those with an additional procedure code for repair of the CBD within 365 days were defined as having a CBD injury.

Main Outcome Measure Survival after cholecystectomy, controlling for patient (sex, age, comorbidity index, disease severity) and surgeon (procedure year, case order, surgeon specialty) characteristics.

Results Of the 1570361 patients identified as having had a cholecystectomy (62.9% women), 7911 patients (0.5%) had CBD injuries. The entire population had a mean (SD) age of 71.4 (10.2) years. Thirty-three percent of all patients died within the 9.2-year follow-up period (median survival, 5.6 years; interquartile range, 3.2-7.4 years), with 55.2% of patients without and 19.5% with a CBD injury remained alive. The adjusted hazard ratio (HR) for death during the follow-up period was significantly higher (2.79; 95% confidence interval [CI]; 2.71-2.88) for patients with a CBD injury than those without CBD injury. The hazard significantly increased with advancing age and comorbidities and decreased with the experience of the repairing surgeon. The adjusted hazard of death during the follow-up period was 11% greater (HR, 1.11; 95% CI, 1.02-1.20) if the repairing surgeon was the same as the injuring surgeon.

Conclusions The association between CBD injury during cholecystectomy and survival among Medicare beneficiaries is stronger than suggested by previous reports. Referring patients with CBD injuries to surgeons or institutions with greater experience in CBD repair may represent a system-level opportunity to improve outcome.

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CHOLECYSTECTOMY IS THE MOST commonly performed elective abdominal surgical procedure (~750000 each year) in the United States.[1] Common bile duct (CBD) injury occurs in 1 of 200 cholecystectomies, is a significant source of patient morbidity after gallbladder surgery, and is the leading source for medical malpractice claims against general surgeons.[1] Repair of a damaged CBD is a technically challenging undertaking that may best be performed by experienced hepatobiliary surgeons. Published results of CBD repair by such surgeons consistently demonstrate a low risk of operative mortality and high rates of short-term and intermediate-term success without the need for reoperation.[2] Reviews of cases that result in litigation, however, indicate a different clinical course for patients with CBD injury.[3] These patients have a high rate of required reoperation, perioperative mortality, and significant deficits in long-term quality of life and functional status. Determining the community-level burden of CBD injury is challenging because both types of reports are susceptible to bias. Reports by experienced surgeons may involve publication bias and reports of cases that progress to litigation may involve selection bias.

The purpose of this study was to describe the impact of CBD injury among Medicare beneficiaries who had undergone cholecystectomy. Specifically, we sought to determine the population-level risk of death after CBD injury, to describe the impact of patient and physician factors on survival, and to identify any system-level interventions that might help improve outcome after CBD injury.

METHODS

Study Design

We used a retrospective cohort design, using Medicare National Claims History (NCH) Part B data from January 1, 1992, through December 31, 1999, that contained *Current Procedural Terminology* (CPT) codes pertaining to either a cholecystectomy, a CBD repair, or biliary disease. The method for determining CBD injury has been previously published.[1] This study

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was exempted from University of Washington Human Subjects Review.

Data Sources and Setting

The Medicare NCH Part B database, maintained by the Center for Medicare & Medicaid Services (CMS), contains all the payment claims for the professional component of services delivered to Medicare beneficiaries in either the inpatient or outpatient setting. Each claim for services delivered to a beneficiary can have 1 or more discrete billable service listed, along with information about each service that includes the coded identifier of the physician providing the care, the type of service performed, and the associated *International Classification of Diseases, Ninth Revision* (*ICD-9*) diagnostic codes. The Medicare Health Insurance Claim (HIC) number identifies the patient for whom the services were delivered. Medicare's Unique Physician Identification Number (UPIN) was used to match Part B data to the American Medical Association (AMA) Physician Masterfile in a previously described process.[4] The AMA Physician Masterfile includes data on physician specialty, board certification status during the year of the procedure, surgeon age, race, sex, and year of graduation from medical school. For this analysis, physicians whom the AMA database described as general surgeons or surgical subspecialists were considered surgical specialists. Two percent of Medicare providers could not be matched to the AMA data.

