



Utility of routine intraoperative cholangiogram during cholecystectomy in children: A nationwide analysis of outcomes and readmissions☆☆☆



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ABSTRACT

Purpose: This study aims to determine postoperative outcomes and readmissions in pediatric cholecystectomy with routine intraoperative cholangiogram (IOC) utilization.

Methods: The Nationwide Readmissions Database 2010–2014 was queried for all pediatric cholecystectomies. A propensity score-matched analysis (PSMA) with over 30 covariates was performed between cholecystectomy alone (CCY) versus those with routine IOC (CCY + IOC, no biliary obstruction, dilatation, or pancreatitis). χ^2 analysis or Mann-Whitney U were used for statistical analysis with $p < 0.05$ set as significant.

Results: 34,390 cholecystectomies were performed: 92% were laparoscopic, most were teenage females (75%, 15 years [13–17]) and did not undergo IOC (75%). Postoperative mortality rate was 0.1%.

The PSMA cohort comprised of 1412 CCY and 1453 CCY + IOC. Patients with CCY alone had higher rates of 30-day (7% vs 5%), 1-year readmissions (13% vs 11%) and had higher rates of overall complications (22% vs 12%) compared with CCY + IOC, all $p < 0.05$. Although uncommon, bile duct injuries were more prevalent in CCY (2% vs 0%, $p < 0.001$), while there was no difference in readmissions for retained stones. Resource utilization was increased in CCY patients, likely due to increased complication rates.

Conclusion: This nationwide PSMA suggests pediatric CCY with routine IOC is associated with decreased readmissions, overall resource utilization, complications, and bile duct injuries.

Type of Study: Retrospective Comparative Study.

Level of Evidence: Level III.

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Intraoperative cholangiogram (IOC) provides intraoperative fluoroscopic imaging of the biliary ducts by injecting contrast into the biliary ductal system. With proper technique and interpretation, IOC can be useful in identifying biliary anomalies or obstructions causing choledocholithiasis, cholangitis, elevated liver enzymes, or pancreatitis. This form of real-time imaging is used during cholecystectomies to avoid iatrogenic bile duct injuries (BDI) that are known to have significant complications such as hepatic failure, secondary biliary cirrhosis, and death [1]. However, although infrequent, IOC may carry the additional risks

of injury to the bile duct as well as a potential increase in cost, operative time, and ionizing radiation. Routine utilization of IOC is controversial, with some studies supporting its use based on its improved patient outcomes, while other studies failing to demonstrate a benefit and only supporting its selective use [2–4]. The current guidelines of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) leave the use of IOC up to the surgeons and the institution as there is no clear evidence to guide its utilization in a routine fashion [5].

Most studies on IOC utilization have been in adult populations. Of the studies done in the pediatric population, it has been found that selective IOC is a safe approach to patients that show clinical, laboratory, or radiological findings of common bile duct stones or dilation [6,7]. While these small-scale studies did suggest that routine IOC in children may reduce adverse events such as BDI and readmission rates, a pediatric cohort study from the California Patient Discharge Database did not show a significant decrease in injury with higher use of IOC or higher surgical volume. However, considering that younger age is associated with higher risk of BDI [8], there is still a need for larger pediatric studies that are nationally representative and include follow-up including readmissions. A specific comparison between pediatric patients that receive routine IOC

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☆☆ How this study should change care: This propensity score-matched analysis of a large, nationwide database suggests that utilization of intraoperative cholangiograms, when used in a routine fashion, is associated with lower rates of readmissions and complications, including injuries to the biliary duct system.

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during cholecystectomy with those that have cholecystectomies alone has yet to be examined.

Furthermore, observational studies utilizing a propensity score-matched analysis, which allows for a more direct comparison between two groups, have not been performed for pediatric cholecystectomy and routine IOC. Thus, we sought to utilize a large, nationally representative database with readmissions data, to determine whether routine IOC in pediatric cholecystectomies is correlated with postoperative complication and readmission rates. We hypothesized that pediatric cholecystectomies with routine IOC would have a reduced rate of postoperative complications and reduced readmissions.

1. Methods

1.1. Data source

The Nationwide Readmissions Database (NRD) is part of a family of databases developed by the Healthcare Cost and Utilization Project (HCUP) and is a subset of the Nationwide Inpatient Sample (NIS). This database was developed to address a large gap in healthcare data – the lack of nationally representative information on hospital readmissions for all ages. The NRD contains approximately 17 million unweighted discharges each year and discharge data from 22 geographically dispersed States, which accounts for 49% of all United States hospitalizations. The NRD also has the unique ability to track patients' readmissions annually to hospitals throughout each state (including both initial admission hospital and different hospitals) by using distinct, patient specific identifiers to track hospital admissions within the database, thus making it an ideal database for studies on nationwide readmissions. It also reduces the likelihood that transfers be counted as readmissions by collapsing multiple records into one if they involve same-day event such as a discharge from one hospital and admission to a different hospital.

