

A Current Profile and Assessment of North American Cholecystectomy: Results from the American College of Surgeons National Surgical Quality Improvement Program

Angela M Ingraham, MD, Mark E Cohen, PhD, Clifford Y Ko, MD, MS, MSHS, FACS,
Bruce Lee Hall, MD, PhD, MBA, FACS

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- BACKGROUND:** Cholecystectomy is among the most common surgical procedures performed in the United States. The current state of cholecystectomy outcomes, including variations in hospital performance, is unclear. The objective of this study is to compare the risk factors, indications, and 30-day outcomes, as well as variations in hospital performance associated with laparoscopic (LC) versus open cholecystectomy (OC) at 221 hospitals during a 4-year period.
- STUDY DESIGN:** Using the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database (2005–2008), patients were identified who underwent cholecystectomy and related procedures (cholangiogram and/or common bile duct exploration). Four outcomes were studied, ie, 30-day overall morbidity, serious morbidity, surgical site infections, and mortality. Forward stepwise logistic regressions yielded patient-level predicted probabilities, and hospital-level observed-to-expected ratios were determined.
- RESULTS:** Of 65,511 patients, 58,659 (89.5%) underwent LC; 6,852 (10.5%) underwent OC. OC patients were considerably older with a higher comorbidity burden. LC patients were less likely to experience any morbidity (3.1% versus 17.8%; $p < 0.0001$), a serious morbidity (1.4% versus 11.1%; $p < 0.0001$), or a surgical site infection (1.3% versus 8.4%; $p < 0.0001$), and less likely to die (0.3% versus 2.8%; $p < 0.0001$). Observed-to-expected ratios for overall morbidity ranged from 0 to 3.55; for serious morbidity, 0 to 3.23; for surgical site infection, 0 to 7.02; for mortality, 0 to 13.05.
- CONCLUSIONS:** Although overall incidence of adverse events is low after LC, substantial morbidity and mortality are associated with OC. Additionally, controlling for patient- and operation-related factors, considerable variations exist in hospital performance when evaluating 30-day outcomes after cholecystectomy. (J Am Coll Surg 2010;211:176–186. © 2010 by the American College of Surgeons)
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Received January 17, 2010; Revised April 5, 2010; Accepted April 6, 2010. From the Division of Research and Optimal Patient Care, American College of Surgeons, Chicago, IL (Ingraham, Cohen, Ko), Department of Surgery, University of Cincinnati, College of Medicine, Cincinnati, OH (Ingraham), Department of Surgery, University of California, Los Angeles (UCLA) and VA Greater Los Angeles Healthcare System, Los Angeles, CA (Ko), and Department of Surgery, John Cochran Veterans Affairs Medical Center, Department of Surgery, School of Medicine, Washington University in St Louis and Barnes Jewish Hospital, St Louis, MO and Center for Health Policy and the Olin Business School at Washington University in St Louis, St Louis, MO (Hall).

Correspondence address: Angela M Ingraham, MD, American College of Surgeons, 633 North Saint Clair St, Floor 22NE, Chicago, IL 60611. email: aingraham@facs.org

Since its introduction in the 1980s, laparoscopic cholecystectomy has transformed the management of, and become the standard of care for, the majority of gallbladder pathologies.^{1,2} It is estimated that, in 2006, approximately 917,000 cholecystectomies were performed in the United States.^{3,4} Additionally, in 2006, cholelithiasis accounted for 376,000 ambulatory surgery visits and 335,000 discharges from short-stay hospitals.^{3,4}

Previous studies of cholecystectomy and its associated diagnoses have focused on the identification of patient risk factors,⁵ burden of common bile duct injuries,^{6,7} timing of surgical intervention,^{8,9} and identification of effective postoperative clinical pathways.¹⁰ Despite the disease burden and surgical volume associated with gallbladder disease, most studies have been conducted using administrative data and have focused on inpatient outcomes. In addition, hospital-level variations in outcomes after cholecystectomy remain unclear.

Abbreviations and Acronyms

ACS	= American College of Surgeons
CBDE	= common bile duct exploration
IQR	= interquartile range
LOS	= length of stay
NSQIP	= National Surgical Quality Improvement Program
OR	= odds ratio
SSI	= surgical site infection

The objective of this study was to assess the risk factors, indications, 30-day outcomes, and variations in hospital performance associated with laparoscopic versus open cholecystectomy and related procedures (cholangiogram and/or common bile duct exploration [CBDE]) at American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) hospitals.

