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Increasing bile duct injury and decreasing utilization of intraoperative cholangiogram and common bile duct exploration over 14 years: an analysis of outcomes in New York State

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Abstract
Introduction During laparoscopic cholecystectomy (LC), common bile duct (CBD) visualization either directly or with cholangiography (IOC) is less routine. Cholangiography can be used to identify and possibly prevent bile duct injury (BDI), which is a dreaded complication of cholecystectomy. The purpose of our study was to evaluate the trend of IOC/CBD exploration and BDI during LC for benign disease.
Methods A state-wide database (SPARCS) was used to identify all LC for benign biliary non-obstructive and obstructive disease between 2000 and 2014 in the state of New York. ICD-9 and CPT codes were used to identify IOC/CBD exploration and BDI. Multivariable logistic regression models were used in examining the linear trend in the risk of complication, 30-day readmission, 30-day ED visits, and BDI among all cholangiogram patients after controlling for possible confounding factors.
Results During 2000–2014, 391,945 patients underwent laparoscopic cholecystectomy. The trend of IOC/CBD exploration performed significantly decreased for LC overall (12.37–10.44%, relative risk = 0.98, p <.0001) and particularly, in the outpatient setting (10.77–7.52%, relative risk = 0.96, p value <.0001). Among patients with IOC, overall complication rate, 30-day readmission rate, and 30-day ED visit rates increased. When looking at overall complication rate, there was an increase by about 4% per year (relative risk = 1.04, p value <.0001). After controlling for confounding factors, the complication risk and 30-day ED visit risk increased through years, while the 30-day readmission risk did not have significant change. Risk of BDI also increased significantly (p = 0.03).
Conclusion In an era of laparoscopy, the rate of IOC/CBD exploration during LC has significantly decreased, while BDI significantly increased.

Keywords Intraoperative cholangiogram · Common bile duct injury · Trends

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Since it advent in the 1980s, laparoscopic cholecystectomy has gained popularity, as it accounts for approximately 1.2 million cases/year in the United States in 2014 [1]. This procedure has been widely accepted both in the surgery community as well as the general public due to its advantages of reduced cost, diseased hospital length of stay (HLOS), and increased patient satisfaction [2–4]. Although it is considered a safe procedure, major morbidity occurs in approximately 5% of the patients [5].

Bile duct injury (BDI) remains a dreaded complication following laparoscopic cholecystectomy. Although its incidence has improved since laparoscopy was first introduced, studies have described an incidence of 0.08% and up to 0.5% [6, 7]. In addition, this complication has been associated with significant morbidity and mortality [8, 9].

Thus, prevention of this complication is of high importance and strategies for minimizing bile duct injuries (BDIs) have become a top priority for general surgeons. Although intraoperative cholangiogram (IOC) is used to identify stones in the common bile duct (CBD), using routine IOC for prevention of BDI is controversial [10]. Some claim that this relatively simple procedure can provide valuable information about the anatomy of the biliary tract, thus improving the safety of LC [11]. In one study, the authors state that the adoption of routine IOC at a university medical center has led to a remarkable reduction in major BDIs, as BDI was 1.9% in the selective IOC group and 0% in the routine IOC group, $p = 0.004$ [12]. Others claim that although it may not lower the rate of BDIs, it can minimize the extent of the injury, thus making it easier to repair [10]. Opponents claim increased cost and operative time as major drawbacks [13]. In addition, IOC requires certain operative skills in order to be performed laparoscopically. Thus, more inexperienced surgeons may not feel comfortable performing this procedure.

The purpose of our study was to assess the trend of IOC/CBD exploration in an era of laparoscopy. In addition, trend of complication rates, including BDI, are examined and compared with those trends among all LC. The importance of this information can help elucidate the role of IOC in LC.

Methods

A retrospective cohort analysis was performed to identify all LC for benign biliary non-obstructive and obstructive disease between 2000 and 2014 using the Statewide Planning and Research Cooperative System (SPARCS). SPARCS is an all-payer, administrative database that collects patient level data on every inpatient and outpatient procedure and Emergency Department (ED) visit in the state of New York. Patients in SPARCS are assigned a unique identifier that permits longitudinal follow-up across many institutions in NYS. IOC/CBD exploration and BDI were defined using the International Classification of Disease, 9th Revision, Clinical Modification procedure codes for inpatient procedures and Current Procedural Terminology codes for outpatient procedures. Patients with age <18 years, incomplete or duplicate records were excluded from the analysis. Variables included incidence of IOC/CBD exploration; patient demographics, such as age, gender, race, insurance; co-morbidities; complications; 30-day readmissions; and 30-day complications.

