

Original Research Article

Short-term outcomes in percutaneous cholecystostomies: a retrospective cohort study

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ABSTRACT

Background: Elderly patients account for over 50% of patients presenting with acute cholecystitis. High risk surgical candidates are often treated with a percutaneous cholecystostomy (PC) as an alternative to acute surgery. This study aims to determine whether any factor during the index admission with acute calculus cholecystitis treated with PC determines whether a delayed cholecystectomy is performed, in addition to whether there are any predictive factors for the presence of ductal stones or recurrent biliary morbidity.

Methods: A single-centred retrospective cohort study on radiologically inserted PCs for calculous cholecystitis between 2011-2017. Patient, radiological, biochemical and microbiological data were collected during the index admission. Primary outcome was whether the patient underwent a cholecystectomy and secondary outcomes included readmission with a further biliary morbidity or ductal stones necessitating an ERCP within 120days of the index cholecystostomy.

Results: 32 patients (median age 77years, median Charlson Index 5) underwent PC with a median follow up of 151 days (range 27-1113). PC drain-related morbidity was 58% with no 30-days or in-hospital mortality. Patient age ($p=0.007$), Charlson Index ($p=0.015$) and a positive bile culture ($p=0.032$) were associated with a delayed cholecystectomy (38.7% of patients). There were no predictive variables for recurrent biliary morbidity within 90days (38.7%). CRP ($p=0.045$), ALP ($p=0.035$) and ALT ($p=0.047$) were predictive of the need for an ERCP for CBD stones (32.3%).

Conclusions: PC is a safe procedure and is effective in overcoming the acute pathology in this comorbid population. However, the near-term prevalence of CBD stones and risk of further biliary morbidity remains significant suggesting that definitive surgery should be considered in suitable cases.

Keywords: Acute cholecystitis, Cholecystectomy, Choledocholithiasis, gallstones, Percutaneous cholecystostomy

INTRODUCTION

Gallstones are prevalent in 10-15% of the adult population in the United Kingdom. It is a common surgical problem with acute cholecystitis alone estimated to account for 10% of all patients presenting as an emergency with abdominal pain.¹ Elderly patients are quoted to account for 50-70% of patients presenting with the diagnosis.² The gold standard for the treatment of

acute cholecystitis in the United Kingdom is established as a cholecystectomy during the index admission or within seven days of presentation.³ In unwell individuals who are deemed high-risk surgical candidates due to coexisting comorbidities, there is ample evidence demonstrating that a percutaneous cholecystostomy (PC) is a safe and effective alternative in treating the acute pathology. A cholecystostomy drains the infected bile or gallbladder empyema though leaves the nidus of the

infection-the gallbladder, usually containing stones, untouched. Excluding the infected fluid aims to reduce the inflammatory process potentially resulting in an improvement in the patient's acute condition.

This technique is used as the definitive treatment of cholecystitis in very high-risk surgical candidates, though it is now often utilized as an adjunct to an interval cholecystectomy in selected patients once the inflammatory process has subsided. Cholecystectomy rates in the literature vary significantly following PC, ranging from <10% to 96%, though this may reflect the fact that percutaneous gallbladder drainage is now increasingly utilised in a less morbid population.⁴⁻⁶

In patients undergoing PC, the presence of stones within the biliary tree exclusive of the gallbladder can potentially cause further complications including jaundice, cholangitis, pancreatitis or alternatively a bile leak in patients undergoing cholecystectomy. For this reason, their identification and removal are often important.

This study aims to determine whether any factor during the index admission with acute cholecystitis treated with PC determines whether a delayed cholecystectomy is performed, in addition to whether there are any predictive factors for the presence of ductal stones or recurrent biliary morbidity.

METHODS

In the centre, the usual protocol for patients presenting with acute calculous cholecystitis is for an acute cholecystectomy or conservative treatment with antimicrobials followed by an interval cholecystectomy if deemed appropriate. Patients deemed too high risk for acute cholecystectomy, failing, or deemed likely to fail conservative management were selected for PC at the discretion of the consultant emergency surgeon on-call.