METHODS

Data acquisition

The ACS NSQIP is among the first, national, validated programs for measuring risk-adjusted surgical outcomes and improving quality of surgical care.¹¹ From medical records and personal communication with patients, comprehensive clinical data about patient demographics, preoperative risk factors and laboratory values, operative information, and perioperative and postoperative outcomes within 30 days of the index operation are collected by surgical clinical reviewers. The ACS NSQIP uses a systematic sampling strategy designed to select broad mixtures of either general and vascular operations, or operations among a larger set of specialties. The sampling procedure is influenced by hospital surgical volume and subject to several oversampling restrictions, including the inclusion of no more than 3 laparoscopic cholecystectomies in any 8-day sampling cycle. Intensive training, continuing education, and on-site audit programs standardize data collection, ensuring consistency and reliability. The ACS NSQIP affords hospitals the ability to conduct in-depth, blinded, quality comparisons with the other participants.¹²⁻¹⁴

Patient identification and outcomes

Patients 16 years of age or older who had undergone a cholecystectomy and related procedures (cholangiogram and/or CBDE) based on primary Current Procedural Terminology codes were identified from the ACS NSQIP database from January 1, 2005, through December 31, 2008 (Current Procedural Terminology codes, see Appendix 1). The 30-day outcomes of interest were overall morbidity, serious morbidity, surgical site infection (SSI) (superficial SSI, deep SSI, organ space SSI, and wound dehiscence),

and mortality. Serious morbidity was defined as having documentation of at least one of the following ACS NSQIP complications: organ space SSI, wound dehiscence, neurological event (stroke or cerebrovascular accident, coma lasting >24 hours, or peripheral neurological deficit), cardiac arrest, myocardial infarction, bleeding requiring transfusion, pulmonary embolism, ventilator dependence >48 hours, progressive or acute renal insufficiency, and sepsis or septic shock. Overall morbidity was defined as having documentation of a serious morbidity or at least one of the following ACS NSQIP complications: superficial SSI, deep SSI, pneumonia, unplanned intubation, urinary tract infection, and deep vein thrombosis. Patients could experience more than 1 of the listed complications. Patients were excluded from having the following complications if the condition was documented preoperatively: wound infection, pneumonia, ventilator-dependence or reintubation, renal failure, stroke, and coma. To determine mortality, surgical clinical reviewers examine medical records, attempt to contact patients a minimum of 3 times by telephone or mail, and query the Social Security Death Index and the National Obituary Archives.

Risk-adjustment factors

Risk factors for 30-day outcomes included patient age, gender, race, body mass index, American Society of Anesthesiologists class, emergency status, and preoperative functional status (as defined by ACS NSQIP). Comorbidities included diabetes, renal disease, dyspnea, ascites, chronic obstructive pulmonary disease, current pneumonia, ventilator-dependence, chronic steroid use, bleeding disorders, heart failure, hypertension, coronary artery disease, peripheral vascular disease, disseminated cancer, weight loss, current chemotherapy or radiotherapy, neurological deficit, preoperative transfusion, wound class, preoperative sepsis, septic shock, or systemic inflammatory response syndrome. Behavioral risk factors included alcohol use and smoking. All risk factors were converted into discrete categories.

Current Procedural Terminology codes were used to categorize surgical procedures by laparoscopic versus open approach, as well as by performance of cholangiogram or CBDE (6 categories, see Appendix 1). ICD-9 codes were used to categorize operations by postoperative diagnosis (5 categories, see Appendix 2). Eleven preoperative laboratory variables were also included (ie, sodium, creatinine, albumin, bilirubin, aspartate aminotransferase, alkaline phosphatase, white blood cell count, hematocrit, platelet count, partial thromboplastin time, and international normalized ratio). Categories of laboratory values were constructed using ACS NSQIP definitions of normal and abnormal¹⁵; missing data constituted a 3rd category.

Statistical analyses

Demographic characteristics and overall morbidity, serious morbidity, SSI, and mortality rates of patients were compared using chi-square tests for categorical and Wilcoxon rank-sum or 2-sided *t*-tests for continuous variables, as appropriate, with significance set at $p < 0.05$. The linear trend in the proportions of approach and outcomes (overall morbidity, serious morbidity, surgical infections, and mortality) over time was evaluated using the Cochran-Armitage trend test. Forward stepwise logistic regressions, with $p \leq 0.05$ for inclusion, identified target variables for hierarchical models and provided c-statistics for discrimination and Hosmer-Lemeshow statistics for calibration. Laparoscopic versus open approach was selected for inclusion in all models. To examine the risk associated with operative approach, the medians of risk for laparoscopic and open approaches for overall morbidity, serious morbidity, SSI, and mortality were compared.

Logistic regression models yielded patient-level predicted probabilities. These probabilities were summed for each hospital to estimate each hospital's risk-adjusted expectation for overall morbidity, serious morbidity, SSI, and mortality. For each hospital, the observed number of events was divided by expected, to produce an observed-to-expected (O/E) ratio. An O/E ratio of 1.0 indicates that the number of observed events equals the number of expected events. O/E ratios < 1.0 indicate better than expected outcomes; ratios > 1.0 indicate worse than expected outcomes. If the confidence interval (95% for overall morbidity, serious morbidity, and surgical site infection; 90% for mortality) of the O/E ratio does not include 1.0, then risk-adjusted outcomes were deemed statistically significant, and the hospital was designated as an outlier.¹⁶ A total of 4 O/E ratios (one for each overall morbidity, serious morbidity, SSI, and mortality) were generated for each hospital, using 2005–2008 data. Because of the unreliability of estimates based on small sample sizes, hospitals ($n = 8$) that submitted < 20 cholecystectomies during the study period were not assigned an O/E ratio.¹⁶

