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Bile duct injury and morbidity following cholecystectomy: a need for improvement

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Abstract

Background Bile duct injury (BDI) remains the most dreaded complication following cholecystectomy with serious repercussions for the surgeon, patient and entire healthcare system. In the absence of registries, the true incidence of BDI in the United States remains unknown. We aim to identify the incidence of BDI requiring operative intervention and overall complications after cholecystectomy.

Methods Utilizing the Truven Marketscan® research database, 554,806 patients who underwent cholecystectomy in calendar years 2011–2014 were identified using ICD-9 procedure and diagnosis codes. The final study population consisted of 319,184 patients with at least 1 year of continuous enrollment and who met inclusion criteria. Patients were tracked for BDI and other complications. Hospital cost information was obtained from 2015 Premier data.

Results Of the 319,184 patients who were included in the study, there were a total of 741 (0.23%) BDI identified requiring operative intervention. The majority of injuries were identified at the time of the index procedure ($n = 533$, 72.9%), with 102 (13.8%) identified within 30-days of surgery and the remainder ($n = 106$, 14.3%) between 31 and 365 days. The operative cumulative complication rate within 30 days of surgery was 9.84%. The most common complications occurring at the index procedure were intestinal disorders (1.2%), infectious (1%), and shock (0.8%). The most common complications identified within 30-days of surgery included infection (1.5%), intestinal disorders (0.7%) and systemic inflammatory response syndrome (SIRS) (0.7%) for cumulative rates of infection, intestinal disorders, shock, and SIRS of 2.0, 1.9, 1.0, and 0.8%, respectively.

Conclusion BDI rate requiring operative intervention have plateaued and remains at 0.23% despite increased experience with laparoscopy. Moreover, cholecystectomy is associated with a 9.84% 30-day morbidity rate. A clear opportunity is identified to improve the quality and safety of this operation. Continued attention to educational programs and techniques aimed at reducing patient harm and improving surgeon skill are imperative.

Keywords Bile duct injury · Laparoscopic cholecystectomy · Postoperative complications

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Background

As one of the most frequently performed procedures in the United States, laparoscopic cholecystectomy is often considered common place and of minimal risk. First performed in 1985 and practiced with increased popularity in the

1990s, laparoscopic cholecystectomy was complicated by increased rate of biliary injury compared to open procedures. This led to significant concern and attempts at technique reform to increase safety and decrease complications [1]. In the first decade after its inception, there was a notable decrease in common bile duct injury (BDI) along with definitive morbidity and mortality benefit over open procedures.

Despite these improvements, the past 20 years have not seen the same decrease in biliary injury rates [2]. The literature consistently reports that 1–2 in 1000 (0.1–2%) patients undergoing laparoscopic cholecystectomy suffer from biliary injury. Additionally, non-BDI complications are relatively common. GallRiks, a Swedish nationwide gallstone surgery registry, recently reported complication rates of 6.1% for elective cholecystectomy and 11.2% in the setting of urgent cholecystectomy [3]. This is consistent with other studies that report a 30-day complications range from 5 to 15% [4–9]. Complication rates approaching 10% for a procedure performed in 750,000 patients per year carries a significant burden for our health care system and the patients. Unfortunately, currently no registry exists of gallstone patients in the United States and most current literature is limited to regional assessments and or nationwide inpatient registries. With over half of laparoscopic procedures being performed as outpatient procedures, these registries fail to capture a significant portion of operations.

Using the New York State regional registry, SPARCS, we previously reported on the long-term incidence of post-laparoscopy complications. This work revealed that the overall complication rate was just shy of 10% [4]. Such high complication rates necessitate a more comprehensive investigation of the United States experience—to both assess the current state of cholecystectomy complications and to develop strategies to decrease the complication rates for these common procedures. We sought to gain a better understanding of potential areas of intervention through nationwide inpatient and outpatient investigation. Beyond providing much needed United States data, we also seek to use these data for The Society of American Gastrointestinal and Endoscopic Surgeons Safe Chole Program (https://www.sages.org/safe-cholecystectomy-program/). This program seeks to provide education and enhance a culture of safety for cholecystectomy. Discovering potential safety deficiencies in current cholecystectomy practice would provide important information for strategic education development by the Safe Chole program.

Methods

Population selection

The Truven Marketscan® Research Database was used for data accrual. This nationwide database is compiled of medical claims data from multiple large employers and over 100 payers. Both employees and dependents are included in the data set, and importantly for the present study, it includes both inpatient and outpatient claims. Data from 2011 to 2015 was used for this analysis, evaluating cholecystectomies performed from 2011 to 2014 and an additional 1 year of postoperative complications monitoring. ICD-9 and procedure codes were used to find patients who had undergone cholecystectomy for benign biliary disease. Trigger diagnoses of benign biliary diseases included cholelithiasis, choledocholithiasis, cholecystitis, biliary dyskinesia, and acute pancreatitis. To assess complications data, only patients with at least 1 year of postoperative data were included for analysis (Fig. 1). Other exclusion criteria included patients without a trigger diagnosis, age under 18, known malignancy (at time of initial operation or during follow-up), and abdominal injury.