1.2. Patient population

The NRD utilizes the International Classification of Disease–Clinical Modification 9th edition (ICD-9CM) to describe patient diagnoses and procedures. The 2010–2014 NRD was queried for all pediatric (age < 18 years) cholecystectomies (ICD-9CM: 51.2). Patients were initially excluded if they were infants (age = 0 years), had diagnoses of any biliary or liver anomaly (ICD-9CM: 75169, V4579, 75,161, 7746) or underwent liver transplantation or any other type of major liver operation where a cholecystectomy would be performed simultaneously (ICD-9CM 50.5–50.5). IOC was defined using ICD-9CM procedure codes 87.53, 87.51, 87.52, 87.54, and 87.59. “Routine IOC” was defined by the absence of signs/symptoms of biliary obstruction (common bile duct: 574.3, 574.4, 574.6, 574.7, 574.8, 576.1, 576.2, 575.9, pancreatitis: 577.0, endoscopic retrograde cholangiopancreatography (ERCP): 51.10). We determined that IOC performed under these circumstances would either be medically required or would fall under the “selective” use category, which was not the purpose of this study. Thus, for the PS-matched analysis, the two cohorts consisted of patients who only had cholecystectomy performed while the routine-IOC cohort underwent simultaneous IOC with their cholecystectomy.

Readmissions were defined as any admission to the hospital within 30-days of the initial hospital admission (index) and any subsequent admissions within 1-year. The NRD provides primary and secondary ICD-9CM diagnoses and procedure codes for these admissions. These codes were used to determine readmissions that occurred for any biliary pathologic process such as CBD obstruction (retained stones, biliary stricture, cholangitis, etc.: 576) and pancreatitis (577.0).

1.3. Statistical analysis

Demographics are reported as n(%). Quantitative variables are reported as mean ± standard deviation (SD) for normally distributed variables or median (IQR) for non-parametric variables. Univariate associations of quantitative variables were analyzed using Student's t-test or Mann–Whitney U test, as appropriate. Qualitative variables were analyzed by cross-tabulation and the chi-square statistic. Owing to the nature of the NRD, all survival/mortality analyses in our study refer to in-hospital survival/mortality. Total cost values were standardized to 2020 US dollars (\$USD), according to inflation rates provided by the US Bureau of Labor Statistics [9]. All analyses were two-sided, and significance was defined at alpha level 0.05.

Propensity score (PS)-matched analysis of cholecystectomy versus cholecystectomy + routine IOC was performed using the nearest neighbor method. For each comparison group, a dataset including demographics, hospital factors, diagnoses, congenital anomalies, and perinatal conditions were matched according to over 30 covariates to construct a fixed ratio-matched cohort for comparison. Propensity score values were assigned via multivariate logistic regression, according to demographic (age, gender), socioeconomic (payer status and median income quartile), hospital characteristics (bed size, location/

Table 1

Patient characteristics of pediatric cholecystectomies, Nationwide Readmissions Database (2010–2014).

Characteristics	n (%)
All Cholecystectomies	34,390 (100)
Mortality during admission	22 (0.1)
Type of Surgery	
Laparoscopic	31,708 (92)
Laparoscopic converted to open	694 (2)
Open	1988 (6)
Sex	
Female	25,614 (75)
Male	8776 (25)
Age^a, years	15 (13–17)
Length of Stay^a, days	3 (2–4)
Admission Type	
Elective	9576 (28)
Non-elective	24,814 (72)
Diagnoses	
Cholelithiasis	26,301 (77)
Cholecystitis	18,851 (55)
Pancreatitis	4920 (14)
Cholangitis	329 (1)
Choledocholithiasis	1601 (5)
Hematologic disease ^b	5121 (15)
Obese	5496 (16)
Additional Procedures	10,048 (29)
IOC	8549 (25)
–Routine	4645 (14)
ERCP	1994 (6)
Charlson Comorbidity Index ≥ 1	5887 (17)
Hospital Type	
Metropolitan Teaching	23,594 (68)
Metropolitan Non-teaching	8140 (24)
Rural	2657 (8)
Hospital Ownership	
Public	5003 (14)
Not-for-profit	26,328 (77)
Investor-owned	3059 (9)
Payer Type	
Public Insurance ^c	18,141 (53)
Private Insurance	13,779 (40)
Self-pay/Other	2470 (7)
Bile Duct Injury	195 (0.6)