RESULTS

During the study period, 65,511 patients undergoing a cholecystectomy at 221 ACS NSQIP hospitals were accrued into the database. Sampled cases were more commonly laparoscopic than open (58,659 [89.5%] versus 6,852 [10.5%]). Laparoscopic cholecystectomy without cholangiogram or CBDE constituted the majority of all sampled procedures ($n = 42,777$ [65.3%]), and laparoscopic cholecystectomy with cholangiogram accounted for 23.6% ($n = 15,480$) (Table 1). Cholecystitis (acute,

Table 1. Distribution of Surgical Approach and Postoperative Diagnoses Associated with 65,511 Cholecystectomies with or without Cholangiogram or CBDE at American College of Surgeons National Surgical Quality Improvement Program Hospitals (2005–2008)

Postoperative diagnosis	Any laparoscopic procedure		Laparoscopic cholecystectomy		Laparoscopic cholecystectomy with cholangiogram		Laparoscopic cholecystectomy with CBDE		Any open procedure		Open cholecystectomy		Open cholecystectomy with cholangiogram		Open cholecystectomy with CBDE		Total*	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Acute cholecystitis	11,372	19.4	7,972	18.6	3,288	21.2	112	27.9	2,719	39.7	2,092	40.1	465	38.9	162	37.2	14,091	21.5
Chronic cholecystitis	4,976	8.5	3,787	8.9	1,184	7.7	5	1.2	271	4.0	226	4.3	44	3.7	1	0.23	5,247	8.0
Other cholecystitis	26,392	45.0	19,348	45.2	6,849	44.2	195	48.5	1,564	22.8	1,120	21.5	319	26.7	125	28.7	27,956	42.7
Cholelithiasis	10,750	18.3	7,979	18.7	2,713	17.5	58	14.4	872	12.7	623	11.9	172	14.4	77	17.7	11,622	17.7
Other	5,169	8.8	3,691	8.6	1,446	9.3	32	8.0	1,426	20.8	1,161	22.2	195	16.3	70	16.1	6,595	10.1
Total	58,659	89.5	42,777	65.3	15,480	23.6	402	0.61	6,852	10.5	5,222	8.0	1,195	1.8	435	0.66	65,511	100

*Results subject to sampling limitations as described. CBDE, common bile duct exploration.

chronic, and other) accounted for the majority ($n = 47,294$ [72.2%]) of surgical indications, regardless of surgical approach. A diagnosis of acute cholecystitis was more frequently associated with a cholecystectomy through a laparoscopic as compared with an open approach ($n = 11,372$ [80.7%] versus $n = 2,719$ [19.2%]; $p < 0.0001$). Patients undergoing an open procedure were more likely to have a postoperative diagnosis of acute cholecystitis than patients undergoing a laparoscopic procedure (39.7% versus 19.4%). A diagnosis of cholelithiasis was also more frequently associated with a cholecystectomy through a laparoscopic as compared with an open approach (10,750 [92.5%] versus 872 [7.5%]; $p < 0.004$), and patients undergoing a laparoscopic procedure were more likely to have a postoperative diagnosis of cholelithiasis than patients undergoing an open procedure (18.3% versus 12.7%). Patients who underwent open procedures were more likely to be considered an emergency case, to be older, and to be assigned any of the comorbidities studied (except for smoking), than those undergoing a laparoscopic procedure (Table 2).

For all procedures, 3,005 (4.6%) patients experienced at least one morbidity, and 350 (0.53%) patients died, although these averages are subject to sampling limitations as described in the methods section. To minimize sampling distortion, event rates should be examined within procedure categories (open or laparoscopic). Overall morbidity, serious morbidity, SSI, and mortality were considerably higher in patients undergoing open as compared with laparoscopic procedures (Table 3). Individual outcomes were also considerably higher in the open as compared with laparoscopic groups. Overall morbidity, serious morbidity, SSI, and mortality were statistically, but not clinically, higher among patients who underwent a laparoscopic cholecystectomy with cholangiogram than those in whom a cholangiogram was not performed. Conversely, overall morbidity, serious morbidity, SSI, and mortality were lower among patients who underwent an open cholecystectomy with cholangiogram than those in whom a cholangiogram was not performed. When examined by year 2005–2008, rates of outcomes (overall morbidity, serious morbidity, surgical infections, and mortality) within the open versus laparoscopic categories did not reveal any significant trends over time (data not shown).

Risk-adjustment models performed well (Table 4). Variables were selected for inclusion based on improvement in model fit p value of ≤ 0.05 . Despite this criterion, selection of postoperative ICD-9 diagnosis late in the stepwise progression (the 14th step of 22 variables for overall morbidity, the 10th step of 21 variables for serious morbidity, the 10th step of 21 variables for serious

morbidity, and the 17th step of 20 variables for mortality) indicates that this variable adds fairly limited explanatory power.

