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Decreasing Mortality From Acute Biliary Diseases That Require Endoscopic Retrograde Cholangiopancreatography: A Nationwide Cohort Study

Paul D. James,*,‡,§ Gilaad G. Kaplan,* Robert P. Myers,* James Hubbard,* Abdel Aziz Shaheen,* Jill Tinmouth,‡ Elaine Yong,‡ Jonathan Love,*,§ and Steven J. Heitman*,§

*Department of Medicine and Community Health Sciences, University of Calgary, Calgary, Alberta; ‡Department of Medicine, University of Toronto, Toronto, Ontario; and §Calgary Research and Education in Advanced Therapeutic Endoscopy, Calgary, Alberta, Canada

BACKGROUND & AIMS: The management of acute biliary diseases often involves endoscopic retrograde cholangiopancreatography (ERCP), but it is not clear whether this technique reduces mortality. We investigated whether mortality from acute biliary diseases that require ERCP has been reduced over time and explored factors associated with mortality.

METHODS: We conducted a cohort study using the Nationwide Inpatient Sample (1998–2008). We identified hospitalizations for choledocholithiasis, cholangitis, and acute pancreatitis that involved ERCP. Multivariate analyses were used to determine the effects of time period, patient factors, hospital characteristics, features of the ERCP procedure, and types of cholecystectomies on mortality, length of stay, and costs.

RESULTS: From 1998 to 2008 there were 166,438 admissions for acute biliary conditions that met the inclusion criteria, corresponding to more than 800,000 patients nationwide. During this interval, mortality decreased from 1.1% to 0.6% (adjusted odds ratio [aOR], 0.7; 95% confidence interval [CI], 0.6–0.8), diagnostic ERCPs decreased from 28.8% to 10.0%, hospitals performing fewer than 100 ERCPs per year decreased from 38.4% to 26.9%, open cholecystectomies decreased from 12.4% to 5.8%, and unsuccessful ERCPs decreased from 6.3% to 3.2% ($P < .0001$ for all trends). Unsuccessful ERCP (aOR, 1.7; 95% CI, 1.4–2.2), open cholecystectomy (aOR, 3.4; 95% CI 2.7–4.3), cholangitis (aOR, 1.9; 95% CI, 1.5–2.3), older age, having Medicare health insurance, and comorbidity were associated with increased mortality.

CONCLUSIONS: In-hospital mortality from acute biliary conditions requiring ERCP in the United States has decreased over time. Reductions in the rate of unsuccessful ERCPs and open cholecystectomies are associated with this trend.

Keywords: ERCP; Death; Outcomes; Cohort Study.

See editorial on page 1160.

Cholangitis, choledocholithiasis, and acute pancreatitis are acute medical conditions that carry a high mortality risk (Table 1).[1] When persistent biliary obstruction accompanies these conditions, relief of biliary obstruction often is best accomplished by endoscopic retrograde cholangiopancreatography (ERCP).[2,3]

Since the first ERCP procedures were reported in 1968,[4] there have been multiple developments that have improved the procedure's efficacy and safety. These include a reduction in the proportion of diagnostic ERCPs,[5] novel biliary cannulation techniques,[6,7] and interventions to reduce ERCP complications such as pancreatitis.[8,9]

Despite multiple reports showing the benefits of ERCP on reducing patient morbidity, nationwide population-based studies regarding the effectiveness of ERCPs on reducing mortality are lacking. Evidence from randomized controlled trials suggest that ERCP performed within 72 hours of presentation to the hospital may lead to improved morbidity, shortened lengths of stay, and reduced costs of hospitalization.[3,10,11] There is

Abbreviations used in this paper: aOR, adjusted odds ratio; CI, confidence interval; ERCP, endoscopic retrograde cholangiopancreatography; LOS, length of stay; NIS, Nationwide Inpatient Sample.

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Table 1. Highlights

What is already known

- In meta-analyses of randomized controlled trials, early ERCP reduces mortality resulting from cholangitis, but not choledocholithiasis or pancreatitis without biliary obstruction
- Studies to date have been underpowered to detect a significant impact of ERCP in reducing mortality from acute biliary conditions
- Early ERCP is associated with decreased LOS and hospital costs
- Laparoscopic cholecystectomies are associated with improved surgical outcomes

Original contributions of this study

- In-hospital deaths from acute biliary conditions (cholangitis, choledocholithiasis, and pancreatitis) requiring ERCP have decreased from 1998 to 2008; this trend is evident after adjusting for patient, hospital, endoscopic procedures, and surgical factors
- The proportion of unsuccessful ERCPs has decreased over time
- Hospital ERCP volume is not associated with a change in mortality risk, LOS, or hospital costs
- Factors associated with lower adjusted mortality, LOS, and hospital costs include lower rates of open cholecystectomies and unsuccessful ERCPs

no consensus regarding the most appropriate time to perform an ERCP for acute biliary obstruction.[1,12–14] Studies to date have been limited by small sample size, short-term follow-up design, and an inability to account for important confounders such as patient comorbidity and hospital characteristics.

Determining factors associated with in-hospital mortality, length of stay (LOS), and costs may help guide decision makers to optimize in-patient outcomes. The primary aim of this study was to determine whether mortality from acute pancreaticobiliary diseases requiring ERCP has improved over time and to explore factors associated with mortality in a real-world setting using a large representative national administrative database. We hypothesized that in-hospital mortality from acute pancreaticobiliary conditions has decreased over time owing to improved medical care and procedural techniques. Further, patient factors such as older age and comorbidity have a negative impact on in-hospital mortality, LOS, and hospital costs.

Methods

Data Source

Data were extracted from the Healthcare Cost and Utilization Project Nationwide Inpatient Sample (NIS) database for the years 1998 to 2008. The NIS is the largest all-payer database of national hospital discharges (~8 million per annum) maintained by the Agency for Healthcare Research and Quality. It represents a 20% stratified random sample of nonfederal acute-care hospitals in the United States including community, general, and academic centers, but not long-term care facilities. Stratified random sampling ensures that the database is representative of the US population and that it accounts for approximately 90% of all hospitalizations. Each data entry includes a patient identifier, demographic data, hospital transfer status, admission type (emergency, urgent, or elective), primary and secondary diagnoses, procedures, insurance status, hospital charges, LOS, hospital characteristics, and hospital charges. Because each record is for a single hospitalization and not a person, there could be multiple records for an individual if they have had several hospitalizations. NIS data compare favorably with the National Hospital Discharge Survey, supporting the validity of this database.[15]

Study Sample

We used International Classification of Diseases, 9th Revision, Clinical Modification diagnosis codes to identify adult patients (>18 y) hospitalized with a primary diagnosis of cholangitis, acute pancreatitis, or choledocholithiasis between 1998 and 2008 (Supplementary Table 1). We excluded patients who did not undergo an ERCP to ensure that only patients with suspected biliary obstruction were considered. We also excluded patients transferred to other institutions because we could not determine their survival status, diagnoses, lengths of stay, or interventions before transfer.

