University Hospitals Plymouth NHS Trust

UK Interventional Radiology Trainee Research Collaborative

BSIRT

IRJ

Multicentre Audit of Cholecystostomy and Further interventions (MACAFI)

A multi-centre clinical audit investigating percutaneous cholecystostomy in the setting of acute calculus cholecystitis and assessing follow up and further Interventional Radiology procedures

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STUDY SUMMARY

Study Title	MACAFI: A UK multi-centre retrospective cohort study investigating percutaneous cholecystostomy in the setting of acute calculus cholecystitis (ACC) and assessing follow up and sequala, with a focus on readmission, cholecystectomy, and further IR procedures
Study Design	Multicentre national audit (retrospective observational)
Study Participants	Patients who underwent percutaneous cholecystostomy for the treatment of acute cholecystitis
Aims/ Objectives	
• **Primary Objective**	To evaluate the use of percutaneous cholecystostomy within the United Kingdom as a treatment option in patients with acute calculous cholecystitis
• **Secondary Objectives**	- Evaluate how the use of percutaneous cholecystostomy has altered during COVID-19 Pandemic - Evaluate the variability of use of percutaneous cholecystostomy as a intervention within the UK and potential factors affecting this. - Propose a standard management pathway following PC - Determine the readmission rates prior to definitive surgical treatment - Evaluate the use of further Interventional Radiology procedures following percutaneous cholecystostomy
Eligibility Criteria	Inclusion Criteria: 1. Patients who had attempted percutaneous cholecystostomy for acute cholecystitis

2. Date of procedure from 01/01/2019 to 01/01/2021

Exclusion Criteria:

1. Patients who were planned for diagnostic aspiration only (no attempted drain inserted)
2. Patients who underwent percutaneous cholecystostomy for any other reason
3. Patients younger than 16 yrs of age and pregnant women

Planned Sample Size	60 local patients with contributions from other centres in the UK (minimum 800 patients expected)
Follow-up Duration	6 months from date of cholecystostomy or date of death, whichever is sooner
Planned Study Period	2years 01/01/2019 and 01/01/2021

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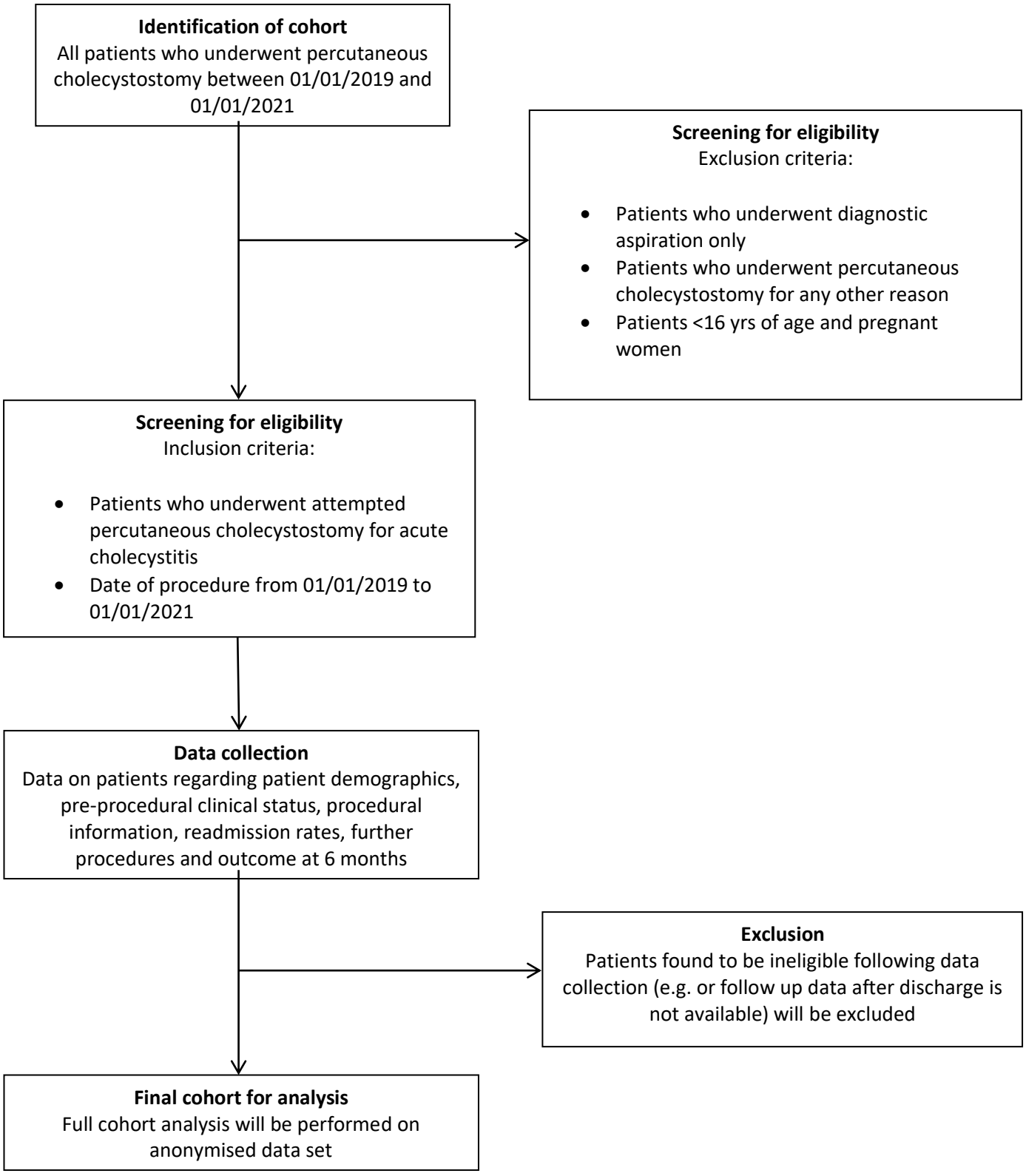
STUDY FLOW CHART