^a Data presented as median (interquartile range), ^bHematologic diseases such as sickle cell disease, thalassemia, spherocytosis, etc., IOC: Intraoperative Cholangiogram, ERCP: Endoscopic Retrograde Cholangiopancreatography, ^cMedicaid/Medicare,

teaching status, region, and type). Propensity score value assignment, case sorting, and matching were performed using SPSS Statistics version 25.0 (International Business Machines Corp., Armonk, New York). After constructing two risk-adjusted comparison groups (cholecystectomy vs. cholecystectomy + routine IOC), we compared outcomes (mortality, postoperative complications, and readmissions) and healthcare utilization (length of stay [LOS], total cost) via chi-squared analysis for categorical data, *t*-test for parametric quantitative variables and Mann-Whitney *U* test for non-parametric quantitative variables. This retrospective comparative analysis was deemed exempt from review from the University of Miami Miller School of Medicine IRB committee as the data source contains deidentified publicly available patient information.

2. Results

2.1. Pediatric cholecystectomy overall patient demographics (Table 1)

Overall there were 34,390 cholecystectomies performed on pediatric patients during the study period. Most were female (75%) with a median age of 15 years (13–17 years). The majority were performed using laparoscopy (92%) with a small portion requiring conversion to open (2%). Most admissions were non-elective (72%) and occurred in metropolitan-teaching hospitals (68%) with non-profit designation (77%). Cholelithiasis was present in 77% of all patients, while cholecystitis and pancreatitis comprised 55% and 14%, respectively. Certain patients required additional procedures (29%) such as IOC (25%) and ERCP (6%). Routine IOC was utilized overall in 14% of patients. Overall, the BDI rate for all cholecystectomies performed was 0.6%, Table 1.

2.2. Readmissions after pediatric cholecystectomies (Table 2)

Overall the median time to readmission was 30 days (8–97). The 30-day readmission rate after pediatric cholecystectomy was 7%, and 11% of these patients were readmitted to a different hospital. Patients who underwent routine IOC (*n* = 4645, 14% of total cohort) had a decreased 30-day readmission at 5%. The 1-year readmission rate was 14% (11% in routine IOC patients) and 15% of these were readmitted to a different hospital. Biliary readmissions, which included retained gallstones, biliary strictures, and other biliary complications, accounted for 9% of all readmissions within one-year of the operation. During the study period, readmissions cost the healthcare system an additional \$102 million dollars, Table 2.

Table 2

Readmissions after discharge from admission for cholecystectomy, Nationwide Readmissions Database (2010–2014).

Characteristics	n (%)
30-day Readmission	2402 (7)
Different hospital	268 (11)
Cholecystectomy only (<i>n</i> = 24,342)	1864 (8)
Routine IOC patients (<i>n</i> = 4645)	240 (5)
1-year Readmission	4793(14)
Different hospital	742 (15)
Cholecystectomy only (<i>n</i> = 24,342)	3667 (15)
Routine IOC patients (<i>n</i> = 4645)	523 (11)
Biliary Readmission*	425 (9)
Time to readmission^a, days	30 (8–97)
Cost Analysis, US Dollars (\$)	Median (IQR)
30-day Readmission	\$7565 (\$4221–\$15,174)
Different Hospital	\$7349 (\$4866–\$15,439)
1-year Readmission	\$8983 (\$4388–\$21,120)
Different Hospital	\$6926 (\$3995–\$12,843)
Total Cost of all Readmissions	\$102,134,236

^a Data presented as median (interquartile range), *Includes retained gallstones, biliary strictures, other biliary complications.

2.3. Propensity score-matched analysis, cholecystectomy only versus routine IOC (PSMA, Table 3)

After PSMA, there was no significant difference in sex, age, and other covariates associated with the matching regression between patients undergoing cholecystectomy alone and cholecystectomy with routine IOC. However, elective admissions were more likely to undergo routine IOC (30% vs 19%, *p* < 0.001) whereas patients who were admitted on the weekend were less likely to have a routine IOC performed (18% vs 21%, *p* = 0.01). Routine IOC was more commonly employed in patients with cholecystitis (63% vs 47%, *p* < 0.001), and less commonly performed in patients with cholelithiasis (82% vs 85%, *p* = 0.01) and/or hematological disorders (13% vs 17%, *p* = 0.001). There was no statistical difference between the two cohorts with respect to a diagnosis of obesity (13% vs 15%, *p* = 0.22).

