SCIENTIFIC PAPER JSLS

Is Laparoscopy a Risk Factor for Bile Duct Injury During Cholecystectomy?

Terrence M. Fullum, MD, Stephanie R. Downing, MD, Gezzer Ortega, MD, MPH, David C. Chang, PhD, MPH, MBA, Tolulope A. Oyetunji, MD, Kendra Van Kirk, BA, MAT, Daniel D. Tran, MD, Ian Woods, BS, Edward E. Cornwell, MD, Patricia L. Turner, MD

ABSTRACT

Background and Objectives: Previously, risk factors for bile duct injury have been identified as acute cholecystitis, male gender, older age, aberrant biliary anatomy, and laparoscopic cholecystectomy.

Methods: A retrospective analysis of the Nationwide Inpatient Sample from 1998 to 2006 was performed with an inclusion criterion of cholecystectomy performed on hospital day 0 or 1. Patient- and hospital-level factors potentially associated with bile duct injury were examined by logistic regression.

Results: A total of 377,424 cholecystectomy patients were identified. There were 1124 bile duct injuries (0.30%), with 177 (0.06%) in the laparoscopic cholecystectomy group and 947 (1.46%) in the open cholecystectomy group ($P <$ .001). On multivariate analysis, significant risk factors for bile duct injury were male gender (odds ratio [OR], 1.21; 95% confidence interval [CI], 1.06–1.38; $P =$ .006), age >60 years (OR, 2.23; 95% CI, 1.61–3.09; $P <$ .001), and academic hospital status (OR, 1.37; 95% CI, 1.05–1.79; $P =$ .02). Acute cholecystitis was associated with a lower risk of bile duct injury (OR, 0.67; 95% CI, 0.46–0.99; $P =$ .044).

Conclusion: Independent risk factors for bile duct injury included male gender, age >60 years, and academic hospital status. Laparoscopic cholecystectomy, obesity, insurance status, or hospital volume was not associated with an increased risk of bile duct injury.

Key Words: Iatrogenic bile duct injury, NIS, Risk factors, Cholecystectomy, Laparoscopic

Division of Minimally Invasive and Bariatric Surgery, Howard University College of Medicine, Washington, DC, USA (Drs. Fullum, Tran).

Department of Surgery, Howard University College of Medicine, Washington, DC, USA (Drs. Downing, Ortega, Oyetunji, Cornwell).

Department of General Surgery, University of California San Diego School of Medicine, San Diego, CA, USA (Dr. Chang).

Howard University College of Medicine, Washington, DC, USA (Van Kirk, Woods).

Department of General Surgery, University of Maryland Medical Center, Baltimore, MD, USA (Dr. Turner).

The authors do not have any conflicts of interest or financial disclosures.

Address correspondence to: Terrence M. Fullum, MD, Howard University College of Medicine, 2041 Georgia Ave NW, Ste 4100B, Washington, DC 20059, USA. Telephone: (202) 865-1286, Fax: (202) 865-3063, E-mail: tfullum@howard.edu

DOI: 10.4293/108680813X13654754535638

© 2013 by *JSLS, Journal of the Society of Laparoendoscopic Surgeons*. Published by the Society of Laparoendoscopic Surgeons, Inc.

INTRODUCTION

Each year, more than 400,000 patients undergo a cholecystectomy, most commonly to treat symptomatic cholelithiasis.[1] Though reported to be uncommon, an iatrogenic bile duct injury (BDI) during a cholecystectomy is a serious complication associated with significant morbidity and death.[2–4] Reports in the early 1990s identified laparoscopic cholecystectomy (LC) as a risk factor for BDI.[3,5–8] Several reasons for this phenomenon were cited, the most common being the "learning curve" of a new and technically demanding skill.[9] Subsequently, articles were published describing recommended techniques to reduce BDI during LC. Notable articles included reports by Hunter[10] recommending the use of a 30° laparoscope and avoidance of tenting; Strasberg,[11] who advocated the use of a "critical view" approach; and Kato et al.,[12] who introduced the "dome down" LC. Over the next 15 to 20 years, LC became the standard of care and surgeon experience with minimally invasive techniques increased dramatically. As a result, there has been a significant reduction in the BDI rate, from 0.5% in 1990 to 0.3% in 2009.[4,7] By use of a large population-based dataset, analyses were performed to identify current risk factors for BDI. Specifically, a multivariate analysis was used to determine whether LC was still a risk factor for BDI. We hypothesize that LC is no longer a predictor of BDI based on the assumption that many surgeons have already surpassed the learning curve.