For patients who underwent cholecystectomy through a laparoscopic approach, median estimated risks of overall morbidity, serious morbidity, SSI, and mortality were 2%, 0.7%, 1%, and 0.06%, respectively (Fig. 1). Conversely, median estimated risks for patients undergoing open procedures were higher, although still generally low (13%, 7%, 8%, and 0.5% for overall morbidity, serious morbidity, SSI, and mortality, respectively). Risks portrayed are based on inclusion of an indicator variable for open versus laparoscopic procedure in the risk modeling. As a result, these estimations are not strictly preoperative estimates. As indicated by the minimal change in regression model parameters, much explanatory power was preserved without incorporation of an indicator for procedure approach (Table 4). When modeling the open procedure as one of the outcomes, postoperative diagnosis was selected as the second step (acute cholecystitis odds ratio [OR] = 1.96; 95% CI, 1.82–2.12; chronic cholecystitis OR = 1.01; 95% CI, 0.88–1.16; cholelithiasis OR = 1.26; 95% CI, 1.15–1.38; other OR = 2.95; 95% CI, 2.71–3.22) in the forward stepwise process of a total of 29 variables, each included based on an improvement in model fit p value of ≤ 0.05 . If an open procedure is considered an intermediate result, then postoperative diagnosis appears to have a substantial association with this result.

Substantial variation was seen in hospital performance for 30-day outcomes after cholecystectomy or related procedures (Fig. 2). Due to small sample sizes, 8 institutions were not assigned an O/E ratio. The range of O/E ratios for overall morbidity was 0 to 3.55; for serious morbidity, 0 to 3.23; for SSI, 0 to 7.02; and for mortality, 0 to 13.05. In these 213 institutions, the number of high outliers ranged from 7 for serious morbidity to 12 for SSI. The number of low outliers ranged from 2 for mortality to 11 for overall morbidity.

For all patients, 26,975 (41.2%) had a length of stay (LOS) (time from operation to discharge) of 0 days, and 38,536 (58.8%) had a LOS of at least 1 day. Median LOS for all patients was 1 day (interquartile range [IQR], 0–2). For the 38,536 patients not discharged on the same day as operation, median LOS was significantly longer for open procedures as compared with laparoscopic procedures (4-day IQR, 3–7 versus 1-day IQR, 1–2; $p < 0.0001$ [Kruskal-Wallis]) (Table 5). For these same patients, median LOS ranged from 1 day for laparoscopic cholecystectomy with or without cholangiogram to 6 days (IQR, 4–8) for open cholecystectomy with CBDE.

Table 2. Distribution of Patient Risk Factors Associated with 65,511 Cholecystectomies at American College of Surgeons National Surgical Quality Improvement Program Hospitals (2005–2008)

Risk factor	Laparoscopic (n = 58,659, 89.5%)		Open (n = 6,852, 10.5%)		Total* (n = 65,511)		p Value
	n	%	n	%	n	%	
Age (y), median (IQR)	48 (35–61)		61 (49–73)		49 (36–63)		<0.0001
Emergency case	4,666	8.0	1,158	16.9	5,824	8.9	<0.0001
Prior operation within 30 d							<0.0001
Yes	335	0.57	154	2.3	489	0.75	
No	47,537	81.0	5,733	83.7	53,270	81.3	
Null	10,787	18.4	965	14.1	11,752	17.9	
Gender							<0.0001
Female	42,857	73.1	3,453	50.4	46,310	70.7	
Male	15,802	26.9	3,399	49.6	19,201	29.3	
Race							<0.0001
White	38,325	65.3	4,610	67.3	42,935	65.5	
Black	5,367	9.2	807	11.8	6,174	9.4	
Other	14,967	25.5	1,435	20.9	16,402	25.0	
Body mass index							<0.0001
Normal	12,408	21.2	1,597	23.3	14,005	21.4	
Overweight	17,880	30.5	2,006	29.3	19,886	30.4	
Obese	25,935	44.2	2,770	40.4	28,705	43.8	
Underweight	793	1.4	181	2.6	974	1.5	
Unknown	1,643	2.8	298	4.4	1,941	3.0	
ASA class							<0.0001
1 No disturbance	8,529	14.5	224	3.3	8,753	13.4	
2 Mild disturbance	35,432	60.4	2,715	39.6	38,147	58.2	
3 Severe disturbance	13,614	23.2	3,259	47.6	16,873	25.8	
4 Life-threatening	1,074	1.8	634	9.3	1,708	2.6	
5 Moribund	10	0.02	20	0.29	30	0.05	
Functional status							<0.0001
Independent	57,042	97.2	5,961	87.0	63,003	96.2	
Partially dependent	1,344	2.3	607	8.9	1,951	3.0	
Totally dependent	273	0.47	284	4.1	557	0.85	
Diabetes	5,967	10.2	1,363	19.9	7,330	11.2	<0.0001
Renal failure (dialysis or acute renal failure)	434	0.74	224	3.3	658	1.0	<0.0001
Dyspnea	3,986	6.8	976	14.2	4,962	7.60	<0.0001
Ascites	316	0.54	225	3.3	541	0.83	<0.0001
Alcohol use	840	1.4	205	3.0	1,045	1.6	<0.0001
Current smoker within 1 y	11,708	20.0	1,323	19.3	13,031	19.9	0.20
COPD	1,407	2.4	443	6.5	1,850	2.8	<0.0001
Pneumonia	134	0.23	87	1.3	221	0.34	<0.0001
Ventilator-dependent	39	0.07	108	1.6	147	0.22	<0.0001
Steroid use for chronic condition	1,072	1.8	252	3.7	1,324	2.0	<0.0001
Bleeding disorder	1,725	2.9	618	9.02	2,343	3.6	<0.0001
Congestive heart failure	307	0.52	159	2.3	466	0.71	<0.0001
Hypertension requiring medication	19,832	33.8	3,749	54.7	23,581	36.0	<0.0001
Coronary artery disease [†]	4,046	6.9	967	14.1	5,013	7.7	<0.0001
Peripheral vascular disease [‡]	407	0.69	170	2.5	577	0.88	<0.0001