The linear trends of cholangiogram surgery volume, the complication rate, readmission rate or ED visit rate for cholangiogram patients, and BDI among cholangiogram patients over different years were examined using log-linear Poisson regression models with year as an explanatory variable. The trend analysis for surgery volume was on record level (537 patients had multiple times of laparoscopic cholecystectomy and only initial cholecystectomy was used), while for complication, 30-day readmission, 30-day ED visit, length of stay and BDI, the analysis was on patient level and patients' first surgery outcome were analyzed. Over-dispersion and under-dispersion were checked and corrected using Quasi-Poisson regression if there were such issues. Furthermore, multivariable logistic regression models were also used in examining the linear trend in the complication risk, readmission risk, ED visit risk, BDI risk among all cholangiogram patients, and admitted ED visit risk among cholangiogram patients having ED visits after controlling for possible confounding factors that were significantly associated with these outcomes based on χ^2 tests, respectively. In these multivariable regression models, any comorbidity/complication was used instead of specific ones because of limited number of events [14]. Welch's test was utilized to compare length of stay across different groups. The linear trend of length of stay for inpatients having cholangiogram was examined using simple linear regression with year as an explanatory variable first and further using a multiple linear regression model after controlling for possible confounding factors that were significantly associated with length of stay based on Welch's test at a significance level of 0.1. Log-transformation was applied to HLOS to make the normality assumption met. Statistical analysis was performed using SAS 9.3 (SAS Institute, Inc., Cary, NC) and significance level was set at 0.05. This study was approved by the institutional review board of Stony Brook Medical Center and New York Department of Health data protection review board.

Results

In total, 392, 485 cholecystectomy records (391,945 patients) were used for analysis between 2000 and 2014: 195,423 (49.8%) inpatient procedures and 197,062 (50.2%) outpatient procedures. Among all LC procedures, the proportion of patients having cholangiogram decreased from 2000 to 2014 overall (12.37–10.44%, RR = 0.98, p value <.0001) and among outpatients only (10.77–7.52%, RR = 0.96, p value <.0001, Table 1).

Univariate analysis showed that for patients undergoing LC with IOC, their overall complication rate, 30-day readmission rate, and 30-day ED visit rates increased (all RRs >1 with p values <0.01, Tables 2, 3, and 4). Patients undergoing LC also had an increase in complications by about 2% (RR = 1.02, p value <.0001, Table 2) and an increase in ED visits by about 4% (RR = 1.04,

Table 1 Incidence of inpatient, outpatient, and total intraoperative cholangiogram by year

Year	Inpatient IOC	Inpatient LC	Outpatient IOC	Outpatient LC	Total IOC	Total LC
2000	2205 (13.67%)	16,129	1420 (10.77%)	13,183	3625 (12.37%)	29,312
2001	2065 (13.71%)	15,062	1518 (10.81%)	14,040	3583 (12.31%)	29,102
2002	2082 (13.88%)	14,998	1729 (11.75%)	14,721	3811 (12.82%)	29,719
2003	1859 (13.29%)	13,992	1595 (11.9%)	13,407	3454 (12.61%)	27,399
2004	1804 (12.96%)	13,916	1779 (11.91%)	14,938	3583 (12.42%)	28,854
2005	1654 (12.52%)	13,211	1892 (12.29%)	15,395	3546 (12.4%)	28,606
2006	1774 (13.38%)	13,255	2063 (12.89%)	16,001	3837 (13.12%)	29,256
2007	1734 (13.38%)	12,956	1608 (13.86%)	11,602	3342 (13.61%)	24,558
2008	1685 (13.46%)	12,519	971 (8.83%)	10,992	2656 (11.3%)	23,511
2009	1719 (13.73%)	12,521	984 (8.18%)	12,036	2703 (11.01%)	24,557
2010	1646 (13.51%)	12,182	934 (7.45%)	12,542	2580 (10.44%)	24,724
2011	1547 (12.81%)	12,076	903 (7.22%)	12,512	2450 (9.96%)	24,588
2012	1484 (12.52%)	11,850	860 (6.78%)	12,690	2344 (9.55%)	24,540
2013	1372 (12.77%)	10,741	802 (6.64%)	12,081	2174 (9.53%)	22,822
2014	1364 (13.62%)	10,015	821 (7.52%)	10,922	2185 (10.44%)	20,937
Total	25,994	195,423	19,879	197,062	45,873	392,485
Relative risk	0.9969 (0.9931, 1.0007)		0.9588 (0.9390, 0.9791)		0.9798 (0.9713, 0.9883)	
p value*	0.1084		<.0001		<.0001	

