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Official Journal of the Irish Medical Organisation

Ir Med J; September 2026; Vol 119; No. 8; P158
28th September, 2026
Original Paper

Cholecystostomy Drainage - Current Practices in a Tertiary Hepatobiliary Unit

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Abstract

Background

Acute calculous cholecystitis (ACC) is a common general surgical emergency and accounts for 20% of symptomatic gallstone presentations. According to the Tokyo Guidelines, severe ACC necessitates cholecystostomy drainage. Percutaneous Cholecystostomy Drains (PCD) are a temporary intervention in acutely unwell patients with gallbladder-related disease who are unfit to undergo surgery. PCD is used with a therapeutic or palliative intent for the management of gallbladder disease based on the condition and the patient's fitness. This study aims to assess the current role of PCDs in a tertiary hepatobiliary referral centre.

Methods

This was a retrospective review of PCD patients treated in a tertiary hepatobiliary referral centre between January 2018 and December 2023. Clinical, radiological, and perioperative outcomes were measured. Descriptive analysis was performed using GraphPad Prism.

Results

Sixty-eight patients were identified over six years. The mean age was 71.6 years, with a male majority. The most common diagnosis was severe cholecystitis with septic shock (23, 33.8%), followed by gallbladder perforation (18, 26.4%). The mean duration of PCD placement was 95.78 days. A post-drainage cholecystectomy was performed in 7 (87.1%) of patients with ASA I-II and 24 (40%) with ASA III-IV (p-value<0.05).

Conclusions

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PCDs are safe and effective in managing surgically unfit patients with severe, complicated ACC. There is a paucity of literature on specific guidelines for the indications, follow-up, and management of PCDs.

Introduction

Acute calculous cholecystitis (ACC) is a common general surgical emergency, accounting for 20% of symptomatic gallstone presentations[1]. Non-operative management of ACC leads to a significant risk of developing future gallstone-related complications. The probabilities of developing biliary colic, biliary obstruction, or pancreatitis are 14%, 19%, and 29% at 6, 12, and 52 weeks, respectively[2]. Current guidelines recommend laparoscopic cholecystectomy for ACC, with many international bodies endorsing the approach[3,4].

The clinical manifestations of ACC vary considerably in severity. First introduced in 2013, the Tokyo guidelines (TG) sought to establish objective parameters for the diagnosis and severity grading of acute cholecystitis[5]. The most recent TG18 classifies acute cholecystitis into grades 1-3 based on organ dysfunction and laboratory values. This classification system predicts inpatient mortality, length of stay (LOS), and surgical outcomes based on disease severity[6-8]. Furthermore, TG18 provides recommendations on optimal treatment strategies, with grade 1 and selected grade 2 cases suitable for acute laparoscopic cholecystectomy, and grade 3 cases suited to more conservative radiological intervention[5]. While early laparoscopic cholecystectomy remains the gold standard, for certain patients with multiple comorbidities, advanced age, and/or sepsis, percutaneous cholecystostomy drains (PCD) may be a safe alternative as a therapeutic or palliative measure[3].

Critics of the CHOCOLATE study (Laparoscopic cholecystectomy versus percutaneous catheter drainage for acute cholecystitis in high-risk patients) suggest that PCD should be reserved for delayed presentation, extensive comorbidities, frailty, or severe systemic illness[9]. There remains significant variation in the clinical indications, duration, removal, and follow-up for PC[10], with no consensus guidelines for their optimal management. This study examined the management and outcomes of PCD in a tertiary hepatobiliary unit.

Methods

This is a retrospective review of all PCD insertions between January 2018 and December 2023 at a tertiary hepatobiliary referral centre. The study evaluated the current clinical practice of managing PCDs. A retrospective database was created following the approval of the local

ethical committee. All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was not required per the Clinical Research Ethics Committee of the Cork Teaching Hospitals and national regulations. Participants were anonymised in accordance with GDPR guidelines. Patients were identified through screening for "cholecystostomy tubes" and "cholecystograms" by the radiology department at the Mercy University Hospital using the radiology *NIMIS* software. Clinical and radiological data were extracted using patients' medical record numbers and their respective scans. The final number of cases analysed was 68, ensuring comprehensive representation of the patient population. Clinical, radiological, and follow-up outcomes were extracted and verified between January and April 2024.

The retrospective database was created using *Excel*, with patients pseudonymised using a unique code in a password-protected file, with sole access granted to the primary investigator (MA). The file was saved on a hospital desktop within the surgical department in accordance with the GDPR. Patient demographics, clinical, and pathological outcomes were retrieved from the *iCare* system. Follow-up data was collected from medical charts and follow-up letters on the *T-PRO* software. Basic demographics included age, gender, American Society of Anaesthesiology (ASA) grade, diagnosis, and source of referral (inpatient versus outpatient). Radiology outcomes included the date and method of PCD insertion, complications, radiological findings (gallbladder perforation, choledocholithiasis or abscess), and the timing of follow-up cholecystogram. Clinical outcomes included LOS, PCD duration, post-drainage cholecystectomy rate, recurrence rate, and readmission rate. The indications for PCD were not specified within the department, and percutaneous drainage was based on the severity of presentation, the presence of incidental malignancy, and the patient's baseline health.

