UK&I BDI

UK and Ireland Bile Duct Injury Registry

Study Protocol v1.5 November 2025

GBIHPBA
Great Britain & Ireland Hepato Pancreato Biliary Association

AUGIS
ASSOCIATION OF UPPER GASTROINTESTINAL SURGERY OF GREAT BRITAIN AND IRELAND

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Getting started

Contact Information

All questions can be directed to: bdi@hpbdata.org

UK&I Bile Duct Injury Project Hub

Find the protocol and all the latest UK&I BDI documentation here: hpbdata.org

Register your team to participate in the UK&I BDI registry here:
https://redcap.hpbdata.org/surveys/?s=YX3R9TTJ9EK47RYJ

Project timelines

Date	Milestone
September 2025	Protocol distribution so centres can apply for Caldicott approval
September-October 2025	REDCap database login distribution opens
October 2025	Data entry opens (retrospective and prospective data input)
December 2026	Study closes for new patients
January 2027	Start of data analysis
January 2029	REDCap database locked for follow-up

Steering Committee

Iain Cameron, Consultant HPB Surgeon, Nottingham University Hospitals

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Ewen Harrison, Professor of HPB Surgery (Database Lead), University of Edinburgh

Background Information & Rationale

Introduction

Cholecystectomy is one of the most commonly performed surgical operations worldwide, with over 70,000 cases being performed annually in the UK(1). Patients are treated for biliary pathologies including biliary colic, cholecystitis and gallstone pancreatitis. Patients who are fit for surgery are offered surgery following presentation with biliary symptoms and undergo cholecystectomy in three main settings:

1. Emergency setting at index admission
2. Elective setting with no previous admissions
3. Delayed setting with one or more previous gall bladder related hospital admissions

Laparoscopic cholecystectomy was first described in 1989 and quickly became the gold standard approach for operations to remove the gallbladder. Initial concerns emerged with this new technique suggesting an increased risk of injury to the common bile duct. In 1995, Steven Strasberg published a key scientific paper analysing the causes of bile duct injury (BDI) during laparoscopic cholecystectomy(2). Subsequently, a great deal of attention has been paid to safety in the context of laparoscopic cholecystectomy to approaches for minimising BDI such as obtaining a "critical view of safety"(3). More recently, the advent of robotic assisted surgery has renewed interest in BDI with concerns about increased risk compared to conventional laparoscopy(4).

There are well established and described techniques to facilitate safe cholecystectomy, including in the presence of and acutely inflamed gallbladder, when the critical view of safety cannot be established(5). The advent of long elective surgical waiting lists in the United Kingdom following the COVID-19 pandemic, together with many patients having had multiple admissions with biliary problems prior to surgery, has anecdotally resulted in an increase in major complications following cholecystectomy. There is data to suggest that the incidence of major bile duct injury is approximately 1 in 500 in the modern surgical era. However, little data exists regarding the true extent of biliary injury during cholecystectomy on a UK- and Ireland-wide basis. It is the opinion of many leading experts in the field of biliary surgery that the establishment of a UK&I-wide registry to document all Strasberg grade B to E injuries would provide useful information to guide and target

educational programmes to reduce the incidence of these life changing complications. It is thought highly unlikely that any Strasberg grade B to E injuries would be managed outside one of the 31 HPB centres within the UK&I and data entry from these centres would capture all of these perioperative injuries. The limited number of injuries that may be treated at a hospital without a HPB unit, are unlikely to be managed without the involvement of specialists from the local HPB centre.

Study Aims

The primary aim of this study is to determine the number and type of Strasberg grade B to E bile duct injuries occurring during laparoscopic cholecystectomy in the United Kingdom over a three-year period. This study period may be extended beyond the initial inclusion dates.

The secondary aims of this study are to:

1. Determine the distribution and sub-specialty interest of surgeons involved in bile duct injuries.

2. Review the initial management of the bile duct injury and which interventions were required.

3. Assess whether there is any difference between early and delayed intervention for bile duct injury repair.

4. Review the long-term outcomes of Strasberg B to E injuries and whether reintervention is required in the three years post injury and repair.