This is a retrospective cohort study on radiologically inserted PCs from a single district general hospital between 2011-2017. Patient data was requested from the hospital audit and radiology departments. Inclusion criteria consisted of patients diagnosed radiologically with acute calculous cholecystitis with ultrasound or computed tomography. Patients with acalculous cholecystitis were excluded.

Data was collected on radiological features including common bile duct diameter, abscess and gall bladder perforation. Pre-procedure biochemistry including alkaline phosphatase (ALP), alanine aminotransferase (ALT), bilirubin and C-reactive protein (CRP) were also documented. Patient demographics were collected including age, Body Mass Index (BMI), co-morbidities and previous abdominal surgery. All patients were scored with a Charlson Index, which is a validated comorbidity

scoring system in predicting 10-year life expectancy (Table 1).⁷

Table 1: The Charlson index scoring system.

Charlson index	Predicted 10-year survival (%)
1	96
2	90
3	77
4	53
5	21
6	2
7+	0

All PC drains were placed aseptically under local anaesthesia by a consultant interventional radiologist either by ultrasound or CT-guided guidance, depending on the patient's anatomy and body habitus. All procedures in this cohort were performed in the radiology department, though can be performed at the bedside such as in the Intensive Care Unit.

Two techniques were utilised-transhepatic through segment six of the liver, or transperitoneal. Either a single pass trocar technique with a locking pigtail catheter and sharp stylet, or serial dilatation with wires and dilators prior to placement of the drain were employed. Bile was aspirated for culture and sensitivity and the gallbladder irrigated with normal saline. The drain was attached to free drainage into a closed system bag and the drain flushed three times per day with 10ml of saline.

Following PC, any further imaging such as Magnetic Resonance Cholangiopancreatography (MRCP) was guided by patient's physiological parameters, pain and biochemistry. Data was collected on all readmissions to the hospital with patients follow up documented as either the last point of contact with the hospital or following definitive surgery.

Drains were usually planned to be left in-situ for a period of up to six weeks prior to removal either in the outpatient department or in theatre during cholecystectomy. Data from the index admission for PC were analysed against the primary outcome of whether the patient underwent a cholecystectomy. Secondary outcomes included readmission with further biliary morbidity and ductal stones necessitating an ERCP within 120days of the index cholecystostomy.

Statistical analysis was undertaken with SPSS software. Univariate analysis, dependent on the nature, frequency and type of data was done with Chi square, Fisher's exact test, independent T-test or Mann-Whitney U test. Multivariate analysis was done by a neural network using a multilayer perception technique with significance defined as $p < 0.05$. The work has been reported in line with the STROCSS criteria.⁸

RESULTS

32 patients underwent PC for acute calculous cholecystitis. Median age at presentation was 77years (range 48-95), including 17 females.

Acute calculous cholecystitis was the emergency presenting complaint in all patients, except for one patient who was already a hospital inpatient under the care of the physicians.

Median duration of symptoms at presentation was 3days with the median length of stay being 11days (range 1-108). One patient was immediately lost to follow up after

discharge from hospital due to be a tourist in the area. For the remaining 31 patients, median follow up until cholecystectomy or date of last contact with the hospital was 151days (range 27-1113).

Median body mass index (BMI) of the cohort was 26.7kg/m² (range 16.9-41.3) with associated comorbidities including eight patients on anticoagulation therapy, five having undergone a previous laparotomy and a further six patients having undergone an endoscopic retrograde cholangiopancreatography (ERCP)-two stented palliatively for cholangiocarcinoma and a cystic pancreatic tumour respectively. Median Charlson Index was 5 (Table 2).

Table 2: Study cohort's individual patient data.