The date of death was obtained from the Enrollment Database, also maintained by CMS, by matching on the beneficiary HIC number. The date of death in the Enrollment Database is derived from the Social Security Administration's database, Master Beneficiary Record. Of all records, 2.5% did not have complete Enrollment Database data. Complete-case-only analysis was performed.

Patients and Variable Definition of CBD Injury

Patients were defined as likely having CBD injuries if they had a cholecystectomy with intraoperative cholangiogram (CPT codes: 49311, 56341, 47563, 47605, 74300, and/or 74301) or without intraoperative cholangiogram (CPT codes: 49310, 56340, 56342, 47562, 47600, 47610, 47612, or 47620 without codes for intraoperative cholangiogram) followed by reoperative repair of the CBD (CPT codes: 47701, 47720, 47721, 47740, 47760, 47765, or 47780) within the subsequent 365 days. We excluded patients with diagnoses of hepatobiliary malignancies or choledochal cysts (*ICD-9* diagnostic codes: 155.1, 156, 156.1, 156.8, 156.9).

Patient-Level Covariates

The Deyo modification[5] of the Charlson comorbidity index (0-3, with 3 indicating greatest comorbidity) was calculated for each patient based on *ICD-9* diagnostic codes from all index records and all prior records that contained a diagnostic code for biliary disease. Records with associated diagnosis codes of pancreatitis, CBD stone, cholangitis, sepsis, and acute cholecystitis or procedure codes including CBD exploration were considered complex.

Physician-Level Covariates

The number of repair procedures (among patients covered by Medicare after 1992) performed by each repairing surgeon before a given operation was defined as *repair case order* and was considered a marker of surgical experience at the time of the procedure. Repair case order was also considered as a continuous variable.

Analysis

The relationship of CBD injury and survival was assessed using multivariable Cox proportional hazard regression analyses. The comparator group for the relative hazard ratio (HR) of mortality after CBD injury included all patients without CBD injury. Reported adjusted hazards for individual variables were in comparison with the lower value of that specific variable. The median follow-up for the entire cohort was 5.6 years, with 25% of patients followed up for 7.4 years or more. The longest follow-up was 10.6 years, and the longest common (for both injured and noninjured patients) follow-up point was 9.2 years. Survival was measured as the time from cholecystectomy until death or August 15, 2002. The proportional hazards assumption was confirmed by inspection of Schoenfeld residuals and log-log plotting.

The cumulative incidence of death was estimated for the entire cohort and then tested between groups of interest (those with and without injury) and graphed as Kaplan-Meier plots. Unadjusted analyses were compared using the log-rank test. Cox regression was used to estimate simultaneously the effect of potential confounders on the association between patient and surgeon characteristics and the hazard of death and to provide estimates of adjusted survival at discrete time points. The analysis was repeated on the cohort that was younger than 65 years to assess the impact of CBD injury on survival in this younger subset of the population. Cox proportional hazards were estimated using SAS (Version 8, SAS Institute, Cary, NC) and STATA (Version 7, STATA Corp, College Station, Tex). A P value of $<.01$ was considered statistically significant.

RESULTS

A total of 1 570 361 patients—62.9% of whom were women and whose mean (SD) age was 71.4 (10.2) years—had a cholecystectomy. Of those 7911 (0.5%) were identified as having CBD injuries. Demographic characteristics of patients with and without CBD injury have been previously decribed[1] (TABLE 1). Injured patients were slightly older, were more likely men, had a higher comorbidity index, and were more likely to have had a cholecystectomy that was considered complex. One third of all patients died within the follow-up period (median survival 5.6 years, interquartile range, 3.2-7.4 years). By the last common follow-up point (9.2 years), 55.2% of patients without CBD injury were alive vs only 19.5% of patients who had a CBD injury. Most of the impact of CBD injury appeared in the first 2 years (FIGURE) after the cholecystectomy. Within the first year after cholecystectomy, the mor-

