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ORIGINAL ARTICLE

Clinical and Survival Outcomes Using Percutaneous Cholecystostomy Tube Alone or Subsequent Interval Cholecystectomy to Treat Acute Cholecystitis

Christina A. Fleming[1] · M. Ismail[1] · R. G. Kavanagh[2] · H. M. Heneghan[3] · R. S. Prichard[1] · J. Geoghegan[4] · D. P. Brophy[2] · E. W. McDermott[1]

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Abstract

Background Percutaneous cholecystostomy (PCT) is a safe method of gallbladder drainage in the setting of severe or complicated acute cholecystitis (AC), particularly in patients who are high-risk surgical candidates. Small case series suggest that PCT aids resolution of acute cholecystitis in up to 90% of patients. However, reluctance is observed in utilising PCT more frequently, due to concerns that we are committing comorbid patients to an interval surgical procedure for which they may not be suitable.

Aim The aim of this study was to assess the clinical and survival outcomes of PCT use, with particular emphasis on a subgroup of patients who did not proceed to cholecystectomy.

Methods A retrospective analysis was performed of all patients with severe acute cholecystitis who required PCT insertion in a tertiary referral hospital from 2010 to 2015. Patient demographics and clinical data including systemic inflammatory response (SIRS) scores at presentation, readmissions and clinical and survival outcomes were analysed. Statistical analysis was performed using SPSS v.22 and GraphPad Prism v.7.

Results In total, 157 patients (59% males) with AC underwent PCT insertion during the study period. Median age at presentation was 71 years (range 29–94). A median SIRS score of 3 was noted at presentation. Patients required a median of two cholecystostomy tube changes/replacements (range 1–10) during treatment. Transhepatic tube placement was the preferred approach (69%) with 31% of tubes being placed via transabdominal approach. Only 55% proceeded to interval cholecystectomy. Of the 70 patients treated with PCT alone, their median age was 75 years. In this subgroup, only 12.9% ($n = 9$) developed recurrent biliary sepsis necessitating readmission following initial resolution of symptoms and tube removal. All episodes of recurrent biliary sepsis presented within 6 months of index presentation, and definitive PCT removal in this group was performed at a median of 3 months. No difference in survival was observed between both groups.

Conclusion Almost 90% of patients with AC who are managed definitively with a PCT will recover uneventfully without recurrent sepsis following PCT removal. This is a viable option for older, comorbid patients who are unfit for surgical intervention and is not associated with significantly increased mortality.

Keywords Percutaneous cholecystostomy tube · Acute cholecystitis · Laparoscopic cholecystectomy · Biliary sepsis

✉ Christina A. Fleming
christina.fleming49@gmail.com

[1] Department of General Surgery, St. Vincent's University Hospital, Dublin 4, Ireland

[2] Department of Interventional Radiology, St. Vincent's University Hospital, Dublin, Ireland

[3] Department of Bariatric Surgery, St. Vincent's University Hospital, Dublin, Ireland

[4] Department of Hepatobiliary Surgery, St. Vincent's University Hospital, Dublin, Ireland

Introduction

Percutaneous cholecystostomy tube (PCT) placement is a safe method of gallbladder drainage.[1] PCT allows source control of biliary sepsis and resolves acute cholecystitis in approximately 90% of patients by decompressing the gallbladder and draining infected bile, allowing resolution of both local inflammation and systemic sepsis.[1] Indications for PCT include severe patient comorbidities precluding general anaesthesia; severe cholecystitis and systemic sepsis; late presentation of biliary sepsis (> 72 h after onset of symptoms) with a relative contraindication

for early laparoscopic cholecystectomy; failure of medical (antibiotic) therapy and continuing sepsis.[1, 2] The subsequent timing of cholecystectomy following PCT insertion is variable, ranging from immediately after clinical improvement to greater than 8 weeks. However, the current recommendation is to perform cholecystectomy (usually laparopscopic cholecystectomy - LC) either within 3 days of the onset of symptoms or 6 weeks following the resolution of symptoms.[2]

The question remains as to whether all patients undergoing PCT drainage require a definitive cholecystectomy. Previous publications have suggested that there is a reluctance to use PCT in older and comorbid patients due to concerns of potentially committing such patients to an interval surgical procedure for which they may not be suitable. While, there is a growing body of evidence that suggests PCT can be used as a definitive treatment, other studies have shown high recurrence rates of biliary sepsis following PCT removal and high rates of emergency surgery when a conservative PCT approach alone is undertaken.[3–7] With conflicting evidence, the overall aim of this study was to assess the clinical utility and safety of PCT as definitive management of acute cholecystitis (AC).

