Revisiting Percutaneous Cholecystostomy for Acute Cholecystitis Based on a 10-Year Experience

Younna Abi-Haidar, MD; Vivian Sanchez, MD; Sandra A. Williams, MS; Kamal M. F. Itani, MD

Objectives: To identify patient characteristics leading to percutaneous cholecystostomy (PC) and to compare outcomes between PC and cholecystectomy (CCY) in patients with acute cholecystitis (AC).

Design: Retrospective cohort study.

Setting: Veterans Affairs Boston Healthcare System.

Patients: All consecutive patients with AC per the Tokyo criteria who underwent PC or CCY from January 1, 2001, through December 31, 2010.

Main Outcome Measures: Differences in baseline characteristics and outcomes between PC and CCY patients, odds of PC vs CCY use, and odds of death after PC or CCY.

Results: Of 480 CCY and 92 PC procedures, 150 CCY and 51 PC procedures were performed for AC. The PC patients were older (70.4 vs 65.0 years, \( P = .01 \)) and had higher leukocyte counts (16 500 vs 14 700/µL [to convert to \( 10^9/L \), multiply by 0.001], \( P = .046 \)), alkaline phosphatase levels (198.2 vs 140.1 U/L [to convert to microkatal per liter, multiply by 0.0167], \( P = .02 \)), Charlson comorbidity index scores (3.0 vs 1.0, \( P < .001 \)), and American Society of Anesthesiologists class (\( P = .006 \)) compared with CCY patients. The PC patients had longer intensive care unit stays (5.9 vs 2.3 days, \( P = .008 \)), longer hospital stays (20.7 vs 12.1 days, \( P < .001 \)), more complications per patient (2.9 vs 1.9, \( P = .01 \)), and higher readmission rates (31.4% vs 13.3%, \( P = .006 \)). On multivariate analysis, a Charlson comorbidity index score of 4 or higher was the only independent predictor of treatment with PC vs CCY (odds ratio, 1.226; 95% CI, 1.032-1.457) and was the only independent predictor of death after PC or CCY (odds ratio, 1.318; 95% CI, 1.143-1.521). No differences in survival were found between the PC and CCY groups (\( P = .14 \)).

Conclusion: Compared with CCY, PC is associated with higher morbidity rates and should be reserved for patients with prohibitive risks for surgery.

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The standard treatment for acute cholecystitis (AC) is cholecystectomy (CCY); however, the outcomes of CCY for AC in elderly and/or critically ill patients have been less than ideal. In elderly patients with AC and a low operative risk, CCY carries a 10% operative mortality rate, which increases by 3-fold in patients with a high operative risk.\(^1\)\(^-\)\(^3\) Rates of conversion from laparoscopic to open CCY are also higher for AC (11%-28%)\(^6\)\(^-\)\(^10\) compared with those for elective CCY (5%).\(^11\)\(^-\)\(^12\) Percutaneous cholecystostomy (PC) has been described as a safe alternative treatment option for AC in elderly or critically ill patients. This treatment modality, however, is not without a unique spectrum of complications and reportedly involves double the total hospital stay of CCY and a 25% rate of readmission for biliary complications.\(^13\)\(^-\)\(^14\) A Cochrane review published in 2009 concluded that there was no level A or level B evidence to support the use of PC over CCY in AC.\(^15\) The review captured 53 studies comprising 1918 patients and found a significantly higher 30-day mortality rate after PC (15.4%) compared with CCY (4.5%) (\( P < .001 \)). Whether the difference in mortality is attributable to PC patients being at higher risk than CCY patients was un-
clear. Other issues precluding a reliable comparison of outcomes between PC and CCY were inconsistencies in the reporting of periprocedural outcomes, inconsistent reporting of disease severity and comorbidities, and unclear inclusion criteria with regard to the ascertainment of AC diagnoses. In an effort to understand the indications for PC in the setting of AC, we studied our cohort of patients who have undergone PC and/or CCY for AC in 10 years at the Veterans Affairs Boston Healthcare System (VABHCS), with the goal of comparing periprocedural factors and outcomes associated with the use of PC vs CCY in the treatment of AC.