(continued)

Table 2. Continued

Risk factor	Laparoscopic (n = 58,659, 89.5%)		Open (n = 6,852, 10.5%)		Total* (n = 65,511)		p Value
	n	%	n	%	n	%	
Disseminated cancer	234	0.40	178	2.6	412	0.63	<0.0001
Weight loss (>10% in last 6 mo)	757	1.3	283	4.1	1,040	1.6	<0.0001
Chemotherapy for malignancy within 30 d preoperatively	168	0.29	83	1.2	251	0.38	<0.0001
Radiotherapy for malignancy in last 90 d	57	0.10	36	0.53	93	0.14	<0.0001
Neurologic disorder [§]	2,292	3.9	769	11.2	3,061	4.7	<0.0001
Transfusion	15	0.03	18	0.26	33	0.05	<0.0001
Preoperative sepsis [¶]	3,914	6.7	1,635	23.9	5,549	8.5	<0.0001

*Results subject to sampling limitations as described.

[†]History of angina 1 month before surgery, history of myocardial infarction 6 months before surgery, previous percutaneous cardiac intervention, or previous cardiac surgery.

[‡]History of revascularization or amputation for peripheral vascular disease and rest pain or gangrene.

[§]CVA or stroke with or without neurological deficit, history of transient ischemic attacks, hemiplegia, paraplegia, impaired sensorium, or quadriplegia.

^{||}Transfusion >4 U packed red blood cells within 72 hours before surgery.

[¶]Preoperative systemic inflammatory response syndrome, sepsis, or septic shock.

[#]Significance calculated with Fisher's exact test due to small sample sizes.

ASA, American Society of Anesthesiologists; IQR, interquartile range.

DISCUSSION

In this study, we provide an overview of patient risk factors, 30-day outcomes, and hospital variation in performance related to cholecystectomy and related procedures at hospitals participating in the ACS NSQIP during a 4-year period. As expected, the majority of procedures sampled were performed laparoscopically. We also demonstrated a substantial burden of overall morbidity, serious morbidity, SSIs, and mortality, which was prominently associated with an open compared with laparoscopic approach. Although the overall incidence of adverse events is relatively low, we have demonstrated considerable variation in hospital outcomes for overall morbidity, serious morbidity, SSI, and mortality.

Findings presented here confirm and build on prior studies in this area. Using a subset of patients from the Agency for Health Care Policy and Research—funded Biliary Tract Disease Patient Outcomes Research Team (PORT) study, indications and outcomes of 1,611 patients undergoing nonincidental cholecystectomy in 1989 as compared with 2,031 patients in 1993 were compared. In 1993, 3.9% of cholecystectomies were performed for a “normal gallbladder”; 65.9% for uncomplicated cholelithiasis; 17.8% for acute cholecystitis without gangrene or empyema; 6.0% for gallbladder gangrene or empyema; and 5.5% for gallstone complications extending beyond the gallbladder.¹⁷ As the ACS NSQIP does not collect pathology data and limits the number of laparoscopic procedures collected, direct comparisons with those numbers cannot be made. Based on ICD-9 codes, a substantially smaller proportion of cholecystectomies within the ACS NSQIP

were performed for cholelithiasis (17.7%), with a much higher percentage of cases being associated with a diagnosis of cholecystitis (72.2%). In a study from phase I of the National Veterans Affairs Surgical Risk study, the number of cholecystectomies performed laparoscopically increased over time (20% between October 1, 1991 and December 31, 1991, versus 51% between October 1, 1993 and December 31, 1993).¹⁸ Because of the increasing number of hospitals participating in, and the strategic sampling employed by, the ACS NSQIP, we are unable to rigorously comment on whether the rate of laparoscopic procedures is increasing over time.