METHODS

A 9-year retrospective analysis was performed of the Nationwide Inpatient Sample (NIS) from 1998 through 2006. The NIS was developed as part of the Healthcare Cost and Utilization Project sponsored by the Agency for Healthcare Research and Quality, established by the federal government. The NIS contains discharge records from

1045 hospitals in 38 states, comprising almost 8 million admissions per year. It is a systematically randomized sample of 20% of all patients admitted to hospitals in the United States.

The inclusion criterion was any record with cholecystectomy as the primary procedure code (*International Classification of Diseases, Ninth Revision* [ICD-9] codes 51.22 [LC] and 51.23 [open cholecystectomy (OC)]) performed on hospital admission day 0 or 1. Procedure codes for bile duct repair (ICD-9 codes 51.36, 51.37, 51.39, 51.71, 51.72, and 51.79) were used as a surrogate for BDI. Patient- and hospital-level factors that were potentially associated with BDI were examined by use of a multivariate analysis. These included age, race, gender, morbid obesity (ICD-9 code 278.01), diagnosis of acute cholecystitis (ICD-9 code 87.50), performance of intraoperative cholangiography (ICD-9 code 87.53), insurance status, academic hospital status, year of procedure (as a surrogate for the impact of time), and hospital annual volume of cholecystectomy. The Charlson comorbidity index was used to adjust for the impact of patient comorbid conditions on risk of death and development of postoperative complications.

The Student t test (for continuous variables) and χ^2 test (for nominal or categorical variables) were used for all bivariate analyses. Adjusted analyses using multiple logistic regressions were performed to determine the independent impact of these variables on the risk of a BDI developing after cholecystectomy. Subset analyses were repeated in patients with acute cholecystitis. All statistical analyses were performed with Stata MP, version 10 (StataCorp, College Station, TX, USA).

Table 1.
Demographics of Patients Who Underwent Cholecystectomy in NIS

	Data
No. of patients	377,424
Median age, y	51
Mean LOS, d	2.8
Gender, n (%)	
Male	112,951 (30.0)
Female	262,985 (70.0)
Ethnicity, n (%)	
White	225,511 (70.8)
Black	25,963 (8.2)
Hispanic	49,887 (15.7)
Other	17,312 (5.4)
Inflammation, n (%)	
Acute cholecystitis	14,650 (3.9)
No acute cholecystitis	362,774 (96.1)
Obesity, n (%)	
Not morbidly obese	368,653 (97.7)
Morbidly obese	8,771 (2.3)
Intervention, n (%)	
OC	64,902 (17.2)
LC	312,522 (82.8)
Year of surgery, n (%)	
1998–2000	127,244 (33.7)
2001–2003	129,783 (34.4)
2004–2006	119,273 (31.9)

RESULTS

A total of 377,424 cholecystectomy patients were identified, of whom 312,522 (82.8%) underwent LC and 64,902 (17.2%) underwent OC. Demographics of these patients are shown in **Table 1**. The mean age at presentation was 51 years, and 70.0% of patients were women. Morbid obesity was a comorbid diagnosis for 2.3% of cholecystectomy patients, with a slightly higher percentage (3.9%) diagnosed with acute cholecystitis. Represented ethnicities were white patients (70.8%), black patients (8.2%), Hispanic patients (15.7%), and patients of other ethnicities (5.3%). Intraoperative cholangiography was performed in 23.5% of the study population. The overall BDI rate was 0.30% (n = 1124). **Table 2** shows the bivariate (unadjusted) analysis by intervention (OC vs LC). Patients who underwent OC were significantly older than those undergoing LC (58.4 years vs 50.0 years, $P < .001$), with an associated increase in length of stay compared with LC patients (5.4 days vs 2.4 days, $P < .001$). Those more likely to undergo OC were men (24.51% vs 14.12% of women, $P < .001$), black patients (18.87% vs 17.55% of white patients, $P < .001$), morbidly obese patients (21.96% vs 17.08% of patients who were not morbidly obese, $P < .001$), and patients with acute cholecystitis (24.63% vs 16.90% of patients without acute cholecystitis, $P < .001$). **Figure 1** shows the increasing proportion of LC compared with OC over the study period.