* *p* value was based on log-linear regression models with correction for over- or under-dispersion

Table 2 Frequency table for LC or IOC patients with complication by year

Year	Having complication among LC	Having complication among IOC
2000	1384 (4.73%)	205 (5.66%)
2001	1337 (4.6%)	181 (5.05%)
2002	1397 (4.71%)	226 (5.94%)
2003	1471 (5.37%)	222 (6.43%)
2004	1476 (5.12%)	221 (6.17%)
2005	1519 (5.33%)	231 (6.53%)
2006	1516 (5.19%)	236 (6.16%)
2007	1527 (6.22%)	253 (7.57%)
2008	1514 (6.44%)	231 (8.7%)
2009	1501 (6.12%)	229 (8.48%)
2010	1559 (6.31%)	237 (9.19%)
2011	1383 (5.63%)	213 (8.72%)
2012	1476 (6.03%)	199 (8.49%)
2013	1314 (5.78%)	187 (8.61%)
2014	1301 (6.22%)	210 (9.62%)
Relative risk	1.02 (1.01, 1.03)	1.04 (1.03, 1.05)
p value*	<.0001	<.0001

* *p* value was based on log-linear regression models with correction for over- or under-dispersion

p value <0.0001, Table 4). After taking other confounding factors such as age, gender, race, region, insurance, inpatient or not, and comorbidity into consideration, the odds of complication risk for patients with IOC increased by about 3% per year (Adjusted OR 1.03, 95% CI 1.02–1.04, *p* value <.0001); and the odds of complication risk for LC patients increased by 2% each year (adjusted OR 1.02, 95% CI 1.02–1.04, *p* value <.0001). After controlling for confounding factors, such as age, gender, race, region, insurance, any comorbidity, and any complication, LC as well as IOC had increased 30-day ED visit risk through 2004–2014 (IOC: adjusted OR 1.04, 95% CI 1.02–1.05,

Table 3 Frequency table for LC or IOC patients with 30-day readmission by year

Year	Having 30-day readmission among LC	Having 30-day readmission among IOC
2000	1221 (4.17%)	163 (4.5%)
2001	1170 (4.02%)	134 (3.74%)
2002	1270 (4.28%)	153 (4.02%)
2003	1135 (4.14%)	123 (3.56%)
2004	1270 (4.41%)	150 (4.19%)
2005	1230 (4.31%)	154 (4.35%)
2006	1221 (4.18%)	173 (4.51%)
2007	1131 (4.61%)	160 (4.79%)
2008	1109 (4.72%)	138 (5.2%)
2009	1123 (4.58%)	135 (5%)
2010	1104 (4.47%)	138 (5.35%)
2011	1067 (4.35%)	119 (4.87%)
2012	1079 (4.41%)	110 (4.69%)
2013	958 (4.21%)	101 (4.65%)
2014	800 (3.82%)	94 (4.3%)
Relative risk	1.002 (0.996, 1.008)	1.016 (1.005, 1.028)
p value*	0.5386	0.0057

* *p* value was based on log-linear regression models with correction for over- or under-dispersion

Table 4 Frequency table for LC or IOC patients with 30-day ED visit by year

Year	Having 30-day ED visit among LC	Having 30-day ED visit among IOC
2004	1843 (6.39%)	241 (6.73%)
2005	2222 (7.79%)	249 (7.03%)
2006	2426 (8.31%)	322 (8.4%)
2007	2111 (8.6%)	257 (7.69%)
2008	2119 (9.02%)	242 (9.11%)
2009	2306 (9.4%)	245 (9.07%)
2010	2350 (9.51%)	231 (8.96%)
2011	2383 (9.71%)	225 (9.21%)
2012	2446 (9.99%)	244 (10.41%)
2013	2228 (9.79%)	205 (9.44%)
2014	2046 (9.78%)	212 (9.71%)
Total	25,640	2807
Relative risk	1.04 (1.02, 1.05)	1.04 (1.02, 1.05)
p value*	<.0001	<.0001

* *p* value was based on log-linear regression models with correction for over- or under-dispersion

Trend analysis for ED visits only used data from 2004 to 2014 since SPARCS only started to collect all ED visits data since 2004

p value <.0001; LC: adjusted *OR* 1.14, 95% CI 1.14–1.14, *p* value <.0001), while the 30-day readmission risk did not have significant linear change between 2000 and 2014 (IOC: adjusted OR 1, 95% CI 0.99–1.01, *p* value = 0.9976; LC: adjusted OR 1, 95% CI 0.99–1, *p* value = 0.3761).