Study Variables

The primary outcome measure was in-hospital mortality. Other outcome measures included LOS and hospital charges. Charges were adjusted for inflation to 2011 dollars using the US Consumer Price Index for medical care.

Our primary exposure of interest was time period, categorized a priori as 1998 to 2002 and 2003 to 2008. Other covariates of interest included patient age, sex, race (white vs nonwhite), type of health insurance, weekend admission status, hospital location, hospital teaching status, hospital annual ERCP volume (<100, 100–200, and >200 ERCPs per year), and ERCP procedure characteristics (involving an intervention, time to ERCP, or unsuccessful ERCP). The ERCP-related interventions were categorized as sphincterotomy/sphincteroplasty, removal of stones, biliary stent insertion, pancreatic duct stent insertion, and nasobiliary drainage tube insertion. Time from hospital admission to ERCP was stratified as 1 day or less, 2 to 3 days, and more than 3 days based on the cut-off values applied in previous studies.[3,10,11] We also determined whether a cholecystectomy was performed during the same admission and, if so, whether a laparoscopic or open approach was performed.

An unsuccessful ERCP was defined as the need to perform further biliary interventions, namely a percutaneous transhepatic biliary drainage or surgical bile duct exploration, after the ERCP during the same hospital admission.[16] Hospital ERCP volume was defined as the number of ERCPs performed per year in each hospital. After a previous related study, we elected to classify low volume as 100 or fewer ERCPs per year and high volume as 200 or more ERCPs per year. Our results were similar when examined using different cut-off values.[16]

For case-mix adjustment, we used the Elixhauser[17] list of 30 comorbidities, a well-validated algorithm for predicting in-hospital mortality caused by a variety of conditions (categorized as 0, 1, 2, and ≥3 comorbidities). Cholangitis, choledocholethiasis, and acute pancreatitis were excluded from this list of comorbidities.

Statistical Analyses

For the primary analyses, we compared patient factors, ERCP procedure characteristics, type of cholecystectomy, hospital characteristics (annual ERCP volume, location, teaching status), timing of admission (weekend vs weekday), and admission diagnosis between the study time periods using Pearson χ^2 and Wilcoxon rank-sum tests as appropriate. To examine the independent association between in-hospital mortality and time period, multivariate logistic regression models were used to adjust for the potential confounding effects of patient demographics, admission status, comorbidities, procedures, hospital characteristics, and time period of admission. Risk estimates were presented as adjusted odds ratios (aORs) with 95% confidence intervals (CIs).

LOS and hospital charges were compared using multivariate linear regression analyses to adjust for the same confounding variables. LOS and charges were transformed logarithmically as a result of their skewed distributions. All models used generalized estimating equations to account for the hierarchical nature of the data (ie, clustering of patients within hospitals). Statistical analyses were performed with SAS-callable SUDAAN (release 11.0.0; Research Triangle Park, NC) to account for the complex sampling design of the NIS.

Sensitivity Analyses

Sensitivity analyses were conducted to evaluate the robustness of our findings. First, we examined mortality trends for acute pancreatitis, choledocholithiasis, and cholangitis individually. Second, we assessed the impact of including the primary and secondary admission diagnoses on the observed trends.

To examine potential differences in outcomes among persons who underwent an ERCP and those who did not while accounting for possible inherent differences between patients in the 2 groups (ie, confounding by indication), we performed propensity-score-matching analyses.[18–20] Propensity scores were computed by modeling a logistic regression with the dependent variable as undergoing an ERCP. A 1:1 control-to-case-matching ratio was used. The same approach was applied to examine the differences in outcomes among persons who underwent a laparoscopic vs open cholecystectomy among all patients who underwent a cholecystectomy at least 1 day after their ERCP (same-day ERCP and cholecystectomies were excluded). Covariate balance between the matched groups was verified for both analyses. Odds ratios for mortality in the matched samples were calculated by conditional logistic regression.

Results

Patient Characteristics

Between 1998 and 2008 there were 166,438 patients (65% female; median age, 60 y) who underwent ERCP for the treatment of ascending cholangitis, acute pancreatitis, or choledocholithiasis (Figure 1 and Table 2). There were multiple modest differences between patients admitted between 1998 and 2002 and 2003 and 2008. Patients who presented to the hospital with an acute biliary condition and underwent an ERCP were about 1 year younger, 6% less likely to be white, and 9% more likely to have 3 or more comorbidities from 2003 to 2008 compared with from 1998 to 2002.

In-Hospital Mortality

Overall, 0.8% of patients died in the hospital. Figure 2 shows the trends in mortality from acute pancreaticobiliary diseases requiring ERCP. Mortality decreased from 1.1% to 0.6% from 1998 to 2008. The odds of mortality were reduced significantly from the time periods of 1998 to 2002 and 2003 to 2008 (aOR, 0.7; 95% CI, 0.6–0.8). This trend also was observed for each pancreaticobiliary disorder when examined separately (aOR, 0.8; 95% CI, 0.5–1.1 for cholangitis; aOR, 0.7; 95% CI, 0.6–0.9 for choledocholithiasis; and aOR, 0.6; 95% CI, 0.5–0.8 for acute pancreatitis; Supplementary Table 2). Cholangitis and acute pancreatitis were associated with increased mortality (aOR, 1.9; 95% CI, 1.5–2.3 and aOR, 1.4; 95% CI, 1.2–1.6 vs choledocholithiasis, respectively). Other patient factors associated with increased mortality included older age, male sex, having 1 or more comorbidities, and having Medicare health insurance (Table 3).

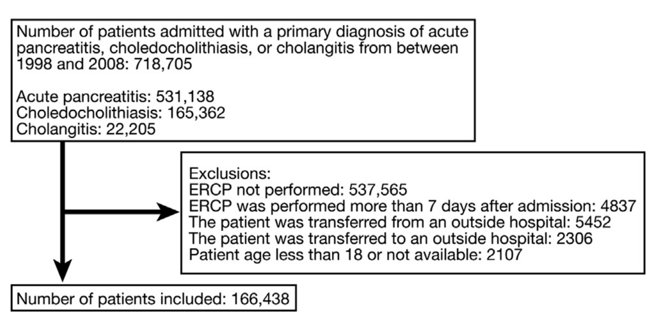

Figure 1. Cohort-derivation flow diagram.