Table 3

Propensity score (PS)-matched comparison of cholecystectomy versus cholecystectomy + routine intraoperative cholangiogram (IOC) in pediatric patients, NRD 2010–2014.

	Cholecystectomy (<i>n</i> = 1412)		Cholecystectomy + routine IOC (<i>n</i> = 1453)		p-Value
	n	%	n	%	
General characteristics					
Sex					0.2
Male	351	25	331	23	
Female	1061	75	1122	77	
Admission on weekend	302	21	257	18	0.01
Elective admission	272	19	442	30	<0.001
Associated diagnoses					
Cholecystitis	668	47	915	63	<0.001
Cholelithiasis	1203	85	1187	82	0.01
Hematological diseases	240	17	184	13	0.001
Obese	207	15	190	13	0.22
Postoperative outcomes					
Mortality	*	<0.01	*	<0.01	0.15
Complications					
Bile duct injury	32	2	*	<0.01	<0.001
CBD exploration	*	1	18	1	0.15
Wound infection	*	<0.1	*	<0.1	0.98
Wound disruption	*	<0.1	*	<0.1	0.15
Reopening surgical site	*	<1.0	*	<0.01	0.1
Perforation or laceration	20	1	*	<0.1	0.002
Septicemia	19	1	*	0.5	0.003
Pneumonia	14	1.0	*	0.5	0.11
Other infections	102	7	47	3	<0.001
Diseases of respiratory system	56	4	22	2	<0.001
Acute GI ulcer or bleed	32	2	*	1	<0.001
Nausea, vomiting, diarrhea	59	4	57	4	0.73
Readmissions					
30-day readmission	102	7	67	5	0.003
30-day readmission – DH	13	1	12	1	0.79
1-year readmission	185	13	155	11	0.04
1-year readmission – DH	29	2	37	3	0.38
Biliary readmits	30	16	17	11	0.16
Biliary obstruction at readmission	17	1	*	0.6	0.06
Resource utilization^a					
Length of stay, days	3 (2–5)		2 (1–3)		<0.001
Cost, USD	11,653 (8514–16,486)		9246 (4185–11,798)		<0.001
Cost of 30 d readmissions (\$USD)	8129 (4182–13,394)		6080 (4184–11,798)		0.36
Cost of 1 y readmissions (\$USD)	9548 (4571–20,194)		7485 (4053–15,552)		0.10

PS values were assigned, and cholecystectomy only and cholecystectomy + routine IOC cohorts underwent risk adjusted, matched comparison using 41 covariates. CBD: Common bile duct, GI, gastrointestinal; DH: different hospital than index, \$USD, US dollars, values have been adjusted according to US inflation rates to the year 2020. ^aResource utilization variables presented as median (interquartile range). Cells marked with an asterisk (*) represent actual values censored from publication in accordance with the Healthcare Cost and Utilization Project Data Use Agreement.

PSMA between cholecystectomy and cholecystectomy with routine IOC revealed an overall low mortality rate (<0.01% for both). While overall complication rates after cholecystectomy were low, certain postoperative complications were found to be associated with choice of procedure. Cholecystectomy alone (when compared against cholecystectomy with routine IOC) was associated with higher rates of BDI (2% vs <0.01%, $p < 0.001$), perforation/laceration (1% vs <0.01%, $p = 0.002$), sepsis (1% vs 0.5%, $p = 0.003$), other infections (7% vs 3% $p < 0.001$), and respiratory system disorders (4% vs 2%, $p < 0.001$). The addition of routine IOC with cholecystectomy was not found to be associated with any increased rates of complications, while certain complications had no difference between the groups.

Resource utilization between cholecystectomy and cholecystectomy with routine IOC was also analyzed with propensity score matching. Patients who underwent routine IOC had decreased hospital lengths of stay (2 [1–3] days vs 3 [2–5] days, $p < 0.001$) and decreased overall index hospital costs (\$9246[\$4185–\$11,798] vs \$11,653[\$8514–\$16,486], $p < 0.001$). At both 30-day and 1-year time intervals for readmissions, there was no difference found between overall costs of readmissions between the two groups.

3. Discussion

This study utilizing a PSMA of a nationwide database (including re-admission data) attempts to determine whether the utilization of routine IOC is associated with decreased post-operative cholecystectomy complications and readmissions. We hypothesized that routine IOC with cholecystectomy in pediatric patients would be associated with decreased complications such as BDI and decreased readmissions. Our analysis demonstrated that patients undergoing routine IOC were less likely to have postoperative complications such as BDI, perforation/laceration, sepsis, other infections, and diseases of the respiratory system. These patients were also less likely to have readmissions to the hospital within 30 days and 1 year, but there were no differences in readmissions due to a biliary etiology. Furthermore, IOC utilized routinely with cholecystectomy was found to have reduced resource utilization, as LOS and total initial hospitalization costs were decreased when compared to the cohort with only cholecystectomy performed.