Introduction

Lay Summary

Gallstones are a very common problem that, whilst often lead to no issues, may lead to issues such as infection within the gallbladder and/or inflammation of the pancreas. This can lead to significant health related complications, particularly in an elderly patient. The best and definitive treatment option for gallstones which are causing a problem is the surgical removal of the gallbladder, which is usually performed through keyhole surgery. However, all operations have associated risks and these are more concerning in an elderly patient who may not be fit enough to undergo the general anaesthetic or the operation itself. An option for these patients is the insertion of a drainage tube in to the gallbladder using the guidance of ultrasound, a percutaneous cholecystostomy. This is a quick procedure that is performed with the patient awake and provides an opportunity to drain out any infected material. However, this does not provide a solution to the underlying problem of gallstones and is currently unable to remove any stones within the duct that drains the gallbladder and liver. However, there are potential options for this which are not currently widely performed within the United Kingdom.

This study aims to analyse the current practice within the United Kingdom for the use of percutaneous cholecystostomy in terms of which patients are being selected and the impact that it has on their management. We also hope to analyse the use of further procedures to remove any gallstones. The results of this study will be used as the basis for the creation of a national management pathway for the use of percutaneous cholecystostomy.

Background

The incidence of gallstone related complications are rising[1], thus leading to increases in waiting list times for elective laparoscopic cholecystectomy (LC)[2]. The gold standard management of acute calculous cholecystitis (ACC) remains a LC with the multicentred 'Chocolate'[3] study demonstrating the benefits of cholecystectomy when compared to percutaneous cholecystostomy (PC) for those felt fit enough to undertake LC. However, there are a number of factors that limit its real-life application including logistics of performing surgery within the first 72 hours or the patients' clinical status, including those admitted to the Intensive Care Unit (ICU) with sepsis which were excluded from this study.

PC provides immediate biliary drainage and may be used as an emergency option in a critically unwell patient as a bridge to surgery, or as the management option of a patient who is not fit for surgery. The number of PC performed per year is continuing to rise[4]. However, there continues to be great variations in practice with regards to the indications, timing and further management of these patients[5]. This may result in impaired patient outcomes due to a lack of standardisation with regards to clinical practice.

Rationale for Study

The study aims to analyse the UK wide practice regarding the use of PC in patients with ACC. We hope to ascertain the current clinical indications for PC in terms of patient selection and severity of illness. As well as this, we will determine the standard practice with regards to timing of PC. ACC may be complicated by the presence of common bile duct (CBD) stones or remaining gallbladder stones which can lead to readmission or increased morbidity and mortality. There are numerous potential further Interventional Radiology (IR) procedures that may be performed in patients following a PC. These include both transhepatic and transcystic approaches to the CBD and gallbladder and cholecystoscopy which may be all used to potentially remove CBD or gallbladder stones as well as cystic duct stent insertion. However, it is not currently known if the use of these further procedures is widespread within the United Kingdom. Following this study, we hope to encourage the creation of a nationwide management pathway for patients following PC.