METHODS

The study was reviewed and approved by the institutional review board at the VABHCS. The computerized medical records of all consecutive patients at the VABHCS who underwent CCY or PC with or without subsequent CCY from January 1, 2001, through December 31, 2010, were identified based on Current Procedural Terminology codes for PC and CCY. Each medical record was reviewed for clinical history, physical examination findings, laboratory values, and radiologic findings at the time of the index presentation, in compliance with the Tokyo criteria for standardization and confirmation of the diagnosis of AC. The Tokyo criteria are a set of guidelines for the definitive diagnosis and severity assessment of AC that were formulated based on a systematic literature review and an expert panel consensus meeting held in Tokyo, Japan, in 2006. On the basis of these criteria, a definitive diagnosis of AC requires at least 1 local inflammation sign in the right upper quadrant (pain, tenderness, mass, or positive Murphy sign) combined with at least 1 systemic sign of inflammation (fever, elevated C-reactive protein level, or elevated white blood cell [WBC] count). If these clinical signs are equivocal and AC is suspected, then a predefined set of radiologic (ultrasonographic, computed tomographic scan, or hepatobiliary scan) findings would suffice to establish a diagnosis of AC. Only those cases in our cohort that fully satisfied the Tokyo criteria were determined to be definitive diagnoses of AC and were included in this study.

The records of included patients were subsequently reviewed for baseline patient characteristics, baseline procedural factors, and periprocedural outcomes for the first diagnosed episode of AC per patient. Baseline patient characteristics were those recorded at the time of presentation for AC, before the institution of antibiotics, and included age, a weighted Charlson comorbidity index score, American Society of Anesthesiologists (ASA) class, and body mass index (BMI; calculated as weight in kilograms divided by height in meters squared).

Procedural factors included type of treatment for AC (PC alone, PC with interval CCY, or CCY alone), severity of AC (grade 1 indicates mild; grade 2, moderate; and grade 3, severe) as per the Tokyo criteria for AC severity assessment, calculous vs acalculous AC, number of days between start of symptoms (as reported on presentation for AC) and diagnosis of AC, number of days between diagnosis of AC and institution of antibiotics, and the highest recorded temperature, alkaline phosphatase level, and total bilirubin level during the index admission for AC. Procedural outcomes after PC, interval CCY, and primary CCY were extracted from the records, and the variables recorded were length of stay (LOS) in the intensive care unit (ICU) during the index treatment admission, total hospital LOS for the index treatment, date and time of death (last checked on March 17, 2011), incidence of complications within 30 days of the procedure, number of complications per patient within 30 days of the procedure, highest complication grade per patient as designated by the complications classification system of Clavien et al. and rate of readmission within 30 postprocedural days. Interval CCY was defined as a CCY performed after PC drainage for AC, during the same hospitalization as that for PC, or on subsequent hospitalization. Complications reviewed for the PC group included those within 30 days of PC and within 30 days of interval CCY.

Bivariate analyses were performed to compare baseline patient characteristics, baseline procedural factors, and periprocedural outcomes between the PC and CCY groups. A t test was conducted to compare the means of the continuous variables and a Fisher exact test to compare the proportions for categorical variables.

A multivariate logistic regression analysis was then conducted to model the odds of PC use compared with CCY use for the treatment of AC. All listed baseline patient characteristics and procedural factors were tested in the model. These same variables, in addition to the use of the PC vs CCY variable, were incorporated into a multivariate survival analysis modeling the odds of death after a PC or CCY procedure. A Cox proportional hazards model adjusted for age and Charlson score was used to compare survival rates over time between the PC and CCY groups. We used 95% CIs in the regression analyses, and \( P < .05 \) was considered significant. All analyses were conducted using SAS statistical software, version 9.1 (SAS Institute, Inc), and data are presented as mean (SD).