Outcomes after cholecystectomy have been studied in various patient populations. Studies from the Veterans Health Administration have found relatively higher morbidity, mortality, and postoperative lengths of stay than those within the private-sector NSQIP. In a study from phase I of the National Veterans Affairs Surgical Risk study, 30-day overall complication rate was 12.6% (15.8% for open cases versus 7.6% for laparoscopic cases).¹⁸ Analyses from the National Veterans Affairs Surgical Risk Study and the Veterans Administration's NSQIP have demonstrated 30-day mortality rates of 1.6% to 2.8% for open cases versus 0.2% to 0.5% for laparoscopic cases.^{18,19} Mean postoperative LOS ranged from 7.3 to 9.2 days for open versus 3.2 to 3.9 days for laparoscopic procedures.^{18,20}

Other studies of nonveteran patient populations undergoing cholecystectomies have documented outcomes similar to those in our study. Within the Nationwide Inpatient Sample, the overall mortality rate was 0.5% for laparoscopic cholecystectomy (n = 1,240,212) and 4% for open

Table 3. Comparison of 30-Day Outcomes after Laparoscopic versus Open Cholecystectomy at American College of Surgeons National Surgical Quality Improvement Program Hospitals (2005–2008)*

	Laparoscopic (n = 58,659 [89.5%])								Open (n = 6,852 [10.5%])								All procedures (n = 65,511)		p Value
	All		Without cholangiogram		With cholangiogram		With CBDE		All		Without cholangiogram		With cholangiogram		With CBDE				
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
Overall morbidity	1,787	3.1	1,270	3.0	502	3.2	15	3.7	1,218	17.8	931	17.8	191	16.0	96	22.1	3,005	4.6	<0.0001
Serious morbidity	790	1.4	552	1.3	232	1.5	6	1.5	762	11.1	594	11.4	112	9.4	56	12.9	1,552	2.4	<0.0001
SSI	762	1.3	545	1.3	212	1.4	5	1.2	577	8.4	437	8.4	96	8.0	44	10.1	1,339	2.0	<0.0001
Mortality	157	0.27	112	0.3	44	0.3	1	0.25	193	2.8	140	2.7	29	2.4	24	5.5	350	0.53	<0.0001
Organ space SSI	189	0.32							166	2.4							355	0.54	
Wound dehiscence	39	0.07							59	0.86							98	0.15	
Neurological event [†]	46	0.08							36	0.53							82	0.13	
Cardiac arrest	54	0.09							54	0.79							108	0.16	
MI	35	0.06							14	0.20							49	0.07	<0.0001
Bleeding requiring transfusion	44	0.08							37	0.54							81	0.12	<0.0001
Pulmonary embolism	56	0.10							31	0.45							87	0.13	<0.0001
Ventilator-dependence >48 h	112	0.19							195	2.9							307	0.47	<0.0001
Progressive or acute renal insufficiency	98	0.17							89	1.3							187	0.29	<0.0001
Sepsis or septic shock	421	0.72							438	6.4							859	1.3	<0.0001
Superficial SSI	506	0.86							326	4.8							832	1.3	<0.0001
Deep SSI	41	0.07							76	1.1							117	0.18	<0.0001
Pneumonia	208	0.35							210	3.1							418	0.64	<0.0001
Unplanned intubation	198	0.34							181	2.6							379	0.58	<0.0001
UTI	380	0.65							145	2.1							525	0.80	<0.0001
DVT	32	0.05							32	0.47							64	0.10	<0.0001

*Results subject to sampling limitations as described.

[†]Neurological event includes stroke or CVA, coma lasting >24 hours, or peripheral neurological deficit.

CBDE, common bile duct exploration; DVT, deep vein thrombosis; SSI, surgical site infection; UTI, urinary tract infection.

Table 4. Risk-adjustment Parameters for Models of 30-Day Outcomes after Cholecystectomies at American College of Surgeons National Surgical Quality Improvement Program Participating Hospitals (2005–2008)

	Overall morbidity			Serious morbidity			SSI			Mortality		
	c-statistic	HL chi-square	p Value	c-statistic	HL chi-square	p Value	c-statistic	HL chi-square	p Value	c-statistic	HL chi-square	p Value
Models using procedure type indicators	0.78	9.73	0.28	0.86	19.05	0.01	0.74	3.55	0.90	0.94	9.27	0.32
Models without procedure type indicators	0.76	10.13	0.26	0.84	18.33	0.02	0.70	7.13	0.52	0.94	8.58	0.38
Modeling open procedure as intermediate outcomes*	0.82	49.56	<0.0001									

*First five variables selected for inclusion in this model are, in order: American Society of Anesthesiologists class (2: mild disturbance, odds ratio [OR] = 1.96; 95% CI, 1.69–2.26; 3: severe disturbance, OR = 3.24; 95% CI, 2.79–3.78; 4: life-threatening, OR = 3.90; 95% CI, 3.21–4.74; 5: moribund, OR = 4.34; 95% CI, 1.68–11.20); ICD-9 diagnosis code (acute cholecystitis, OR = 1.96; 95% CI, 1.82–2.12; chronic cholecystitis, OR = 1.01; 95% CI, 0.88–1.16; cholelithiasis, OR = 1.26; 95% CI, 1.15–1.38; other, OR = 2.95; 95% CI, 2.71–3.22); wound class (contaminated/dirty/infected, OR = 1.89; 95% CI, 1.78–2.02); preoperative international normalized ratio (missing variable, OR = 0.71; 95% CI, 0.64–0.79; INR ≥ 1.4 , OR = 1.18; 95% CI, 1.04–1.35); and age (40 to 59 years, OR = 1.66; 95% CI, 1.52–1.81; 60 to 79 years, OR = 2.25; 95% CI, 2.05–2.47; older than 80 years, OR = 2.09; 95% CI, 1.84–2.37).

