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Percutaneous cholecystostomy: prognostic factors and comparison to cholecystectomy

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Abstract

Background—Data regarding long-term outcomes following percutaneous cholecystostomy (PC) are limited, and comparisons to cholecystectomy (CCY) are lacking. We hypothesized that chronic disease burden would predict 1-year mortality following PC, and that outcomes following PC and CCY would be similar when controlling for preprocedural risk factors.

Methods—We performed a 10-year retrospective cohort analysis of patients with acute cholecystitis managed by PC ($n = 114$) or CCY ($n = 234$). Treatment response was assessed by systemic inflammatory response syndrome (SIRS) criteria at PC/CCY and 72 h later. Logistic regression identified predictors of 30-day and 1-year mortality following PC. PC and CCY patients were matched by age, Tokyo Guidelines (TG13) cholecystitis severity grade, and VASQIP calculator predicted mortality ($n = 42$/group).

Results—The presence of SIRS at 72 h following PC was associated with 30-day mortality [OR 8.9 (95% CI 2.6–30)]. SIRS at 72 h was present in and 21.4% of all PC patients, significantly higher than unmatched CCY patients (4.7%, $p = 0.048$). Independent predictors of 1-year mortality following PC were DNR status [19.7 (2.1–186)], disseminated cancer [7.5 (2.1–26)], and congestive heart failure [3.9 (1.4–11)]. PC patients with none of these risk factors had 17.9% 90-day mortality and no deaths after 90 days; late deaths continued to occur among patients with DNR, CHF, or disseminated cancer. At baseline, PC patients had greater acute and chronic disease burden than CCY patients. After matching, PC and CCY patients had similar age (69 vs. 70 years), TG13 grade (2.4 vs. 2.4), and predicted 30-day mortality (5.5 vs. 6.8%). Matched PC patients had

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Compliance with Ethical Standards

Disclosures Tyler J. Loftus, Elisha M. Collins, Camille G. Dessaigne, Amber N. Himmler, Alicia M. Mohr, Ryan M. Thomas, Charles E. Hobson, George A. Sarosi Jr. and William J. Zingarelli have no conflicts of interest to disclose.

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higher 30-day mortality (14.3 vs. 2.4%, $p = 0.109$) and 180-day mortality (28.6 vs. 7.1%, $p = 0.048$).

Conclusions—Treatment response to PC predicted 30-day mortality; DNR status, and chronic diseases predicted 1-year mortality. Although the matching procedure did not eliminate selection bias, PC was associated with persistent systemic inflammation and higher long-term mortality than CCY.

Keywords

Cholecystitis; Percutaneous cholecystostomy; Cholecystectomy; Prognosis; Outcomes; Mortality

Percutaneous cholecystostomy (PC) may be performed for high-risk operative candidates with acute cholecystitis as an alternative to cholecystectomy (CCY). PC may function as a temporizing measure for patients with calculous cholecystitis, or as definitive therapy for patients with no gallstones who are at low risk for recurrence [1, 2]. Incidence of PC has increased over time despite controversy fueled by the paucity of direct comparisons to CCY and limited prognostic data for outcomes following PC [3–6]. The purposes of this study were to compare outcomes following PC versus CCY and to identify predictors of 30-day and 1-year mortality following PC. We hypothesized that chronic disease burden would predict 1-year mortality following PC, and that outcomes following PC and CCY would be similar when controlling for preprocedural risk factors.

