

Original Research Article

A retrospective study of percutaneous cholecystostomy outcomes in a community hospital

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Received: 26 June 2023

Revised: 05 August 2023

Accepted: 16 August 2023

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ABSTRACT

Background: The gold standard of treatment for acute cholecystitis (AC) typically involves operative intervention, specifically cholecystectomy. However, initial nonoperative management rather than immediate cholecystectomy has been recommended for critically ill patients. Non-operative interventions, such as percutaneous cholecystostomy (PCT), may represent viable alternatives. The current study examines risk factors associated with worse outcomes of AC among critically ill patients with AC treated conservatively.

Methods: This retrospective study examined data from 121 patients with AC presenting to a NYC-area community hospital. Differences in demographic, clinical, and procedural characteristics were examined in relation to post-operative outcomes, including mortality.

Results: The sample tended to be older, with 31% of patients identifying as non-Hispanic white. One-third of the sample were admitted to the ICU. The median time between admission placement and PCT was 2 days, the median time PCT was left in place was 42 days. The overall 90-day mortality rate was 21% and 33% among ICU patients. Patients identifying as non-Hispanic white and those with more severe clinical presentation were at higher risk for mortality within 90 days. Admission to intensive care units (ICU) was significantly associated with 90-day mortality.

Conclusions: The results of the current study provide a snapshot into the profiles of patients at-risk for negative outcomes following PCT placement. Sociodemographic risk factors and clinical severity were associated with increased risk of mortality among patients seen at a diverse, community hospital. These findings support the use of risk-stratified decision making regarding non-operative treatments of AC.

Keywords: AC, PCT, Post-operative outcomes, Community hospital, Critically ill patients

INTRODUCTION

Gallstones occur in approximately 10-15% of the population in the United States with 10-20% having symptomatic disease.¹ The incidence of AC is estimated to be 20 million cases per year and roughly 1/3 of patients who develop gallstones subsequently develop AC.² Certain sociodemographic characteristics (e.g., older age,

female) and clinical presentation (e.g., type and severity of comorbid conditions) have been linked to worse outcomes.

The gold standard treatment of AC is cholecystectomy, most commonly by laparoscopy, robotic surgery in more recent studies, and less frequently by open approach.^{2,3} However, initial, nonoperative management rather than immediate cholecystectomy has been recommended for patients who are critically ill.⁴ Mortality rates as high as 19% have been reported.⁵ Therefore, treatment decisions

for AC are risk stratified. Contraindication to general anesthesia, coagulopathy or bleeding disorders and delayed presentation (>72 hours after onset of symptoms) are some previously observed risk factors.⁶ For a subset of patients with AC, immediate surgery is necessary, however, debate exists regarding the timing of surgery and other treatment components.² Non-operative managements include antibiotics and PCT drainage by interventional radiology (IR) by transperitoneal or transhepatic approach, based on the personal preference of the radiologist and the accessibility of the gallbladder.⁷

We aim to study the characteristics, diagnostic modalities and outcomes of patients with AC treated with PCT drainage.

METHODS

Design and sample

The current study consisted of a retrospective chart review of patient visits to Flushing hospital medical center in Queens, NY, between January 1st, 2012 and December 31st, 2020. The study was approved by the hospital's institutional review board (IRB). As this was a retrospective study, patient consent was not required. The study was completed in accordance with strobe criteria. The primary inclusion criteria used was a diagnosis of AC and treatment with placement of a PCT tube for AC. Patients with AC who were treated conservatively with only antibiotics or who underwent surgery on index admission were excluded. This resulted in a final sample of 121 patients.

Data and analytic plan

Data for the sample was extracted from the hospital medical record (EMR). Data included patient demographics, diagnostic modalities, fluid cultures, length of stay, complications of PCT, readmission and subsequent surgical procedures. Illness severity was operationalized using the Charlson comorbidity index (CCI) and admission to intensive care units (ICU). Cases were confirmed by review of selected charts by members of the treatment team. Mortality was measured at 90 days from discharge. All patients without documented encounters were considered lost to follow-up.

Descriptive statistics were calculated for characteristics of interest. Mean/SD or median/IQR were reported as appropriate. Bivariate comparisons were used to examine differences in postoperative outcomes across demographic, clinical and procedural characteristics. Due to low sample size, subgroup analysis of ICU vs. non-ICU patients was used to adjust for confounding factors between settings. Parametric or nonparametric tests were used as appropriate, with a $p < 0.05$ considered significant. Baseline characteristics were compared between those lost to follow up and those with documented encounters to account for any significant differences between groups.

Descriptive statistics are reported for the sample as a whole, unless otherwise indicated.

