

# Age and Obesity are Independent Predictors of Bile Duct Injuries in Patients Undergoing Laparoscopic Cholecystectomy

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#### Abstract

*Introduction* Introduction Introduction Introduction of cholecystectomy. The aim of this study was to assess predictors of bile duct injury using a national database.

*Methods* The Nationwide Inpatient Sample (2010–2012) was queried for laparoscopic cholecystectomy. We used a) diagnoses for bile duct injury and b) bile duct injury repair procedure codes as a surrogate marker for bile duct injuries.

*Results* A total of 1,015 patients had bile duct injury. The mean age was  $58.2 \pm 19.7$  years, 53.5 % were males, and median Charlson co-morbidity score was 2 [2, 3]. Multivariate analysis revealed morbid obesity [2.8 (2.1–4.3); p = 0.03] and age >65 [1.5 (1.05–2.1); p = 0.01] as the independent predictors for bile duct injury in patients undergoing cholecystectomy.

*Conclusion* Our study finds a new association between obesity, aging, and bile duct injuries which has never been reported in literature before.

## Introduction

Cholecystectomy is one of the most commonly performed abdominal surgical procedures in the United States [1]. Iatrogenic common bile duct (CBD) injury occurs in 1 in 200 cholecystectomies, is a significant source of patient morbidity after gallbladder surgery, and is the leading

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source for medical malpractice claims against general surgeons [2].

Several studies in the past have identified risk factors for bile duct injury using local or regional data. Reports in the early 1990's identified laparoscopic cholecystectomy as a risk factor for bile duct injury [1, 2]. Several reasons for this phenomenon were then cited, the most common being the "learning curve" of a new and technically demanding skill [3]. Subsequently, articles were published describing recommended techniques to reduce bile duct injuries during laparoscopic cholecystectomy [4, 5]. Over the next 15 to 20 years, laparoscopic cholecystectomy became the standard of care, and as the surgeons' experience with minimally invasive techniques increased, the rates of bile duct injury reduced from 0.5 % in 1990 to 0.3 % in 2009 [6, 7].

However, bile duct injury remains an important cause of morbidity and mortality in this subset of patients. Secondly, there is a lack of recent national data in terms of

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Acute cholecystitis	574.0, 574.00, 574.01, 574.1, 574.10, 575.0
·	575.12, 575.10, 574.11, 574.10
Chronic cholecystitis	575.11
Choledocholelithiasis	574.3, 574.4, 574.5, 574.6x, 574.7x, 574.8x, 574.9x, 574.5x, 576.x
Calculus of the gallbladder without cholecystitis	574.2, 574.20
Gallstone pancreatitis	577.0 and (ii) a concurrent diagnosis of cholelithiasis/ cholecystitis

predictors of bile duct injury with the change in disease pattern, etiology, and patient demographics especially with the increasing epidemic of obesity and the aging population presenting at our medical centers. Therefore, the aim of this study was to assess predictors of bile duct injury in patients undergoing elective and emergent cholecystectomy using a national database.

## Methods

The Nationwide Inpatient Sample (2010, 2011, and 2012) was queried for patients who underwent elective and emergent laparoscopic cholecystectomy. The NIS is an administrative database and represents the all-payer inpatient experience of a 20 % stratified probability sample of American nonmilitary, nonfederal hospitals for each year under consideration [8].

All patients with a primary diagnosis of calculus of the gallbladder, acute cholecystitis, gall stone pancreatitis, acute-on-chronic cholecystitis, chronic cholecystitis, and choledocholelithiasis and a primary procedure of a laparoscopic cholecystectomy (ICD-9-CM codes: 51.22) were included in the study. (Table 1) Patients undergoing elective or emergent laparoscopic cholecystectomy were included in our analysis. We defined emergent cholecystectomy as laparoscopic cholecystectomy that was performed on hospital day 0 or 1 after an unplanned admission to the hospital (ICD9 code: 51.23). We excluded cases of open cholecystectomy, and patients with missing data in regards to the injury status of the bile duct. However, patients who were converted to open cholecystectomy (V64.4, V64.41) and those who underwent intraoperative cholangiogram (IOC) during the primary operation were included in the analysis. Because of a limitation of the NIS whereby the treatment of patients who were discharged to another medical institution is not linked to the initial treating hospital records, such patients were also excluded from analysis.