Methods

Study population

We performed a retrospective cohort analysis of 348 consecutive patients with acute cholecystitis managed by PC ($n = 114$) or CCY ($n = 234$) at a Veterans Affairs hospital from January 1, 2004 through October 1, 2014. Institutional Review Board approval was obtained. Our radiology and surgery databases were searched for patients with acute cholecystitis and procedural codes for PC and CCY. Patients who underwent PC and subsequent CCY were analyzed in the PC cohort. Pregnant women, patients with concomitant cholangitis or gallstone pancreatitis, and subjects with less than 30-day follow-up were excluded. Although subtotal CCY may be a safe and effective option under certain circumstances [7], these patients were excluded to decrease heterogeneity in the CCY cohort. Treatment response was assessed by systemic inflammatory response syndrome (SIRS) criteria [8] at the time of the procedure and 72 h later. The primary endpoints were mortality at 30, 180 days, and 1 year. 1-year follow-up within the VA system was 96%.

Matching procedure

Cholecystitis was characterized by Tokyo (TG13) severity grade (1 = mild uncomplicated cholecystitis, 2 = moderate cholecystitis characterized marked local inflammation or systemic toxicity, and 3 = severe cholecystitis characterized by evidence of organ dysfunction) [9]. The response to PC was assessed by systemic inflammatory response syndrome (SIRS) criteria [8]. PC patients were matched to CCY patients 1:1 based on VASQIP predicted 30-day mortality. For General Surgery operations, the VASQIP Fiscal

Year 2015 Model uses 42 variables to predict 30-day and 180-day postoperative mortality. For each PC patient, the CCY cohort was searched for the subject with the closest corresponding predicted mortality. If this subject had predicted mortality within 0.99% of the PC patient, both subjects were set aside into matched groups. In this manner, 90 PC patients were matched to 90 CCY patients. Next, patients were matched by TG 13 grade. Of the 90 PC patients, 36 were grade III, 24 were grade II, and 30 were grade I. Of the 90 CCY patients, 18 were grade III, 39 were grade II, and 33 were grade I. The 18 grade III CCY patients were matched to 18 grade III PC patients according to age by the greedy nearest-neighbor method (the first patient was paired with the closest age match, both were set aside, and the process was repeated). Grade II patients were matched by the same method. Grade I patients were excluded, as PC is not recommended for this population [10, 11]. This process matched 42 PC patients to 42 CCY patients with similar baseline characteristics (Table 1).

Statistical analysis

The analytic plan followed the STROBE recommendations for observational cohort studies [12]. Multiple logistic regression was performed to identify predictors of 30-day and 1-year mortality following PC with SPSS (version 23, IBM, Armonk, NY). All conditions present on admission listed in Table 1 were considered for inclusion in the prediction models. Univariate regression was performed to identify variables associated with the outcome of interest. Variables with significant collinearity ($|r| \geq 0.20$, $p < 0.05$) to other variables in the model were eliminated, and all remaining variables were entered into the regression equation. Models were compared by area under the receiver operating characteristic curve (AUROC) [13, 14]. AUROC for different models were compared as described by DeLong et al. [15] using SAS (version 9.3, SAS Institute, Cary, NC). Kaplan–Meier curves were generated in GraphPad Prism (version 6.05, GraphPad Software, La Jolla, CA) and compared using the Mantel-Cox log-rank test. Significance was set at $\alpha = 0.05$.

Results

Patient characteristics

At baseline, PC patients were older, had higher incidence of acalculous cholecystitis, and had greater acute and chronic disease burden (Table 1). Predicted 30-day mortality was significantly higher in the PC cohort (10.9 vs. 2.7%, $p < 0.001$). After matching, PC and CCY patients had similar predicted 30-day mortality (5.5 vs. 6.8%), TG grade (2.4 vs. 2.4), and age (69 vs. 70 years). Matched CCY patients had significantly higher rates of calculous cholecystitis (95 vs. 76%, $p = 0.026$) as well as higher incidence of chronic obstructive pulmonary disease, although this difference was not statistically significant (41 vs. 19%, $p = 0.055$). The matching procedure eliminated significant differences between groups for each of the following variables: age, TG13 severity grade, temperature, creatinine, dialysis status, disseminated cancer, preprocedural chemotherapy, preprocedural radiotherapy, and body mass index, and do-not-resuscitate status.