Methods

All patients who presented with AC to a tertiary referral centre (St. Vincent's University Hospital)over a 5-year period (2010–2015) were assessed for inclusion suitability. Patients were identified through the Hospital Inpatient Enquiry (HIPE) database. This is a prospectively maintained medical record database used in Irish hospitals. Disease conditions are coded in keeping with the ICD-10 guidelines, 2008, version 8. This list was cross-referenced with a list of all PCTs placed in the Interventional Radiology Suite during the stated time period using the radiology information system (RIS). St. Vincent's University hospital is a tertiary referral teaching hospital and National Centre for Hepatobiliary Surgery in the Republic of Ireland. Patients with AC were suitable for inclusion if a PCT was inserted during index admission for AC management. The diagnosis of AC was based on a combination of clinical, biochemical and radiological findings at presentation. All patients were empirically placed on broad spectrum antibiotics at the time of presentation if a diagnosis of AC was suspected. A pragmatic clinician and patient preference approach was taken when considering PCT use. In keeping with the literature, PCT was preferred in older, multi-morbid patients with significant sepsis at presentation and prolonged duration from onset of symptoms.

Variables collected for analysis included patient demographic data (age and gender); inflammatory marker and liver function test (LFT) results at presentation including white cell count (WCC), c-reactive protein (CRP), bilirubin, gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP) and alanine aminotransferase (ALT); imaging modalities used [ultrasound (US), computed tomography (CT), magnetic resonance cholangiopancreatography (MRCP)] to diagnose AC; PCT procedural data, number of tube insertions, tube complications and duration of symptoms to time of PCT insertion. A systemic inflammatory response score (SIRS) was calculated on each patient at presentation as a measure of inflammatory activity of disease at presentation to hospital and is previously described.[8] Outcomes were compared between patients having PCT treatment alone and those who had PCT as initial treatment followed by interval LC. Clinical outcomes recorded included recurrent colic or biliary sepsis following initial resolution of symptoms and requirement for readmission to hospital. Thirty-day mortality rate and overall survival rates were also calculated and compared.

Percutaneous Cholecystostomy Tube Technique

All PCT insertions were performed by an Interventional Radiologist in a dedicated Interventional Radiology suite, using a combination of US and fluoroscopic guidance. Two techniques were utilised: a transhepatic and transabdominal approach, dependent on operator preference or individual patient access issues. The transhepatic approach was generally favoured as this theoretically provides a more stable tube position and decreases bile leaks and the risk of biliary peritonitis. Procedures were performed under conscious sedation using midazolam and fentanyl. After infiltration of 1% lignocaine, the gallbladder was accessed under US guidance using 5-Fr one-step needle. The tract was then dilated over a 0.035″ wire and an 8-Fr or 10-Fr locking pigtail percutaneous cholecystostomy catheter was inserted under fluoroscopic guidance. Position was confirmed fluoroscopically with the injection of contrast through the PCT and a fluid sample was collected for microbiological examination. PCTs were routinely exchanged every 6–8 weeks under fluoroscopic guidance if remaining in situ. Dislodged PCTs were re-inserted based on clinical grounds. Decision on tube removal timing was made on a patient specific basis. General principles followed in this decision-making process included the following: a tubogram is performed in the radiology department to assess tube placement and position and biliary outflow; patient sepsis is resolved; patient medical condition is stable to facilitate the procedure; by 6 weeks an appropriate foreign body reaction around the drain site should protect from bile leak following drain removal.

Statistical Analysis

Statistical analysis was performed using IBM SPSS, version 22 and GraphPad Prism, version 7. The following tests were used as appropriate: Student t test, χ^2 test, Fisher's exact test and Wilcoxon rank sum test. Kaplan-Meier curves were generated for survival analysis. Statistical significance in all instances was observed at $p < 0.05$.

Results

Patient Selection and Characteristics

A total of 672 patients were admitted with a primary diagnosis of AC during the study period. Of these, 157 patients received a PCT as primary management (Table 1), of which 59% ($n = 93$) were male and 41% ($n = 64$) were female. The median age at presentation was 71 years (range 29–94). Of this group, 45% ($n = 70$) were treated definitively with PCT, while 55% ($n = 87$) proceeded to an interval cholecystectomy following initial PCT treatment (Fig. 1). Median symptom duration from onset to PCT insertion was 3.6 days and a median SIRS score of 3 was noted at presentation (range 1–4). Of those who proceeded to surgery 71% ($n = 62$) were completed laparoscopically, 25% ($n = 22$) were performed open and three cases (3.4%) were converted from laparoscopic to open. One incidental gallbladder adenocarcinoma was identified on histology examination and all others showed acute ± chronic cholecystitis.

