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Cholecystectomy following percutaneous cholecystostomy tube placement leads to higher rate of CBD injuries

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Abstract

Introduction Percutaneous cholecystostomy tube (PCT) placement is often the management of severe acute cholecystitis in the unstable patient. PCT can be later reversed and cholecystectomy performed. The purpose of this study is to investigate the incidence of subsequent cholecystectomy and clinical factors associated with subsequent procedure.

Methods The SPARCS, an administrative database, was used to search all patients undergoing PCT placement between 2000 and 2012 in the state of New York. Using a unique identifier, all patients were followed for subsequent cholecystectomy procedures for at least 2 years. Patients were also followed up to 2014 for potential CBD injury during subsequent laparoscopic (LC) or open cholecystectomy (OC). Univariate and multivariable regression analysis were performed when appropriate.

Results There were 9738 patients identified who underwent PCT placements. The incidence of patients who had a PCT in 2000–2012, which subsequently underwent cholecystectomy increased from 25.0% in 2000 to 31.7% in 2012. In addition, patients undergoing subsequent LC increased from 11.8% in 2000 to 22.2% in 2012, while the incidence of OC decreased from 13.2% in 2000 to 9.5% in 2012. After accounting for other confounding factors, younger male patients, race as white compared to black, who didn't have any complications during PCT placement were more likely to undergo subsequent cholecystectomy ($p < 0.05$). Average time to LC was 122.0 days versus 159.6 days for OC ($p < 0.0001$). From the patients who underwent cholecystectomy following PCT, 47 patients experienced CBD injury (1.6%).

Conclusions Incidence of cholecystectomy following PCT increased during the study period. Surgeons seem to be more comfortable performing LC as rate of LC increased from 11.8 to 22.2%. However, rate of CBD injury is higher during subsequent cholecystectomy compared to that of the general population. Caution should be used when performing subsequent cholecystectomy following PCT, as these procedures may be more technically challenging.

Keywords Cholecystostomy tube · Cholecystectomy · Bile duct injury

Laparoscopic cholecystectomy (LC) is one of the most common surgical procedures performed today, with approximately 950,000 done yearly in the US in 2014 [1]. Although relatively safe, the most feared complication of LC is Bile Duct Injury (BDI). Rates of BDI injury during LC have been estimated between 0.025 and 0.08% [2–4]. An increased risk of BDI injury has been associated with more severe disease [5]. In order to help avoid BDI injury in patients with severe cholecystitis, and others in whom immediate surgery may not be safe (i.e., critically ill or elderly patients), percutaneous cholecystostomy (PCT) may be used as a temporizing measure [6, 7].

There have been several studies on the appropriate timing of cholecystectomy following PCT, with varying results [8, 9]. Only a handful of studies have reported on the rate of eventual cholecystectomy after PCT, and the incidence of BDI injury during these subsequent surgeries. One randomized controlled trial found that of 224 patients with acute

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cholecystitis, 54 required PCT, and of these three required emergency cholecystectomy and 28 underwent elective LC at a later date, with an 8% conversion rate [10]. Suzuki et al. in a retrospective analysis of 82 patients who underwent PCT for acute cholecystitis, reported that 34% eventually underwent LC, with a mean time of 7 weeks between PCT and surgery and a conversion rate of 32% [11].

A recent meta-analysis concluded that there is not sufficient evidence to determine the safety and efficacy of PCT and subsequent LC in high-risk patients with acute cholecystitis [12]. The purpose of this study is to help fill the gap in this literature by determining the rate of cholecystectomy after PCT, the clinical factors associated with this subsequent procedure, and the incidence of CBD injury in LC performed after PCT.

Methods

Following New York Department of Health and Institutional Review Board approval, all patients requiring PCT placement between 2000 and 2012 in the state of New York were identified using the New York State SPARCS Database. SPARCS is a comprehensive all payer administrative database that currently collects all patient level data on patient characteristics, diagnoses, and treatments during inpatient stays, emergency department visits, ambulatory surgery, and outpatient visits in the state of New York [13]. All healthcare facilities in New York state are required to submit data to SPARCS with the purpose to create a statewide data set to improve the quality of medical care. Patient information is de-identified and patients are assigned a unique identifier, thus patients can be followed across institutions in the state of New York.

Patients with age < 18 years, missing information, lost to follow up ($n = 3771$, and hospital mortality $n = 2452$, 18.2%) were excluded from analysis. Through the use of a unique identifier, patients were followed up until 2014 to identify patients who underwent a subsequent cholecystectomy, either open or laparoscopic. Patients with CBD injury were also identified in a similar way.