Table 2. Characteristics of Patients Admitted for Cholangitis, Choledocholithiasis, or Acute Pancreatitis and Who Underwent an ERCP, 1998–2008

Characteristic	Total	1998–2002	2003–2008	*P* value[a]
Patients, n	166,438	72,709	93,729	
Age, *y*				<.0001
Median (IQR)	60 (41–75)	60 (41–75)	59 (40–76)	
Died, %				<.0001
No	99.2	99.1	99.3	
Yes	0.8	0.9	0.7	
LOS, *days*				<.0001
Median (IQR)	4 (2–7)	4 (2–7)	4 (2–6)	
Total charges, *$*				<.0001
Mean (SD)	39,717 (311)	33,810 (394)	44,295 (442)	
Age, %				<.0001
<40	23	22	24	
40–60	27	27	28	
>60	49	51	49	
Sex, %				.0034
Male	35	35	36	
Female	65	65	64	
Health insurance, %				<.0001
Medicare	42	43	42	
Medicaid	10	9	11	
Private including HMO	38	40	36	
Self-pay/other	10	8	11	
Race, %				<.0001
Nonwhite	29	26	32	
White	71	74	68	
Geographic US region, %				.0002
Northeast	20	21	20	
Midwest	22	23	22	
South	36	36	36	
West	21	19	23	
Location/teaching status, %				<.0001
Rural	9	11	8	
Urban nonteaching	48	46	49	
Urban teaching	43	44	43	
Elixhauser[17] comorbidities, %				<.0001
0	31	36	27	
1	25	26	24	
2	20	19	20	
3+	24	19	28	
Weekend admission, %				.0004
No	77	78	78	
Yes	23	22	22	
Yearly ERCP volume, %				<.0001
<100	32	35	30	
100–200	37	38	36	
>200	31	27	34	
ERCP type, %				<.0001
Biliary stent insertion	10.2	8.4	11.6	
Pancreatic stent insertion	2.3	2.2	2.3	
Nasobiliary drainage tube insertion	0.2	0.4	0.1	
Removal of stones	31.7	29.1	33.8	
Sphincterotomy/sphincteroplasty	37.4	36.2	38.4	
Diagnostic	18.2	23.7	13.8	
Cholecystectomy type, %				<.0001
Laparoscopic	41	39	43	
Open	8	10	7	
None	50	51	50	
Admission diagnosis, %				<.0001
Acute pancreatitis	29	32	27	
Choledocholithiasis	66	63	68	
Cholangitis	5	5	5	

Table 2. Continued

Characteristic	Total	1998–2002	2003–2008	*P* value[a]
Days to ERCP, %				<.0001
0–1	49	49	49	
2–3	34	33	35	
4–7	17	17	16	
Unsuccessful ERCP, %				<.0001
No	96	95	96	
Yes	4	5	4	

IQR, interquartile range; HMO, health maintenance organization.
[a]For continuous variables, the Wilcoxon rank-sum test was used. For categoric variables, the Pearson χ^2 test was used.

Procedure Characteristics

From 1998 to 2008, the proportion of unsuccessful ERCPs decreased from 6.3% to 3.3% (Figure 3*A*; $P < .0001$), diagnostic ERCPs decreased from 28.8% to 10.0% ($P < .0001$), hospitals performing fewer than 100 ERCPs per year decreased from 38.4% to 26.9% ($P < .0001$), and admissions involving an open cholecystectomy decreased from 12.4% to 5.8% (Figure 3*B*; $P < .0001$).

Compared with the performance of laparoscopic cholecystectomy, open cholecystectomy (aOR, 3.4; 95% CI, 2.7–4.3) and no cholecystectomy (aOR, 1.9; 95% CI, 1.6–2.2) were associated strongly with mortality. Unsuccessful ERCP also was associated with increased mortality (aOR, 1.7; 95% CI, 1.4–2.2). Hospitals that performed fewer than 100 ERCPs per year experienced similar mortality as those that performed more than 200 ERCPs per year (aOR, 1.0; 95% CI, 0.8–1.2). ERCPs performed more than 3 days after admission to the hospital were not associated with increased mortality (aOR, 1.1; 95% CI, 0.9–1.3; Table 3).

Length of Stay and Hospital Charges

Overall, the median LOS was 4 days (interquartile range, 2–7 days), and the mean total hospitalization charges were US $39,717 per patient. Patients admitted with cholangitis and acute pancreatitis had a 23% (95% CI, 20%–25%) and 30% (95% CI, 29%–31%) increase in their adjusted LOS as well as a 19% (95% CI, 17%–22%) and a 17% (95% CI, 16%–18%) increase in adjusted hospital charges compared with choledocholithiasis, respectively (Table 4). Open cholecystectomy was associated with a 59% greater adjusted LOS (95% CI, 57%–61%) and a 28% increase in hospital charges (95% CI, 26%–30%) compared to laparoscopic cholecystectomy. Patients admitted to a hospital that performed fewer than 100 ERCPs per year experienced no difference in adjusted LOS (3%; 95% CI, 2%–5%) and hospitalization costs (−5%; 95% CI, −9% to −2%) compared to patients admitted to a hospital performing more than 100 ERCPs per year. ERCPs performed more than 3 days after admission to the hospital were related to a 106% increase in adjusted LOS (95% CI, 103%–109%) and a 53% increase in adjusted hospitalization costs (95% CI, 50%–55%) compared with ERCPs performed within 1 day of admission. Unsuccessful ERCPs were linked to a 37% increase in adjusted LOS (95% CI, 34%–39%) and a 31% increase in adjusted hospitalization costs (95% CI, 28%–33%).

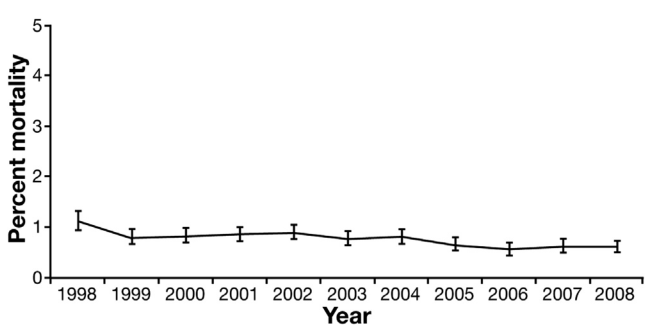

Figure 2. Mortality among patients admitted for acute biliary conditions who underwent an ERCP in the United States from 1998 to 2008.

Sensitivity Analyses

Mortality trends were generally similar using both primary and secondary diagnoses (Supplementary Table 3), with time period (aOR, 0.8; 95% CI, 0.7-0.8), open cholecystectomy (aOR, 3.0; 95% CI, 2.5–3.6), and unsuccessful ERCP (aOR, 1.9; 95% CI, 1.7–2.3) remaining associated with mortality. In addition, the association between mortality and Medicaid health insurance (aOR, 1.4; 95% CI, 1.1–1.7), biliary stent insertion (aOR, 1.2; 95% CI, 1.1–1.4), and a delay of more than 3 days from admission to ERCP (aOR, 1.3; 95% CI, 1.2–1.5) were significant.