Percutaneous Cholecystostomy Tube Results

The majority of patients required a median of two cholecystostomy tube changes/replacements (range 1–10) throughout their treatment, all of which were placed using US and fluoroscopic guidance (Table 2). Transhepatic tube placement was the preferred approach in 69% ($n = 109$) with 31% ($n = 48$) of tubes being placed via transabdominal approach. Change of PCT following dislodgement was performed as a day case. PCTs remained in situ for a median of 11 weeks (range 1–60). In total, 28.7% ($n = 48$) of patients developed a complication. These included a local leak/skin complication (10.2% ($n = 16$)), dislodgement (17.8% ($n = 28$)) and one patient (0.6%) developed a hepatic bleed which settled conservatively and did not require blood transfusion.

Table 1 Patient characteristics at presentation and imaging and surgical procedures performed. SIRS, systemic inflammatory response syndrome; US, ultrasound; CT, computed tomography; MRCP, magnetic resonance cholangiopancreatography

Age (years)	
Median	71.05
Range	29–94
Gender (*n* (%))	
Male	93 (59)
Female	64 (41)
Symptom duration (days)	
Median	3.6
Range	1–21
SIRS	
Median	3
Range	1–4
Imaging (*n* (%))	
US	105 (66.9)
CT	122 (77.7)
MRCP	38 (24.2)
Surgical outcomes (*n* (%))	
Laparoscopic	62 (71.3)
Open	22 (25.3)
Converted	3 (3.4)
Complications	10 (11.5)

Comparison of Clinical Outcomes and Survival

Table 3 compares clinical characteristics between those treated with PCT alone and those who proceeded to interval cholecystectomy following initial PCT placement. The PCT alone group were significantly older (median age 75 years vs. 68 years, $p = 0.004$) and had higher GGT levels (211 U/L vs. 123 U/L, $p = 0.033$) at presentation than the group who subsequently proceeded to surgery. Otherwise, the groups were comparable. Ten patients (11.5%) who underwent surgery developed a post-operative complication, all requiring readmission to hospital. Complications included five surgical site infections, four intra-abdominal collections and one bile leak. In the PCT alone group, nine patients (12.9%) developed biliary sepsis following PCT removal. All nine required readmission to hospital for intravenous antibiotics and two (2.9%) had a further PCT placed. None proceeded to emergency or interval cholecystectomy. All episodes of recurrent sepsis presented within 6 months of index presentation, and definitive PCT removal (of those reinserted) was performed at a median of 3 months.

Survival data was available on 147 patients at a median follow-up of 24 months (range 1–108 months). Figure 2 depicts Kaplan-Meier curves for both 30-day mortality from insertion of first PCT and overall survival. Thirty-day mortality was not significantly different between PCT alone and PCT with interval cholecystectomy groups (3% ($n = 2$) vs. 2.4% ($n = 2$), $p = 0.78$). Overall mortality in the PCT alone group was 13.8% ($n = 9$) and 9.6% ($n = 8$) in those who had PC and cholecystectomy. This difference in mortality was not significant ($p = 0.36$).

Discussion

Percutaneous cholecystostomy tube (PCT) placement is emerging as an effective treatment for complicated acute cholecystitis (AC). In a large patient cohort, this study highlights that definitive treatment of AC with PCT had comparable outcomes compared to those who proceeded to an interval laparoscopic cholecystectomy (LC) following intial PCT placement. Almost 90% of patients treated with PCT alone