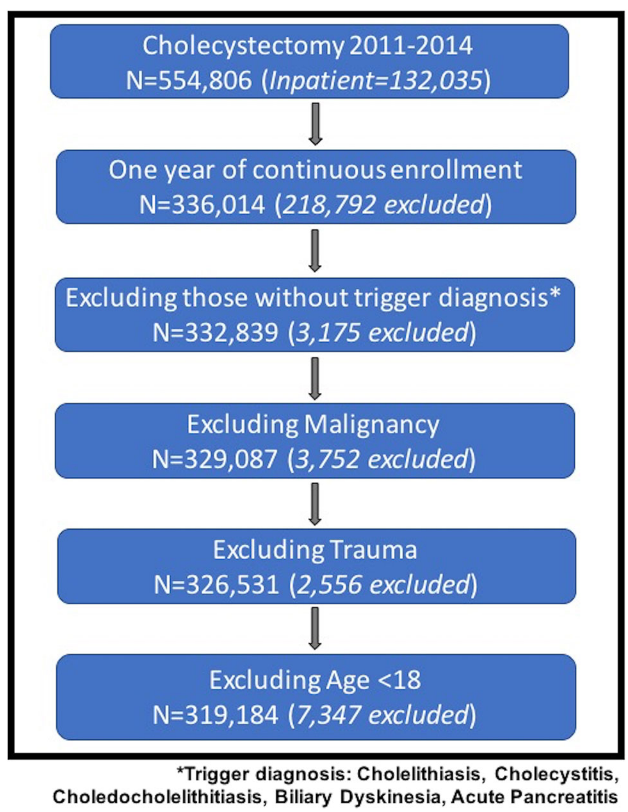

Fig. 1 Population selection

Bile duct injury and other complications

To identify the potential complications incurred by patients within the 1 year after surgery, ICD-9 and procedural codes were assessed (Supplemental Table 1). We chose to classify BDIs as injury necessitating operative repair and, thus, identified BDIs by postoperative procedure codes of hepatectomy, hepaticojejunostomy or any other bile duct surgery were used as a surrogate for BDI. All other complications were similarly identified using ICD-9 codes. Data at index operation, 30 days postop and a year post cholecystectomy, were obtained.

Statistical analysis

Descriptive statistics were used for quantitative results. Mean and standard deviation were reported where appropriate. Reimbursement was log transformed and analyzed with generalized linear model. The analysis was performed with 2011–2015 Truven Health Marketscan® commercial claims and encounters data. Hospital cost data were obtained from 2015 Premier data.

Results

During the study period, 319,184 patients met inclusion criteria and had at least 1 year of continuous enrollment in the Truven database allowing for complications analysis. Basic demographics are listed in Table 1. The mean age of patients was 43.8 years and the majority were women (73.6%). Additionally, the mean Charleston Comorbidity Index was less than one, which suggests a majority of the patients included for analysis were otherwise relatively heathy without significant medical comorbidities.

Table 1 Demographics

	n = 319,184 (%)
Mean age (STD)	43.83 (12.01)
Mean Charleston Comorbidity Index (STD)	0.19 (0.52)
Age categories	
18–29	46,907 (14.7)
30–39	68,074 (21.3)
40–49	84,426 (26.5)
50–59	89,111 (27.9)
60–64	30,666 (9.6)
Male	84,107 (26.4)
Female	235,077 (73.6)
Region	
Northeast	45,866 (14.4)
North Central	72,636 (22.8)
South	140,949 (44.2)
West	52,218 (16.4)
Unknown	7515 (2.4)

BDI

A total of 741 common bile duct injuries (0.23%) that required reoperation were identified. The majority were identified at the index operation (533, 72.9%) with an additional 102 (13.8%) noted at 30 days and the remaining 106 (14.3%) diagnosed between 30 days and 365. Patients with BDI were more likely to be older (46.09 vs. 43.83 years) and male.

An analysis of payment variation between patients with BDI and without BDI revealed a predictably higher amount for payment for those with BDI with an adjusted total payment of 1.33 × BDI patients (Table 2). Notably, these data are only available for inpatient analysis, although it is unlikely that uncomplicated outpatient laparoscopic cholecystectomies would result in a greater financial burden than an inpatient procedure.