Age	Charlson index	Comorbidities
48	4	Loeys-dietz syndrome, aortic valve replacement, thoracic aneurysm dissection/repair, abdominal aortic aneurysm, hypertension.
55	2	Hypertension, sleep apnoea, peptic ulcer disease (PUD).
57	3	Diabetes, pulmonary sarcoidosis, obesity.
61	2	Previous <i>Legionella</i> pneumonia requiring extracorporeal membrane oxygenation, hypertension, subtotal colectomy for clostridium difficile colitis/parastomal hernia.
64	2	Obesity (BMI 35.5).
64	2	Nil.
65	3	Myocardial infarction (MI), hypertension.
65	3	PUD, single vessel coronary artery disease.
67	2	Nil (Tourist - no follow up).
68	6	Myeloma, hypertension, transient ischemic attack.
69	6	Cholangiocarcinoma, hypertension.
70	4	PUD, coronary artery bypass graft, hypertension.
74	6	Diabetic neuropathy, chronic obstructive pulmonary disease (COPD), previous pulmonary embolus, Parkinson's disease, non-pituitary gigantism.
74	4	Dementia.
74	4	Recent subtotal colectomy for cancer, diabetes, hypertension.
77	6	Pacemaker (heart block), atrial fibrillation (AF)(warfarin), diabetic retinopathy, hypertension.
77	4	Diabetes, AF, hypertension.
77	6	AF (Apixaban), advanced Motor Neurone Disease (tetraplegia), diabetes.
78	5	Prostate cancer.
78	10	AF (warfarin), diabetes, cardiovascular accident (CVA), MI, hypertension, cirrhosis.
78	4	AF (Warfarin), CVA, previous open necrosectomy and incisional hernia (rooftop incision).
79	5	Heart failure, COPD/occupational lung disease, exercise tolerance of 20 yards.
79	4	AF (Warfarin), heart failure, Intensive Care Unit transfer with respiratory failure/sepsis.
79	6	AF (Warfarin), radiation enteritis due to Prostate cancer, CABG, syndrome of inappropriate antidiuretic hormone secretion (SIADH), pulmonary hypertension.
83	7	Chronic Kidney Disease (CKD), diabetes, heart failure.
84	5	Hypertension, diabetes.
85	9	Pacemaker (asystolic pauses), dementia, diabetes, cystic neoplasm of pancreas.
86	5	MI/Angioplasty (Fondaparinux).
91	9	CKD, prostate cancer, hypertension, heart failure, pacemaker (trifascicular heart block), diabetic nephropathy.
92	5	AF (Warfarin), septic shock with acute renal failure.
92	5	PUD, hypertension.
95	7	Heart failure, Pacemaker, occluded superior mesenteric artery, hypertension, diabetes, previous open right hemicolectomy for cancer.

Table 3: Variables predictive of future cholecystectomy or ERCP.

Variable	N=31	Cholecystectomy		p =	ERCP 120 days		p =
		Yes	No		Yes	No	
Patient factors							
Sex	31	12	19	0.886	10	21	0.316
Age	31	12	19	0.007	10	21	0.268
Active cancer	7	2	5	0.676	0	7	0.069
Cardiovascular disease (excluding hypertension)	20	8	12	1	8	12	0.248
Lung disease/sleep apnoea	6	1	5	0.363	3	3	0.346
Diabetes	12	2	10	0.065	3	9	0.703
Anticoagulation	8	2	6	0.433	4	4	0.218
Previous laparotomy	5	1	4	0.624			
Previous laparotomy, cancer or ERCP	11	1	10	0.02			
Charlson index	31	12	19	0.015	10	21	0.425
BMI	31	12	19	0.475	10	21	0.244
Level 2/3 admission	4	0	4	0.139			
Biochemistry							
WCC	31	12	19	0.826	10	21	0.312
CRP	31	12	19	0.845	10	21	0.045
Bilirubin	31	12	19	0.509	10	21	0.675
ALP	31	12	19	0.484	10	21	0.035
ALT	31	12	19	0.535	10	21	0.047
Radiology							
Gallbladder perforation or local/liver abscess	8				5	3	0.072
Bile duct >8mm	16				4	12	0.446
Bacteriology							
Positive bile culture	16	4	12	0.032	5	11	0.621
Positive blood culture	5	2	3	1	2	3	0.621