Short-term outcomes

Clinical response 72 h after PC and CCY is illustrated for matched cohorts in Fig. 1. Matched PC patients were more likely to have a persistent SIRS response 72 h following

their procedure (21.4 vs. 4.7%, $p = 0.048$). The presence of SIRS 72 h after PC was associated with 30-day mortality (Table 2). Integrating SIRS criteria with the VASQIP calculator increased the sensitivity and specificity of model predictions, but the observed increase in AUROC did not reach statistical significance (VASQIP calculator AUROC: 0.72 (95% CI 0.58–0.85); integrated model AUROC: 0.83 (95% CI 0.72–0.93); difference between AUROC: 0.11 (95% CI 0.01–0.24, $p = 0.062$). Although matched PC and CCY patients had similar predicted 30-day mortality (5.5 vs. 6.8%, $p = 0.228$) and 180-day mortality (14.0 vs. 16.5%, $p = 0.382$), PC patients had somewhat higher 30-day mortality (14.3 vs. 2.4%, $p = 0.109$) and significantly higher 180-day mortality (28.6 vs. 7.1%, $p = 0.048$) (Fig. 2, exact values listed in Table 3). Causes of death for matched PC patients who died within 30 days are listed in Table 4.

Long-term outcomes

Ninety-day mortality following PC was 24.4%, 180-day mortality was 25.7%, and 1-year mortality was 29.8%. Do-not-resuscitate (DNR) status was the strongest predictor of 1-year mortality, followed by disseminated cancer and congestive heart failure (CHF) (Table 2). Patients with disseminated cancer had 60% 1-year mortality and were analyzed as a separate group. Of the remaining 99 patients, those with DNR status or CHF had significantly higher 1-year mortality following PC (37.5%) than patients without DNR status or CHF (17.9%) (Fig. 3).

Interval CCY was performed in 38 patients at an average 104 days following PC. Twenty-three cases were performed laparoscopically, eight were converted from laparoscopic to open, and seven were planned open procedures. None of the gallbladder specimens in the interval CCY group contained cancer; three patients in the primary CCY group (1.3%) had gallbladder cancer found incidentally on pathologic examination. Among interval CCY patients, there was one mortality which occurred on postoperative day 21 in a 72 year old Veteran with coronary artery disease, CHF, peripheral vascular disease, and chronic renal insufficiency. His postoperative course was complicated by non-ST elevation myocardial infarction, unplanned reintubation, pneumonia, and acute on chronic renal insufficiency requiring hemodialysis. The cohort of 76 patients who underwent PC without interval CCY had 23.7% 30-day mortality and 42.1% 1-year mortality. 6 of these patients had a DNR order, 14 had disseminated cancer, and 21 had CHF. Forty-two patients in this cohort had their PC tube removed without replacement.

Discussion

Patients who underwent PC carried a substantial burden of acute and chronic disease, hindering direct comparison to CCY. The matching procedure generated PC and CCY groups with similar characteristics, but statistically and clinically significant differences in the incidence of acalculous cholecystitis remained. In addition, the PC group may have had risk factors that were not included in the VASQIP surgical risk calculator, rendering calculator predictions inaccurate. However, several studies have demonstrated that the VASQIP calculator performs well in predicting mortality [16–18]. Ashfar et al. [19] validated the VASQIP calculator in predicting 30-day postoperative mortality for a cohort of

1618 Veterans age >80 who underwent major general, cardiac, orthopedic, urologic, or vascular surgery, reporting AUROC 0.82. Although the VASQIP surgical risk calculator has not been validated specifically for CCY patients, the weight of evidence supports its accuracy.