RESULTS

Demographic characteristics

Of the 121 patients included in the sample, the average age was 70.7 (SD=17.1). The sample was split roughly across genders (52.9% identified as female). Female patients were older on average than male patients, with average ages of 74 (SD=17.4) and 66 (SD=16), respectively. Patients identifying as Caucasian were the largest racial/ethnic group (31.4%), followed by Hispanic (29.8%), then Asian (24.8%; see Table 1 for the distribution across all racial/ethnic groups). A majority of patients (69%, $n=84$) were admitted from home, while another 26% ($n=31$) were admitted from nursing homes.

Clinical characteristics

The most common co-morbidities in the sample were hypertension (60.2%), followed by coronary artery disease (CAD; 54%), then diabetes (39.4%). The average CCI score was 5.12 (SD=3). Bile cultures were negative in the majority of patients, but when positive, the most common bacteria identified were *E. coli* (17.4%), *Klebsiella pneumonia* (15.6%), while 21.5% were polymicrobial.

Eighty percent of cases of acute cholecystitis were diagnosed using either computed tomography (CT) scan of the abdomen (CTAb) or ultrasound (US), equal to 38.8% and 42.1% of cases respectively. The remaining 19.1% of cases were diagnosed with a combination of either CT, US, MRCP, or HIDA.

Procedural characteristics and postoperative outcomes

A third of the sample were admitted to the ICU. Of these, the most common indication for placement of PCT was septic shock, (43%), 15% had respiratory compromise, and 5% for acute kidney injury (AKI). Thirteen percent of patients were on anticoagulants.

The median time from admission to PCT placement was 2 days (interquartile range (IQR)=4, range=0-34 days). Of the 41 patients in the sample admitted to the ICU, 43.9% had a PCT placed in this setting. The median time PCT was left in place was 42 days (IQR=46, range=2-308 days). The mean time to PCT was longer on Wednesdays and Sundays (median/IQR=5/7.5 and 4/3.5, respectively) compared to other days. Post-discharge, 17% of patients had confirmed PCT removal, while 20% of patients were lost to follow up and therefore missing data relating to removal. Among patients lost to follow up, 79% ($n=19$) were admitted from home, with the remaining patients admitted from nursing homes. Among patients with documented follow up encounters, 30% subsequently underwent cholecystectomy, 57.9% of these via laparoscopy. The analytic sample's overall 90 days

mortality rate was 21% and within the ICU population was 33%. The 90-day mortality rate for the sample peaked in 2018, at 36% (n=4/11 patients). The full set of descriptive statistics for the sample can be seen in Table 1. No differences in demographic, clinical nor procedural factors were observed between patients lost to follow-up and the rest of the sample.

Bivariate comparisons across settings

Covariate analysis

Sociodemographic, clinical, and procedural characteristics were compared across settings and primary outcomes. Patients seen in the ICU had higher CCI scores ($p=0.01$) than patients seen in other settings. Although fisher's exact tests showed differences in the overall distribution of racial and ethnic identities across settings ($p=0.02$), post hoc tests revealed these differences were no longer significant when accounting for multiple comparisons. Similarly, omnibus tests indicated significant differences in ages across ethnicities ($p=0.03$), but post hoc tests revealed this significance was illusory. No differences were observed by ethnicity and CCI. No differences by gender were observed.

Patients with higher CCI scores were more likely to have a greater duration between admission and PCT placement ($\rho=0.20$, $p=0.03$). No other differences in time to PCT placement were observed across sociodemographic characteristics nor setting. No significant differences were found at baseline between patients lost to follow up and those included in the analytic sample across these predictors.

Mortality

Significant differences in mortality were also observed across racial and ethnic identities ($p<0.001$). Post hoc tests showed that patients identifying as non-Hispanic white accounted for 60% of all mortalities within 90 days (n=12/20) and had significantly greater risk of mortality compared with other racial and ethnic identities ($p=0.01$). While specific comorbidities (i.e., hypertension, diabetes) were not significantly related to increased risk for mortality, higher scores on CCI were associated with significantly greater mortality ($p=0.01$) as was older age ($p=0.003$), with patients who expired having two points greater mean CCI (mean=6.75, SD=2.11 vs. mean=4.72, SD=2.99, for expired and non-expired patients, respectively) and an average age of 79.83 (SD=12.04) compared to an average age of 68.40 (SD=17.50) in other patients. ICU patients also had a significantly higher 90-day mortality rate than patients seen in other settings (point estimate=0.19, 95% CI=[0.1, 0.3], $p=0.02$, odds ratio (OR)=1.2). High CCI was significantly related to 90-day mortality only among patients seen outside the ICU (point estimate=0.026, 95% CI=[0.0, 0.1], $p=0.02$, OR=1.03). This relation was not observed among patients seen in the

ICU (point estimate=0.02, 95% CI=[-0.03, 0.07], $p=0.42$, OR=1.03).