The bivariate analysis of risk of BDI is shown in **Table 3**. Patients who had a BDI were significantly older than those who had an uneventful cholecystectomy (59.3 years vs 51.4 years, $P < .001$). Those patients who had a BDI had a longer length of stay than uninjured patients (8.1 days vs

Table 2.
Bivariate Analysis by Type of Intervention for Patients Who Underwent Cholecystectomy in NIS

	OC	LC	*P* Value
No. of patients (%)	64,902 (17.20)	312,522 (82.80)	
Mean age, y	58.4	50.0	<.001
Mean LOS, d	5.4	2.4	<.001
Gender, n (%)			<.001
Male	27,679 (24.51)	85,272 (75.49)	
Female	37,136 (14.12)	225,849 (85.88)	
Ethnicity, n (%)			<.001
White	39,580 (17.55)	185,931 (82.45)	
Black	4,899 (18.87)	21,064 (81.13)	
Hispanic	6,795 (13.62)	43,092 (86.38)	
Other	2,795 (16.10)	14,517 (83.90)	
Weight, n (%)			<.001
Not morbidly obese	62,976 (17.08)	305,677 (82.92)	
Morbidly obese	1,926 (21.96)	6,845 (78.08)	
Inflammation, n (%)			<.001
No acute cholecystitis	61,293 (16.90)	301,481 (83.10)	
Acute cholecystitis	3,609 (24.63)	11,041 (75.37)	
Year of surgery, n (%)			<.001
1998–2000	24,581 (19.32)	102,663 (80.68)	
2001–2003	21,588 (16.63)	108,195 (83.37)	
2004–2006	17,786 (14.91)	101,487 (85.09)	

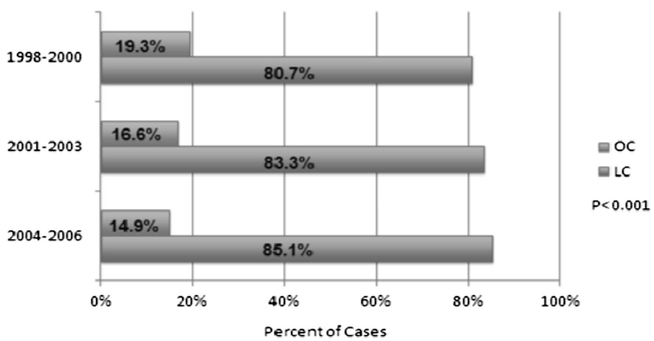

Figure 1. Proportion of cases performed by approach and year of study.

2.9 days, $P < .001$). Men also had a higher incidence of BDI compared with women (0.38% vs 0.27%, $P < .001$). The proportion of OCs performed showed a statistically significant decrease, from 19.5% in the initial 3 years of the study to 15.1% in the past 3 years ($P < .001$). Furthermore, during the same periods, there was a decrease in the overall incidence of documented BDI (0.33% in 1998–2000 vs 0.27% in 2004–2006, $P = .02$) (**Figure 2**).

Table 3.
Bivariate Analysis by Injury for Patients Who Underwent Cholecystectomy in NIS