Therefore, the possibility that CCY is more effective than PC for high-risk surgical candidates with acute cholecystitis deserves further attention. A Cochrane Database systematic review by Gurusamy et al. [1] was intended to establish the role for PC in high-risk surgical patients but included only two randomized clinical trials: one trial comparing early CCY after PC with late CCY after PC [20] and one trial comparing PC with conservative management [21]. Analysis of these studies was inadequate to provide recommendations for the use of PC in high-risk patients. Several authors have established the safety and efficacy of early CCY for patients with acute cholecystitis, including high-risk populations [6, 22, 23]. In addition, a recent propensity-matched analysis by Dimou et al. [24] found that cholecystostomy tube placement was associated with increased mortality among elderly patients with Grade III cholecystitis. However, level I evidence comparing PC to CCY is lacking. Efforts to address these issues are ongoing [25].

On systematic review of 53 studies incorporating 1918 PC patients, Winbladh et al. [2] reported that 85.2% had clinical improvement within 72 h, consistent with our results. The strength of the SIRS response at 72 h in predicting 30-day mortality may be attributable to a variety of factors. Patients who improved after PC may represent a cohort whose acute illness was primarily or entirely attributable to acute cholecystitis rather than a comorbid inflammatory process. Alternatively, patients who did not improve following PC may have been disproportionately affected by ongoing inflammation of a necrotic gallbladder wall, rendering biliary decompression and drainage insufficient to address the source of ongoing inflammation. Finally, drain clogging or dislodgement within the peritoneal cavity may have played a role, although it is impossible to accurately assess these events retrospectively. Whatever the cause, the presence of SIRS 72 h after PC was strongly associated with 30-day mortality. Persistent SIRS appears to be a useful metric to gauge the therapeutic efficacy and prognosis following PC. These findings gain relevance in the context of recent work by Smith et al. [26] which reinforced the validity of measuring 30-day mortality by demonstrating significant correlation to long-term outcomes. While 30-day mortality remains an important benchmark, our survival curves suggest that measuring 90-day mortality captures a substantial number of deaths which appear to be temporally related to the inciting event.

Notably, there were 30 patients with Grade I TG13 cholecystitis who underwent PC during the study period. These patients had acute cholecystitis in conjunction with another disease process posing increased risk for perioperative and postoperative morbidity and mortality, but did not qualify as Grade II or III cholecystitis. For example, a patient with a 48-h history of acute cholecystitis, white blood cell count 17×10^9/L, a nonpalpable gallbladder, and no imaging evidence of gallbladder gangrene or empyema has Grade I cholecystitis, even if they also have a pulmonary embolism with preserved PaO_2/FiO_2 ratio, a recent myocardial infarction in the absence of hypotension and vasopressor requirements, or a significant chronic disease burden that does not meet criteria for organ failure. However, because Grade

I cholecystitis is not an indication for PC per TG13 guidelines, such patients from excluded from the matched analysis.

The major limitations of this study are its retrospective design, propensity to introduce selection bias, a paucity of female subjects, and a tendency toward late presentation at Veterans Health Administration facilities [27]. The high proportion of interval cholecystectomies performed open (18%) or converted to open (21%) underscores the unique nature of our patient population and practice patterns. Therefore, these findings may not be generalizable for many practices and clinical scenarios. The effects of selection bias were minimized by matching PC and CCY patients based on VASQIP predicted 30-day mortality, severity of cholecystitis, and age. Although the VAS-QIP surgical risk calculator is well validated, it cannot account for clinical gestalt and surgeon judgement, does not include several disease-specific variables, and was not designed to predict mortality for nonsurgical procedures like PC. In addition, the VASQIP calculator was designed for 30- and 180-day outcome predictions, and may not be suitable for 1-year outcomes. Finally, risk calculators and disease-severity scoring systems should not replace clinical judgement, and experienced clinicians often recognize situations in which PC is prudent for a high-risk patient with acute cholecystitis, and situations in which algorithms may underestimate the likelihoods of perioperative morbidity and mortality. Therefore, randomized trials are needed to provide level I evidence supporting complex management decisions for high-risk surgical candidates with acute cholecystitis [28].