To maintain a sound 1:1 matching by propensity score analysis while balancing the distribution of important covariates, we could match only 54% (44,810 of 83,099; Supplementary Table 4) of the ERCP cases where a cholecystectomy was not performed during the same admission. We found that undergoing an ERCP was associated with a significantly lower mortality risk (OR,

Table 3. Predictors of In-Hospital Mortality in Patients Admitted for Acute Biliary Diseases and Who Underwent an ERCP in the United States, 1998–2008

Characteristic	Unadjusted OR (95% CI)	Adjusted[a] OR (95% CI)
Time period		
1998–2002	Ref.	Ref.
2003–2008	0.7 (0.7–0.8)	0.7 (0.6–0.8)
Age group		
<40 y	Ref.	Ref.
40–60 y	4.9 (3.2–7.5)	2.3 (1.5–3.6)
>60 y	21.7 (14.6–32.3)	4.6 (3.0–7.3)
Sex		
Female	Ref.	Ref.
Male	1.7 (1.6–2.0)	1.3 (1.2–1.5)
Health insurance		
Private	Ref.	Ref.
Medicare	6.0 (5.0–7.1)	2.1 (1.7–2.6)
Medicaid	1.3 (0.9–1.7)	1.4 (1.0–1.9)
Self-pay/other	1.2 (0.8–1.8)	1.6 (1.1–2.2)
Race		
White	Ref.	Ref.
Nonwhite	0.8 (0.7–0.9)	1.2 (1.0–1.4)
Unknown	–	1.1 (0.9–1.3)
Geographic US region		
South	Ref.	Ref.
Northeast	1.0 (0.9–1.2)	1.0 (0.8–1.1)
Midwest	0.9 (0.8–1.1)	0.8 (0.7–1.0)
West	0.7 (0.6–0.9)	0.8 (0.7–0.9)
Location/teaching status		
Rural	Ref.	Ref.
Urban nonteaching	0.9 (0.7–1.1)	1.0 (0.8–1.2)
Urban teaching	0.9 (0.8–1.1)	1.0 (0.8–1.3)
Elixhauser[17] comorbidities		
0	Ref.	Ref.
1	4.5 (3.2–6.2)	2.5 (1.8–3.6)
2	10.3 (7.6–14.0)	4.5 (3.2–6.3)
3+	19.8 (14.8–26.5)	7.6 (5.5–10.5)
Weekend admission		
No	Ref.	Ref.
Yes	1.1 (1.0–1.3)	1.1 (1.0–1.3)
Yearly ERCP volume		
>200	Ref.	Ref.
100–200	1.0 (0.9–1.2)	1.0 (0.8–1.2)
<100	1.1 (1.0–1.3)	1.0 (0.8–1.2)
ERCP type		
Diagnostic	Ref.	Ref.
Biliary stent insertion	1.1 (1.0–1.4)	1.2 (1.0–1.4)
Pancreatic stent insertion	0.9 (0.6–1.2)	1.0 (0.7–1.5)
Nasobiliary drainage tube insertion	2.2 (1.1–4.4)	2.1 (1.0–4.4)
Removal of stones	0.5 (0.4–0.6)	0.8 (0.7–1.0)
Sphincterotomy/ sphincteroplasty	0.6 (0.5–0.7)	0.8 (0.7–1.0)
Cholecystectomy type		
Laparoscopic	Ref.	Ref.
Open	5.9 (4.9–7.1)	3.4 (2.7–4.3)
None	2.8 (2.4–3.3)	1.9 (1.6–2.2)
Admission diagnosis		
Choledocholithiasis	Ref.	Ref.
Acute pancreatitis	1.5 (1.3–1.7)	1.4 (1.2–1.6)
Cholangitis	2.8 (2.3–3.4)	1.9 (1.5–2.3)

Table 3. Continued

Characteristic	Unadjusted OR (95% CI)	Adjusted[a] OR (95% CI)
Days to ERCP		
0–1	Ref.	Ref.
2–3	1.0 (0.9–1.2)	0.8 (0.7–1.0)
4–7	1.8 (1.5–2.1)	1.1 (0.9–1.3)
Unknown	–	1.3 (1.1–1.5)
Unsuccessful ERCP		
No	Ref.	Ref.
Yes	2.8 (2.4–3.4)	1.7 (1.4–2.2)

[a]Model adjusted for time period, age, sex, race, health insurance, comorbidities, hospital, and procedure characteristics.

0.5; 95% CI, 0.5–0.6). By using a similar approach, we were able to match 75% (4158 of 5536; Supplementary Table 5) of cholecystectomy cases where an open cholecystectomy was performed. Having an open cholecystectomy was associated with an increased risk of death (OR, 6.0; 95% CI, 3.5–10.4).

Discussion

This study showed a reduction in mortality from cholangitis, choledocholithiasis, and acute pancreatitis involving an ERCP over time using a large population-based, nationally representative database. Our findings

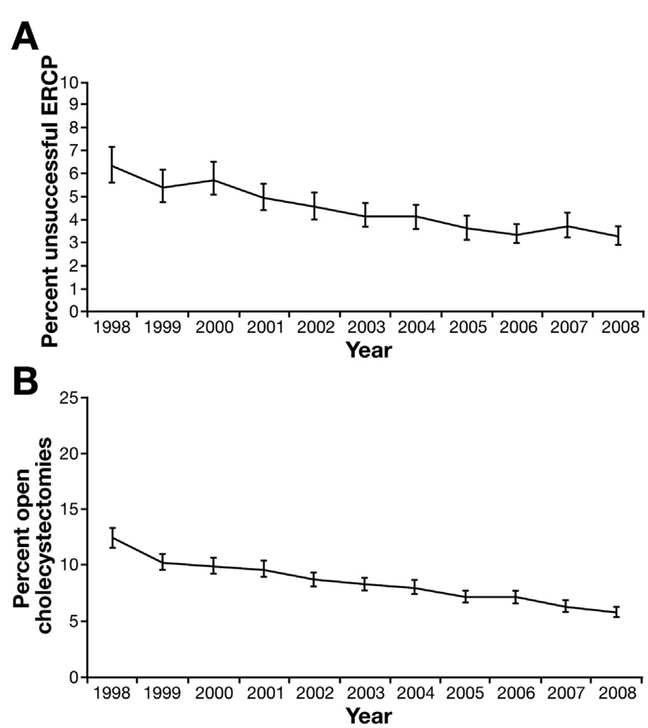

Figure 3. Percentage of cases in which an (*A*) open cholecystectomy was performed and percentage of (*B*) unsuccessful ERCPs among patients admitted for acute biliary conditions who underwent an ERCP in the United States from 1998 to 2008.