	BDI	No BDI	*P* Value
No. of patients (%)	1,124 (0.30)	376,300 (99.70)	
Mean age, y	59.3	51.4	<.001
Mean LOS, d	8.1	2.9	<.001
Gender, n (%)			<.001
Male	699 (0.38)	112,526 (99.62)	
Female	425 (0.27)	262,286 (99.73)	
Ethnicity, n (%)			<.001
White	694 (0.31)	224,817 (99.69)	
Black	67 (0.26)	25,896 (99.74)	
Hispanic	110 (0.22)	49,777 (99.78)	
Other	77 (0.44)	17,235 (99.56)	
Weight, n (%)			.071
Not morbidly obese	1,107 (0.30)	367,546 (99.70)	
Morbidly obese	17 (0.19)	8,754 (99.81)	
Inflammation, n (%)			.051
No acute cholecystitis	1,093 (0.30)	361,681 (99.70)	
Acute cholecystitis	31 (0.21)	14,619 (99.79)	
Intervention, n (%)			<.001
LC	177 (0.06)	312,345 (99.94)	
OC	947 (1.46)	63,955 (98.54)	
Year of surgery, n (%)			.02
1998–2000	423 (0.33)	126,821 (99.67)	
2001–2003	375 (0.29)	129,408 (99.71)	
2004–2006	266 (0.27)	119,007 (99.73)	

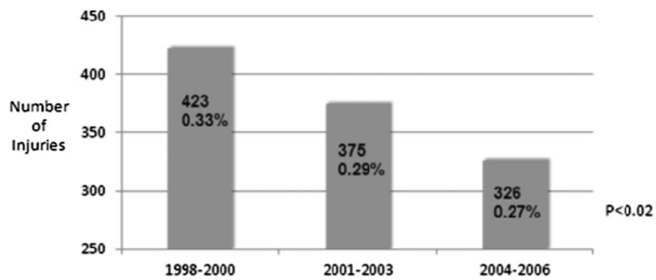

Figure 2. Incidence of BDI.

The adjusted analysis for the risk of BDI is shown in **Table 4**. Male gender (odds ratio [OR], 1.23; 95% confidence interval [CI], 1.07–1.41; $P = .003$), age >60 years (OR, 2.31;

Table 4.
Multivariate Logistic Regression for Risk of BDI Among Patients Who Underwent Cholecystectomy in NIS

	OR	95% CI	*P* Value
Age			
<25 y	1.00		Referent
25–40 y	1.01	0.69–1.47	.970
40–60 y	1.20	0.84–1.71	.308
>60 y	2.31	1.64–3.25	<.001
Gender			
Female	1.00		Referent
Male	1.23	1.07–1.41	.003
Ethnicity			
White	1.00		Referent
Black	0.94	0.72–1.23	.649
Hispanic	0.94	0.73–1.20	.612
Other	1.01	0.33–3.05	.991
Weight			
Not morbidly obese	1.00		Referent
Morbidly obese	0.52	0.26–1.05	.068
Inflammation			
No cholecystitis	1.00		Referent
Cholecystitis	0.70	0.47–1.04	.081
Insurance status			
Uninsured	1.00		Referent
Insured	1.66	0.24–11.26	.604
Hospital factors			
Non-teaching hospital	1.00		Referent
Teaching hospital	1.35	1.04–1.76	.026
Volume	1.00	1.00–1.00	.838

Table 5.
Multivariate Logistic Regression for Risk of Death Among Patients Who Underwent Cholecystectomy in NIS

	OR	95% CI	*P* Value
Injury			
No BDI	1.00		Referent
BDI	2.37	1.36–4.12	.002
Age			
<25 y	1.00		Referent
25–40 y	1.12	0.58–2.18	.738
40–60 y	1.52	0.82–2.82	.182
>60 y	7.90	4.31–14.47	<.001
Gender			
Female	1.00		Referent
Male	1.29	1.15–1.45	<.001
Ethnicity			
White	1.00		Referent
Black	1.21	0.95–1.54	.123
Hispanic	0.87	0.70–1.08	.196
Other	0.78	0.26–2.31	.648
Weight			
Not morbidly obese	1.00		Referent
Morbidly obese	0.72	0.43–1.19	.197
Inflammation			
No cholecystitis	1.00		Referent
Cholecystitis	2.32	1.90–2.83	<.001
Hospital factors			
Non-teaching hospital	1.00		Referent
Teaching hospital	1.07	0.93–1.23	.346
Volume	1.00	1.00–1.00	.076

95% CI, 1.64–3.25; $P < .001$), and treatment received at a teaching institution (OR, 1.35; 95% CI, 1.04–1.76; $P = .026$) were all associated with increased odds of BDI. LC, however, was not an independent predictor of BDI. Other factors (ethnicity, obesity, insurance status, diagnosis of acute cholecystitis, and hospital volume) were also not associated with the risk of BDI.