Conclusions

Among PC patients, the presence of SIRS 72 h following PC was associated with the increased 30-day mortality, and may be a useful indicator of therapeutic efficacy and prognosis. When controlling for VASQIP predicted 30-day mortality, TG13 severity of cholecystitis, and age, PC was associated with persistent systemic inflammation and increased long-term mortality compared with CCY. These findings must be interpreted in the context that matching procedures do not eliminate selection bias, the VASQIP calculator was not designed for percutaneous procedures like PC, and the practice setting limits generalizability. Therefore, randomized trials comparing PC with CCY for high-risk patients with acute cholecystitis are needed.

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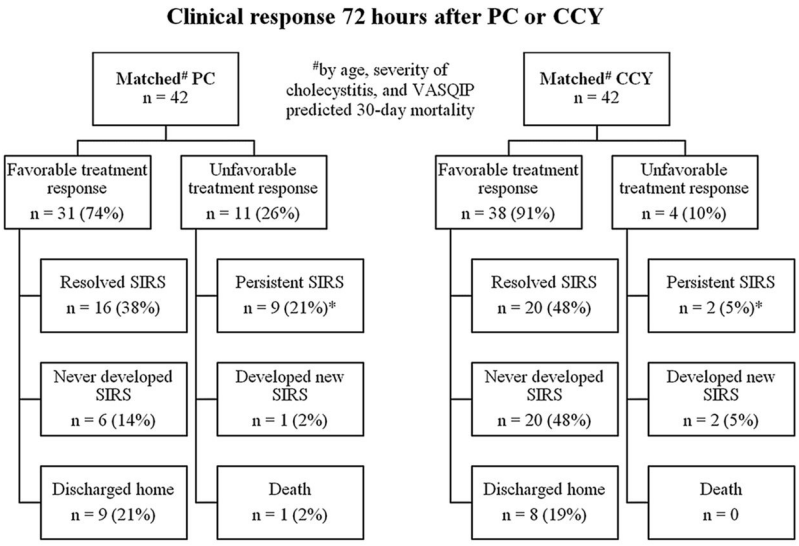

Fig. 1.

Outcomes 72 h after percutaneous cholecystostomy (PC) and cholecystectomy (CCY) (*SIRS* systemic inflammatory response syndrome, *$p = 0.048$)

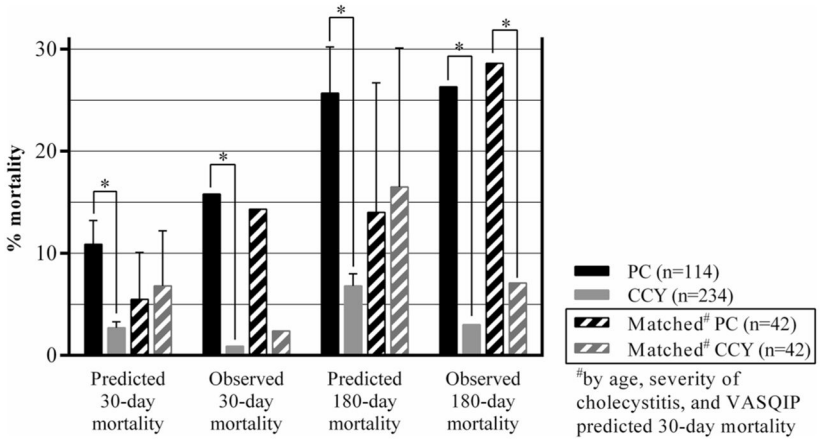

Fig. 2.