During their admission, four patients required escalation to level 2 or 3 care-two for cardiovascular, one for respiratory and one for renal support. Inflammatory markers were elevated almost universally with a median white cell count (WCC) and C-reactive protein (CRP) of $15.7 \times 10^9/L$ (range 5.7-39.5) and 339mg/dL (6-629) respectively prior to intervention.

Median liver function values were bilirubin $21 \mu\text{mol/L}$ (6-173), alanine transaminase (ALT) 49U/L (11-708) and alkaline phosphatase (ALP) 257U/L (66-1218). Prior to PC, radiological investigation encompassed seven patients undergoing USS alone, 17 CT alone and 8 patients received both imaging modalities. 8/32 (25%) of patients were found to have a locally perforated gallbladder or abscess and 16 were found to have common bile duct (CBD) diameter of >8mm.

All patients had an initial attempt at an USS guided PC, with a single case being converted to CT-guided due to the poor views attained due to patient obesity. Two patients required a further image-guided drain of an associated abscess. Of 31 patients followed up, eighteen patients had either positive bile or blood bacteriology cultures.

Twenty-four patients had bile cultures of which sixteen had a positive culture. *Escherichia coli* was the most commonly cultured bacteria with 11 growing more than a single species. Twenty-two patients undertook blood cultures resulting in 5 positive results.

Escherichia coli was again the most prevalent with other cultured bacteria included *Proteus mirabilis*, *Morganella morganii* and *Clostridium perfringens*. There were no immediate technical complications during the procedures.

Drains were in-situ for a median period of 36days (range 4-270) and drain-related morbidity was 18/31 (58%). Ten patients accounted for 14 hospital attendances with drain-related morbidity. 14 drains were displaced unintentionally with other morbidities including pain (1), drain blockage (1), chest wall abscess (1) and one individual developing a cholecystocutaneous fistula requiring an ERCP. There were no 30-day or in-hospital mortalities though four patients died during the follow-up period. Recurrent biliary sepsis was a contributing factor in one mortality from congestive heart failure (day 51 of follow up). Other causes of mortality were cholangiocarcinoma (74days), cystic pancreatic tumour (205days) and mesothelioma (1114days).

During follow up, one patient developed a chole-cysto-duodenal fistula rendering a cholecystectomy unnecessary. 12/31 patients underwent cholecystectomy, with the remainder being treated conservatively. 7/12 patients underwent a laparoscopic cholecystectomy (2 being subtotal), 3 were converted from laparoscopic to open with the remaining 2 cases being open. Two patients re-presented postoperatively, one with a 3cm subhepatic collection which was treated conservatively, with another patient needing an ERCP for a ductal stone. Both patients had undergone a laparoscopic converted to open procedure.

Median interval time from cholecystostomy until cholecystectomy was 90 days (range 28-341). Univariate analysis showed that patient age ($p=0.007$), Charlson index ($p=0.015$), positive bile culture ($p=0.032$) and whether the patient had undergone a previous laparotomy, ERCP or previously suffered from a malignancy ($p=0.02$) were significant determinants of whether patients would undergo an interval cholecystectomy. Neither of these factors were shown to statistically significant during multivariate analysis (Table 3). Following discharge from the index admission, 12/31 (38.7%) patients were responsible for 15 acute readmissions with recurrent gallstone-related morbidity. Five patients suffered recurrent cholecystitis requiring a second PC.

A further five admissions with cholecystitis were treated with antimicrobials. The remaining readmissions were

accounted for with gallstone pancreatitis (2), cholangitis (1), subhepatic abscess (1) and liver abscess (1). All readmissions were within the first 90days of follow up. No variables from the index admission was found to be a significant predictor of a further gallstones-related admission or morbidity during follow up.

