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What is the fate of the cholecystostomy tube following percutaneous cholecystostomy?

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Abstract
Introduction Cholecystectomy is the preferred treatment for acute cholecystitis with percutaneous cholecystostomy (PC) considered an alternative therapy in severely debilitated patients. The aim of this study was to evaluate the efficacy and outcomes of PC at a tertiary referral center.
Methods We retrospectively reviewed all patients that had undergone PC from 2000 to 2014. Data collected included baseline demographics, comorbidities, details of PC placement and management, and post-procedure outcomes. The Charlson comorbidity index (CCI) was calculated for all patients at the time of PC.
Results Four hundred and twenty-four patients underwent PC placement from 2000 to 2014, and a total of 380 patients had long-term data available for review. Within this cohort, 223 (58.7 %) of the patients were male. The mean age at the time of PC placement was 65.3 ± 14.2 years of age, and the mean CCI was 3.2 ± 2.1 for all patients. One hundred and twenty-five (32.9 %) patients went on to have a cholecystectomy following PC placement. Comparison of patients who underwent PC followed by surgical intervention revealed that they were significantly younger ($p = 0.0054$) and had a lower CCI ($p < 0.0001$) compared to those who underwent PC alone.
Conclusions PC placement appears to be a viable, long-term alternative to cholecystectomy for the management of biliary disease in high-risk patients. Old and frail patients benefit the most, and in this cohort PC may be the definitive treatment.

Keywords Cholecystostomy tube · Percutaneous cholecystostomy · Acute cholecystitis

Acute cholecystitis is a common indication for hospital admission and nearly 10 % of all patients who present for evaluation of abdominal pain are diagnosed with the condition [1]. Cholecystectomy is considered the standard of care for "surgically fit" patients with biliary disease [2]. Evolution in the surgical approach to acute cholecystitis over the past two decades has allowed laparoscopic cholecystectomy to replace open cholecystectomy, with upwards of 750,000 million patients undergoing laparoscopic cholecystectomy annually in the USA [3, 4].

Despite being a commonly performed procedure, urgent cholecystectomy in the setting of acute cholecystitis carries a significant risk of morbidity and mortality [5]. Nevertheless, elective cholecystectomy following medical management is not without associated risks. Specifically, non-operative intervention may not prevent progression of biliary disease to gangrene, perforation, empyema formation, or peritonitis. From a public health standpoint, patients scheduled for elective cholecystectomy following resolution of acute disease are noted to have high hospital readmission rates while awaiting surgery, longer length of hospital stay, and increased rate of conversion from laparoscopic to open

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cholecystectomy compared to those who undergo cholecystectomy at the onset of acute disease [5].

The risks associated with acute cholecystitis are proportionately higher in the elderly, defined as those above 65 years of age [6]. In this patient population, insertion of a percutaneous cholecystostomy (PC) tube may serve as an effective alternative for the management of acute biliary disease, especially for those with significant co-morbidities [7, 8]. The use of PC was first introduced in 1980 and has since become a well-accepted treatment modality in those unfit to undergo a surgical procedure, patients that have failed conservative management, or as a "bridge to surgery" [3, 9, 10]. PC offers the advantage of a minimally invasive approach to gallbladder decompression that can be performed at the bedside in extremely ill patients.

Several studies have examined the outcomes of PC; however, the majority of these studies are limited by small sample sizes or are focused on specific biliary disease processes, limiting the clinical utility of such studies. The purpose of this study was to evaluate the efficacy and outcomes of PC in a tertiary referral center.

Methods

After institutional review board approval, medical charts were retrospectively reviewed to identify patients who received PC from 2000 to 2014, thus providing a minimum of 1-year follow-up. All patients included in this study were confirmed to be poor surgical candidates at the time of tube placement. A patient was deemed a poor surgical candidate at the discretion of the Attending Surgeon with consideration of the Tokyo guidelines [11]. The decision to proceed with PC tube placement occurred in patients with ongoing biliary symptoms despite 48–72 h of medical therapy, at the time of consultation in those patients who were transferred from on outside hospital 48–72 h after the onset of symptoms, and in those patients with co-occurring active issues that made transport to the operating room unsafe. The biliary indications for PC tube placement were either acute calculous cholecystitis, or a calculous cholecystitis. All patients who had PC tube placement related to malignancy were excluded from our study.