Chi square tests with exact p values based on Monte Carlo simulation were utilized to examine the marginal association between patients' characteristics, comorbidities and complications with whether to have follow-up cholecystectomy. Factors that were significant based on Chi square test were further considered in a multivariable logistic regression model. In this model, aggregated comorbidities and complications were used instead of specific ones. In multivariable regression analysis, an OR > 1 indicated that one category was more likely to have follow-up cholecystectomy than the reference category, and OR < 1 indicated that one category was less likely to have follow-up cholecystectomy than the reference category. When examining factors related to the time interval between patients' cholecystostomy tube surgery and follow-up cholecystectomy, Wilcoxon's rank sum test and Kruskal–Wallis test were utilized to compare the difference in the time interval among two or more groups, respectively. Statistical analysis was performed using SAS 9.4 (SAS Institute Inc., Cary, NC) and significance level was set at 0.05.

Results

Between 2000 and 2012, there were 9738 percutaneous cholecystostomy tubes placed (Table 1). There were 2998 (30.8%) subsequent cholecystectomies performed. The top

Table 1 Number of initial cholecystostomy tube records found each year

Year	Cholecystostomy tube	Cholecystectomy	Laparoscopic cholecystectomy	Open cholecystectomy
2000	356	89 (25.00%)	42 (11.80%)	47 (13.20%)
2001	398	104 (26.13%)	56 (14.07%)	48 (12.06%)
2002	460	124 (26.96%)	61 (13.26%)	63 (13.70%)
2003	527	160 (30.36%)	89 (16.89%)	71 (13.47%)
2004	569	159 (27.94%)	92 (16.17%)	67 (11.78%)
2005	640	199 (31.09%)	114 (17.81%)	85 (13.28%)
2006	746	226 (30.29%)	135 (18.10%)	91 (12.20%)
2007	807	246 (30.48%)	163 (20.20%)	83 (10.29%)
2008	865	276 (31.91%)	160 (18.50%)	116 (13.41%)
2009	984	314 (31.91%)	199 (20.22%)	115 (11.69%)
2010	1060	359 (33.87%)	235 (22.17%)	124 (11.70%)
2011	1094	351 (32.08%)	217 (19.84%)	134 (12.25%)
2012	1232	391 (31.74%)	274 (22.24%)	117 (9.50%)
Total	9738	2998 (30.79%)	1837 (18.86%)	1161 (11.92%)

five reasons for percutaneous cholecystostomy tube were biliary tract disease (57.7%), septicemia (14.9%), pancreatic disorders (2.7%), complications of surgical procedures (2.1%), and acute myocardial infarction (1.7%). Average time interval between cholecystostomy tube and cholecystectomy was 101.9 ± 53.5 days. The incidence of laparoscopic cholecystectomy significantly increased from 2000 to 2012, as 11.8% underwent laparoscopic cholecystectomy in 2000 compared to 22.2% in 2012. The rate of open cholecystectomy significantly decreased from 2000 to 2012, as there were 13.2% in 2000 to 9.5% in 2012. Patients who ended up with open cholecystectomy had a longer time period to cholecystectomy compared to patients who had laparoscopic cholecystectomy (159.6 vs. 122 days, p value < 0.0001). There is no significant difference between cholecystectomy patients with and without CBD injury in terms of time interval between cholecystectomy tube and cholecystectomy. From the patients who underwent subsequent cholecystectomy, 532 patients (17.8%) had the procedure at a different institution.