Five patients required an ERCP during their index admission. Four were indicated for an obstructing ductal calculus with one patient requiring a stent exchange. In total, 10 patients would undergo an ERCP for stone disease within 120 days following a cholecystostomy. Predictive variables for the need for a future ERCP for a CBD stones included an elevated CRP ($p=0.045$), ALP ($p=0.035$) and ALT ($p=0.047$), however none were found to maintain their significance in a multivariate analysis. In isolation, a dilated bile duct of greater than 8mm was not a reliable predictor of a bile duct stone (Table 3).

DISCUSSION

In this cohort, author presented 32 patients with a median age of 77years, who underwent 37 PCs under radiological guidance. Only a single case required conversion from being US-guided to CT-guided due to obesity. There were no immediate complications, indicating a safe procedure. Of the 31 patients followed up, median Charlson index was 5 with the most prevalent patient comorbidities being cardiovascular disease (65%), diabetes (39%) and lung disease (19%) with 26% on anticoagulation therapy.

Table 4: Recent percutaneous cholecystostomy publications and reported outcomes.

Study (year)	n	Follow up	PC morbidity %	CBD stones %	Biliary symptom recurrence %	Definitive surgery rat	Mortality %
Horn T et al ⁹	278	Median 5years	37.0	n/a	23.5	28.4	4.7 (30days)
Viste A et al ¹⁰	104	Median 12months	10.5	7.7	n/a	28.8	3.8 (30days), 23.1 (overall)
Furtado R et al ¹¹	55	Median 68months	44.0	44	14.5 (*AC and cholangitis)	44.0	9 (index admission) median survival 5years
Wang CH et al ¹²	184	1year	n/a	Excluded	AC 6.5 at 2 months, 9.2 at one year	32.6	2.7 (12months)
Pang KW et al ¹³	71	Median 37months	28.2	16.9	AC 11.9	45.1	8.5 (Index admission), 32.4 (overall)
Boules M et al ¹⁴	380	Minimum 1year	22.6	n/a	6.1 readmitted at 1 month	32.9	38.5 (30-day), 48.6 (60-day), 60.7 (overall)
Zarour S et al ¹⁵	119	n/a	40.3	Excluded	AC 39.4	40.0	5 (30-day), 5.9 (in-hospital)

*AC = acute cholecystitis

Comparing this results with other recent studies (Table 4) needs to be placed in the context of the variation in

patient comorbidities in each cohort, transhepatic versus trans-peritoneal approach, duration of antibiotics,

imaging protocols, emergency theatre capacity, type/length of follow-up and the retrospective nature of the vast majority of papers.⁹⁻¹⁵ The only constant seems to be the generally elderly population in which the procedure is undertaken.

The variation in patient selection for such intervention is probably best reflected in study mortalities, which range from 0% during the index admissions such as in this cohort, to 38.5% at 30-days, though one study has described a median survival of 5 years. Most studies report a significant morbidity related to PC with tube displacement being the commonest, which could be considered a relatively minor morbidity.^{9-11,13-15} Though in the cohort, there were no direct procedural complications apart from a single chole-cysto-cutaneous fistula, other more serious complications described in the literature include bleeding requiring embolization, bile leaks and a visceral perforation necessitating laparotomies.^{11,13} In addition to the retrospective nature of most similar studies, most studies interpretation of what consists a morbidity are not similar, which explains the wide variety in its reported prevalence.