Methods

Overview of Study Design

The UK and Ireland National Bile Duct Injury (BDI) registry is a prospective national multicentre cohort study coordinated and run by the Great Britain Ireland HPB Association in collaboration with the Association of Upper Gastrointestinal Surgeons. Patients presenting to tertiary referral HPB centres over a three-year period between January 2024 and December 2026 who have sustained a Strasberg B to E injury will be registered within the study cohort. Details of their initial operation, presentation of the bile duct injury and subsequent management in the tertiary centre, together with long term outcomes and the need for re-intervention will be documented. Each HPB centre within the United Kingdom will have two designated leads who will be responsible for coordinating the entry of data into the UK&I registry on behalf of that centre. If patients are treated outside a HPB unit, the HPB consultants involved in the management will be asked to enter these patients into the registry, with appropriate local governance approval.

UK&I Bile Duct Injury Project Hub
You can find the latest protocol, paper forms and information at https://hpbdata.org

Site Eligibility

- Any hospital in the United Kingdom providing specialist hepatopancreatobiliary (HPB) services where bile duct injuries are routinely managed.

Study Population

The study population will include all patients undergoing cholecystectomy (laparoscopic, open or robotic) in any hospital in the United Kingdom who sustain a perioperative complication which is subsequently deemed to be a Strasberg B to E grade bile duct injury.

Patient Eligibility Criteria

Consecutive patients with a bile duct injury should be included if they meet all of the following criteria:

- Sustained a Strasberg B to E bile duct injury from 1st January 2024 to 31st December 2026 following cholecystectomy (any operative approach)
- Patients managed at the specialist HPB unit or who have been referred to and are being managed with input from the HPB unit
- Patients undergoing cholecystectomy for suspected benign biliary disease (including patients in whom gallbladder cancer is unexpectedly found on histology)

Exclusion criteria will include patients having a cholecystectomy as part of another procedure, for example a Whipple's procedure or a transplant operation, and patients in whom gall bladder malignancy is suspected preoperatively from radiological imaging.

Data Collection

Data should be entered using a combination of the case report form (Appendix A) along with the data dictionary (Appendix B) to successfully record the necessary data on all eligible patients. Data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application hosted and managed by the University of Edinburgh, United Kingdom. No patient identifiable data will be uploaded or stored on the REDCap database.

Follow-up Period

Centres will be asked to undertake patient follow up and enter data at least four time points:

1. 30 day follow up after discharge from hospital following bile duct injury management.
2. One-year follow up after discharge from index admission.
3. Two-year follow up after discharge from index admission.
4. Three-year follow up after discharge from index admission.
5. Patients may be eligible for further data entry points if appropriate funding can be secured.

Record identifiable information for follow-up

To enable longitudinal follow-up, a secure copy of REDCap ID and hospital / NHS number must be kept within a locally-stored file on the NHS network (i.e. shared drive). At least 2 permanent staff must have access to this file..

The key to successful follow up in these patients has several important components.

1. Ensure that a list of all patient IDs and corresponding REDCap ID is kept in a safe secure computer to allow follow up of these patients. This should be in the form of an encrypted spreadsheet held securely on the local hospital computer network by a member of the data collection team.
2. Where it is anticipated that a hospital lead may change then the new lead / supervising consultant should facilitate the secure storage of both patient ID and corresponding REDCap ID.
3. Please ensure that your local audit office and governance bodies are clear that this will be a follow up study with several times of data entry for each patient.

Project Team Structure

Each registered UK&I HPB centre must have a supervising or lead consultant, and in most cases, there will be two consultants jointly fulfilling this role. They are responsible for ensuring the quality of data entered from each centre and in addition a lead registrar/trainee should be appointed.