Other complications

The complication rate was 5.07% at index operation (Table 3) and 4.77% at 30 days for a total complication rate of 9.84% at 30 days (Table 4). Complications occurred in 16.6% of the patients at 1-year follow-up. However, understanding to what extent the operative procedure resulted in 1-year complications beyond BDI was challenging. The most common complications occurring at the index procedure were intestinal disorders (1.2%), infectious (1%), and shock (0.8%). The most common complications identified within 30-days of surgery included infection (1.5%), intestinal disorders (0.7%) and systemic inflammatory response syndrome 0.7%). These complications, therefore, resulted in overall cumulative rates of 2.0% for infection, 1.9% for intestinal disorders, 1.0% for shock and 0.8% for systemic inflammatory response syndrome.

Discussion

With over 750,000 laparoscopic cholecystectomies performed annually in the United States, the majority (55%) of which occur in the outpatient setting, these procedures are often considered basic or routine [10, 11]. Despite its commonality, laparoscopic cholecystectomy continues to be a procedure with significant morbidity, nearly 10% in our nationwide analysis of both inpatient and outpatient

Table 2 Bile duct injury costs

	Adjusted payment difference with bile duct injury[a]	95% CI	P value
Total payment	$8,206	$10, 139)	<.0001
Physician payment	$1,486	($1,151, $1,821)	<.0001
	Adjusted payment difference with bile duct injuries (ratio)[b]	95% CI	P value
Total payment	1.33	(1.26, 1.40)	<.0001
Physician payment	1.39	(1.15, 1.67)	<.0001

[a]Adjusting for patient demographic and comorbidities

[b]Costs were log transformed. Adjusting for patient demographic and comorbidities

Table 3 Complications at index procedure

	n	%
All	16,178	5.07
Intestinal disorders[a]	3,751	1.17
Bacterial diseases	3,245	1.01
Shock	2,441	0.76
Renal failure	1,848	0.58
Phlebitis	1,588	0.50
Pneumonia	1,511	0.47
Surgical error	1,498	0.47
Respiratory failure	1,163	0.36
Hemorrhage	747	0.23
Digestive disorders[b]	700	0.22
Hypertension	627	0.20
Pulmonary edema	596	0.19
Common bile duct (CBD) injury	533	0.17
Systemic inflammatory response syndrome	384	0.12
Myocardial infarction	325	0.10
Enteritis[c]	274	0.09
Pulmonary embolus	271	0.08
Cardiac complications	222	0.07
Mechanical ventilation	80	0.03
Abscess	71	0.02

[a]Intestinal disorders was defined with ICD 9 diagnosis code, including: ileus, paralytic; volvulus; adhesions, intestinal w/obstruction obstruction, intestinal; vomiting, postop-gi surgery; peritoneal abscess

[b]Digestive disorders was defined with ICD 9 diagnosis code 997.4, complications, digestive system

[c]Enteritis was defined with ICD 9 diagnosis code, including: 557.0, acute vascular insufficiency of intestine 557.9, Unspecified vascular insufficiency of intestine

Table 4 Complications at 30 days postop

	n	%
All	15,227	4.77
Bacterial diseases	4,853	1.52
Intestinal disorders[a]	2,222	0.70
Systemic inflammatory response syndrome	2,136	0.67
Phlebitis	1,975	0.62
Pneumonia	1,644	0.52
Digestive disorders[b]	1,405	0.44
Renal failure	941	0.29
Shock	894	0.28
Pulmonary embolus	788	0.25
Hemorrhage	629	0.20
Surgical error	593	0.19
Respiratory failure	521	0.16
Hypertension	377	0.12
Pulmonary edema	224	0.07
Myocardial infarction	197	0.06
Enteritis[c]	123	0.04
Common bile duct (CBD) injury	102	0.03
Abscess	55	0.02
Vascular disorders	49	0.02
Cardiac complications	43	0.01

[a]Intestinal disorders was defined with ICD 9 diagnosis code, including: ileus, paralytic; volvulus; adhesions, intestinal w/obstruction obstruction, intestinal; vomiting, postop-gi surgery; peritoneal abscess

[b]Digestive disorders was defined with ICD 9 diagnosis code 997.4, complications, digestive system

[c]Enteritis was defined with ICD 9 diagnosis code, including: 557.0, acute vascular insufficiency of intestine 557.9, unspecified vascular insufficiency of intestine

procedures. Additionally, with an estimated BDI rate of 0.23%, the incidence of BDI appears to have plateaued without further improvement over the past decade.