Table 5 shows the multivariate logistic regression for increased odds of death after cholecystectomy in patients. Again, male gender (OR, 1.29; 95% CI, 1.14–1.45; $P < .001$) and age >60 years (OR, 7.90; 95% CI, 4.31–14.47; $P < .001$) were independently associated with an increased odds of death. Other predictors of death were the diagnosis of acute cholecystitis (OR, 2.32; 95% CI, 1.90–2.83; $P < .001$) and presence of BDI (OR, 2.37; 95% CI, 1.36–4.12; $P < .001$).

DISCUSSION

This study showed that BDI was significantly associated with male gender, age >60 years, and treatment received at a teaching institution. LC and a diagnosis of acute cholecystitis, however, were not associated with increased odds of BDI. The increased risk of BDI in men could not be explained in our study. This may reflect socioeconomic influences that are difficult to discern from a large database review. Despite numerous studies showing the differences in cancer[13–16] and trauma[17–20] care by socioeconomic and insurance status, there was no indication that insurance status impacted BDI rates. The increased risk of BDI in teaching institutions may be associated with the complexities of patients treated at these centers or the learning curve associated with resident training (or both).[21,22]

Interestingly, BDI was not associated with a diagnosis of acute cholecystitis. In fact, there was a lower risk of BDI with acute cholecystitis in both LC and OC subsets. Furthermore, no significant decrease in the risk of BDI with increasing hospital volume was found. This finding and the fact that LC was not an independent risk factor for BDI may also support the concept that the era of current practice has surpassed the learning curve.

After we controlled for other factors, LC was shown to be associated with a reduced risk of BDI. However, these results should be interpreted against the backdrop of data collection methodology for the NIS. First, the NIS does not capture the repair of BDIs for patients who were diagnosed after discharge after their initial treatment. Because the length of stay is shorter for LC over OC, it may be possible that some of these (delayed diagnosis) BDI patients would be within the LC group. Furthermore, because the NIS does not code by intent of operation, if a BDI was noticed during the initial operation and the surgeon converted an LC to an open approach for repair, the operation may be coded as an OC. Despite this fact, the total number of BDIs decreased over time. The adjusted risk of death after cholecystectomy still echoed as a risk factor for BDI, even after we controlled for the presence of such an injury and comorbid conditions in the Charlson index. Male patients, patients aged >60 years, and patients who had a BDI all showed an independent increased risk of death. Although patients diagnosed with acute cholecystitis were not found to be at an increased risk of BDI, they were at an increased risk of death. Variables not associated with an increased risk of death included patient ethnicity, insurance status, morbid obesity, hospital teaching status, and hospital volume.

Limitations to this study are those of any retrospective or administrative-based study. As noted earlier, the only patients captured were those diagnosed with a BDI during the same hospital stay. Any patients with a missed BDI that was diagnosed during a subsequent hospitalization would not have been included. Finally, a selection bias existed with these data; those patients who underwent OC likely did so because of safety considerations. These patients likely had anatomic or physiological barriers that prohibited the surgeon from performing a safe LC and therefore put them at higher risk for BDI during OC as well. Despite these limitations, the results show that the percentage of cholecystectomies performed laparoscopically has increased over the 9-year period of the study whereas the rate of BDI has decreased over the same period.

CONCLUSIONS

Male gender, age >60 years, and treatment in a teaching hospital are all independent risk factors for BDI. Male gender and age >60 years were also risk factors for death after cholecystectomy. Having a BDI or being diagnosed with acute cholecystitis was an additional independent risk factor for death after cholecystectomy. LC, patient ethnicity, insurance status, diagnosis of morbid obesity, and patient hospital volume were not associated with either risk of BDI or risk of death. In this study laparoscopy was not found to be a risk factor for BDI during cholecystectomy. The overall rate of BDI has decreased over time, whereas the rate of LC has increased. These results may reflect increased knowledge and experience with laparoscopic techniques, particularly LC. We believe that the overall learning curve is diminishing as resident teaching methods and experience in laparoscopy improve.