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tality rate (adjusted for age, sex, and comorbid illness) was 6.6% in patients without CBD injury and 26.1% in those with injury. After approximately 3 years, the rates of death appeared to equalize. The unadjusted HR for death was 4.09 times higher (95% confidence interval [CI], 4.06-4.11) and the adjusted HR for death 2.8 times higher (HR 2.79; 95% CI, 2.71-2.88) for patients with a CBD injury vs those without injury. The HR significantly increased with advancing age, case complexity, and comorbidity index (TABLE 2). The impact of CBD injury on survival was also identified in younger patients (Figure). Of the 178 381 patients in the younger cohort (mean [SD] age, 54.8 [10.9] years), the HR of death after CBD injury (adjusting for sex, age, and comorbidity index) was 2.7 times higher than among those without CBD injury (95% CI, 2.4-3.0), even though the absolute rate of death was lower in this younger cohort.

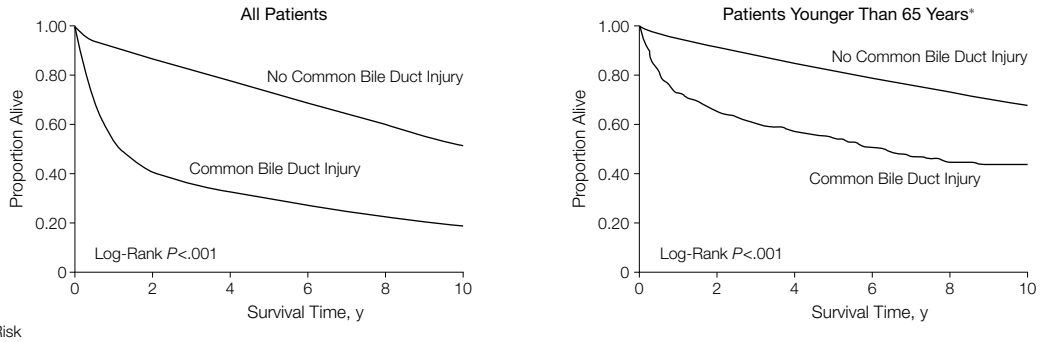
There were 1 458 821 patients without and 7719 patients with CBD injury who had complete records available for survival analysis. Overall, 91.4% of these patients underwent only 1 operative repair and the odds of a patient having multiple repair operations decreased by 30% with each successive year compared with the year before it (odds ratio [OR], 0.70; 95% CI, 0.65-0.82). Only 500 surgeons performed more than 10 repairs. The repairing surgeon was the same as the injuring in approximately 75% of repairs. After adjusting for other patient and surgeon variables, the hazard of death was 11% greater when the repairing surgeon was the same as the surgeon who performed the cholecystectomy (HR, 1.11; 95% CI, 1.02-1.20). Correspondingly, the level of experience of the repairing surgeon was linked to survival. The median number of repairs performed by repairing surgeons was 5 (interquartile range, 2-9) and increasing surgical experience was associated with an increased likelihood of survival. The adjusted hazard for death decreased 11% for every increase of 1 case order in the repairing surgeon's level of experience (HR, 0.89; 95% CI, 0.82-0.98). When considered at each point of the experience curve of the repairing surgeon, with each repair the adjusted hazard of survival to at least 1 year increased by approximately 2% (HR, 0.98; 95% CI, 0.97-1.00) and based on logistic regression the predicted probability of death within the first year after repair was derived for each level of experience.

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

Variable	No CBD Injury (N = 1 562 450)	CBD Injury (n = 7911)
Patient-level variables		
Age-mean (SD), y†	71.4 (10.5)	73.5 (9.5)
Sex, % women†	62.9	53.9
Non-Hispanic white, %	88.8	88.2
Complex biliary 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, % men	96.7	96.6
Percent performed in first 20 cholecystectomies†§	24.8	35.1
Case order, mean (SD)†‖	64.3 (59.2)	62.9 (61.5)
General or specialist, %‖	95.6	95.5
Board certified, %†	80.8	82.4
Years since medical school graduation, mean (SD)†	22.1 (9.8)	21.5 (9.6)

*Adapted from Flum et al.[1]
†Differences statistically significant at $P<.001$.
‡The comorbidity index ranges from 0 to 3, with 3 representing the greatest comorbidity.
§Case order among Medicare patients starting January 1, 1992.
‖Specialty code designated as general surgeon or other surgical subspecialist.