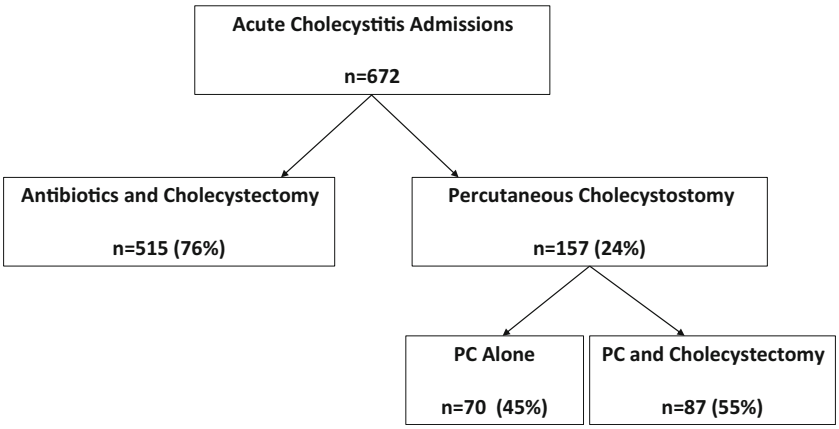

Fig. 1 Flow chart to outline patient selection for study inclusion. A total of 157 patients received a percutaneous cholecystostomy tube of which 87 patients subsequently proceeded to cholecystectomy. PC, percutaneous cholecystostomy

in this cohort made a full recovery and no difference in survival was observed between this group and those initially treated with PCT who proceeded to interval cholecystectomy. Our 28% complication rate is comparable to International data.[9] It also identifies that older patients were more likely to be treated with PCT alone and not proceed to interval LC but a significantly longer duration of placement is not observed compared to those who proceed to surgery. We can conclude from this data that not all patients initially treated with PCT require an interval cholecystectomy and definitive treatment with PCT is a viable and safe option. This may be particularly useful in patients who have absolute or relative contraindications for general anaesthesia. For these patients, definitive treatment with PCT alone may be a better option.

In the cohort of PCT alone-treated patients, a 30-day mortality rate of 3% and overall mortality of 13.8% was observed with a median follow-up of 24 months. While this is a short follow-up timeframe, the study cohort is an elderly population (median age at presentation was 71 years). This is more favourable than other reports on this topic which have reported 1-year mortality rates as high as 23–37.7%.[6, 10] The strongest level of evidence reporting on survival in PCT use as definitive treatment for AC is a Cochrane review published in 2013, specifically looking at 'high-risk' patients.[2] This review combined data from two randomised controlled trials which cumulatively included 156 patients. The first study showed no difference in morbidity or mortality between patients treated with initial treatment with PCT and interval early or delayed LC but all patients in that study underwent LC at some stage.[11] The second study compared early (< 72 h) PCT alone to conservative treatment (antibiotics, intravenous fluid hydration) and again no difference in morbidity or mortality was observed. Furthermore, 86% of patients had resolution of symptoms following PCT placement and only 49% proceeded to LC.[12] The study we describe was designed to explore the efficacy of PCT placement as a definitive treatment for AC not to answer the specific question on whether PCT alone is as effective as LC in definitive management of AC. The results of the CHOCOLATE trial, a randomised controlled trial specifically comparing LC to PCT alone as definitive treatments for AC in high-risk patients will attempt to answer this question.[13]

The ability to predict which patients will do well with PCT treatment alone and which patients are more likely to relapse and potentially require high risk, sometimes emergency cholecystectomy is important in surgical practice. Chang et al. aimed to identify in high-risk patients with AC, the time interval to relapse, and factors influencing relapse following PCT removal.[3] In their study, seven of 60 patients treated with PCT alone developed relapse of biliary symptoms of which four were successfully managed with reinsertion of PCT and conservative treatment and three underwent LC.[3] No clinical or radiological factors were significantly different between those that did and did not develop recurrent symptoms. In our study we identified, elderly patients with high SIRS at presentation have non-inferior outcomes when treated with

Table 2 Percutaneous cholecystostomy tube characteristics for entire study cohort

Placement technique (*n* (%))	*N* (%)
Transabdominal	48 (31)
Transhepatic	109 (69)
Number of tubes	
Median	2
Range	1–10
Duration of tube placement (weeks)	
Median	11.7
Range	1–60
Complications (*n* (%))	
Total	45 (28.7)
Leak/skin complications	16 (10.2)
Dislodged	28 (17.8)
Other	1 (0.7)
Interval to complication (weeks)	
Median	7.7
Range	1–44

Table 3 Comparison of characteristics between patients who received definitive treatment with a percutaneous cholecystostomy (PC) tube compared to patients initially treated with PC and proceeded to interval cholecystostomy. SIRS, systemic inflammatory response score; US, ultrasound; CT, computed tomography; MRCP, magnetic resonance cholangiopancreatography; WCC, white cell count; CRP, c-reactive protein; GGT, gamma-glutamyl transferase; ALT, alanine aminotransferase