RESULTS

A total of 480 CCY and 92 PC procedures were performed at the VABHCS during the 10-year study period. Of these, 150 CCY procedures (31.2%) and 51 PC procedures (55.4%) were completed for the treatment of AC per the Tokyo criteria and constituted our study sample. The decision to perform every PC procedure was made by a senior surgeon based on a higher risk-benefit ratio for acute CCY. All PC procedures were performed by an interventional radiologist using the transhepatic Seldinger technique. Table 1 shows the results of a bivariate analysis comparing baseline characteristics between the PC and CCY groups. The PC patients (mean age, 70.4 [13.9] years) were significantly older (\( P = .01 \)) than the CCY patients (mean age, 65.0 [13.3] years). The ASA classifications of 3 to 4 vs 1 to 2 (88.2% vs 68.7%, \( P = .006 \)), median Charlson comorbidity scores (3.0 [range, 0-8] vs 1.0 [range, 0-9], \( P < .001 \)), mean WBC counts (16 500/µL [5800/µL] vs 14 700/µL [5200/µL]) [to convert to microkatal per liter, multiply by 0.001], \( P = .046 \)), and mean alkaline phosphatase levels (198.2 [186.2] U/L vs 140.1 [137.8] U/L) [to convert to microkatal per liter, multiply by 0.0167], \( P = .02 \)) were also significantly higher in PC patients compared with CCY patients. Differences in time from start of symptoms to diagnosis of AC, time from diagnosis of AC to institution of antibiotics, AC grade of 2 to 3 vs 1, calculous vs acalculous AC, mean temperature, mean total bilirubin levels, and mean BMI scores were nonsignificant between PC and CCY patients. The outcomes of all 51 PC procedures are illustrated in Figure 1. After completion of PC, 3 patients (5.9%) died during the index hospitalization, at a mean of 13.3 (range, 2.0-14.0) days after PC. Another 5 patients (9.8%) underwent CCY during the index hospitalization, at a mean of 8.6 (range, 2.0-14.0) days after PC.
At the index admission. The CCY was performed within 24 hours of admission in 39 patients (24.0%). There was no 30-day postoperative mortality after elective CCY. Fourteen (35.9%) of the evaluated PC patients did not undergo CCY; 5 (35.7%) of these patients had a diagnosis of acalculous AC, another 5 (35.7%) were deemed at high operative risk, and 4 (28.6%) refused surgery. Three (21.4%) of the patients with inoperable conditions were readmitted at least once for biliary complications (recurrent AC, acute cholangitis, and PC leak), and 5 (35.7%) died during follow-up at a mean of 230.2 (range, 35.0-555.0) days after PC.

In the CCY group (Figure 2), 98 (65.3%) of the 150 patients diagnosed as having AC underwent CCY during the index admission. The CCY was performed within 24 hours of admission in 39 patients (39.8%), of whom 2 (5.1%) died within 30 days of CCY, 7 (17.9%) underwent open CCY, 25 (64.1%) underwent laparoscopic CCY, and 7 (17.9%) converted from laparoscopic to open CCY.
The remaining 59 patients (60.2%) underwent CCY after 24 hours from admission; 1 (1.7%) of them died within 30 days of surgery, 26 (44.1%) underwent open CCY, 12 (20.3%) underwent laparoscopic CCY, and 21 (35.6%) converted from laparoscopic to open CCY. Another 52 AC patients (34.7%) were discharged from the hospital for a delayed CCY after a mean hospital LOS of 12.2 (range, 2.0-58.0) days. An elective CCY was performed in 48 (92.3%) of these patients, of whom 1 (2.1%) died within 30 days of operation. Three (6.3%) of the elective CCY procedures were performed with an open approach, 34 (70.8%) were completed laparoscopically, and 11 (22.9%) were conversions from laparoscopic to open.

Another 4 (7.7%) of the discharged patients were readmitted for an emergency CCY; all 4 patients underwent open CCY, and none experienced 30-day postoperative mortality.

Bivariate analysis of differences in postprocedural outcomes (Table 2) revealed significantly longer ICU stays (3.9 [8.3] vs 2.3 [6.2] days, \( P = .008 \)), longer hospital stays (20.7 [11.4] vs 12.1 [9.5] days, \( P < .001 \)), a higher readmission rate (31.4% vs 13.3%, \( P = .006 \)), and a higher mean number of complications per patient (2.9 [2.1] vs 1.9 [2.6], \( P = .01 \)) for the PC group compared with the CCY group. No significant differences were noted between the PC and CCY groups for occurrence of complications and rates of highest complication grades (as per the classification of Clavien et al\(^{18}\)) per patient.

On multivariate analysis incorporating all baseline patient and procedural variables, the only independent pre-
dictor of PC vs CCY was a Charlson comorbidity score of 4 or higher (odds ratio [OR], 1.226; 95% CI, 1.032-1.457) (Table 3). Age, ASA class, BMI, time to diagnosis, time to treatment, severity of AC, presence of gall bladder calculi, temperature, and laboratory values (WBC count, total bilirubin level, and alkaline phosphatase level) were nonsignificant factors in the odds of PC vs CCY model.

The results of a multivariate survival analysis modeling the odds of death after PC or CCY are given in Table 3. The analysis included all baseline patient and procedural variables, in addition to PC vs CCY treatment. A Charlson comorbidity index score of 4 or higher (OR, 1.318; 95% CI, 1.143-1.521) was again an independent predictor of postprocedure death over time. Mean BMI was significantly associated with postprocedure survival (OR, 0.849; 95% CI, 0.783-0.920). All other variables, including treatment with PC vs CCY, were nonsignificant determinants of survival.