Placement of PC tubes was performed by the Interventional Radiology Department using local anesthesia and either ultrasound or computed tomography guidance. A subcostal, transperitoneal approach was the routine approach used at our institution. Fluoroscopy was used to confirm guidewire placement into the gallbladder, and a Seldinger technique was used to place an 8–12 French pigtail catheter at the discretion of the Interventional Radiologist. More recently, biliary fluid has been aspirated and sent for laboratory analysis at the time of PC. Patients were followed by the General Surgery teams following placement. Removal, PC tube exchange, and surgical intervention were determined based on the clinical progression of the patient by the managing team.

Data collected for each patient included baseline patient demographics, comorbidities as reflected in the Charlson comorbidity index (CCI), details of PC tube placement and management, gallbladder fluid characteristics, duration of tube placement, and post-procedure outcomes. Patients in the PC group were followed until PC tube removal or death. Patients that eventually underwent cholecystectomy after having a PC placed were followed until their first postoperative visit or until the time of death. Patients requiring reinsertion of PC tube were followed until the time of reinsertion or until the time of death.

Comparisons were made between those who underwent PC alone, PC tube placement followed by surgical intervention, and those who required reinsertion of a PC following elective removal, using Kruskal–Wallis and Pearson tests. Statistical analysis was performed using R version 3.2.3, and significance was defined as $p < 0.05$.

Results

A total of 503 patients underwent PC placement from 2000 to 2014 at our institution. Seventy-nine of these patients underwent PC for decompression of the biliary tree in the presence of known malignancy and were thus excluded from our analysis. An additional 44 patients were lost to follow-up after initial PC and were also excluded from further analysis. Three hundred and eighty patients remained for analysis; 223 (58.7 %) of the patients were male and 157 (41.3 %) were female. The mean age at the time of PC tube placement was 65.3 ± 14.2 years of age. The average CCI was 3.2 ± 2.1, and the average CCI with age adjustment was 5.2 ± 2.7.

Patients were deemed a poor surgical candidate based on the following five different criteria: cardiac, including cardiac surgery within 2 months of the onset of biliary symptoms or other acute cardiac concerns; concomitant pulmonary infection; end-stage liver disease with cirrhosis; hemodynamic instability; or new diagnosis of pulmonary embolism or other indications for systemic anticoagulation that could not be stopped for surgical intervention. The majority of the patients who underwent PC had either a cardiac concern or hemodynamic instability preventing acute surgical intervention.

Of the defined study group, 244 (64.2 %) patients underwent PC tube placement only. Within this cohort, 143 (58.6 %) patients were male and the mean age at the time of PC was 67.1 ± 14.0 years of age. The average CCI was 3.6 ± 2.2, and the average CCI with age adjustment was

5.7 ± 2.6. Additional details regarding the indication for PC tube placement, size of PC tube placed, and numbers of tube exchanges are listed in Table 1.

In terms of morbidity and mortality within the PC tube placement only cohort, a total of 9 (3.7 %) patients were readmitted within 30 days of index tube placement due to abdominal pain or biliary related concerns. One hundred and forty-eight (60.7 %) patients died following PC tube placement, with 57 (38.5 %) patients dying within 30 days of PC tube placement and an additional 15 (10.1 %) patients dying within 60 days of PC tube placement. The average time from PC tube placement to death was 166 days. No death was directly related to PC tube placement. Eighty-five (34.8 %) patients underwent elective PC tube removal at the discretion of the treating physician following resolution of biliary symptoms and evidence of a patent cystic duct on a cholangiogram. Fifty-nine (24.2 %) patients currently have a PC tube in place and are not candidates for cholecystectomy.

A cholecystectomy was performed following PC tube placement in 125 (32.9 %) patients, of which 76 (60.8 %) patients were male. The average time from PC tube placement to surgery was 103 days and occurred following resolution of the criteria for which the patient was deemed a poor surgical candidate at the time of original surgical consultation. The average age at the time of PC tube placement in this cohort was 61.3 ± 13.8 years of age, and the average age at the time of surgery was 61.5 ± 13.8 years of age. The average CCI was 2.4 ± 1.8, and the average CCI with age adjustment was 4.0 ± 2.4. A total of 13 (10.4 %) patients

Table 1 Patient demographics and cholecystostomy variables stratified by treatment group