Table 4. LOS, Hospitalization Charges, and Average Daily Charges by Year of Admission, Admission Diagnosis, Hospital ERCP Volume, Therapeutic ERCP, and Type of Cholecystectomy, 1998–2008

Characteristic	Median LOS, days (IQR)	Adjusted[a] percentage change in LOS (95% CI)	Mean hospitalization charges, US dollars (SD)	Adjusted[a] percentage change in hospitalization charges (95% CI)
Time period				
1998–2002	4 (2–7)	Ref.	$33,810 (394)	Ref.
2003–2008	4 (2–6)	-1 (-2 to 0)	$44,295 (442)	27 (24–30)
Admission diagnosis				
Choledocholithiasis	5 (3–8)	Ref.	$38,036 (303)	Ref.
Acute pancreatitis	4 (2–6)	30 (29–31)	$43,088 (412)	17 (16–18)
Cholangitis	4 (3–7)	23 (20–25)	$41,805 (879)	19 (17–22)
Yearly ERCP volume				
>200	4 (2–6)	Ref.	$40,718 (765)	Ref.
100–200	4 (2–7)	3 (1–4)	$40,409 (508)	-2 (-6 to 1)
<100	4 (3–7)	3 (2–5)	$37,983 (394)	-5 (-9 to -2)
ERCP type				
Diagnostic	5 (3–8)	Ref.	$40,683 (400)	Ref.
Biliary stent insertion	5 (3–8)	9 (8–10)	$45,132 (537)	18 (16–20)
Pancreatic stent insertion	5 (3–8)	5 (1–8)	$40,501 (1101)	8 (5–11)
Nasobiliary drainage tube insertion	5 (3–9)	18 (10–25)	$47,962 (2685)	26 (16–35)
Removal of stones	4 (2–6)	-4 (-5 to -3)	$38,054 (332)	3 (2–5)
Sphincterotomy/ sphincteroplasty	4 (2–6)	-3 (-4 to -2)	$39,071 (378)	3 (2–4)
Cholecystectomy type				
Laparoscopic	4 (3–6)	Ref.	$43,001 (331)	Ref.
Open	8 (6–11)	59 (57–61)	$65,532 (739)	28 (26–30)
None	4 (2–6)	-19.5 (-20.2 to -18.8)	$32,652 (331)	-39 (-40 to -38)
Days to ERCP				
0–1	3 (2–5)	Ref.	$33,420 (391)	Ref.
2–3	4 (3–6)	45 (43–47)	$40,911 (428)	21 (20–23)
4–7	7 (5–10)	106 (103–109)	$53,108 (635)	53 (50–55)
Unknown	–	32 (30–34)	–	19 (16–23)
Unsuccessful ERCP				
No	4 (2–6)	Ref.	$38,085 (303)	Ref.
Yes	7 (5–11)	37 (34–39)	$63,162 (1070)	31 (28–33)

[a]Adjusted for period of admission, age, sex, race, health insurance, comorbidities, hospital and admission characteristics, ERCP characteristics, and in-hospital cholecystectomy.

were robust to multiple sensitivity analyses. They were consistent whether our analysis was limited to primary diagnoses, expanded to include primary and secondary diagnoses, or when we performed propensity score matching to adjust for confounding by indication. Further, these results are consistent with previous reports that have documented improved patient outcomes with ERCP.[11,21] Previous studies have been limited by small sample size and brief periods of observation, which may explain their inability to show an impact of ERCP on mortality.

We believe that improved in-hospital mortality over time may be attributed to 3 major developments. First, the proportion of laparoscopic cholecystectomies being performed has increased over time. This surgical approach has been shown to improve outcomes while reducing complications in patients with cholelithiasis.[2,22] Second, improved ERCP procedure techniques, such as increasing the proportion of cases that involve therapeutic interventions, the use of interventions to reduce post-ERCP pancreatitis, and a decrease in the number of unsuccessful ERCPs, may have contributed.[23,24] Finally, early goal-directed resuscitation and timely medical management is effective in patients with sepsis,[25,26] cardiac arrest,[27] and cholangitis.[28] One might argue that the reduction in mortality reflects a selection of healthier patients. However, the proportion of patients with 1 or 2 comorbidities did not change appreciably, while the proportion of patients with 3 or more comorbidities increased over time, suggesting that this is not the case.

Unsuccessful ERCP is associated with increased adjusted mortality, LOS, and hospital costs. Although our definition does not identify all unsuccessful ERCP cases, it operationalizes available data and has been shown previously to be associated with hospital ERCP volume, LOS, and costs.[13,16] Unsuccessful ERCP may be an important and readily available service quality indicator for future health service evaluation and planning. Future studies validating the accuracy of this variable are needed.

In a systematic review and meta-analysis performed by Tse and Yuan[3] that included 5 randomized controlled trials and 644 patients, it was concluded that ERCPs performed within 72 hours reduced mortality from cholangitis but not from noninfectious biliary obstruction or acute pancreatitis. We did not observe an association between time to ERCP and mortality from acute pancreaticobiliary conditions after adjusting for patient, diagnosis, and procedural characteristics. This observation may reflect appropriate triaging of cases to early ERCP at the time of admission to the hospital or that the impact of early ERCP on mortality is in fact negligible. In contrast, delaying ERCP is associated with greater LOS and hospitalization costs, highlighting the potential resource implication of prolonging ERCP waiting times. Hendrick et al[29] showed that the day of admission is associated with varying times to ERCP and suggested that matching resource availability with patterns of demand may reduce wait times, LOS, and costs.

The performance of open cholecystectomies was strongly associated with increased in-hospital mortality, LOS, and hospitalization costs. This result is supported by a recent large retrospective study by Sinha et al,[22] who observed an increased risk of bile duct injury, mortality, and prolonged LOS with open cholecystectomy operations. Laparoscopic cholecystectomy is the preferred approach and a low rate of open cholecystectomies may serve as a quality target to achieve optimal patient outcomes.

There was a greater risk of in-hospital mortality among patients who did not undergo a cholecystectomy. Nguyen et al[30] observed that 51% of patients admitted for acute gallstone pancreatitis underwent a cholecystectomy during the same hospitalization, with notably reduced rates among African Americans (44%) and Asians (43%). This implies that factors other than severity of illness may influence the decision to perform a cholecystectomy during the same admission.

Varadarajulu et al[16] noted that patients who underwent an ERCP at hospitals with a high ERCP volume (>200 per year) experienced a shorter LOS and lower ERCP failure rates. Their NIS database study was limited to patients admitted between 1998 and 2001. By using the same data set and analytic methods, but over a longer study period, we failed to observe a difference in mortality, LOS, or hospital costs based on hospital ERCP volume. This was unchanged when we varied the upper or lower ERCP volume cut-off levels.