Predicted and observed mortality rates 30 and 180 days following percutaneous cholecystostomy (PC) and cholecystectomy (CCY) (*$p < 0.05$)

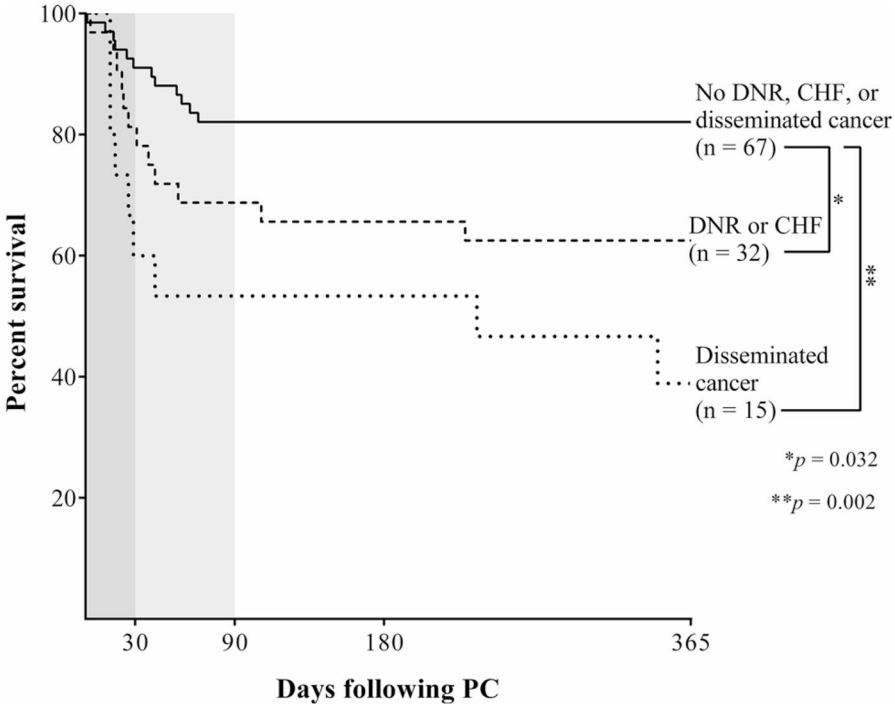

Fig. 3.

Kaplan–Meier survival curves following percutaneous cholecystostomy (PC) (*DNR* do-not-resuscitate status, *CHF* congestive heart failure)

Table 1

Patient characteristics at the time of percutaneous cholecystostomy (PC) or cholecystectomy (CCY)

Patient characteristics	PC *n* = 114	CCY *n* = 234	*p*	Matched PC *n* = 42	Matched CCY *n* = 42	*p*
Age (years)	71 ± 12	66 ± 11	<0.001	69 ± 11	70 ± 9	0.708
Male	110 (96%)	210 (90%)	0.035	40 (95%)	40 (95%)	–
ASA physical status classification	3.5 ± 0.7	3.4 ± 0.8	0.560	3.5 ± 0.5	3.6 ± 0.5	0.388
Calculous cholecystitis[a]	85 (75%)	210 (90%)	<0.001	32 (76%)	40 (95%)	0.026
TG13 severity grade[a]	2.1 ± 0.9	1.6 ± 0.7	<0.001	2.4 ± 0.5	2.4 ± 0.5	>0.999
Temperature (°C)[a]	37.4 ± 0.9	37.1 ± 0.8	0.014	37.4 ± 0.8	37.3 ± 0.9	0.877
White blood cell count (x10^9/L)	14.0 ± 7.1	12.9 ± 4.6	0.082	14.7 ± 7.0	15.0 ± 4.6	0.881
Creatinine (mg/dL)	1.7 ± 1.9	1.0 ± 0.3	<0.001	1.5 ± 1.2	1.2 ± 0.5	0.097
International normalized ratio	1.4 ± 0.6	1.1 ± 0.1	<0.001	1.4 ± 0.5	1.2 ± 0.2	0.039
Myocardial infarction[b]	6 (5%)	1 (0.4%)	0.006	2 (5%)	0	0.494
Congestive heart failure	23 (20%)	39 (17%)	0.457	5 (12%)	11 (26%)	0.164
COPD	30 (26%)	54 (23%)	0.594	8 (19%)	17 (41%)	0.055
Ascites	6 (5%)	5 (2%)	0.187	3 (7%)	3 (7%)	–
On dialysis	5 (5%)	0	0.004	1 (2%)	0	> 0.999
Active smoker	27 (24%)	67 (29%)	0.369	8 (19%)	15 (36%)	0.141
Chronic steroid use	7 (6%)	11 (5%)	0.609	2 (5%)	1 (2%)	>0.999
Outpatient oral hypoglycemic use	18 (16%)	34 (15%)	0.751	8 (19%)	7 (17%)	>0.999
Outpatient insulin use	38 (33%)	58 (25%)	0.098	12 (29%)	14 (33%)	0.814
Disseminated cancer	15 (13%)	1 (0.4%)	<0.001	1 (2%)	1 (2%)	>0.999
Chemotherapy within 30 days	9 (8%)	1 (0.4%)	<0.001	1 (2%)	0	>0.999
Radiotherapy within 90 days	4 (4%)	0	0.011	0	0	–
Weight loss >10% over 6 months	10 (9%)	12 (5%)	0.240	1 (2%)	4 (10%)	0.360
Body mass index	28 ± 6	30 ± 6	0.003	30 ± 7	29 ± 6	0.360
Do-not-resuscitate order	7 (6%)	0	<0.001	2 (5%)	0	0.494