Longer time from admission to PCT placement differed significantly between patients who expired compared to those who did not (point estimate=0.016, 95% CI=[0.01, 0.3], $p=0.002$, OR=1.016), with patients who expired having a median time from admission to PCT placement of 5 days (interquartile range (IQR)=13.25), compared to other patients' median time from admission to PCT of 2 days (IQR=3). The relation between expiration and longer time to PCT placement was only significant among patients seen in the ICU (point estimate=0.02, 95% CI=[0.0, 0.3], $p=0.03$, OR=1.02) and not among patients seen outside the ICU (point estimate=0.01, 95% CI=[-0.01, 0.02], $p=0.3$, OR=1.01).

Table 1: Descriptive statistics for the sample, (n=121).

Variables	Overall sample, (%)
Age (SD) (In years)	70.7 (SD=17.1)
Gender	
Male	47.1
Female	52.9
Race and ethnicity	
Hispanic	29.8
African American	11
Asian	24.8
Caucasian	31.4
Admitted from	
Home	69
Nursing home	26
Comorbidities	
Hypertension	60.2
Coronary artery disease	54
Diabetes	39.4
Charlson comorbidity index	5.12 (SD=3)
Bile cultures	
<i>E. coli</i>	17.4
<i>Klebsiella</i>	15.6
Diagnostic modality	
CTAB	38.8
US	42.1
CT/US/MCRP/HIDA	19.1
Procedural characteristics	
Time (Days) to PCT placement	2 (IQR=4)
Time (Days) PCT left in place	42 (IQR=46)
PCT removed	17
Cholecystectomy	30
90-day mortality rate	21

DISCUSSION

The need for risk-stratified treatment decisions and lack of consensus on optimal course create competing demands for clinicians and surgeons. We aimed to characterize the demographic and clinical profiles of patients undergoing PCT placement at a community hospital. We examined

how risk factors relate to differences in treatment course and outcomes.

Patients in this sample ranged in age, with notable differences observed across genders. As in previous studies, older age was associated with significantly greater risks of mortality. In contrast to other studies, e. g., in Winblad et al sample was highly diverse.⁵ Racial and ethnic differences in mortality rates were observed, specifically patients identifying as non-Hispanic white accounted for significant proportions of mortality rates. Although multivariate analysis was not conducted due to small sample size, lack of differences in CCI and ICU placement across ethnicities suggests other, specific factors may be at work. Characterizing these profiles of patients with PCT was an aim of this study, as the generalizability of other studies findings may be limited.

Bile cultures in our sample highlighted some differences compared to other studies as well. Our study demonstrated that the majority of bile cultures were found to have no growth, however; whenever they were positive, *E. coli* (17%), *Klebsiella* (15.6%), *Enterobacter* (8%) and *Streptococcus* (<1%) were also identified. This is less than reported elsewhere. For example, Hadi et al found bile cultures were positive in 171 of 509 patients with acute cholecystitis (33.6%).⁸ They reported the most common organism isolated from bile culture was predominantly gram-negative organisms, especially *E. coli* (46%), follow by *Pseudomonas* and *Staphylococcus aureus*.^{8,9} Of the gram-positive organism, *Enterococcus* 11 (8%) was the most common.⁸

Clinical risk factors were often seen in patients from our sample and mirrored previous findings. In the literature, the co-morbid conditions increasing patient's operative risks include a number of conditions, such as hypertension, myocardial infarction, and diabetes. These conditions were also frequently observed in our sample, with hypertension being the most common comorbidity. However, individual comorbidities were not significantly related to mortality rates, suggesting that overall disease severity, rather than specific clinical profiles, may confer greater risk for serious post PCT complications. Similar findings were seen in a study by Cherng et al in which 80% of patients had at least one comorbidity, with a mean number of 2.6 comorbidities.⁷ However, in our study, the mean CCI score was 5.12, indicating more severe disease burden.

Procedural characteristics and post PCT outcomes have been shown to vary across studies. This may contribute to a lack of recommendations for the ideal time to PCT. In our study, increased time to PCT placement was significantly associated with increased risk of mortality. To our knowledge, the optimal duration and risks of the PC indwelling tube has not been analyzed in randomized controlled trials. A systematic review by Macchini et al reported a range for timing of the drain removal between 2 to 193 days, while Blanco et al suggested that the tube should be maintained in place for at least 4 weeks after the

procedure to ensure optimum time for tract maturation.^{10,11} Cherng et al reported their median length of stay (LOS) between PCT placement and discharge to be 4 days, with a wide range of 1 to 76 days.⁷ The authors also found that LOS was significantly shorter in patients managed with cholecystectomy in comparison to those managed with PCC. In our study, PCT was left in place for a median of 42 days, placing it among the lower end of estimates across studies reviewed by Macchini et al.¹⁰