	Percutaneous cholecystostomy group only $N = 244$	Percutaneous cholecystostomy + cholecystectomy group $N = 125$	Reinsertion group $N = 11$	p value
Age at time of placement, *N* (mean, SD)	67.1 ± 14.0	61.3 ± 13.8	65.5 ± 16.4	0.0054
CCI (score, SD)	3.6 ± 2.2	2.4 ± 1.8	3.3 ± 1.8	<0.0001
CCI with age (score, SD)	5.7 ± 2.6	4.0 ± 2.4	5.0 ± 2.7	<0.0001
Indications for insertion (*N*, %)				0.57
Acalculous cholecystitis	105 (43.0 %)	50 (40.0 %)	4 (36.4 %)	
Calculous cholecystitis	131 (53.7 %)	73 (58.4 %)	7 (63.6 %)	
Gangrenous cholecystitis	8 (3.3 %)	2 (1.6 %)	0 (0.0 %)	
Size of PC tube (*N*, %)				0.67
8Fr	96 (39.3 %)	53 (42.4 %)	2 (18.2 %)	
8.5FR	30 (12.3 %)	12 (9.6 %)	2 (18.2 %)	
10F	112 (45.9 %)	56 (44.8 %)	7 (63.6 %)	
12Fr	6 (2.5 %)	4 (3.2 %)	0 (0.0 %)	
Number of tube exchanges (*N*, %)			N/A	0.79
0	166 (68.0 %)	79 (63.2 %)		
1	40 (16.4 %)	24 (19.2 %)		
2	22 (9.0 %)	11 (8.8 %)		
3	2 (0.8 %)	5 (4.0 %)		
4	3 (1.2 %)	2 (1.6 %)		
5	2 (0.8 %)	2 (1.6 %)		
6	4 (1.6 %)	0 (0.0 %)		
7	1 (0.4 %)	0 (0.0 %)		
8	2 (0.8 %)	2 (1.6 %)		
9	1 (0.4 %)	0 (0.0 %)		
10	1 (0.4 %)	0 (0.0 %)		
30-day readmissions	9 (3.7 %)	13 (10.4 %)	1 (9.1 %)	0.023
Total mortality	148 (60.7 %)	21 (16.8 %)		0.01
30-day	57 (38.5 %)	4 (19.0 %)		
60-day	72 (45.6 %)	8 (38.0 %)		

N number, *SD* standard deviation, *CCI* Charlson comorbidity index

were readmitted within 30 days of index tube placement and prior to surgical intervention. Thirty-day readmission for ongoing biliary symptoms prompted earlier surgical intervention in a majority of these patients. Of note, the rate of readmission was significantly higher in this intervention arm than in either those patients who underwent PC tube placement only or those patients who required reinsertion of a PC tube ($p = 0.002$).

Seventy-one (56.8 %) patients underwent laparoscopic cholecystectomy, 45 (36.0 %) an open cholecystectomy, and 9 (7.2 %) patients required conversion from a laparoscopic to an open cholecystectomy. A total of 21 (16.8 %) patients died postoperatively; 4 (19.0 %) patients died within 30-days of surgical intervention, while an additional 4 (19.0 %) patients died within 60 days of surgical intervention. The average time from surgical intervention to death was 561 days, and no death was directly related to the surgery itself. Patients within this cohort had a significantly lower mortality rate than either of the other two intervention arms ($p = 0.01$).

Eleven (2.9 %) patients required PC tube reinsertion following elective removal of the original PC tube. Within this cohort, 9 (81.18 %) were female and the average age at the time of placement was 65.5 ± 16.4 years of age. The average CCI was 3.3 ± 1.8, while the average CCI with age adjustment was 5.0 ± 2.7. Six (54.5 %) patients within this cohort went on to have surgery following reinsertion of the PC tube. Only one (9.1 %) patient was readmitted within 30 days of original PC tube placement. Finally, four (36.3 %) patients died following reinsertion of PC tube; only one (25 %) patient died within 30 days of reinsertion, and no patients died within 60 days. No death was related to biliary pathology.

With respect to patient age and comorbidities, those who underwent PC only were significantly older and frailer when compared to those who underwent surgical intervention and those who required PC reinsertion (Table 1). There was no statistically significant difference between these groups in terms of the average size of tube placement or number of PC tube exchanges (Table 1). Eighty-six (22.6 %) patients experienced a tube complication with tube dislodgement ($N = 37$, 43.0 %) being the most common occurrence (Table 2). However, there were no deaths related to tube complications within this cohort.

Discussion

Fifty to seventy percent of all surgical admissions for acute cholecystitis are in the elderly population [12]. The risk of surgical intervention in this patient population is significantly higher than that of the general population, with an estimated mortality rate of 46 % in those with comorbid conditions [6, 12]. Our study shows that PC is an effective long-term management strategy for acute biliary disease this high-risk patient population. This finding is consistent with previous studies that demonstrate the long-term utility of PC [3, 6, 13, 14].