An age- and Charlson comorbidity index score-adjusted survival analysis of PC vs CCY revealed a trend toward lower survival in the PC group; however, this difference did not reach statistical significance (P = .39) (Figure 3).

Table 4. Qualitative Comparisons of the Rates of Different Types of Complications in PC Patients, Primary Laparoscopic CCY Patients, and Primary Laparoscopic Converted to Open CCY Patients

<table>
<thead>
<tr>
<th>Type of Complication</th>
<th>PC (n = 51)</th>
<th>Laparoscopic CCY (76 of 150 Procedures)</th>
<th>Laparoscopic to Open CCY (36 of 150 Procedures)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatobiliary</td>
<td>22 (43.1)</td>
<td>7 (9.2)</td>
<td>9 (25.0)</td>
</tr>
<tr>
<td>PC related</td>
<td>3 (5.9)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Iatrogenic injury</td>
<td>8 (15.7)</td>
<td>35 (46.1)</td>
<td>12 (33.3)</td>
</tr>
<tr>
<td>Organ systems</td>
<td>35 (68.6)</td>
<td>22 (28.9)</td>
<td>19 (52.8)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (7.8)</td>
<td>1 (1.3)</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Death within 30 days of procedure</td>
<td>3 (5.9)</td>
<td>1 (1.3)</td>
<td>0</td>
</tr>
</tbody>
</table>

Abbreviations: CCY, cholecystectomy; NA, not applicable; PC, percutaneous cholecystostomy.

The general medical condition of our PC patients is a reflection of the older age and higher prevalence of comorbidities seen in our veteran patient population. Our PC patients were of comparable age (70.4 years) to those studied in the literature (68.1 years), yet a higher proportion of them (88.2%) had an ASA classification of 3 to 4 compared with a weighted mean proportion equal to 76.1% of 148 patients studied in the literature.9–10,22 Our patients also had a longer mean hospitalization time for PC (20.7 days) compared with 5.9 days23 and 9.8 days9 in studies that have reported mean LOS. Because PC is indicated in severely ill patients, these numbers demonstrate that we have selected a higher-risk group of patients for treatment with PC and that, at worst, we did not overtreat our veteran patients with PC. On the other hand, our CCY patients were significantly younger (65.0 years, P = .01), with a significantly lower rate of ASA 3 to 4 classification (68.7%, P = .006), a lower median Charlson comorbidity index score (1.0, P < .001), and a shorter mean hospital LOS (12.1 days, P < .001) compared with our PC patients.

The severity of AC, another indication for PC, was higher in our PC patient group compared with other PC patients in the literature. Our PC patients presented with AC after a mean interval of 6.3 (7.1) days from the start of symptoms; this interval was longer than the mean interval reported in one study (2.4 days; range, 4.0-11.0 days)23 and the median intervals of 3.0 days (range, 1.0-21.0 days)24,25 and 4.5 days (range, 2.0-14.0 days)20 reported in 3 other studies. Another study of veteran patients reported a mean of 2.7 days from the start of symptoms to PC,26 which was again shorter than our mean time to diagnosis. The severity of AC in our PC patient group is also indicated by the rate of conversion from laparoscopic to the open approach during interval CCY procedures, which was higher at 21.9% (7 of 32 procedures) compared with a weighted mean conversion rate of 11.7% (range, 0%-31.0%) calculated in 178 interval CCY patients in the literature.9,20,24,25,27 Our CCY-only group had a 24.0% (36 of 150 procedures) conversion rate, which was again on the higher end of the 11.0% to 28.0% reported range of CCY conversion rates.9,7,10,28-30

When indexes of patient illness and AC severity were factored into our multivariate analysis, the only independent predictor of PC vs CCY was the Charlson comorbidity index. These results indicate that our patients’ comor-
bid conditions and general medical risks for surgery were more important than the duration or severity of AC in determining their treatment with PC vs CCY. This is despite the higher severity of AC cases at our institution compared with cases studied in the literature.

On multivariate survival analysis incorporating all patient and procedural variables, the Charlson comorbidity index remained the only independent predictor of death over time after PC or CCY. Our age- and Charlson comorbidity index score–adjusted plot of survival over time showed lower, although nonsignificant, survival rates in PC patients compared with CCY patients (P = .39).