For data collection purposes, each HPB centre should aim to recruit a “mini team” of up to 6 local collaborators for data collection and entry. Medical students, nurse specialists or doctors (either in training or trust grades) can act as local collaborators and their participation is encouraged. Each local “mini team” should include at least one doctor in training to provide additional local support for any participating medical students or nurse specialists. Additional collaborators can be recruited to facilitate collection of one, two and three follow up data.

Primary Outcome Measures

The primary outcome measure of this study is to determine the number and type of Strasberg grade B to E bile duct injuries occurring during laparoscopic cholecystectomy in the United Kingdom over a three-year period, which required either transfer to a tertiary referral HPB centre or involvement of local HPB surgeons for management.

Secondary Outcome Measures

The secondary outcome measures are described below:

1. Determine the distribution and sub-specialty interest of surgeons involved in bile duct injuries.

2. Review the initial management of the bile duct injury and which interventions were required.

3. Assess whether there is any difference between early and delayed intervention for bile duct injury repair.

4. Review the long-term outcomes of Strasberg B to E injuries and whether reintervention is required in the three years post injury and repair.

Data Analysis and Sample Size

Initially, data will be reported using descriptive analyses. Comparisons between groups will be undertaken using appropriate parametric and non-parametric analyses. Multilevel logistic regression multivariate models will be constructed to account for case mix when undertaking analysis of factors influencing long term results after BDI. Prespecified subgroup analyses will be made by operative urgency (emergency vs delayed surgery) and to assess outcomes for different Strasberg subtype injuries depending on management option chosen. Identification of hospital or surgeon-specific performance will not be reported. Following analysis, results will be fed back to participants at the centre level, but no other centres will be identifiable. It is anticipated that all 31 UK&I HPB centres will take part in this study with an expectation that there will be between 500 and 700 patients entered into the registry over a 3-year period.

Data Governance

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. Collaborators will be given secure REDCap project server login details, allowing safe anonymised data storage on the REDCap database. The service is managed and hosted by the University of

Edinburgh, United Kingdom. The security of the study database system is governed by the policies of the University of Edinburgh. These include best practices of network firewalls, system and security monitoring and two factor authentication. REDCap access privileges will be managed and maintained by the BDI steering committee and the University of Edinburgh to ensure that users can only access data relevant to their site. That is, data from one site cannot be viewed by data collectors from a different site, local data will only be accessible to local collaborators and the data analysis team. Collaborator access will be limited to their site only.

Personnel handling data collection will be medical professionals including medical students, consultants and doctors in training. All data will be collected from medical records and no new data will be collected directly from patients. The named local consultant leads will ensure data completeness and accuracy. The data dictionary (Appendix B) includes only fields that would be necessary for subsequent analysis. Collaborators can either enter data directly onto REDCap or use paper case report forms (Appendix A), although the former is encouraged. Collaborators are required to leave any papers with personal information in a designated safe storage space (a locked room or cabinet) while not using them. Patient-identifiable information items will be minimised to age and sex. Sex and age will be used to identify the overall demographics of the study population and an essential pre-requisite to meaningful analysis of our data. These data points present negligible risks of inadvertent patient identification and will be presented in aggregate format.

Collaborators will be given individual, unique, secure login details with a password to the REDCap project server before the start of the project. Passwords are stored as an encrypted one-way hash of the password. Users are auto logged out after 30 mins of no activity. Access will be revoked once data collection and follow-up is complete. All transmission and storage of web-based information by this online system is encrypted and was designed to be compliant with HIPAA-Security Guidelines. Any patient identifiable information stored by collaborators will not be available for data-analysis and are automatically stripped. Logins will only be issued on confirmation of local study registration, and no patient data can be uploaded or stored on the REDCap database until this is fulfilled. All data must be handled in accordance with local data governance policies and paper copies of any data should be destroyed as confidential waste.

There will be no data published at the level of the patient, surgeon, or hospital, preventing patients from being identified. The anonymization process includes:

1. The full dataset will be evaluated against the eligibility criteria, and any ineligible cases will be excluded.

2. The REDCap record ID will be stripped from the dataset (the only linkage between any locally stored lists of patient records).