The heterogeneity of patients who undergo PC creates the potential for therapeutic challenges. Although our study shows that PC is a viable long-term option for the management of biliary disease, there is a risk of at least 25 % for recurrence following initial treatment of acute cholecystitis [14]. Patients in whom cholecystectomy was deferred due to an acute illness or delayed presentation should be considered for surgical intervention following PC. However, each decision should be made on an individual basis, following careful assessment, as some patients do not return to a desired physical health state. Furthermore, this consideration should occur with the knowledge of the associated risks of surgical intervention following an episode of acute cholecystitis. Although somewhat contradictory, evidence in the literature suggests that there is an increased risk of conversion to an open cholecystectomy and bile duct injury in those patients who undergo elective cholecystectomy following PC for acute cholecystitis [5]. This may be partially attributed to PC tube placement as a known risk factor for adhesive disease is the cutaneous tract formed from this procedure. This finding is supported by our study that showed a conversion rate of 10.9 % in those patients who underwent cholecystectomy following PC tube placement. Furthermore, because of these known risks, many surgeons prefer to proceed with an open cholecystectomy rather than attempt a laparoscopic approach. Observed in our cohort, and perhaps related to the surgical approach chosen, is the fact that no bile duct injuries or leaks were observed.

Further emphasizing the diversity of this patient population is the difference in mortality rates between those who underwent PC only and those who had a cholecystectomy following PC tube placement. Our study found that 60.7 % of patients who underwent PC only died, while only 16.8 % of those who underwent cholecystectomy after PC died. To put these mortality rates into perspective, the mortality rate for elective cholecystectomy is reported to be less than 1 %, confirming that this is a high-risk patient population [15–17]. Furthermore, 38.5 % of patients who died following PC died within 30 days of tube placement, while only 19.0 % of patients who died following surgical intervention died within 30 days of their operation. This difference in mortality rates highlights the differences in associated comorbidities as well as concurrent active issues between the two cohorts. Indeed, many of the patients who underwent PC tube placement only had active cardiac issues related to recent surgery or decompensation of chronic, underlying cardiac conditions, which ultimately

Table 2 Tube complications by treatment group

Tube complication type	Percutaneous cholecystostomy group only $N = 244$	Percutaneous cholecystostomy + cholecystectomy group $N = 125$	Reinsertion group $N = 11$
Sepsis following PCT placement (*N*, %)	2 (0.8 %)	3 (2.4 %)	0 (0.0 %)
Tube leakage (*N*, %)	9 (3.7 %)	9 (7.2 %)	0 (0.0 %)
Tube dislodgement (*N*, %)	24 (9.8 %)	13 (10.4 %)	0 (0.0 %)
Tube occlusion (*N*, %)	11 (4.5 %)	9 (7.2 %)	0 (0.0 %)
Bleeding requiring intervention (*N*, %)	3 (1.2 %)	3 (2.4 %)	0 (0.0 %)

PCT percutaneous cholecystostomy tube, *N* number

resulted in poor outcomes for these patients. In these extremely ill patients, triaging of patient issues and medical-directed therapy is critical. In this scenario, PC placement can occur simultaneously with other efforts directed at improving those conditions that are an imminent threat to the patient's survival.

To date, this is the largest cohort of patients that have undergone PC to be investigated. Nevertheless, our study does have some limitations. First, this is a retrospective study which entails inherent limitations. Second, this review is limited to a single institution, which creates the potential for treatment bias. Finally, this study is based on a tertiary care hospital with referral of high-risk patients that creates the potential for selection bias.

Conclusions

PC tube placement should be considered a first-line therapy for elderly and highly comorbid patients with acute biliary disease. Prospective studies are needed to compare the efficacy and patient outcomes of PC tube placement versus medical therapy only in this high-risk patient population. This will allow for standardization of care in the management of such patients.

Author's contribution Mena Boules and Ivy N. Haskins were involved in writing of manuscript and data entry; Mario Farias-Kovac and David Schechtman were involved in data entry; Alfredo Daniel Guerron was involved in data entry/study concept: Gordon McLennan and Michael Samotowka were involved in study concept; Colin P. O'Rourke was involved in statistical support; R. Matthew Walsh was involved in final review/study concept; and Gareth Morris-Stiff was involved in final writing of manuscript/final review/study concept.

Compliance with ethical standards

Disclosures Dr. Mena Boules, Dr. Ivy Haskins, Dr. Mario Farias-Kovac, Dr. Alfredo Daniel Guerron, David Schechtman, Dr. Gordon McLennan, Dr. Michael Samotowka, Colin P. O'Rourke, Dr. R. Matthew Walsh and Dr. Gareth Morris-Stiff have no conflicts of interest or financial ties to disclose.

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