Figure. Proportion Surviving After Common Bile Duct Injury



No. at Risk												
Common Bile Duct Injury												
No	1 458 821	1 265 487	937 488	579 466	278 804	53 543	178 381	161 935	119 007	71 853	33 592	6422
Yes	7719	2942	2056	1288	633	143	576	375	265	154	70	14

Proportion of patients surviving after cholecystectomy with or without common bile duct injury.
*The mean age of those younger than 65 years was 54.8 years.

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Beyond experience, the characteristics of the repairing surgeon had minimal effect on survival after repair. When controlling for all covariates (TABLE 3), the features linked to an increase in the hazard for death were patient age, comorbidity index, and the same surgeon performing both the cholecystectomy and the repair. After controlling for patient factors, those who had more than 1 repair operation were not at significantly higher risk of death (HR, 1.05; 95% CI, 0.97-1.14).

COMMENT

Survival after cholecystectomy-related CBD injury was significantly reduced in a nationwide cohort of nearly 1.6 million Medicare beneficiaries undergoing cholecystectomy. Although this cohort represented approximately one third of all patients undergoing cholecystectomy nationwide in any given year, the age of this cohort was considerably older than the age of all patients undergoing cholecystectomy and included younger patients with disability, renal disease, or both. These patients were nearly 3 times more likely to die within 10 years after cholecystectomy than noninjured patients, even after controlling for age and comorbid illnesses. We also found that improved survival was more likely when a different, more experienced surgeon performed the CBD repair, but that 75% of repair procedures were in fact performed by the same surgeon associated with the injury. Perhaps the most striking finding of this study was the dramatic difference we found between published estimates of mortality after CBD injury and the population-based outcomes. This may help explain the apparent discrepancy between reported outcomes and those described in cases of CBD injury that progress to litigation.

Since an acknowledged influence on the outcome of CBD repair is the expertise of the repairing surgeon[6] and the number of attempted repairs before the definitive repair, it is possible that surgeons with the best results are likely to review and publish their work. In fact, a review of the outcomes of 40 published case series[2] evaluating 561 (0.5) of 114 000 patients with CBD injuries indicated that repair of the CBD resulted in failures in only 4.9% with no reported deaths. In the largest case series to evaluate specifically the outcomes after repair of the CBD, the mortality rate was 0% and the operative success 95%,[7] with a very low rate of reoperation. Reports of repairs of CBD strictures in the open era detailed a rigorous but quite successful procedure with long-term satisfactory results in nearly 90% of those undergoing repair.[8-13] Reported short-term[14] and long-term outcomes[7,15-28] in the laparoscopic era are also quite good (TABLE 4) with 90% to 95% success and a low rate of reported mortality (0%-14.2%). Of these case series, the average length of follow-up was 41.3 months and 17 (2.8%) of 602 patients with CBD injury died. It is difficult to reconcile these excellent outcomes with the significant impairments in quality of life identified after CBD.[29-30]

Several variables may be associated with adverse outcome following CBD repair, including the degree of injury severity,[31] associated vascular injury,[26] and comorbid conditions. One

Table 2. Cox Proportional Hazards of Death After Cholecystectomy by Common Bile Duct (CBD) Injury (N = 1 570 361)

Variable	Hazard Ratio (95% Confidence Interval)	
	Adjusted*	Unadjusted
Patient factors		
CBD injury	2.79 (2.71-2.88)	4.09 (4.06-4.11)
Age per yearly increase†	1.06 (1.06-1.06)	1.06 (1.06-1.06)
Women‡	0.67 (0.66-0.67)	0.69 (0.68-0.70)
Non-Hispanic white‡	0.80 (0.79-0.80)	0.95 (0.94-0.95)
Charlson comorbidity index per increase in unit, scale 0-3†§	1.67 (1.66-1.68)	1.85 (1.84-1.85)
Surgeon factors		
Age†	1.00 (1.00-1.00)	1.00 (1.00-1.00)
Surgical specialist‡	0.95 (0.94-0.95)	0.88 (0.87-0.88)
Case considered complex‡	1.12 (1.11-1.13)	1.21 (1.20-1.22)
Each increase in the number of practice years†	1.00 (1.00-1.00)	1.00 (1.00-1.00)