Outcome measure was bile duct injury. We used a) diagnoses for bile duct injury (868.02) and b) bile duct injury repair procedure codes (51.36, 51.37, 51.39, 51.71, 51.72, and 51.79) as a surrogate marker for bile duct injuries. Endoscopic retrograde cholangiopancreatography (ERCP) with dilatation and stent placement of the ampulla, biliary, or pancreatic duct (ICD 9 Code: 51.84, 52.98) was used as a marker for bile duct injury only if the patient has a diagnosis of bile duct injury (ICD9 code: 868.02) or had no evidence of choledocholethiasis so that we don't include patients who received ERCP for stone retrieval. ERCP with sphincterotomy and papillotomy for bile duct stone (51.85), ERCP with brushings and/or biopsies (51.14, 52.14), ERCP with excision of a lesion within the biliary or pancreatic duct (51.64, 52.21, 51.69), and ERCP with manometry (51.15) were not used as surrogate markers for bile duct injury. Patients with missing values in the database for bile duct injury diagnosis and/or bile duct injury repair procedures were also excluded. (Table 2)

Multivariate analyses controlled for patient- and hospital-level factors potentially associated with CBD Injury, including age of presentation, sex, morbid obesity (ICD-9 code 278.01), diabetes mellitus, insurance status, diagnosis of acute cholecystitis (ICD-9 code 87.50), performance of intraoperative cholangiography (ICD-9 code 87.53), academic hospital status, year of surgery, and ethnicity. Race/ ethnicity was defined using the NIS categories of white, African American, Hispanic, Asian, and other. Data are reported as mean and standard deviation values or

Table 2     ICD 9 codes of bild	duct injury	repair procedures
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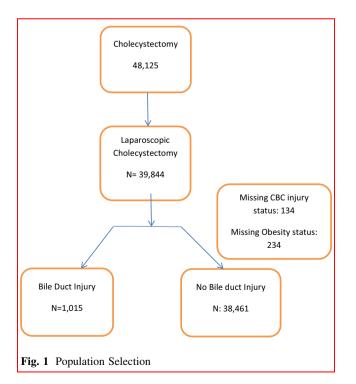
Procedure	
Choledochoenterostomy	51.36
Anastomosis of hepatic duct to gastrointestinal tract; kasai portoenterostomy	51.37
Other bile duct anastomosis	51.39
Simple suture of common bile duct	51.71
Choledochoplasty	51.72
ERCP	51.84, 52.98
Repair of other bile ducts	51.79

ERCP endoscopic retrograde cholangiopancreatography

frequencies. Data analysis was performed with STATA version 11 (College Station, TX, USA). Proportions were analyzed for categorical or ordinal data. Univariate analysis was performed by means of the  $\chi^2$  test in order to determine statistical significance with a two-tailed alpha level of 0.05. Multivariate logistic regression models for mortality and inpatient complications were created from statistically significant or near statistically significant variables on univariate analysis (p < 0.1); odds ratios (ORs) and 95 % confidence intervals (95 % CIs) were reported.

## Results

A total of 48,125 patients were reviewed, of which 39,844 patients had laparoscopic cholecystectomy. The mean age was 58.2  $\pm$  19.7 years, 53.5 % were males, and median Charlson co-morbidity score was 2 [2, 3]. 71 % (n = 28,289) of these patients were white followed by Hispanics (16 %). 21 % (n = 8,367) of the patients in the study were uninsured. The most common disease process requiring laparoscopic cholecystectomy was acute cholecystitis (41 %; n = 16,366) followed by chronic cholecystitis (31 %). The rate to conversion from laparoscopic to open cholecystectomy was 18 % (n = 7,171). IOC was obtained in 31 % of the patients. 61 % of the patients underwent emergent laparoscopic cholecystectomy. Bile duct injury occurred in 1,015 patients (2.6 %). Figure 1



highlights the screening process. In terms of co-morbidities 32 % of the patients had a diagnosis of morbid obesity.

Univariate analysis revealed age  $\geq 65$  ( $p \leq 0.01$ ), male gender (p = 0.04), morbid obesity (p = 0.001), emergent laparoscopic cholecystectomy (p = 0.02), teaching hospital status (p = 0.021), and hospital region (p = 0.01) to be associated with CBD injury. Multivariate analysis revealed morbid obesity [2.8 (2.1–4.3); p = 0.03] and age  $\geq 65$  [1.5 (1.05–2.1); p = 0.01] as the independent predictors for bile duct injury in patients undergoing laparoscopic cholecystectomy. Table 3 highlights the results of the univariate and multivariate models.

## Discussion

Literature in cardiovascular medicine, medical and surgical oncology, and trauma have all highlighted the adverse outcomes associated with obesity and aging [9]. Out study highlights that obesity and age are significant predictors for an adverse outcome namely CBD injury in patients undergoing laparoscopic cholecystectomy. Our analysis of the national database reveals that obese patients are 3 times more likely to have a CBD injury as compared to their counterparts.

The relationship between obesity and cholecystectomy is complex and not well studied in literature. Secondly, the data published on the topic have showed contrasting results. In a recent study, published authors showed that BMI was not a predictor of conversions or surgical morbidity in patients undergoing laparoscopic cholecystectomy [10]. One of the reasons for this difference is that they stratified obesity into three grades based on BMI, and that the study only had two patients who had a CBD injury. Contrastingly, in a recent study by Zdichavsky et al. authors show that obesity has been associated with increased operative time and hence more intraoperative complications [11]. We believe that the CBD injury in obese patients may be due to error of perception and misidentification of anatomy, which can lead to technical errors compounded by acute inflammation and difficult dissection leading to CBD injury.