Marginally, hospital length of stay (HLOS) did not have a significant change between 2000 and 2014 among IOC patients (*p* value = 0.2446, Table 5); while it showed a decreasing trend among LC (*p* value = 0.0065, Table 5). However, HLOS dropped 0.25% per year among both IOC and LC after adjusting for age, gender, race, insurance, health region, and any comorbidity, any complication (IOC: 95% CI 0.07–0.43%, *p* value = 0.0075; LC: 95% CI 0.21–0.29%, *p* value <.0001).

When examining rate of BDI among all LC patients, there is a rate of approximately 0.09% (25/29,312) in 2000 (Table 6). This rate had a significant increasing trend by

Table 5 Average HLOS for LC or IOC patients by year

Year	HLOS among LC	HLOS among IOC
2000	2.07 ± 3.81	2.43 ± 3.38
2001	2 ± 3.76	2.38 ± 3.55
2002	1.97 ± 3.42	2.29 ± 3.21
2003	2.1 ± 3.91	2.36 ± 4.02
2004	1.96 ± 3.43	2.24 ± 3.57
2005	1.9 ± 3.49	2.06 ± 3.40
2006	1.82 ± 3.17	2.03 ± 3.73
2007	2.15 ± 3.52	2.28 ± 3.64
2008	2.14 ± 3.44	2.72 ± 4.18
2009	1.98 ± 3.23	2.60 ± 3.77
2010	1.89 ± 3.26	2.51 ± 3.35
2011	1.87 ± 3.72	2.53 ± 3.61
2012	1.76 ± 2.85	2.38 ± 2.93
2013	1.67 ± 2.79	2.37 ± 3.15
2014	1.71 ± 3.88	2.38 ± 3.57
Change per year	−0.02 (−0.04, −0.01)	0.01 (−0.01, 0.03)
p value*	0.0065	0.2446

* *p* value was based on Wald test in linear regression

Table 6 Frequency table for BDI after LC or IOC (2000–2013)

Year	CBD injury among LC	CBD injury among IOC
2000	25 (0.09%)	6 (0.17%)
2001	32 (0.11%)	8 (0.23%)
2002	40 (0.13%)	8 (0.22%)
2003	31 (0.11%)	6 (0.18%)
2004	31 (0.11%)	6 (0.17%)
2005	19 (0.07%)	6 (0.17%)
2006	34 (0.12%)	16 (0.43%)
2007	32 (0.13%)	4 (0.12%)
2008	42 (0.18%)	11 (0.42%)
2009	37 (0.15%)	7 (0.26%)
2010	34 (0.14%)	6 (0.24%)
2011	31 (0.13%)	6 (0.25%)
2012	26 (0.11%)	7 (0.30%)
2013	37 (0.16%)	11 (0.51%)
Total	451 (0.12%)	108 (0.25%)
Relative risk	1.03 (1.0002, 1.06)	1.06 (1.01, 1.11)
p value*	0.0487	0.0297

* *p* value was based on log-linear regression models with correction for over-dispersion

around 3% per year. Similarly, there was a rate of 0.17% (6/3479) rate of BDI among cholangiogram patients in 2000, which increased significantly by around 6% from 2000 to 2013 (Table 6). This type of linear increasing trend also existed among LC after adjusting for patents' age, insurance, race, inpatient or not, IOC patient or not, any comorbidity and overall complication (adjusted OR 1.03 with 95% CI 1.00–1.06, p value = 0.0189); while among IOC there was no significant linear trend for CBD risk (adjusted OR 1.03 with 95% CI 0.98–1.08, p value = 0.2064). Marginally, BDI was more common in patients >65 years of age (p <0.0001), Asian and African American, those with inpatient procedures, those with certain co-morbidities (congestive heart failure, hypertension, diabetes, renal failure, liver disease, obesity, coagulopathy, and fluid, and electrolyte disorders). After considering these variables in one multivariable regression model, only patients with inpatient procedures were more likely to have CBD injury (p value <0.0001, Table 7).