Comparing patients who underwent subsequent cholecystectomy vs. no cholecystectomy, patients' age, gender, race, and insurance, most comorbidities and complications were significantly different between the two groups. Younger patients were more likely to undergo subsequent cholecystectomy (e.g., 18–49 vs. ≥ 80: 33.7% vs. 24.2%, p < 0.0001). In addition, male patients were more likely to undergo subsequent cholecystectomy compared to female patients (32.6% vs. 28.9%, p value = 0.0001). Other differences can be seen in Table 2. Patients without comorbidities were more likely to undergo subsequent cholecystectomy (62.7% vs. 37.3%, p value = 0.0001) as well as patients with tobacco use (24.1% vs. 9.3%, p = 0.01), Congestive Heart Failure (CHF) (24.1% vs. 18.2%, p < 0.001), Pulmonary disease (3.8% vs. 2.8%, p value = 0.02), neurological disorders (9.5% vs. 6.5%, p < 0.001), Renal failure (13.8% vs. 11.8%, p value = 0.01) liver disease (5.3% vs. 3.6%, p value = 0.001), metastatic cancer (7.1% vs. 1.8%, p < 0.0001), coagulopathy (9.8% vs. 6.7%, p value < 0.0001), weight loss (10.5% vs. 5.8%, p value < 0.0001), fluid and electrolyte (39.2% vs. 30.9%, p value < 0.0001), and deficiency anemia (17.2% vs. 13.7%, p value < 0.0001). In addition, patients with any complication during the original hospitalization were less likely to undergo subsequent cholecystectomy (64.2% vs. 50.5%, p value < 0.0001). Following multivariable logistic regression model, accounting for all the rest variables significant from univariate analysis, patient's age, gender, race, region, and any comorbidity were significantly associated with having subsequent cholecystectomy (p value < 0.05) (Table 3).

Among the 2998 patients who had a subsequent cholecystectomy, rate of CBD injury was 1.6% (n = 47 patients). Average HLOS following CBD injury was 5 days. In addition, 34.6% of patients with subsequent cholecystectomy had at least one complication (n = 1037). Mortality at subsequent cholecystectomy was 2.3% (n = 68).

Table 2 Descriptive table for patients' characteristics and comorbidities and complications comparing cholecystostomy tube patients with and without follow-up cholecystectomy

Variable	Level	Total	Without follow-up cholecystectomy (N = 6740)	With follow-up cholecystectomy (N = 2998)	p value
Patients' characteristics					
Age group	18–49	942 (10.45%)	625 (66.35%)	317 (33.65%)	< 0.0001
	50–59	1004 (11.14%)	673 (67.03%)	331 (32.97%)	
	60–69	1569 (17.40%)	1052 (67.05%)	517 (32.95%)	
	70–79	2215 (24.57%)	1433 (64.70%)	782 (35.30%)	
	≥ 80	3285 (36.44%)	2491 (75.83%)	794 (24.17%)	
Gender	Female	4718 (48.45%)	3354 (71.09%)	1364 (28.91%)	0.0001
	Male	5020 (51.55%)	3386 (67.45%)	1634 (32.55%)	
Race/ethnicity	White	5967 (61.28%)	4164 (69.78%)	1803 (30.22%)	0.0002
	Black	1209 (12.42%)	878 (72.62%)	331 (27.38%)	
	Asian	327 (3.36%)	218 (66.67%)	109 (33.33%)	
	Hispanic	1155 (11.86%)	744 (64.42%)	411 (35.58%)	
	Other	1080 (11.09%)	736 (68.15%)	344 (31.85%)	
Insurance	Medicaid	863 (8.86%)	582 (67.44%)	281 (32.56%)	0.0135
	Medicare	5763 (59.18%)	4058 (70.41%)	1705 (29.59%)	
	Commercial	3083 (31.66%)	2078 (67.40%)	1005 (32.60%)	
	Other	29 (0.30%)	22 (75.86%)	7 (24.14%)	
Comorbidities					
Any Comorbidity	No	708 (7.27%)	444 (62.71%)	264 (37.29%)	0.0001

Table 3 Estimated odds ratios and their 95% confidence intervals of possible predictors for follow-up cholecystectomy

Variable	Level	Odds Ratio	95% CI	*p* value[a]
Age group	18–49 versus ≥ 80	1.53	1.27–1.84	< 0.0001
	50–59 versus ≥ 80	1.52	1.28–1.81	
	60–69 versus ≥ 80	1.53	1.32–1.76	
	70–79 versus ≥ 80	1.70	1.51–1.92	
Gender	Female versus Male	0.88	0.80–0.97	0.0080
Race/ethnicity	Asian versus White	0.98	0.76–1.27	0.0086
	Black versus White	0.77	0.66–0.89	
	Hispanic versus White	1.04	0.90–1.21	
	Other versus White	0.96	0.83–1.12	
Insurance	Commercial versus other	1.56	0.62–3.92	0.4780
	Medicaid versus other	1.53	0.60–3.86	
	Medicare versus other	1.67	0.66–4.18	
Any comorbidity	Yes versus no	0.86	0.72–1.02	0.0904
Any complication	Yes versus no	0.58	0.53–0.64	< 0.0001

[a]*p* value was based on Wald test from multiple logistic regression

Discussion

Although cholecystectomy is the treatment of choice for acute cholecystitis, in high-risk populations, it is associated with higher morbidity and mortality [14]. Percutaneous cholecystostomy tube offers an alternative treatment with a safer profile [15]. However, the rate and safety of subsequent cholecystectomy remains unknown. This study shows that 30.8% of patients underwent subsequent cholecystectomy, with majority of these procedures performed laparoscopically (18.9%) and a significant portion (11.9%) performed using an open approach. Furthermore, the incidence of laparoscopic cholecystectomy following PCT increased from 2000 to 2012, while incidence of open procedures decreased.