References:

1. DeFrances CJ, Lucas CA, Buie VC, Golosinskiy A. 2006 National Hospital Discharge Survey. *Natl Health Stat Report*. 2008;5:1–20.

2. Andren-Sandberg A, Alinder G, Bengmark S. Accidental lesions of the common bile duct at cholecystectomy. Pre- and perioperative factors of importance. *Ann Surg*. 1985;201:328–332.

3. Nenner RP, Imperato PJ, Alcorn CM. Serious complications of laparoscopic cholecystectomy in New York State. *N Y State J Med*. 1992;92:179–181.

4. Hogan AM, Hoti E, Winter DC, et al. Quality of life after iatrogenic bile duct injury: a case control study. *Ann Surg*. 2009;249:292–295.

5. Caputo L, Aitken DR, Mackett MC, Robles AE. Iatrogenic bile duct injuries. The real incidence and contributing factors—implications for laparoscopic cholecystectomy *Am Surg*. 1992;58:766–771.

6. Flum DR, Cheadle A, Prela C, Dellinger EP, Chan L. Bile duct injury during cholecystectomy and survival in Medicare beneficiaries. *JAMA*. 2003;290:2168–2173.

7. Moossa AR, Mayer AD, Stabile B. Iatrogenic injury to the bile duct. Who, how, where? *Arch Surg.* 1990;125:1028–1030, discussion 1030–1031.

8. Stabile BE. Laparoscopic cholecystectomy-associated bile duct injuries. *West J Med.* 1998;168:40–41.

9. Windsor JA, Pong J. Laparoscopic biliary injury: more than a learning curve problem. *Aust N Z J Surg.* 1998;68:186–189.

10. Hunter JG. Avoidance of bile duct injury during laparoscopic cholecystectomy. *Am J Surg.* 1991;162:71–76.

11. Strasberg SM. Avoidance of biliary injury during laparoscopic cholecystectomy. *J Hepatobiliary Pancreat Surg.* 2002;9: 543–547.

12. Kato K, Matsuda M, Onodera K, Kobayashi T, Kasai S, Mito M. Laparoscopic cholecystectomy from fundus downward. *Surg Laparosc Endosc.* 1994;4:373–374.

13. Al-Refaie WB, Gay G, Virnig BA, et al. Variations in gastric cancer care: a trend beyond racial disparities. *Cancer.* 2010;116: 465–475.

14. Cardarelli R, Kurian AK, Pandya V. Having a personal health-care provider and receipt of adequate cervical and breast cancer screening. *J Am Board Fam Med.* 2010;23:75–81.

15. Chang DC, Zhang Y, Mukherjee D, et al. Variations in referral patterns to high-volume centers for pancreatic cancer. *J Am Coll Surg.* 2009;209:720–726.

16. Kwok J, Langevin SM, Argiris A, Grandis JR, Gooding WE, Taioli E. The impact of health insurance status on the survival of patients with head and neck cancer. *Cancer.* 2010;116:476–485.

17. Zarzaur BL, Stair BR, Magnotti LJ, et al. Insurance type is a determinant of 2-year mortality after non-neurologic trauma. *J Surg Res.* 2009;160:196–201.

18. Rosen H, Saleh F, Lipsitz SR, Meara JG, Rogers SO. Lack of insurance negatively affects trauma mortality in US children. *J Pediatr Surg.* 2009;44:1952–1957.

19. Haider AH, Chang DC, Efron DT, Haut ER, Crandall M, Cornwell EE III. Race and insurance status as risk factors for trauma mortality. *Arch Surg.* 2008;143:945–949.

20. Dozier KC, Miranda MAJ, Kwan RO, Cureton EL, Sadjadi J, Victorino GP. Insurance coverage is associated with mortality after gunshot trauma. *J Am Coll Surg.* 2010;210:280–285.

21. Kauvar DS, Braswell A, Brown BD, Harnisch M. Influence of resident and attending surgeon seniority on operative performance in laparoscopic cholecystectomy. *J Surg Res.* 2006;132: 159–163.

22. Ferzli GS, Fiorillo MA, Hayek NE, Sabido FS. Chief resident experience with laparoscopic cholecystectomy. *J Ad Lap Surg Tech.* 1997;7:147–150.