Our study had several limitations. First, the validity of the diagnosis and procedure codes we used must be considered. Previous investigations suggest that codes for cholangitis and acute pancreatitis are accurate.[31,32] Similar studies for choledocholithiasis, cholecystectomy, or any of the ERCP interventions have not been performed. Second, because the date of diagnosis was not available, we could not determine cases of pancreatitis that occurred after the ERCP procedure. Pancreatitis is a recognized complication of ERCP and future studies should examine the association between post-ERCP pancreatitis and in-hospital mortality. Third, we could not elucidate factors that contributed to unsuccessful ERCPs. Recent studies have suggested that both patient and procedure factors contribute to the risk of unsuccessful ERCPs; however, the role of the endoscopist is less clear and warrants further evaluation.[33] Fourth, a small proportion of patients were excluded from our analyses because of inadequate endoscopic details, absent or negative values regarding time to procedures, and missing data regarding mortality. Although more than 95% of the data were available for most variables, race and days to ERCP were missing in 23% and 26% of the cohort, respectively. These variables were included in the analyses because they have been shown to predict mortality, as well as access to surgical and endoscopic procedures.[6,10,11,23,30] Fifth, the NIS database is unable to link individual patients between or within hospitals and thus we could not adjust for within-patient correlations. Sixth, with the absence of laboratory and imaging data, we cannot confirm the presence of biliary obstruction and relied on International Classification of Diseases, 9th Revision, Clinical Modification codes to determine the diagnoses. We also could not examine whether there was ongoing biliary obstruction post-ERCP or determine how ERCP affected patient morbidity. Finally, our mortality analyses were limited to in-hospital deaths. Whether the associations we observed exist among outpatients warrants investigation.

The principal strength of analyzing NIS data is its substantial sample size and geographic representativeness throughout the United States. This allows for a nation-wide, population-based evaluation of important but uncommon outcomes using high-quality data acquired in a real-world setting. Other strengths of our study include the ability to control for patient comorbidity as well as consider key outcomes such as hospital LOS and costs using patient-level data.

In conclusion, mortality from acute pancreaticobiliary diseases requiring ERCP has decreased over time. This may be partially attributable to improvements in medical care as well as surgical and ERCP performance characteristics.

Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Clinical Gastroenterology and Hepatology* at www.cghjournal.org, and at http://dx.doi.org/10.1016/j.cgh.2013.09.054.

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Reprint requests
Address requests for reprints to: Steven J. Heitman, MD, MSc, FRCPC, Division of Gastroenterology, University of Calgary, 3280 Hospital Drive NW, Calgary, Alberta T2N 4Z6, Canada. e-mail: steven.heitman@ucalgary.ca; fax: (403) 592-5090.

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Supplementary Table 1. ICD-9-CM Codes Included in the Analyses

Variable definition	ICD-9-CM codes
Diagnoses	
Cholangitis	576.1
Choledocholithiasis	574.3–574.9
Acute pancreatitis	577.0
Procedures	
ERCP	51.10–51.11, 51.81–51.88, 52.13–52.14, 52.21, 52.92–52.94, 52.97–52.98
Sphincterotomy/ sphincteroplasty	51.81–51.85, 52.98
Endoscopic removal of stones	51.88, 52.94
Biliary stent insertion	51.87
Pancreatic stent insertion	52.93
Nasobiliary drainage tube insertion	51.86, 52.97
Laparoscopic cholecystectomy	51.23–51.24
Open cholecystectomy	51.21–51.22

ICD-9-CM, International Classification of Diseases, 9th Revision, Clinical Modification.

Supplementary Table 2. Predictors of In-Hospital Mortality in Patients Admitted for Acute Pancreatitis, Choledocholithiasis, or Cholangitis and Who Underwent an ERCP in the United States, 1998–2008

Characteristic	Acute pancreatitis, aOR[a] (95% CI)	Choledocholithiasis, aOR[a] (95% CI)	Cholangitis, aOR[a] (95% CI)
Time period			
1998–2002	Ref.	Ref.	Ref.
2003–2008	0.6 (0.5–0.8)	0.7 (0.6–0.9)	0.8 (0.5–1.1)
Age group, *y*			
<40	Ref.	Ref.	Ref.
40–60	2.3 (1.2–4.3)	3.3 (1.5–7.2)	0.6 (0.2–1.7)
>60	4.0 (2.1–7.6)	7.7 (3.6–16.5)	1.4 (0.5–4.0)
Sex			
Female	Ref.	Ref.	Ref.
Male	1.6 (1.3–1.9)	1.2 (1.0–1.5)	1.1 (0.8–1.6)
Health insurance			
Private	Ref.	Ref.	Ref.
Medicare	2.1 (1.6–2.9)	2.5 (1.8–3.5)	1.3 (0.7–2.3)
Medicaid	1.6 (1.0–2.5)	1.4 (0.8–2.4)	0.8 (0.3–2.1)
Self-pay/other	1.4 (0.9–2.4)	2.1 (1.3–3.5)	0.6 (0.2–2.1)
Race			
White	Ref.	Ref.	Ref.
Nonwhite	1.2 (0.9–1.5)	1.2 (0.9–1.5)	1.6 (1.0–2.7)
Unknown	1.0 (0.7–1.3)	1.1 (0.8–1.3)	1.8 (1.1–3.2)
Geographic US region			
South	Ref.	Ref.	Ref.
Northeast	1.0 (0.7–1.3)	0.8 (0.7–1.0)	1.3 (0.8–2.0)
Midwest	0.8 (0.6–1.0)	0.8 (0.6–1.0)	0.9 (0.5–1.6)
West	0.9 (0.7–1.1)	0.9 (0.7–1.1)	0.4 (0.2–0.8)
Location/teaching status			
Rural	Ref.	Ref.	Ref.
Urban nonteaching	0.9 (0.6–1.2)	1.1 (0.8–1.5)	1.0 (0.5–1.9)
Urban teaching	1.0 (0.7–1.4)	1.1 (0.8–1.5)	1.0 (0.5–2.1)
Elixhauser[17] comorbidities			
0	Ref.	Ref.	Ref.
1	3.4 (1.9–6.0)	2.2 (1.4–3.6)	1.6 (0.7–3.8)
2	5.3 (3.1–9.3)	4.1 (2.6–6.6)	3.3 (1.4–7.5)
3+	8.3 (4.8–14.4)	8.0 (5.1–12.6)	3.8 (1.7–8.7)
Weekend admission			
No	Ref.	Ref.	Ref.
Yes	1.1 (0.9–1.4)	1.0 (0.8–1.2)	1.4 (0.9–2.0)
Yearly ERCP volume			
>200	Ref.	Ref.	Ref.
100–200	1.0 (0.7–1.3)	1.0 (0.8–1.2)	1.1 (0.7–1.7)
<100	1.1 (0.9–1.5)	1.0 (0.8–1.2)	0.8 (0.5–1.3)
ERCP type			
Diagnostic	Ref.	Ref.	Ref.
Biliary stent insertion	1.4 (1.0–1.9)	0.9 (0.6–1.1)	1.6 (1.0–2.6)
Pancreatic stent insertion	1.1 (0.7–1.8)	0.7 (0.3–1.5)	1.6 (0.5–4.7)
Nasobiliary drainage tube insertion	3.7 (1.1–12.6)	1.3 (0.3–5.3)	2.6 (0.6–10.3)
Removal of stones	1.1 (0.8–1.4)	0.6 (0.5–0.8)	0.9 (0.5–1.6)
Sphincterotomy/ sphincteroplasty	0.9 (0.7–1.1)	0.7 (0.5–0.9)	0.8 (0.5–1.4)
Cholecystectomy type			
Laparoscopic	Ref.	Ref.	Ref.
Open	3.9 (2.6–5.9)	3.1 (2.3–4.0)	3.9 (1.4–11.1)
None	2.5 (1.9–3.3)	1.6 (1.3–2.0)	1.3 (0.6–2.9)
Days to ERCP			
0–1	Ref.	Ref.	Ref.
2–3	0.5 (0.4–0.7)	1.0 (0.8–1.3)	1.0 (0.6–1.5)
4–7	0.7 (0.5–0.9)	1.6 (1.3–2.1)	1.0 (0.6–1.7)
Unknown	1.1 (0.8–1.5)	1.4 (1.1–1.7)	1.0 (0.5–2.0)
Unsuccessful ERCP			
No	Ref.	Ref.	Ref.
Yes	1.5 (0.8–2.7)	1.6 (1.2–2.2)	2.1 (1.0–4.4)