Results for basic demographics, clinical outcomes, and radiological findings were analysed using descriptive statistical methods. Continuous variables were presented as the mean with standard deviation or the median with interquartile range. Categorical variables were analysed using the Chi-Squared test. *GraphPad Prism* was used for data analysis.

Results

Basic Demographics

Between January 2018 and December 2023, sixty-eight patients underwent PCD insertion at this tertiary hepatobiliary referral centre. The mean age was 71.59 years, with a male majority (66.18%). The most common ASA grade was III (35 [51.4%]), followed by ASA IV (25 [36.7%]). Forty-seven cases were referred internally, while twenty-one were external referrals from

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regional hospitals. The inpatient referral group had a higher rate of ASA IV (42.86%) compared to the external referral group (38.89%) (p-value = 0.7755).

The most common indication for drainage was severe cholecystitis with septic shock (23 [33.8%]), followed by gallbladder perforation (18 [26.4%]). Seven cases underwent percutaneous drainage as a palliative procedure secondary to an obstructing cancerous mass. There were four cases of pancreatic cancer, two cases of cholangiocarcinoma, and the last case was duodenal adenocarcinoma causing external CBD compression. Cases with palliative drainage were kept in the final analysis, as they represent an essential cohort for percutaneous drainage. One case required an Endoscopic Retrograde Cholangiopancreatography (ERCP), which resulted in an iatrogenic CBD perforation. Two cases proceeded to laparotomy, one for a palliative hepaticojejunostomy and the other for abscess drainage. Basic patient demographics are shown in **Table 1.**

Basic Demographics		Value
Age		71.59 years (mean)
Sex	Male	45 (66.18%)
	Female	23 (33.82%)
ASA Grade	ASA II	8 (11.8%)
	ASA III	35 (51.4%)
	ASA IV	25 (36.7%)
Diagnosis	Acute Cholecystitis	23 (33.8%)
	Gallbladder Empyema	4 (5.8%)
	Gallbladder Perforation	18 (26.4%)
	Gallbladder Perforation With Liver Abscess	9 (13.2%)
	Cholangiocarcinoma	2 (2.9%)
	Pancreatic Cancer with Biliary Obstruction	4 (5.8%)
	Duodenal Adenocarcinoma	1 (1.3%)
	Ascending Cholangitis Secondary to Gallstones	6 (8.8%)
	Others	3 (4.4%)

Table 1. *Basic Demographics Of Patients Underwent Percutaneous Cholecystostomy Drainage Between January 2018 and December 2022.*

Radiological Outcomes of PCD Insertion

The predominant mode of insertion was transhepatic (50 [73.5%]), followed by transperitoneal insertion (12 [17.6%]). Three complications were reported: one procedure-related and the others drain-related. One case involved a hepatic artery injury necessitating embolisation and subsequent laparotomy. The drain-associated complications included a bile leak leading to a subcapsular abscess and a liver abscess. Four cholecystostomy drains required replacement and repositioning due to dislodgement or breakage of the catheters.

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Fifteen patients had CBD stones on their index MRCP, and nine of them underwent post-drainage ERCP due to choledocholithiasis and concomitant ascending cholangitis. Follow-up cholecystograms were performed in 42 cases (61.7%), with the majority performed within six weeks (33 [78.5%]). There was no clear documentation of clamping tests. The mean duration of PCD placement was 95.78 days. The main radiological outcomes are illustrated in **Table 2**.

Radiological Outcome		***Value***
Mode of Insertion	***Transhepatic***	***50/68 (73.5%)***
	Transperitoneal	***12/68 (17.6%)***
	Unknown	***6/68 (8.8%)***
Radiological Findings	***CBD stones***	***15/68 (22.0%)***
	Gallbladder Perforation	***27/68 (39.7%)***
	Hepatic Abscess	***7/68 (10.2%)***
Post Procedure Outcomes	***Re-intervention***	***11/68 (16.1%)***
	Complications	***3/68 (4.4%)***
	Other procedures (I.E. ERCP, externalization of biliary drain)	***6/68 (8.8%)***
	Future PTC	***6/68 (8.8%)***
Post Insertion Cholecystogram		***42/68 (61.7%)***
Timing of Cholecystogram	***< 6 weeks***	***33/42 (78.5%)***
	6-12 weeks	***3/42 (0.7%)***
	>12 weeks	***6/42 (14.2%)***
Duration of PCD insertion		***95.78 days (mean)***

Table 2. *Radiological Outcomes Post PCD insertion.*

Clinical Outcomes Post Percutaneous Drainage

The mean LOS during the index admission was 15.75 days (SD 11.23, 95% CI 12.77-18.74). Seven patients had septic shock and multiorgan failure resulting in inpatient mortality, of which, four had palliative percutaneous drainage for obstructing malignancies. No cholecystectomies were performed during the index admission, and the remaining patients were discharged or transferred to their respective centres with planned outpatient follow-up.