Percutaneous cholecystostomy was also associated with significantly longer ICU stays (P = .008), longer hospital stays (P < .001), a higher number of complications per patient (P = .01), and a higher readmission rate (P = .006) compared with CCY. Although PC patients were followed up for a mean of 67.1 (range, 9.0-555.0) days with their PC tube in place, they had a 21.4% rate of readmission and a 35.7% death rate, indicating a high risk of morbidity and mortality with long-term CCY treatment.

Despite the morbidity associated with conversion to open CCY, our patients in the primary laparoscopic group who converted to the open CCY procedure experienced lower rates of hepatobiliary complications (25.0% vs 43.1%), organ systems complications (52.8% vs 68.6%), and other complications (2.8% vs 7.8%) compared with PC patients.

Our results indicate that PC should be reserved for patients with prohibitive risks for surgery, irrespective of the severity of AC or the risk of conversion from laparoscopic to open CCY. Targeted investigations into operative risk stratification models for AC patients are warranted.

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Correspondence: Kamal M. F. Itani, MD, Veterans Affairs Boston Healthcare System, 1400 VFW Pkwy, West Roxbury, MA 02132 (Kamal.Itani@va.gov).

Author Contributions: Study concept and design: Abi-Haidar, Sanchez, and Itani. Acquisition of data: Abi-Haidar, Sanchez, Williams, and Itani. Analysis and interpretation of data: Abi-Haidar, Sanchez, Williams, and Itani. Drafting of the manuscript: Abi-Haidar and Itani. Critical revision of the manuscript for important intellectual content: Abi-Haidar, Sanchez, Williams, and Itani. Statistical analysis: Abi-Haidar and Williams. Obtained funding: Itani. Administrative, technical, and material support: Abi-Haidar, Sanchez, and Itani. Study supervision: Sanchez and Itani.

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REFERENCES

Cholecystectomy or Percutaneous Cholecystostomy for Acute Cholecystitis

Is It Any Clearer Which to Choose?

Percutaneous cholecystostomy (PC) under ultrasonographic guidance was first introduced in 1979, yet it is not clear in what circumstances the technique is preferred over cholecystectomy. Percutaneous cholecystostomy has been used in higher-risk, often elderly and critically ill patients. As a result, reports comparing the percutaneous technique with cholecystectomy have shared a retrospective study design and have not evaluated comparable groups. Abi-Haidar et al., in this issue of the Archives, describe a 10-year cohort of patients who underwent both techniques. As in other studies, the PC patients were older, had higher American Society of Anesthesiologists (ASA) classification, and had more comorbidities. They experienced more readmissions and complications and had a longer hospital stay. Most patients undergoing PC ultimately required cholecystectomy, during either the index or a subsequent admission.

It is clear that cholecystectomy during the primary hospitalization is desirable to avoid subsequent admissions, hepatobiliary complications, and additional surgery. Yet 2 patient populations warrant thoughtful clinical decision making: those with critical illness and those with a high likelihood of conversion from a laparoscopic to an open procedure. In the case of critical illness, particularly patients who develop acute cholecystitis during an intensive care unit stay, PC has a continued role in light of evidence that emergency cholecystectomy in the critically ill is associated with higher mortality rates than cholecystectomy. Conversion from laparoscopic to open surgery is associated with more complications. For this reason, cholecystectomy should be considered thoughtfully in particularly high-risk patients, such as those classified as having ASA IV disease or those with severe cardiac disease. If surgical therapy is chosen, an initial laparoscopic approach is preferred. In the high-risk patients in whom conversion to open surgery is required and might result in increased complications with risk of death, an old option is worth considering: cholecystostomy, a technique that can be readily used laparoscopically. We have used laparoscopic cholecystostomy in a number of critically ill patients with good outcomes, although additional procedures, such as cholecystectomy or clearance of gallstones from the gallbladder, might be necessary when the patient’s condition has improved.

Kortram et al plan to perform a multicenter trial of PC vs laparoscopic cholecystectomy in high-risk surgical patients. Until then, the nuances of surgical decision making in this patient population remain difficult and require thoughtful clinical judgment.

Rocco Orlando III, MD

Author Affiliation: Department of Surgery, Hartford Hospital and University of Connecticut School of Medicine, Hartford.

Correspondence: Dr Orlando, Hartford Hospital, 80 Seymour St, Hartford, CT 06102 (rorland@harthosp.org).

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