Discussion

Currently, the use of IOC during LC has decreased over time. In our study, this number is between 10 and 12% in the state of New York. Since its introduction in the 1930s [15], its benefits have been considerably debated. Many advocate routine use of IOC [12, 16, 17], although selective use has been advised as well [18]. IOC is used to show the presence of stones or provide information about aberrant anatomy, in addition to identification of BDI [19], thus it can be used to prevent or decrease the severity of injuries [12]. Opponents consider IOC as a time consuming, cumbersome, and unnecessary procedure.

In the current study, we examined the use of IOC during LC for benign non-obstructive and obstructive biliary disease. The rate of performing IOC during LC has significantly decreased from 2000 to 2014, which shows that surgeons are performing this procedure less. In addition, the rate of complications, including BDI, and 30-day readmissions have significantly increased for patients undergoing LC with IOC (Fig. 1), despite these patients having less co-morbidities over time. This may reflect more surgeon's inexperience with the procedures, or that fact that cholangiography is now only performed in cases of difficult anatomy or feared complication, potentially even after that complication has occurred. The proportion of all patients with cholangiogram decreased by about 2% per year and the rate of BDI increased by around 6% per year. This rate of injury increased in both the LC overall (p = 0.049) and the LC with IOC groups (Table 6). Thus, the increase is independent of the presence of a cholangiogram.

Since the introduction of LC in 1990s, the rate of BDI was found to be higher compared to open cholecystectomy [12, 20]. Fletcher et al. showed that compared to open procedures, LC carries a twofold risk of BDI. Fletcher advocated for operative cholangiography and suggested a

Table 7 Estimated ORs and their 95% CI of explanatory variables for BDI (including interaction term between IOC patient and year)

Variable	Levels	Odds ratio with 95% CI	p value*
Year	Non-IOC patients	1.04 (1.01–1.06)	0.0032
	IOC patients	1.05 (1.002–1.1)	
Age	18–29 vs ≥65	0.55 (0.37–0.82)	0.0031
	30–44 vs ≥65	0.55 (0.4–0.77)	
	45–64 vs ≥65	0.71 (0.53–0.95)	
Any comorbidity	Yes vs no	1.07 (0.87–1.33)	0.5171
Inpatient or not	Yes vs no	5.43 (3.75–7.86)	<.0001
Insurance	Medicaid vs commercial	1.08 (0.78–1.48)	0.5563
	Medicare vs commercial	0.9 (0.66–1.22)	
	Other or unknown vs commercial	1.28 (0.81–2.03)	
Race	Asian, non-hispanic vs White, non-hispanic	1.35 (0.77–2.37)	0.1692
	Black, non-hispanic vs White, non-hispanic	1.22 (0.9–1.66)	
	Hispanic vs white, non-hispanic	0.79 (0.59–1.07)	
	Other vs white, non-hispanic	0.93 (0.71–1.22)	