*Each variable was adjusted for all other variables listed.
†The hazard estimate is for each increase in 1 unit compared with the value before it.
‡The hazard estimate is for the presence of this variable compared with those who were not positive for this variable.
§The value 3 for the comorbidity index indicates the greatest comorbidity.

Table 3. Cox Proportional Hazards of Death After Common Bile Duct Injury for People With Complete Records (n = 7719)*

Variable	Hazard Ratio (95% Confidence Interval)
Patient factors	
Age per yearly increase†	1.03 (1.03-1.03)
Women‡	0.91 (0.70-1.18)
Non-Hispanic white‡	0.92 (0.83-1.00)
Charlson index per increase in unit, scale 0-3†§	1.84 (1.78-1.90)
Repairing surgeon factors	
Age†	1.00 (0.99-1.01)
Surgical specialist‡	1.02 (0.87-1.22)
Board certified‡	0.97 (0.88-1.08)
Same surgeon for cholecystectomy and repair‡	1.11 (1.02-1.20)
Each increase in the number of practice years‡	0.99 (0.97-1.00)
Each increase by 1 in the case-order experience†	0.98 (0.97-1.00)
Multiple repair operations	1.05 (0.97-1.14)

*Each variable was adjusted for patient and repairing surgeon characteristics.
†The hazard estimate is for each increase in 1 unit compared with the value before it.
‡The hazard estimate is for the presence of this variable compared with those who were not positive for this variable.
§The value 3 for the comorbidity index indicates the greatest comorbidity.

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Table 4. Previous Reports of Mortality After Long-term Follow-up of Patients With Major Common Bile Duct (CBD) Injury Following Laparoscopic Cholecystectomy

Source	Follow-up, mo*	Major CBD Injuries	No. of Deaths
Nealon and Urrutia,[15] 1996	32	23	0
Mirza et al,[16] 1997	30	27	1
Gigot et al,[17] 1997	49	65	6
Walsh et al,[18] 1998	36	34	0
Bauer et al,[19] 1998	12	32	1
Taragona et al,[20] 1998	36	16	1
Topal et al,[21] 1999	63	16	1
Lillemoe et al,[7] 2000	25.8	156	0
Johnson et al, [22] 2000	55	27	0
Csendes et al,[23] 2001	Not specified	24	0
Tsalis et al,[24] 2003	52	7	1
Chaudhary et al,[25] 2002	50.4	41	1
Mathisen et al,[26] 2002	60	22	3
Slater et al,[27] 2002	60	64	1
Al-Ghnaniem and Benjamin,[28] 2002	80.4	48	1
Total	41.3	602	17 (2.8%)

*Weighted based on study size.

of the most modifiable components of adverse outcome may relate to the experience of the surgeon. In a study of 46 cases of CBD injury that progressed to litigation, the primary surgeon's repair was successful only 27% of the time vs a 79% success rate among surgeons at referral centers.[32] In that study only 47.8% of these cases were referred to the specialty center. Stewart and Way[33] reported that the rate of successful primary repair to be only 17% when performed by the injuring surgeon who is presumably less experienced at CBD repair.