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Out of the remaining patients, fourteen experienced outpatient mortality, and fifteen patients were readmitted before surgery. Thirteen readmissions were considered unsuitable for surgery due to comorbidities, with only two proceeding to definitive cholecystectomy. Twenty-five patients proceeded to surgery without readmission, and seven were lost to follow-up. A detailed description of the patient's clinical outcomes is shown in **Figure 1.**

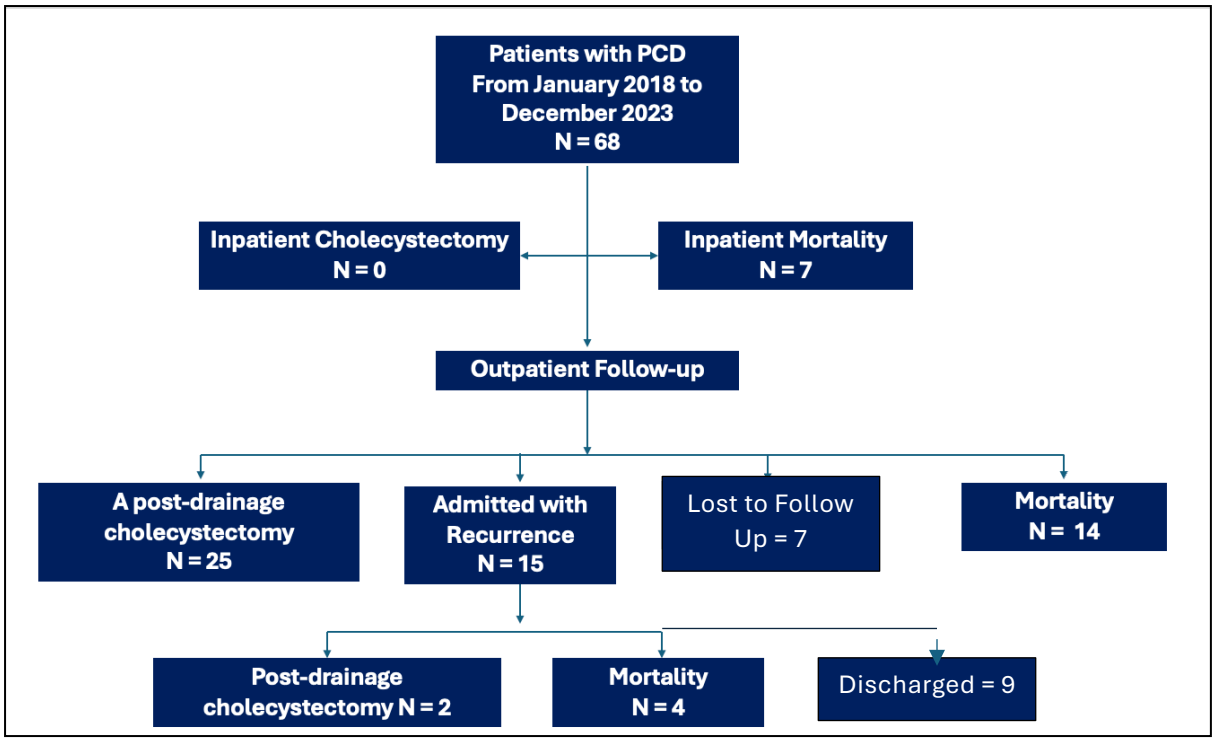

Figure 1. *Clinical Outcomes of Patients post PCD Insertion between January 2018 and December 2023.*

The readmission rate was 22%, with ACC recurrence as the most common cause (15), followed by choledocholithiasis. Twenty-seven patients underwent a post-drainage cholecystectomy, with a mean duration between the PCD and surgery of 164.8 days (SD 167.3, 95% CI 99.92-229.7). The rate of post-drainage cholecystectomy was significantly higher in patients with ASA I-II (7 [87.1%]) than in patients with ASA III-IV (24 [40%]) (p-value <0.05). Of the twenty-seven cholecystectomies performed, nineteen were laparoscopic, six were open, and one was converted to open. Five of the open cholecystectomies were performed for curative purposes, while one was a palliative procedure. The overall mortality at the time of data collection was 36.7%, and the 30-day mortality rate was 19.11% (13).