Similar to our findings, Suzuki et al. found a rate of cholecystectomy after PCT of 34%, with a mean of 7 weeks to procedure. In this study, laparoscopy was attempted in 25 patients but required conversion to an open approach in 32% of patients ($n = 8$). Four patients had a planned open cholecystectomy [11]. Paran et al., examined prospectively the safety of initial conservative treatment with PCT in patients admitted for acute calculous cholecystitis [10]. Fifty-five patients required PCT placement, and among these patients, five patients did not improve. Two of the patients (3.6%) had severe concomitant multi-organ failure and died. Forty-nine patients were discharged with the PCT and 25 patients (51%) underwent laparoscopic cholecystectomy with a low conversion rate (8%) and minor complications (16%) [10].

Others have examined the timing of laparoscopic cholecystectomy following PCT placement, which remains controversial [8, 9, 16]. For example, Bickel et al. found that early cholecystectomy (within 2 days of surgery) was associated with shorter rate of conversion to open surgery [8]. Inoue et al. on the other hand, found that a shorter interval between PCT and surgery was associated with a higher rate of surgical complications. In a retrospective study of 67 patients with PCT followed by laparoscopic or open cholecystectomy, postoperative complications were more frequent when cholecystectomy was performed less than 216 h compared to over 216 h [9].

An important question that this study did not answer is the rate of recurrence of cholecystitis in patients who did and did not undergo a subsequent cholecystectomy following PCT. However, in a small study of 50 patients, Morse et al. showed that of 13 patients who subsequently had their PCT removed, eight patients developed recurrent cholecystitis. Of these patients, five had eventual cholecystectomy or repeat cholecystostomy, and three remaining patients died. The authors argued that in critically ill patients, cholecystostomy tubes should remain in place until patient can undergo cholecystectomy, and that removal of the tube without subsequent cholecystectomy was associated with high recurrence of cholecystitis (61.5%) and death (23.1%) [17]. However, this study had relatively small number of patients and further larger studies should be performed to collaborate these findings.

This study shows that patients who ended up having an open cholecystectomy had a longer time to cholecystectomy (average time interval 159.6 days vs. 122 days, p value < 0.0001), most likely reflecting higher morbidity with procedures in this patient population and delay of surgery. The incidence of CBD injury was same between the two groups; however, overall incidence of CBD injury subsequent cholecystectomy was significantly higher than previously reported [4], with 47 patients (1.6%) requiring a reconstructive procedure. Although cholecystectomy following PCT may be a reasonable option, surgeons should be aware of a higher rate of this dreaded complication.

Reviewing the literature, the authors were not able to find any large scale data to evaluate the rate of cholecystectomy following PCT placement. However, despite this, the study still has several limitations, some of which are attributable to the use of an administrative database, such as errors, lack of clinically rich data (vital signs, labs, or imaging) and lack of detailed operation information (e.g. operation duration, blood loss, or other operative variables). Although the SPARCS data are gathered for the purpose of assisting hospitals, agencies, and health care organizations with decision making regarding planning and monitoring of inpatient and ambulatory surgery services and costs, thus making it a very rigorous process, there is still potential for miscoding and errors during data submission. In addition, the SPARCS database fails to capture patients who leave NYS and receive further care outside of the state. However, the database is able to capture admissions and procedures to other institutions within the state, which may otherwise be overlooked. Lastly, this study only examines procedures within the state of New York, thus generalization cannot be applied nationwide.

Conclusions

Incidence of cholecystectomy following PCT increased during the study period. Surgeons seem to be more comfortable performing LC after PCT, demonstrated by the increased rate of LC from 11.8 to 31.7%. However, incidence of CBD injury in cholecystectomy is higher after PCT compared to that of the general population. Although cholecystectomy following PCT can be attempted, caution should be used, as these procedures may be more technically challenging.

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Compliance with ethical standards

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