A more recent evaluation of management trends, however, found that more than 50% of procedures were performed by the primary surgeon[27] and our study further identified a 75% frequency of repair by the initial surgeon. A report from the Connecticut laparoscopic surgery registry demonstrated that a better rate of success was acheived among patients undergoing repairs at the originating hospital than what has been previously noted.[34] However, recent surveys of medical malpractice cases involving CBD injuries reinforce the importance of surgeon experience with repairs and note that on average patients whose procedure was performed by less experienced surgeons had 2.2 repairs with much more varied outcomes.[35]

Population-based evaluations may be helpful in assessing a more generalizeable rate of outcome after CBD injury than that identified in case series. Survival after cholecystectomy in the population at large is good, with mortality rates as low as 0.5% noted in a recent national survey.[36] Mortality after CBD injury, however, is harder to evaluate. In 2 recent analyses from Switzerland, variable mortality rates of 0%[37] and 9.4%[38] were identified after CBD injury, with little other than selection bias to explain this difference. Given that only a fraction of patients are sent to referral centers and that the outcomes of the repair are likely linked to the experience of the surgeon repairing the injury, the community-based rate of mortality after CBD injury is likely to be higher than previously reported.

The results of our study demonstrate the nationwide impact of CBD injury on survival in Medicare beneficiaries and encompass a broad range of surgeon types, experience level, and practice environments. In this way, we believe these findings more closely reflect the experiences of the average patient in the average community. Since this is, in fact, where CBD injuries occur, we believe these estimates are more relevant when counseling patients. Furthermore, evaluations in the community at large may better help identify system-level opportunities for quality improvement.

As detailed in our previous work,[1] there were limitations in both the variables included in this database and the technique used to select patients with CBD injury that may have affected the completeness and accuracy of these estimates. Furthermore, in this analysis we describe survival estimates after cholecystectomy and CBD injury in an older population of patients, and it is unclear to what extent these findings may be generalizeable to the community at large. The average age of patients undergoing cholecystectomy in reported series of CBD injury (47 years)[2] was considerably lower than that identified in our study.

Although the absolute rate of death after CBD injury found in this study may be limited to the population of patients older than 65 years, the relative hazard of death within the follow-up period may have greater applicability to the general community. Although most patients whose care is covered by CMS are older than 65 years, those with chronic renal failure and those who are medically disabled in all age groups are also included. To better evaluate the relevance of our finding in a younger segment of the cohort, we performed a subset analysis on the more than 175 000 patients younger than 65 years (mean age 54.8 years) and found that the HR for death after CBD injury was 2.7 times higher in this younger population compared with the younger patients without a CBD injury. This nearly identical rate suggests that the association between CBD injury and survival is apparent across a broad selection of the population undergoing cholecystectomy.

Unfortunately, cause of death was unavailable in this analysis. There are other components of the data set that are limiting. For example, the case order of the repair is a proxy for case order in that it is derived for each surgeon based only on repairs performed in patients covered by Medicare after 1991. It therefore likely undercounts the experience of surgeons performing repairs in patients not covered by Medicare or before 1992. Given that we found a relationship between surgeon

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inexperience and outcome this may be considered a conservative bias.

Furthermore, given that patients with CBD injury benefit from multimodality care (eg, care provided by gastroenterologists, interventional radiologists, diagnostic radiologists) and that surgeons with greater experience with CBD repair probably also perform procedures at referral centers that specialize in this multimodality care. On some level, surgeon experience may act as a proxy for better hospital resources. Although in this analysis, we could not distinguish the effect of hospital resources on patient outcome from surgeon experience, we believe this potential confounding strengthens the recommendation for patient referral to high-volume centers after CBD injury. Finally, this is a case-only analysis, and records that did not have surgeon-matching information were excluded (about 2% of all patients). The effect of these missing data on the analysis is unclear, but there is no reason to suspect that missing data were related to the exposure of interest.

In conclusion, this is the first study, to our knowledge, that demonstrates the population-based impact of CBD injury on survival. We found that among Medicare beneficiaries, after adjusting for all covariates, patients having a major CBD injury were nearly 3 times more likely to die during the first few years after cholecystectomy compared with patients without CBD injury. Improved survival was noted when the repair was performed by a different surgeon than the one who performed the cholecystectomy. Similarly, increased experience of the repairing surgeon was linked to better outcomes. Based on this nationwide analysis, we suggest that patients with CBD injury should be referred to a surgeon and to an institution with greater experience in CBD repair. This may represent a system-level opportunity to improve outcome after CBD injury during cholecystectomy.

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