	PC alone ($n = 70$) N (%)	PC and cholecystectomy ($n = 87$) N (%)	p value
Age			
Median (range)	75 (35–94)	68 (29–92)	0.004
Gender			
M:F	39(56):31(44)	54(62):33(38)	0.66
SIRS			
Median (range)	3 (1–4)	3 (2–4)	0.54
Imaging findings			
Cholecystitis	35 (50)	43 (49)	0.38
Empyema	7 (10)	10 (12)	
Perforation	28 (40)	34 (39)	
Blood (mean (SD))			
WCC	15 (6.5)	15 (6.4)	0.671
CRP	197 (110)	165 (130)	0.136
Bili	44 (108)	24 (27)	0.125
GGT	211 (335)	123 (131)	0.033
ALT	76 (145)	45 (49)	0.078
Number of tubes			
Median (range)	1.7 (1–9)	1.3 (1–10)	0.179
Duration of tube insertion (weeks)			
Median (range)	11 (4–48)	11.9 (1–60)	0.721
Complications (n (%))			
Total	22 (31.5)	23 (26.2)	0.127
Leak/skin complications	6 (8.6)	10 (11.5)	
Dislodged	16 (22.9)	12 (13.6)	
Other	–	1 (1.1)	
Interval to complications (weeks)			
Median (range)	8.6 (1–44)	6 (1–36)	0.504

PCT alone compared to those who proceed to interval LC following initial PCT placement. Furthermore, we identified that 40% of the PCT alone group had radiological evidence of gallbladder perforation as well as cholecystitis at presentation. The optimal timing of PCT insertion has previously been investigated.[14, 15] Early insertion (within 24 h of hospital admission) has been investigated in 209 patients by Chou et al., and their results suggest that early insertion is actually associated with less procedure related bleeding and shorter hospital stay compared to PCT insertion > 24 h.[15] Others have also shown a reduced rate of adverse surgical outcomes when interval surgery is performed, i.e. reduced conversion from LC to open procedure when PCT is inserted early and source control of biliary sepsis is achieved.[14]

This study has a number of limitations. As a retrospective study, there are inherent difficulties with data collection and

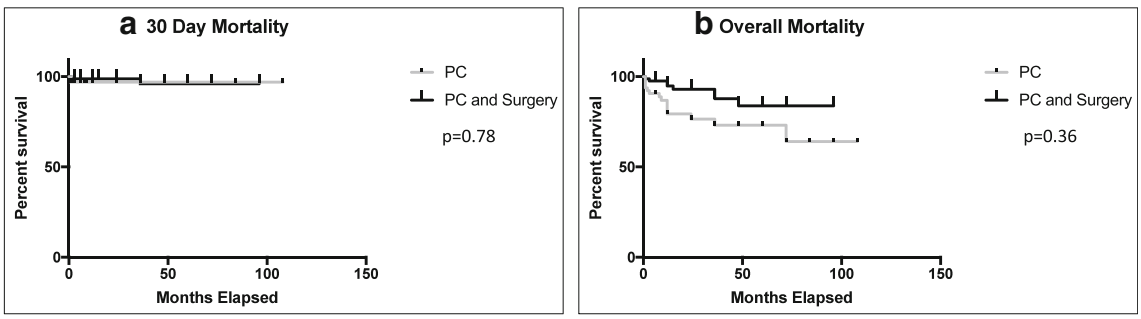

Fig. 2 Kaplan-Meier curve showing no significant difference in 30-day (**a**) or overall (**b**) survival in patient treated with PC alone or those who are treated with PC and proceed to subsequent cholecystectomy

assessment as well as an inability to identify which patients intended for PCT alone crossed over from a PCT alone to interval cholecystectomy. Patients were identified through the HIPE database. As outlined in our methodology, the HIPE system is in place to monitor patient workload, admissions and procedures performed. However, previous studies have shown that its accuracy can be as low as 86% at times.[16, 17] Finally, survival data was only available on 147 patients with a short follow-up period.

Conclusion

PCT is a safe method of definitive management for AC. Use of a PCT does not commit a patient to an interval LC and does not impact overall survival and therefore may be considered a favourable option in comorbid patients with high risk of surgical morbidity.

Author Contribution Study conception and design—CAF, MI, HMH, RSP, EWMcD
Data collection—CAF, MI, RGK
Data analysis—CAF, MI, HMH
Manuscript preparation and review—CAF, MI, RGK, HMH, RSP, JG, DPB, EWMcD

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