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Discussion

Acute cholecystitis can be classified as mild, moderate, or severe based on clinical and biochemical parameters related to sepsis and multi-organ failure[11]. Contemporary data support early laparoscopic cholecystectomy in surgically fit patients presenting with ACC[4]. In Ireland, restricted access to emergency theatres, patient comorbidities, and physiological extremes at presentation are the main obstacles to emergency cholecystectomies[12]. PCD have emerged as an acceptable alternative for acutely unwell patients[11,13].

Similar to the Tokyo guidelines, the World Society of Emergency Surgery guidelines also endorse PCD as an alternative definitive treatment for patients with severe comorbidities [3, 14]. In our study, nearly 90% of patients who underwent drainage were ASA III+. Our most common indication for percutaneous drainage was severe acute cholecystitis with septic shock, followed by gallbladder perforation, indicating a very comorbid and acutely unwell patient group, which is in line with the recommended indications for percutaneous drainage.

We report a complication rate of 4.4%, consistent with international reports of post-procedural complications of up to 9%, most commonly drain dislodgement, bile leak, post-insertion haemorrhage, and worsening sepsis [13,15].

Retrospective cohort studies suggested that a pre-removal cholecystogram did not affect the overall recurrence rate, whereas a clamping test performed 48 hours to 2 weeks effectively prevented recurrence of cholecystitis[16-18]. In our cohort, there is no consensus on post-drainage imaging or the optimal timing of PCD removal. Post-insertion cholecystograms were performed in 61.7% of our cases, with the majority occurring within the first six weeks post-insertion. Clamping tests were rarely documented during the clinical course before drain removal.

Previous studies have suggested waiting 4-6 weeks prior to removal to allow for tract maturation and to avoid early bile leak[12,19]. Noh et al. suggested leaving the PCD in place for at least 2 weeks for transhepatic and 3 weeks for transperitoneal insertion to allow for tract maturation [16]. Our institution's mean PCD placement duration was 95.9 days, indicating variability in the timing of PCD removal. Patients with longer durations had longer index hospital admissions and poorer outcomes compared to those with shorter durations. Moreover, patients with longer PCD duration were more comorbid with a higher ASA IV score than those with shorter duration.

While PCD can be considered a definitive procedure in those who are unfit for surgical intervention, interval laparoscopic cholecystectomy should be considered if surgically fit. Studies have shown that post-drainage cholecystectomy is a safe procedure with a low perioperative complication rate (5.3–8.6%), and low mortality rates[18,20]. The timing of a post-

drainage cholecystectomy should ideally be within 4-8 weeks to avoid PCD-related complications and recurrence of biliary disease[21]. Woodward et al. demonstrated a higher rate of complications when interval cholecystectomy is performed within four weeks of PCD insertion[22]. In our patient cohort, the mean time from drain insertion to cholecystectomy was 164.8 days. The wide range in the duration between drain insertion and a definitive cholecystectomy can be attributed to the severity of illness, poor baseline functional status, and restricted access to theatres.

The rate of post-drainage cholecystectomy is variable and, despite safety and low morbidity rates, it remains uncommon in the UK and Ireland due to restricted access to theatre and patient comorbidities[12]. De Mestral et al. reported a post-drainage cholecystectomy rate of 40% at 1 year after drainage and a recurrence rate of 49% in patients who did not undergo definitive treatment[23]. Other studies indicated a cholecystectomy rate as low as 14%, suggesting that PCD can be regarded as a safe, definitive procedure for managing biliary disease[24,25]. Our post-drainage cholecystectomy rate was 39.7%, with a readmission rate of 22%. Patients who undergo PCD tend to be comorbid with acute physiological compromise. A low rate of post-drainage cholecystectomy is expected in this cohort due to their poor baseline functional status and comorbidities.

The findings of this study highlight the heterogeneity and ambiguity in the management and follow-up of PCD. Currently, there are no standardised guidelines for the indications, management and follow-up of PCD. Moreover, studies have suggested that the lack of guidelines for managing cholecystostomy drains contributes to poor outcomes[26]. This was a retrospective single-centre study with a small sample size, which limits the generalizability of our data. The study was conducted in a hepatobiliary centre where laparoscopic cholecystectomy for acutely inflamed gallbladders is a viable option, given the availability of expertise and emergency theatres. This may not be the case in hospitals without a hepatobiliary department on site. The inclusion of palliative PCD may have skewed survival data and the rate of definitive cholecystectomy. However, the study aimed to highlight the lack of consensus guidelines or established algorithms on the optimal management of percutaneous cholecystostomy drains.

PCDs are safe and effective in managing surgically unfit patients with severe, complicated ACC. Advisory guidelines from a tertiary centre are needed to further clarify the indications, follow-up and management of PCDs.

Declarations of Conflicts of Interest:
None declared.

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