HL, Hosmer-Lemeshow; SSI, surgical site infection.

cholecystectomy (n = 147,190) among patients with acute cholecystitis.²¹ A meta-analysis comparing 98 studies of laparoscopic cholecystectomy (78,747 patients) with 28 studies of open cholecystectomy (12,973 patients) demonstrated that the laparoscopic approach was associated with lower mortality than the open approach (0.086% to 0.16% versus 0.66% to 0.74%).²² In addition, after laparoscopic cholecystectomy, complication rates for urinary tract infection ranged from 0.12% to 0.69%, for myocardial infarction 0.05% to 0.48%, and for wound infection 0.51% to 1.11%.²² A retrospective review of prospectively collected data from 22,953 patients undergoing cholecystectomy for acute or chronic cholecystitis within the Swiss Association of Laparoscopic and Thoracoscopic Surgery database between 1995 and 2003 reported a mortality rate of 0.003% (73 patients) and an overall postoperative complication rate of 7.5% (1,741 patients).⁵ In the Biliary Tract Disease

PORT study, the prevalence of the majority of complications identified in 1989 and 1993 was <2%. In 1993, reported in-hospital mortality after a laparoscopic versus open cholecystectomy was 0.4% versus 1.5% (p = 0.986).¹⁷ Within the Biliary Tract Disease PORT study, mean LOS decreased between 1989 and 1993, with the mean LOS in 1993 being 2.0 days after the laparoscopic approach (SD = 4.7 days) and 8.9 days after an open procedure (SD = 18.3 days).¹⁷ These results are relatively similar to those in our study of 1.09 versus 6.35 days for laparoscopic versus open procedures, respectively.

This research, based on a rigorous, clinical dataset of recently performed cholecystectomies, contributes valuable information to the body of knowledge surrounding the care of patients undergoing cholecystectomies in North America. In addition to insights provided about risk-adjustment, a uniquely valuable aspect of the results reported here is that few studies have addressed the hospital-level variations in outcomes for patients undergoing cholecystectomy.^{19,23} For example, in one study, aspects of safety (discharge disposition, cholangiogram rates, and conversion rates) and patient selection (comorbidity burden, diagnoses, and social demographics) were compared between hospitals versus freestanding surgical centers performing elective laparoscopic cholecystectomy.²³ Patients treated at freestanding surgical centers tended to be younger, with fewer comorbidities, and underwent more intraoperative cholangiograms with no difference in the rate of conversion than those treated at hospitals. Due to limitations of the database, no comparison of outcomes could be performed. In another study, a lack of correlation between procedural and surgical specialty volume after 8 operations, including laparoscopic and open cholecystectomy, was demonstrated in the Veterans Health Administration hospitals.¹⁹ Mean O/E ratios for mortality by quartile of procedural volume ranged from 0.87 to 1.67 for

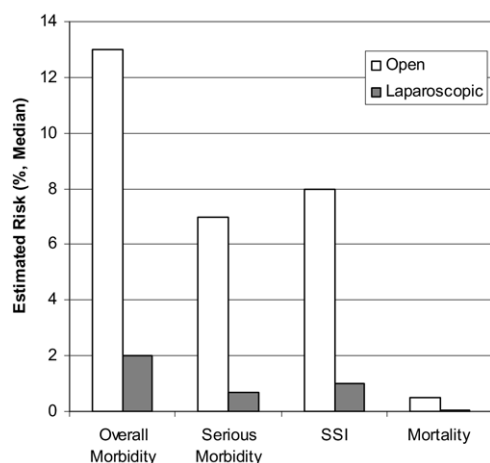
**Figure 1.** Estimated risk of 30-day overall morbidity, serious morbidity, surgical site infection, and mortality for open versus laparoscopic cholecystectomy at American College of Surgeons National Surgical Quality Improvement Program hospitals (2005 to 2008).



Figure 2. Depiction of American College of Surgeons National Surgical Quality Improvement Program hospital performance on four 30-day outcomes after cholecystectomy. The high and low outlier legend on this figure refers to the color rendition. Outlier status, however, is partially redundant with location; low outliers tend toward the left portion of the plots and high outliers tend toward the right. O/E, observed to expected ratio.