Data points

- Patient demographics
- Type of admission hospital (DGH vs tertiary referral centre)
- Date of admission
- Imaging diagnosis date
- Imaging modality first confirmed (Ultrasound/CT/MR)
- Complicated / uncomplicated disease
- If complicated (perforation, biloma, emphysematous, gangrenous)
- Levels of Lipase / Amylase
- Bilirubin pre and post cholecystostomy
- Gallstones Y/N
- Intensive Care admission Y/N
- 30 day and 90 day mortality
- Highest C-Reaction Protein pre cholecystostomy
- WCC pre cholecystostomy
- GFR pre cholecystostomy
- Indication for cholecystostomy (Definitive treatment, bridge to surgery, Unknown)
- Cholecystostomy insertion date
- Access route (transhepatic or transperitoneal)
- Tube size (French)
- Technical success (Y/N)
- If no, reason for unsuccessful cholecystostomy
- Procedure related morbidity (Y/N)
- If yes (abscess, bleeding, biloma, tube dislodgement)
- Discharge date
- Sample sent to microbiology (Y/N)
- Organism grown from culture sample (y/n)
- Readmitted y/n + when
- Indication for readmission
- Total number of cholecystostomy's performed?
- Readmission discharge date
- Total number of readmissions within 6 months
- Alive at 6 months Y/N
- Date of last follow up
- Date of death. If so what cause?
- Time from first presentation of ACC to definitive stone treatment (cholecystectomy).
- Readmission after cholecystostomy before cholecystectomy
- Evidence of being unfit for cholecystectomy on request card
- Were they offered any attempt at removal of gallstones via same tract?
- If so what method?
- Readmission after cholecystostomy before cholecystectomy
- Evidence of being unfit for cholecystectomy on request cards?

STUDY DESIGN AND METHODS

Research Window

This national audit will investigate the use of percutaneous cholecystostomy and further interventions in patients with acute calculous cholecystitis. This will include data from patients undergoing the procedure in Plymouth and other centres within the United Kingdom. The study period is 2 years from 01/01/2019 and 01/01/2021 which should allow for a large enough sample size of patients.

- Most large Interventional Radiology units would expect to perform around 30 percutaneous cholecystostomy's per year. Therefore, with the multi-centre nature of this retrospective analysis, this should provide an adequate cohort for analysis. Even smaller Interventional Radiology units within District General Hospitals (DGH) will still perform percutaneous cholecystostomy's so will be included within the study.
- The data collection period has been selected to allow for a minimum 6 month follow up period in order to analyse re-admission rates, further interventions or morbidity/mortality.

Data Collection

Data will be collected by each participating centre and will be maintained on an anonymised database.

Data collected falls into the following categories (examples given after each category are not exhaustive):

- Participant ID number (anonymised)
- Demographics: Age, gender, date of admission
- Comorbidities: Diabetes, cardiovascular disease, respiratory disease, previous history of cancer
- Pre-procedural imaging: Dates, modalities, diagnosis
- Treatments offered prior to procedure: Antibiotics, IV fluids
- Procedure: Date, procedural findings
- Intra-operative complications
- Post-operative complications: Types, date of occurrence, treatment
- Follow up: readmissions, 90-day mortality, cause of death, further interventions

ETHICAL AND REGULATORY COMPLIANCE

Ethical Approval and Registration

This retrospective audit has been registered and approved by the local audit department. Each centre involved within the audit will be expected to register the audit within their own department and a template audit registration form will be provided for this purpose. All data will be held anonymised at the point of collection and no patient identifiable information will be stored.

Funding

No external sources of funding have been sought for this study. Data will be collected at all centres by clinical research staff who are otherwise salaried and will be contributing data for free in exchange for appropriate recognition in the research output of the study.

Publication Policy

Final results of the study will be disseminated via presentations at appropriate scientific meetings and conferences and publication in appropriate peer-reviewed journals. Authorship will involve named individuals involved in study design and manuscript preparation with the UK IR Trainee Research group, with individuals collecting data at hospital sites being specifically named as collaborators.

References

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2. Palmisano S, Benvenuto C, Casagranda B, Dobrinja C, Piccinni G, de Manzi-ni N. Long waiting lists and health care spending The example of cholecystectomy. Ann Ital Chir. 2015 Jul-Aug;86(4):327-32.

3. Loozen C, Van Santvoort H, Van Duikvendijk P, Beselink M, Gouma D, Nieu-wenhuijzen G et al. Laparoscopic cholecystectomy versus percutaneous catheter drainage for acute cholecystitis in high risk patients (CHOCOLATE): Multicentre randomised clinical trial. BMJ 2018;363:3965

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