Data are presented as mean ± standard deviation or n (%)

TG13 Tokyo criteria grade for severity of acute cholecystitis, *ASA* American Society of Anesthesiologists, *COPD* chronic obstructive pulmonary disease

[a]Not a VASQIP surgical risk calculator input variable

[b] Within six months.

Table 2

Multivariate predictors of 30-day and 1-year mortality after percutaneous cholecystostomy (PC)

Outcome factor(s)	OR	95% CI	*p*
30-day mortality			
SIRS 72 h after PC	8.9	2.6–30	<0.001
1-year mortality			
Do-not-resuscitate status	19.7	2.1–186	0.009
Disseminated cancer	7.5	2.1–26	0.002
Congestive heart failure	3.9	1.4–11	0.010

OR odds ratio, *CI* confidence interval, *SIRS* systemic inflammatory response syndrome

Table 3

Predicted and observed mortality rates for unmatched and matched groups of patients who underwent percutaneous cholecystostomy (PC) or cholecystectomy (CCY) as initial management of acute cholecystitis

Outcome	Analysis	PC	CCY	*p*
Predicted 30-day mortality	Unmatched	10.9 ± 0.6	2.7 ± 4.3	<0.001
	Matched	5.5 ± 4.6	6.8 ± 5.4	0.228
Observed 30-day mortality	Unmatched	18 (15.8)	2 (0.9)	<0.001
	Matched	6 (14.3)	1 (2.4)	0.109
Predicted 180-day mortality	Unmatched	25.7 ± 4.5	6.8 ± 1.2	<0.001
	Matched	14.0 ± 12.7	16.5 ± 13.6	0.382
Observed 180-day mortality	Unmatched	30 (26.3)	7 (3.0)	<0.001
	Matched	12 (28.6)	3 (7.1)	0.020

Matched by age, severity of cholecystitis, and VASQIP predicted 30-day mortality. Data are presented as mean ± SD or *n* (%)

Table 4

Causes of death for matched percutaneous cholecystostomy (PC) patients with mortality within 30 days of PC

Age	Sex	Cause of death
85	Male	Pneumonia, ARDS
57	Male	Stroke/hospice
59	Male	Diffuse lymphoma/hospice
65	Male	Myocardial infarction
63	Male	Pulmonary embolism
75	Male	PEA arrest

Matched to cholecystectomy patients by age, severity of cholecystitis, and VASQIP predicted 30-day mortality.

ARDS acute respiratory distress syndrome, *PEA* pulseless electrical activity