[a]Model adjusted for time period, age, sex, race, health insurance, comorbidities, hospital, and procedures characteristics.

Supplementary Table 3. Predictors of In-Hospital Mortality in Patients Admitted for Acute Biliary Conditions (Together), Acute Pancreatitis, Choledocholithiasis or Cholangitis (Individually), and Who Underwent an ERCP in the United States, 1998–2008

Characteristic	Acute biliary conditions (together), aOR[a] (95% CI)	Acute pancreatitis, aOR[a] (95% CI)	Choledocholithiasis, aOR[a] (95% CI)	Cholangitis, aOR[a] (95% CI)
Time period				
1998–2002	Ref.	Ref.	Ref.	Ref.
2003–2008	0.8 (0.7–0.8)	0.7 (0.6–0.8)	0.8 (0.7–0.9)	0.8 (0.7–0.9)
Age group, *y*				
<40	Ref.	Ref.	Ref.	Ref.
40–60	2.3 (1.7–3.0)	2.9 (1.8–4.6)	2.4 (1.4–3.9)	1.3 (0.8–2.1)
>60	4.0 (3.0–5.3)	5.2 (3.2–8.4)	4.6 (2.8–7.8)	2.0 (1.3–3.2)
Sex				
Female	Ref.	Ref.	Ref.	Ref.
Male	1.4 (1.2–1.5)	1.6 (1.4–1.9)	1.3 (1.2–1.5)	1.1 (1.0–1.3)
Health insurance				
Private	Ref.	Ref.	Ref.	Ref.
Medicare	1.7 (1.5–1.9)	1.4 (1.2–1.8)	2.3 (1.8–3.0)	1.5 (1.2–1.8)
Medicaid	1.4 (1.1–1.7)	1.3 (0.9–1.8)	1.8 (1.2–2.5)	1.3 (0.9–1.8)
Self-pay/other	1.2 (0.9–1.5)	1.2 (0.8–1.7)	1.3 (0.8–2.0)	1.2 (0.8–1.7)
Race				
White	Ref.	Ref.	Ref.	Ref.
Nonwhite	1.3 (1.1–1.4)	1.2 (1.0–1.4)	1.2 (1.0–1.4)	1.4 (1.2–1.7)
Unknown	1.0 (0.9–1.2)	0.9 (0.7–1.2)	1.1 (0.9–1.3)	1.1 (0.9–1.4)
Geographic US region				
South	Ref.	Ref.	Ref.	Ref.
Northeast	1.0 (0.9–1.1)	1.0 (0.8–1.2)	0.9 (0.7–1.0)	1.2 (1.0–1.5)
Midwest	0.8 (0.7–0.9)	0.8 (0.7–1.1)	0.7 (0.6–0.9)	0.9 (0.7–1.2)
West	0.9 (0.8–1.0)	0.9 (0.7–1.1)	0.8 (0.7–1.0)	1.1 (0.9–1.3)
Location/teaching status				
Rural	Ref.	Ref.	Ref.	Ref.
Urban nonteaching	1.1 (0.9–1.3)	1.4 (1.0–1.9)	1.0 (0.8–1.2)	1.3 (0.9–1.8)
Urban teaching	1.2 (1.0–1.5)	1.4 (1.0–2.0)	1.0 (0.8–1.3)	1.5 (1.1–2.1)
Elixhauser[17] comorbidities				
0	Ref.	Ref.	Ref.	Ref.
1	2.3 (1.8–2.8)	2.9 (1.9–4.3)	2.5 (1.7–3.5)	1.6 (1.1–2.3)
2	3.5 (2.8–4.3)	4.3 (2.9–6.5)	3.8 (2.7–5.4)	2.5 (1.8–3.5)
3+	5.6 (4.6–6.9)	7.3 (4.9–10.8)	6.5 (4.6–9.2)	3.6 (2.6-4.9)
Weekend admission				
No	Ref.	Ref.	Ref.	Ref.
Yes	0.94 (0.85–1.04)	1.1 (0.9–1.3)	0.9 (0.8–1.1)	0.9 (0.7–1.0)
Yearly ERCP volume				
>200	Ref.	Ref.	Ref.	Ref.
100–200	1.0 (0.9–1.1)	0.9 (0.8–1.1)	1.1 (1.0–1.3)	0.9 (0.8–1.1)
<100	1.0 (0.9–1.1)	1.0 (0.8–1.2)	1.1 (0.9–1.3)	0.9 (0.7–1.1)
ERCP type				
Diagnostic	Ref.	Ref.	Ref.	Ref.
Biliary stent insertion	1.2 (1.1–1.4)	1.4 (1.1–1.7)	0.9 (0.8–1.2)	1.4 (1.1–1.6)
Pancreatic stent insertion	1.0 (0.8–1.3)	0.9 (0.6–1.3)	1.0 (0.7–1.6)	1.2 (0.8–2.0)
Nasobiliary drainage tube insertion	1.9 (1.1–3.1)	1.7 (0.5–5.7)	1.0 (0.4–2.7)	2.7 (1.3–5.5)
Removal of stones	0.7 (0.6–0.8)	0.9 (0.6–1.1)	0.6 (0.5–0.7)	0.6 (0.4–0.7)
Sphincterotomy/sphincteroplasty	0.73 (0.65–0.81)	0.8 (0.7–1.0)	0.6 (0.5–0.7)	0.8 (0.7–1.0)
Cholecystectomy type				
Laparoscopic	Ref.	Ref.	Ref.	Ref.
Open	3.0 (2.5–3.6)	3.9 (2.8–5.4)	2.8 (2.2–3.5)	3.1 (2.1–4.5)
None	2.6 (2.3–3.0)	3.0 (2.4–3.8)	2.3 (1.9–2.7)	3.0 (2.2–4.1)
Admission diagnosis				
Choledocholithiasis	Ref.	Ref.	Ref.	Ref.
Acute pancreatitis	1.1 (1.0–1.2)	–	–	–
Cholangitis	1.9 (1.7–2.1)			