Despite the very short term follow up, this cohort has a high prevalence of recurrent biliary morbidity at almost 40% which is similar to Zarour S et al, and Flexer SM et al though the latter's follow up period was nearly three years. It has previously been suggested that leaving a PC in-situ for over two weeks increases the risk of early symptom recurrence, possibly by gallbladder mucosal irritation or bacterial colonization of the drainage catheter.¹⁵⁻¹⁹ The median duration of PC drainage varies enormously in the literature from 5-60days highlighting the lack of guidance regarding best practice in this area.^{20,21}

Few studies have documented their prevalence of choledocholithiasis, and once again this is difficult to compare when all studies have varying protocols for tubograms and MRCPs for visualizing the bile duct. Prevalence ranges 7.7-44% though some studies exclude patients with ductal stones from their data sets. Though we identified CRP, ALP and ALT as significant biochemical indicators of ductal stones, this significance was lost with multivariate analysis suggesting biochemistry is not a reliable substitute for radiology in this setting.^{10,11}

PC in combination with antimicrobials is argued to be an adequate alternative to cholecystectomy, though most recommend delayed definitive surgery.²²⁻²³ This data supports the need for definitive surgery if possible, given the high prevalence ductal stones and recurrent biliary morbidity, however, each case must be considered on their own merits. Some evidence even supports that a cholecystectomy may not be necessary at all.²⁴⁻²⁵ A Gurusamy KS et al, based on two small randomized trials was unable to determine the role of percutaneous cholecystostomy in the clinical management of high-risk

surgical patients with acute cholecystitis.¹⁶ An adequately powered randomized clinical trial on this subject was suggested, which is currently being undertaken, comparing PC with laparoscopic cholecystectomy in high risk patients presenting with acute cholecystitis.²⁷

PC is widely accepted by surgeons as a bridging technique towards a delayed elective cholecystectomy, with one study reporting a of 96% completion rate.⁵ It was apparent that the risk of converting to open surgery in these patients is much higher than the general population with many surgeons opting directly to an open procedure in selected cases as opposed to commencing laparoscopically. Some have reported an increased risk of postoperative abscess in PC patients, speculated as being secondary to colonised adhesions from the historical tract.¹¹

In the National Health Service (NHS), an acute cholecystectomy is considered the gold standard management of acute cholecystitis and this should be undertaken within a week of diagnosis. Though a common procedure, an emergency cholecystectomy for acute cholecystitis carries a risk of significant morbidity and mortality.²⁸ However, in comparison to a delayed cholecystectomy, an acute cholecystectomy leads to a lower rate of readmission rates, shorter length of stay, better quality of life and therefore has a health economic benefit.³ Tokyo guidelines suggest that Grade 1 cholecystitis be treated with an acute cholecystectomy, but those with inflammation ongoing for 5-7days should be treated conservatively with antimicrobials with or without cholecystostomy, followed by delayed cholecystectomy.²⁸

However, there will always be a subset of patients that cannot be treated surgically, be it due to health or logistical reasons. Inevitably, an increase in life expectancy leads to an increasing elderly population, often surviving for longer with their comorbidities due to medical advances. This suggests that the proportion of patients deemed not to be surgical candidates will grow in future and these patients will be left with the option of a percutaneous cholecystostomy or conservative management.

As a healthcare profession, there is little we can do in the acute setting do to suddenly convert a surgically unfit patient into a candidate for a cholecystectomy. However, what can be done is improve this current model of care to expand access and increase the availability of an emergency cholecystectomy to suitable patients. Given the burden of gallstone disease on the healthcare system, the NHS currently needs to prioritise the efficient management of those presenting acutely and are suitable surgical candidates. Acute cholecystectomy rates range widely 0.2-35% in acute hospital trusts and as with most hospitals, access to the emergency theatre and the availability of an upper gastrointestinal surgeon will be two prominent factors that account for this variation. This

may explain how a small number of relatively healthy patients were treated with a cholecystostomy in this cohort, though this was not specifically examined.²⁹

CONCLUSION

PC is a safe procedure and is effective in overcoming the acute pathology in this comorbid population. However, the near-term prevalence of CBD stones and risk of further biliary morbidity remains significant suggesting that definitive surgery should be considered in suitable cases.

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