Several studies in literature have shown age, gender, and ethnicity to a significant predictor in CBD injury. We did find male gender significant in our univariate model; however, it was nonsignificant in the multivariate model. An NIS database analysis published in year 2010 showed that Asian ethnicity is a significant predictor for bile duct injury in patients undergoing cholecystectomy [12]. We did not identify ethnicity as a predictor for bile duct injury. The difference in the results may be attributed to the inclusion criteria and the method of analysis of the data. We did not study patients who were under open cholecystectomy unlike the previous study; secondly the authors used the

Table 3 Univariate and multivariate analysis of predictors of CBD injury

Variable	Univariate			Multivariate						
	OR	95 % CI	p value	OR	95 % CI	p value				
Patient characteristics										
Age <55	Reference	Reference								
55–65	1.01	0.85-1.02	0.56	_	_	-				
<u>≥</u> 65	1.76	1.14-5.2	0.03	1.55	1.05-2.1	0.01				
Male gender	0.81	0.70-0.93	0.04	0.86	0.73-1.00	0.072				
Ethnicity	0.99	0.92-1.06	0.812	_	_	-				
Insurance status	1.09	0.72-1.16	0.6	_	_	-				
Diabetes mellitus	1.01	0.87-1.18	0.889	_	_	_				
Morbid obesity	3.28	2.94-3.74	0.001	2.8	2.1-4.3	0.03				
Disease process										
Calculus of the gall bladder	Reference									
Acute cholecystitis	1.56	0.56-1.96	0.5	_	_	_				
Choledocholelithiasis	1.01	0.87-1.18	0.889	_	_	_				
Chronic cholecystitis	3.28	2.94-3.74	0.001	_	_	_				
Surgical intervention										
Emergent vs elective	1.77	1.62-3.96	0.021	0.85	0.67-1.38	0.184				
Lap converted to open	0.96	0.58-1.87	0. 3	_	_	_				
Use of IOC	1.36	0.78-4.24	0.1	_	_	_				
Hospital characteristics										
Teaching hospital	0.77	0.62-0.96	0.021	0.85	0.67-1.08	0.184				
Weekend admission	0.66	0.78-1.56	0.23	-	_	_				
Hospital region <sup>a</sup>	1.16	1.08-1.24	0.01	1.05	0.91-1.13	0.247				

<sup>a</sup> Patients outside the Northeast region versus those of Northeast region

1998–2006 version of NIS which had significant missing data in terms of obesity. Secondly, we stratified our patient population on the basis of age. We could not stratify our patients on the basis of BMI, as NIS data doesn't not account for BMI.

We found age as a significant predictor for bile duct injury. This relationship has been identified by other researchers. Flum et al. have shown that age and co-morbidities were an independent predictor of mortality after CBD injury [13]. With the increase in the age of our patients presenting to our hospital, our data highlight that this patient population is at a higher risk for a surgical complication after laparoscopic cholecystectomy. The reason may be in the co-morbidities associated, baseline frailty, use of anticoagulants, and previous abdominal surgeries in this patient population [14–19].

The conversion rate in our study was 18 % which is higher than reported literature [20]. We believe it may be due to the increasing complexity of gall bladder surgery with the increasing age of our patients, increasing comorbidities, and use of anti-platelet/anticoagulants. In a retrospective analysis by Kauvar et al., the conversion rate in elderly patient was noted to be 22 % and significantly higher than their younger counterparts [21].

Interestingly we found that the disease process and academic status of the hospital were not associated with bile duct injuries. Several studies have shown that acute cholecystitis is associated with CBD injury, while others have shown that urban hospitals and specialist surgeons have lower rates of CBD injury [14].

We did not discuss the financial implications of CBD injury as they have already been reported using NIS database. The authors showed that the mean length of stay for patients that sustained a CBD injury was 5.8 days with an average inpatient mortality rate of 6.35 % annually. This resulted in mean hospital charges of \$215.8 million annually. In the year 2010, hospital charges were \$357.5 million or 25.5 % higher than the previous year [15, 16].

The results of the study should be interpreted in the context of its limitations. Because the NIS is an administrative database, the accurate assessment of patient case mix, including co-morbidities and the separation of preexisting comorbid factors from postoperative complications, can be difficult [17, 18]. Secondly, we did not have long-term outcomes [22, 23]. Third, we excluded patients that were transferred to other facilities. We, however, believe that this doesn't lead to any selection bias as NIS is a national database with a large patient population which reduces this bias, and secondly, majority of the participating hospitals in NIS have the resources and the skills required to manage these patients with bile duct injuries. Further limitation of using administrative data is that variables not captured by the database may have contributed to the outcomes evaluated. The biggest limitation in the study is the missed bile injury/delay in diagnosis which NIS doesn't allow us to identify.

#### Conclusion

Our study finds a new association between obesity and bile duct injuries which has never been reported in literature before. The effect of obesity on outcomes in biliary surgery needs prospective evaluation.

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