Supplementary Table 3. Continued

Characteristic	Acute biliary conditions (together), aOR[a] (95% CI)	Acute pancreatitis, aOR[a] (95% CI)	Choledocholithiasis, aOR[a] (95% CI)	Cholangitis, aOR[a] (95% CI)
Days to ERCP				
0–1	Ref.	Ref.	Ref.	Ref.
2–3	0.9 (0.8–1.1)	0.8 (0.7–1.0)	0.9 (0.8–1.1)	1.1 (0.9–1.3)
4–7	1.3 (1.2–1.5)	0.9 (0.7–1.2)	1.5 (1.3–1.8)	1.5 (1.2–1.8)
Unknown	1.5 (1.3–1.7)	1.3 (1.0–1.7)	1.6 (1.3–1.9)	1.5 (1.2–1.9)
Unsuccessful ERCP				
No	Ref.	Ref.	Ref.	Ref.
Yes	1.9 (1.7–2.3)	2.1 (1.5–3.0)	1.7 (1.3–2.2)	2.0 (1.5–2.6)

NOTE. Primary and secondary diagnoses are included.
[a]Model adjusted for time period, age, sex, race, health insurance, comorbidities, hospital, and procedures characteristics.

Supplementary Table 4. Characteristics of Patients With Acute Biliary Conditions Who Did Not and Did Undergo an ERCP After Propensity Score Matching, 1998–2008

Characteristic	No ERCP	ERCP	*P* value	Standardized difference, %
Patients, n	44,810	44,810		
Time period, %			.317[a]	
1998–2002	45.3	45.3		−0.0090
2003–2008	54.7	54.7		0.0090
Age, %			.801[b]	
<40 y	16.5	16.5		0
40–60 y	29.9	29.9		−0.0049
>60 y	53.6	53.6		0.0045
Sex, %			.414[a]	
Male	37.4	37.4		−0.000092
Female	62.6	62.6		0.000092
Health insurance, %			.920[b]	
Medicare	48.7	48.7		−0.0045
Medicaid	8.6	8.6		0.0080
Private including HMO	35.4	35.4		0
Self-pay/no charge/other	7.3	7.3		0
Race, %			.572[b]	
Nonwhite	21.1	21.1		0
White	56.0	56.0		−0.0090
Unknown	22.9	22.9		0.0106
Geographic US region, %			.809[b]	
Northeast	21.1	21.1		0.0164
Midwest	23.1	23.1		0
South	35.9	35.9		0
West	19.9	19.9		−0.0168
Location/teaching status, %			.978[b]	
Rural	9.4	9.4		0
Urban nonteaching	46.5	46.5		−0.0045
Urban teaching	44.1	44.1		0.0045
Elixhauser[17] comorbidities, %			.423[b]	
0	23.4	23.4		−0.0210
1	24.0	24.0		0.0157
2	21.5	21.5		0.0109
3+	31.0	31.0		−0.0048
Weekend admission, %			.059[a]	
No	78.2	78.2		−0.0270
Yes	21.8	21.8		0.0270
Yearly ERCP volume, %			.954[b]	
<100	35.2	35.2		−0.0047
100–200	34.1	34.1		0
>200	30.6	30.6		0.0048
Admission diagnosis, %			1.000[b]	
Acute pancreatitis	66.0	66.0		0
Choledocholithiasis	25.1	25.1		0
Cholangitis	8.9	8.9		0
Died			<.0001[a]	
No, %	98.0	99.0		7.8548
Yes, %	2.0	1.1		−7.8548
Missing, n	26	26		

HMO, health maintenance organization.
[a]McNemar test.
[b]Bowker test of symmetry.

Supplementary Table 5. Characteristics of Patients With Acute Biliary Conditions Who Underwent a Cholecystectomy After an ERCP, Laparoscopic vs Open Cholecystectomy, 1998–2008

Characteristic	Laparoscopic cholecystectomy	Open cholecystectomy	*P* value	Standardized difference, %
Patients, n	4158	4158		
Time period, %			1.000[a]	
1998–2002	42.7	42.7		0
2003–2008	57.3	57.3		0
Age, %			.421[b]	
<40 y	14.8	15.0		0.41
40–60 y	22.8	22.8		0.06
>60 y	62.4	62.2		−0.35
Sex, %			.602[a]	
Male	42.2	42.1		−0.15
Female	57.8	57.9		0.15
Health insurance, %			.183[b]	
Medicare	55.7	55.6		−0.15
Medicaid	7.5	7.5		0
Private including HMO	28.9	28.7		−0.37
Self-pay/no charge/other	8.0	8.2		0.88
Race, %			.343[b]	
Nonwhite	25.2	25.2		0
White	63.4	63.2		−0.50
Unknown	11.4	11.6		0.75
Geographic US region, %			.829[b]	
Northeast	32.9	32.8		−0.10
Midwest	7.0	7.0		−0.19
South	38.9	39.1		0.39
West	21.2	21.1		−0.24
Location/teaching status, %			.632[b]	
Rural	5.9	5.9		0
Urban nonteaching	52.1	52.0		−0.29
Urban teaching	42.0	42.1		0.29
Elixhauser[17] comorbidities, %			.132[b]	
0	24.3	24.1		−0.45
1	23.0	23.2		0.57
2	20.0	19.8		−0.54
3+	32.7	32.9		0.36
Weekend admission, %			.513[a]	
No	76.1	76.8		1.52
Yes	23.9	23.3		−1.52
Yearly ERCP volume, %			.129[b]	
<100	34.0	33.9		−0.15
100–200	39.0	38.8		−0.30
>200	27.0	27.3		0.49
Admission diagnosis, %			1.000[b]	
Acute pancreatitis	16.3	16.3		0
Choledocholithiasis	82.9	82.9		0
Cholangitis	0.8	0.8		0
Died, %			<.0001[a]	
No	99.6	97.8		−16.06
Yes	0.4	2.2		16.06

HMO, health maintenance organization.
[a]McNemar test.
[b]Bowker test of symmetry.