* p value was based on multivariable logistic regression

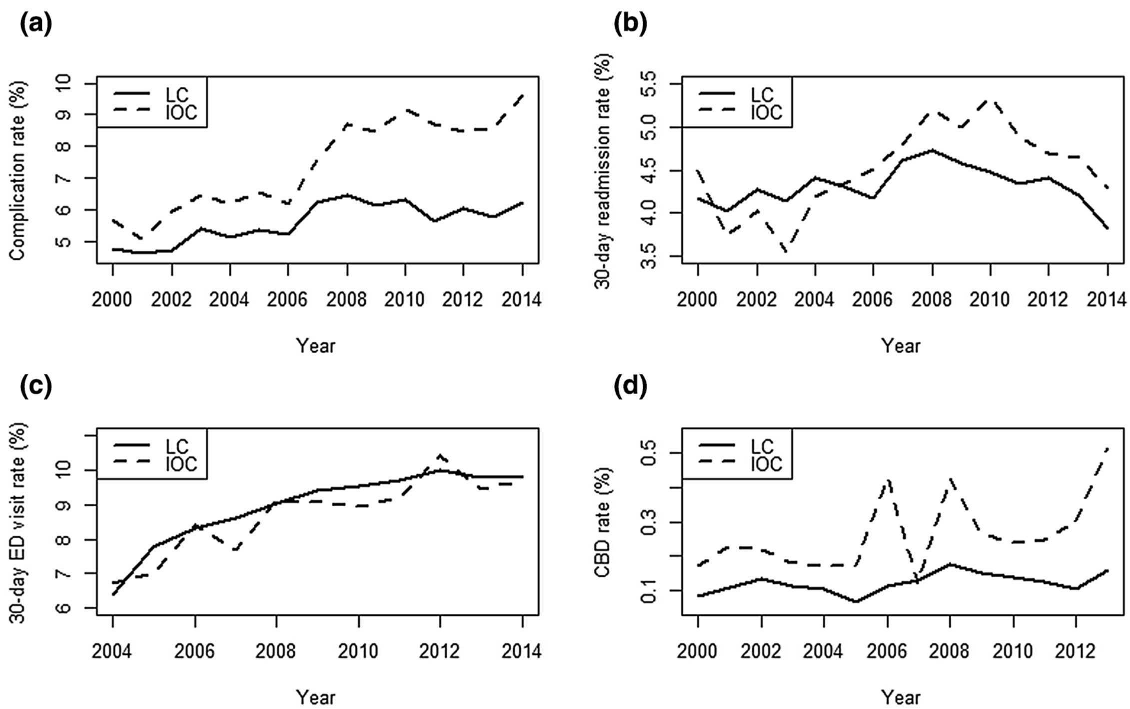

Fig. 1 The yearly rates of laparoscopic cholecystectomy or intraoperative cholangiogram in patients with (**A**) complication, (**B**) 30-day readmission, (**C**) 30-day ED visit, (**D**) CBD injury

reduced rate for all injuries and leaks with IOC (OR 0.5, 95% CI 0.35–0.7) [20]. The increase in BDI was attributed to the learning curve of LC, as this study was examining procedures being performed between 1988 and 1994 [20]. Due to concern for these injuries, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has made it a high priority to promote the adoption of a universal culture of safety during laparoscopic cholecystectomy. The Safe Cholecystectomy Task Force was initiated in order to reduce BDI. The group endorses liberal use of IOC especially in difficult cases or unclear anatomy [21].

Similar to our study, Buddingh recently advocated for use of IOC for reduction of BDI. The group described their experience in the Netherlands with adoption of routine IOC during LC and reported BDI prior and following adoption of this policy. In this study, 421 patients underwent cholecystectomy with selective IOC versus 435 patients with routine IOC. The rate of major BDI was 1.9% in the selective IOC group compared to 0% in the routine IOC group ($p = 0.004$) [12]. Alvarez et al. performed a retrospective analysis of patients with routine IOC between 1991 and 2012, which comprised of 11,423 patients. Twenty patients (0.17%) sustained a BDI with 18 of these patients being diagnosed at the time of IOC. The authors also concluded that routine use of IOC a high-volume center was associated with low incidence of BDI and helped in early detection [22]. Others have examined the use of cholangiography (groups with and without IOC) and did not find that routine use of IOC reduces BDI or the number of injuries missed during surgery (both 0.3%, $p = 0.755$) [23].

Our study has several limitations, including the limitations that are inherent to the use of retrospective data in a prospectively maintained database. Although we show an increase in BDI in groups with and without IOC, we suspect some of the IOCs are performed following BDI. We also do not know the experience of physicians with laparoscopic cholecystectomy or IOC, which may play a significant role in outcomes. Finally, we may undercapture the true rate of BDI as any outpatient facility with purely outpatient ERCP for bile duct injury may not have been reported. This should only magnify the trends identified.

Despite these limitations, the main advantage of our study is the use of a longitudinal data across many institutions in the state of New York. Through the use of a unique identifier we were able to track patients across institutions and throughout time, which is a main disadvantage of other databases, which may only capture 30-day outcomes. We are able to describe the trends over time of both LC, IOC, and determine complications, in addition to readmission and ED visits across institutions.

Conclusion

Our study shows a concerning increase in CBD injury in patients with and without IOC between 2000 and 2014 in the state of New York. At the same time, the rate of IOC/CBD exploration during LC has significantly decreased. In addition, the rate of complications and 30-day ED visits increased, although HLOS showed a decreasing trend. Routine IOC at time of LC may help early identification and potentially decrease the rate of BDI.

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Compliance with ethical standards

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