Our study demonstrates the overall 30-day readmission rate after cholecystectomy was 7% and stratified further into groups including cholecystectomy only (8%) and cholecystectomy with routine IOC (5%). Recent studies of the pediatric surgical population for 30-day readmission rates demonstrated rates from 4 to 6.5% [10–12] and a study of the pediatric population in California demonstrated 30-day and 1-year readmission rates after cholecystectomy at 7% and 9% respectively [8]. Our study is consistent with Kelley-Quon et al. as our data demonstrates a 30-day readmission rate of 7% [8]. However, patients who received routine IOC had a decreased 30-day readmission rate (5%) and after propensity score matched analysis had statistically significantly lower rates of both 30-day and 1-year readmission rates when compared to a matched cohort of only cholecystectomy. In the adult population, studies on readmissions after cholecystectomy and IOC have also demonstrated reduced readmission rates with utilization of IOC [13,14].

Complications after cholecystectomy in the pediatric population have been previously described [8,15,16] and include general postoperative concerns such as postoperative hemorrhage, perforation/laceration, and infections (among others). However, the most feared complication of the cholecystectomy remains an injury to the CBD, which can have very serious long-term effects. Currently there remains a lack of prospective, randomized data in the pediatric population regarding whether IOC usage decreases the overall incidence of complications such as BDI. The adult literature including meta-analyses and large cohort database analyses suggest that IOC usage may be associated with decreased rate of BDI when used in a routine fashion [2,4,5,14,18,19], however this remains at Level II evidence, grade B recommendations according to guidelines published by SAGES [5]. Our propensity-score

matched analysis demonstrates that IOC when used in a routine fashion is associated with decreased rates of BDI and other postoperative complications such as perforation/laceration, sepsis and other infections. We surmise this is due to the IOC's ability to accurately visualize the biliary anatomy, which in turn allows for decreased rates of biliary complications and other operative complications such as perforation and laceration of adjacent organs. Another explanation for decreased complications is that surgeons or hospitals that routinely utilize IOC during cholecystectomy may have improved advanced laparoscopic skills or other advanced care characteristics which may translate to overall decreased complications. Our study suggests that IOC is not only safe, but when utilized routinely is associated with a decrease in the worst complications in the pediatric population and can potentially offer therapeutic benefit and avoid a secondary ERCP.

Concern for utilizing IOC in a routine fashion often arises due to its overall increase in operative time [14,20], which some argue increases the overall cost and burden to the healthcare system. We performed an additional analysis regarding resource utilization to determine whether routine IOC usage would have an effect. Between the matched cohorts, the routine usage of IOC demonstrated decreased length of stay and decreased overall hospitalization costs. Other analyses in the adult population have also suggested that not only is routine IOC cost-effective, but that it also was associated with a cost/life-year saved amount of \$13,000 [21,22]. While our data also demonstrates an increased risk for readmission in cholecystectomy only patients, which brings its own costs, we did not find a statistically significant difference in readmission costs between the two groups.

This study has several limitations. The study design is observational, and thus is unable to control for unmeasurable variables such as specific hospital factors, surgeon-specific factors and intraoperative factors such as inflammation or aberrant anatomy. While this study attempts to stratify IOCs in terms of "routine" usage and "medical" usage, this determination is based on comorbid conditions such as biliary obstruction or pancreatitis, and thus some routine IOCs could be miscategorized. Further limitations include those of retrospectively collected administrative databases like the NRD such as errors in data sampling, collection measures, usage of the ICD-9 coding scheme, and possible administrative errors during data entry. Additionally, the NRD cannot follow patients across years or if the patients are readmitted across state lines. However, HCUP estimates that less than 5% of readmissions occur across state lines [23]. Despite these limitations, the NRD is the largest database that allows for following readmissions across different hospitals in the US and as such is an invaluable tool to study postoperative complications and readmissions in the pediatric population. While the findings of this study add to the overall knowledge of utilization of IOC in pediatric patients, a prospective trial comparing these two groups is warranted.

4. Conclusion

This propensity score-matched analysis of a national pediatric population demonstrates routine IOC utilization with cholecystectomy is safe and is associated with decreased complications (including bile duct injury), decreased hospital readmissions, and an overall decrease in resource utilization. Thus, routine IOC in pediatric cholecystectomies may be a cost-effective strategy to reduce future complications and readmissions.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jpedsurg.2020.09.047>.

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