Table 5. Comparison of Postoperative Length of Stay among Patients after Cholecystectomy with or without Cholangiogram or CBDE at American College of Surgeons National Surgical Quality Improvement Program Hospitals (2005–2008)

Procedure	LOS = 0		LOS > 0		Analyses including only patients with LOS > 0			
	n	%	n	%	Mean	SD	Median	IQR
All procedures	26,975	41.2	38,536	58.8				
Any laparoscopic procedure	26,889	99.7	31,770	82.4	2.02	3.10	1	1–2
Laparoscopic cholecystectomy	20,675	76.7	22,102	57.4	1.96	3.11	1	1–2
Laparoscopic cholecystectomy with cholangiogram	6,128	22.7	9,352	24.3	2.14	3.05	1	1–2
Laparoscopic cholecystectomy with CBDE	86	0.32	316	0.82	2.99	3.19	2	1–4
Any open procedure	86	0.32	6,766	17.6	6.44	7.78	4	3–7
Open cholecystectomy	51	0.19	5,171	13.4	6.38	7.96	4	3–7
Open cholecystectomy with cholangiogram	34	0.13	1,161	3.0	6.31	7.29	4	3–7
Open cholecystectomy with CBDE	1	0.00	434	1.1	7.48	6.66	6	4–8

CBDE, common bile duct exploration; LOS, length of stay; IQR, interquartile range.

open cholecystectomy and from 0.83 to 1.56 for laparoscopic cholecystectomy. As only mean O/E ratios were reported, the range of O/E ratios for mortality cannot be compared with those in our study.

Results of our study must be considered in light of several limitations, in addition to those related to the sampling algorithm already described. First, the ACS NSQIP does not currently collect information about conversion from a laparoscopic to an open approach. It would be very interesting to know what proportion of open procedures were planned as open preoperatively. Second, some complications of particular interest when performing cholecystectomies (ie, bile leaks, bile duct injuries) are not abstracted. The ACS NSQIP has recognized these limitations and is implementing a procedure-specific approach to case selection and data abstraction, which will include recording complications unique to particular operations.^{24,25} Third, the ACS NSQIP does not collect information about patient symptomatology, diagnostic studies, or preoperative diagnosis, so the appropriateness of performing a cholecystectomy cannot be analyzed. Although postoperative diagnosis was selected for inclusion in all models, it should be noted that as the ACS NSQIP does not abstract preoperative diagnosis, these estimations of risk are not based strictly on preoperative information. Fourth, pathology results are not collected, limiting analyses of these issues. Finally, hospitals participating in the ACS NSQIP currently tend to be large academic centers with an emphasis on quality improvement; this might limit the generalizability of our results.

This work provides an overview of patient risks and 30-day outcomes for cholecystectomies performed at hospitals participating in the ACS NSQIP during a 4-year period (2005 to 2008). Although overall morbidity and mortality

associated with cholecystectomies are low, results highlight potential areas to target quality improvement initiatives, such as care after open procedures, where the burden of complications appears greatest. There is also documented variations in outcomes between hospitals, raising the possibility for large-scale improvement in processes and outcomes for this population through identification and dissemination of best practices. Although additional research is needed to identify the best practices of hospitals with lower than expected rates of adverse events after cholecystectomy specifically, the ACS NSQIP has developed a Best Practices Initiative for participating hospitals, which includes Best Practices Guidelines and Case Studies to identify and promote effective quality improvement initiatives. Using these resources and results presented here, health care professionals can examine complication and mortality rates at their own institutions and potentially identify areas in need of improvement, targeting quality improvement efforts appropriately.

Appendix 1. Groupings of Current Procedural Terminology Codes for Laparoscopic and Open Cholecystectomy at ACS NSQIP Hospitals

Any laparoscopic procedure	47562, 47563, 47564
Laparoscopic cholecystectomy	47562
Laparoscopic cholecystectomy with cholangiogram	47563
Laparoscopic cholecystectomy with CBDE	47564
Any open procedure	47600, 47605, 47610
Open cholecystectomy	47600
Open cholecystectomy with cholangiogram	47605
Open cholecystectomy with CBDE	47610

Appendix 2. Groupings of ICD-9 Codes to Categorize Diagnoses After Laparoscopic and Open Cholecystectomy at ACS NSQIP Hospitals

Acute cholecystitis	574.00, 574.01, 574.30, 574.31, 574.60, 574.61, 574.80, 574.81, 575.0, 575.12
Chronic cholecystitis	575.11
Other cholecystitis	574.10, 574.11, 574.40, 574.41, 574.70, 574.71, 575.1, 575.10
Cholelithiasis	574.20, 574.21, 574.50, 574.51, 574.90, 574.91
Other*	575.2, 575.3, 575.4, 575.5, 575.6, 575.8, 575.9

*ICD-9 codes listed here represent those related to gallbladder or cystic duct pathology; the "Other" category also includes all diagnoses not related to the gallbladder or cystic duct.

Author Contributions

Study conception and design: Ko, Hall

Acquisition of data: Ingraham, Cohen

Analysis and interpretation of data: Ingraham, Cohen, Ko, Hall

Drafting of the manuscript: Ingraham, Cohen, Hall

Critical revision: Ingraham, Cohen, Ko, Hall

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