When first introduced, the benefits of laparoscopy over open cholecystectomy were obvious, with near immediate decreases in wound infection and serious complications such as pneumonia and sepsis [5]. Despite these improvements, the increased rate of BDI was quickly acknowledged, with the incidence of BDI reported around 0.5% [12]. Since that time, great strides in laparoscopic training and attempts at improving the safety in laparoscopic procedures decreased the incidence of BDI [13]. Unfortunately, most recent reports suggest that rates of BDI after laparoscopic cholecystectomy have plateaued [14, 15]. GallRiks, the largest nationwide database of laparoscopic cholecystectomies (50,000 patients), recently reported an incidence of 0.3% in their analysis of 50,000 laparoscopic cholecystectomy patients. Though our BDI injury rate was somewhat lower, it supports the persistent nature of this costly complication. Importantly, the BDI rate in our analysis includes both inpatient and outpatient procedures in a relatively healthy population, suggesting that all who undergo cholecystectomy have inherent risk of BDI. This is despite strategic efforts to decrease this risk over the past decades.

Given the commonality of laparoscopic cholecystectomies, BDI rates of 0.1–0.3% result in significant patient morbidity and health care expenditures. Particularly considering that the majority of BDI could be potentially preventable. Recently, investigations into the consequences of major bile duct in jury in both quality of life and long-term health implications have been pursued. In a study comparing laparoscopic cholecystectomy patients, 54 of whom experienced BDI and 50 without injury, Melton et al. reported significantly worse psychological scores in the BDI group compared to control laparoscopic cholecystectomy patients as well as national averages [16]. Similarly, a study of 50 patients with BDI compared to 74 patients who underwent laparoscopic cholecystectomy without injury, Moore et al. reported inferior quality of life scores for those who suffered from BDI [17]. Furthermore, it does not appear that these outcomes improve over time, with those who suffer from BDI reporting consistently worse quality of life scores years post injury [17, 18].

Data on long-term health outcomes of these injuries is limited, given the relatively novel nature of laparoscopic cholecystectomies. We recently reported on the mortality implications in the state of New York after BDI. A retrospective review of 125 patients with BDI revealed an increase from 8.8 to 20% in all-cause mortality for those with BDI, despite repair [8]. Sinha et al. in a study of over 400,000 cholecystectomy patients found that those with BDI had a 6× higher 1-year mortality rate than those without BDI [19].

The costs of BDI are also significant. The results of our analysis revealed a 126% increase in payments for those with BDI compared to non-BDI patients. Given the increased length of stay and multiple procedures often required in the setting of BDI, such findings are not surprising. Though significant variation exists, most studies claim costs of care are greater than $100,000 for iatrogenic BDI injury [20, 21]. Additionally, BDIs are by and far the most common malpractice claim in gastrointestinal surgery; making up half of general surgery laparoscopic claims and 20% of all general surgery litigation [22, 23]. In the United States, 20–30% of laparoscopic BDIs result in malpractice litigation of some sort, whereas it is rare to see litigation after an open procedure [23]. Multiple studies have analyzed the risks for litigation: these include younger age, procedure performed after 2001, delay in diagnosis, and repair at index hospital or by index surgeon [24–26].

Beyond the feared BDI—perhaps often overlooked—is the overall complication rate of laparoscopic cholecystectomy. Complication rates for all cholecystectomies are reported to be as high as 8–12% and significantly higher in the setting of acute cholecystectomy [3, 4, 27]. Notably, these complication rates are as high or higher than reported from other—more "complex"—laparoscopic procedures including gastric bypass and ventral hernia repair [28, 29]. Our data support these findings with an overall 9.84% 30-days complication rate. Furthermore, these complications are not benign with sepsis, pneumonia, and serious infections listed amongst the complications in our cohort.

This study has many strengths including utilizing both inpatient and outpatient data on a large nationwide scale. Yet, the database analysis has clear limitations. First, being a payer driven system, Medicaid and Medicare data are not included in our analysis. Also, we only included BDIs which necessitated operative interventions, BDIs which underwent endoscopic intervention or resulted in patient death could not be assessed, nor were cystic duct leaks identified in this analysis Further, since this was an administrative database analysis, corroboration of injuries and complications through chart review was not possible. We were also unable to rule out duplicate complications between the index procedure, 30-day, and 1-year post-procedural. The use of the Truven Database also limits the follow-up results, only to data obtained within the system, and it is possible that additional complications may have been treated outside of the data captured within the system. Additionally, certain patient demographics were unobtainable as they were not listed in the system.

Conclusions

Despite the frequency with which is performed, laparoscopic cholecystectomy remains associated with significant morbidity and costs albeit increased efforts to improve its safety. Our data utilizing both inpatient and outpatient information corroborate findings from previously reported inpatient and local studies. Given the near 10% complication rate and persistent incidence of BDI, continued vigilance and efforts to improve outcomes and enhance safety standards around this procedure are warranted.

Compliance with ethical standards

Disclosures Meredith Barrett, Horacio J. Asbun, Hung-Lung Chien, L. Michael Brunt and Dana A. Telem have no conflicts of interest or financial ties to disclose

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