One possible explanation for the lack of standardized removal times are the variations in post PCT course and difficulties with patient follow-up. Altieri et al reviewed 9,738 patients who underwent PCT placement between 2000-2012 in the state of New York, and reported that 31.7% underwent subsequent interval cholecystectomy.¹² Thirty-two percent of our patients underwent an interval cholecystectomy: Laparoscopic (57.9%), robotic (18.4%), lap converted to open (13.2%), open chole (5.3%), robotic converted to open (2.6%), laparoscopic partial chole (2.6%); 21 (17%) had tube removal without cholecystectomy, 20% of our patients were lost to follow-up. In comparison, Chern et al in a study of 185 patients, found that 105 patients (56%) subsequently underwent cholecystectomy with PCT removed during surgery.⁷ Elective removal of PCT occurred in 27 patients (25.7%) without surgery. Cholecystectomy was done in 85% by laparoscopy, 6% laparoscopy converted to open approach and 8% open cholecystectomy. Among the 80 patients who did not undergo surgery, only 6 (7.5%) patients had PCT documented as removed either by accident or by a physician. The difficulties observed in our sample relating to coordination of care and compliance with treatment post-discharge appear in line with other studies, and likely represent a significant barrier to standardization of treatment protocols. Perhaps more importantly, both our study and the literature reviewed above strongly suggest that while tube cholecystostomy placement is often not the final treatment, and the time to removal and subsequent surgical approaches vary significantly.¹⁰

In terms of complications, Alvino et al found PCT tube placement to be successful in 91% of cases, with a low rate of adverse events.¹³ During the procedure, vasovagal reactions, hemorrhages, pneumothorax in the transhepatic approach and bile leak with use of the transperitoneal route can all occur. Later on, leakage or pain around the tube, dysfunction or tube dislodgement, account for the majority of the complications related to tube placement.⁷ In our study, there were no immediate complications identified and the main complication within 30-days was identified to be tube dislodgement and found in 6 patients.

Controversial outcomes are reported in the literature. Baron et al in their 2015 article on Interventional radiology approaches revealed that the majority of the patients with PCT (96.4%) had no recurrence of acute cholecystitis during a median follow-up period of 275 days.³ Schlottman et al comparing cholecystectomy vs cholecystostomy in 200,000 patients from 2000 to 2014 advocated for

cholecystectomy in the absence of prohibitive surgical risks, considering the increased length of stay and post procedural morbidity and in hospital mortality for patients undergoing PCT.¹⁴ Colonna et al echoed this sentiment, finding that PCT might be too conservative, overused, and condemning patients to the burden of destination tubes.¹⁵ According to Baron et al patients who receive PCT have better aesthetic outcomes, a shorter recovery time, and less pain.³ No statistically significant difference was found amongst the patients who received cholecystectomy and those who did not with respect to complications and re-intervention.^{2,15} Winbladh reports that cholecystostomy is associated with a high success rate of over 90% and a very low procedural mortality rate of just 0.5%.⁵ In our study the mortality from 90 days of admission was 21% with most occurring in patients that were admitted into the ICU. The high mortality rate and extended LOS may be attributed to the fact that patients who undergo PCT, are older with an increased disease severity index precluding a formal cholecystectomy and not to the procedure itself. In a recent study, Saddetin et al reported a 19% mortality of their critically ill patients with PCT, with 13% undergoing interval cholecystectomy in 6 to 8 weeks after the PCT, with a follow up period from 1 month to a year.¹⁶

Limitations

The current study is limited by small sample size and a single hospital setting. These factors precluded the use of multivariate models for analyzing specific outcomes, such as mortality, or statistical differences across institutions. The use of a larger sample would allow for more rigorous modeling of interactions and other potential confounds.

CONCLUSION

PCT is an effective and safe initial treatment in patients with acute cholecystitis that are acutely ill with prohibitive risks for cholecystectomy, and in some patients it may be the definitive treatment. In some respects, the results of our study align with those of previous research. Specifically, in terms of time to PCT, duration of time PCT and rates of cholecystectomy. However, we examined these outcomes in a diverse patient sample with greater disease burden than what was seen in other studies. In the select population that demonstrates significant clinical improvement, planned interval cholecystectomy accomplished after medical optimization should be performed. A proactive and timely approach to follow-ups is imperative, given the high number of patients lost to follow-up. Randomized clinical trials in the future using a larger sample will help clarify the ideal timing of PCT placement, duration for optimal outcomes.

Twenty percent of the sample was lost to follow up, echoing findings from previous studies. Future research should focus on this issue to identify better post discharge modalities for tracking patients with PCT to determine the optimal timing of removal and subsequent cholecystectomy when feasible.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Mejia J, Meghpara M, Wain O, Liguori T, Nithisoontorn S, Solomon R et al. A retrospective study of percutaneous cholecystostomy outcomes in a community hospital. *Int Surg J* 2024;11:160-5.