Hospital related variables: separate variables will be collected via an online questionnaire describing each hospital's local policies, facilities, and procedures. This will be distributed to the hospital leads during the start of the study.

Local Project Registration

In all centres, the UK&I registry project should be registered as a clinical audit or service evaluation project. It is unlikely to be necessary to require formal ethical approval. It is the responsibility of the local hospital leads at each site to ensure that the study is registered appropriately according to local regulations. When registering the UK&I Bile Duct Injury (BDI) Registry as a clinical audit it should be emphasised that:

1. The UK&I BDI registry is a national audit, and all data collected will measure current practise and evaluate the management of bile duct injuries.
2. This project will not require any changes to be made to normal patient pathways or treatment.
3. All data from the registry will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. Each collaborating centre will have an individual secure REDCap server login for each collaborator.

Registration

Registration is automated process and is a guided, step-by-step process. You can register your UK&I BDI team at: https://redcap.hpbdata.org/surveys/?s=YX3R9TTJ9EK47RYJ

It is also advised that the HPB centre leads circulate the protocol to the surgical directors and governance leads in their local referring network as some the registry data will relate to procedures performed in hospitals outside the main HPB centres.

Authorship

All authors will be credited in accordance with National Research Collaborative authorship guidelines. All research outputs from the UK&I BDI registry will be listed under a single authorship of UK&I Bile Duct Injury registry, Association of Upper GI Surgeons of Great Britain and Ireland, Great Britain and Ireland HPB Association.

Requirements for authorship on UK&I BDI outputs include:

- Success in obtaining all relevant local approvals for data entry into the UK&I BDI registry.
- Successful data collection of at least one eligible patient
- Individual sites must ensure that complete datasets (>95% of data points entered per record), together with high case ascertainment.
- All data must be uploaded to the REDCap database by the closure deadline.

All collaborators will be listed as PubMed-citable collaborators in accordance with the roles defined below so long as the minimum requirements for authorship are met.

Writing group: a group of doctors, medical students and external advisory members responsible for the overall scientific content, data analysis and preparation of research manuscripts.

Steering committee: a core group consultants and trainees who have overall responsibility for protocol design, project coordination and data handling.

External advisory group: external oversight for this project will be provided where appropriate by the committee of the Great Britain and Ireland HPB Association

Statistical analysis: a small team of dedicated statisticians who take overall responsibility for the statistical analysis plan and quality assurance of da ta analysis.

Hospital Leads: each participating HPB centre will have two leads who act as a point of contact for data collection. At each site usually this will be a consultant HPB surgeon but could also be a specialist registrar or clinical fellow. Hospital leads will have overall responsibility for site governance registration and coordination of the local team. The supervising leads will have to oversee the validity of the data entered and ensure a complete accurate data set is returned for each patient. Units which fail

to submit data or who withdraw participation will be excluded from the authorship list. If substantially incomplete data is submitted, the writing group may decide to exclude that unit from further analysis.

Local collaborators: a team of up to four people responsible for data collection over the defined study period will be identified (this is in addition to the two leads). This team should ideally be formed off a heterogeneous group with different levels of clinical training. Each collaborating team should participate in the creation of the local systems required including registering the audit, identifying patients, collecting data and completing follow up. Additional collaborators can be recruited to help with the collection of the 1, 2 and if appropriate 3-year follow-up data.

References

1. Lunevicius R, Nzenwa IC, Mesri M. A nationwide analysis of gallbladder surgery in England between 2000 and 2019. Surgery. 2022 Feb 1;171(2):276–84.

2. Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Coll Surg. 1995 Jan;180(1):101–25.

3. Strasberg SM, Brunt ML. Rationale and Use of the Critical View of Safety in Laparoscopic Cholecystectomy. J Am Coll Surg. 2010 Jul;211(1):132.

4. Mullens CL, Sheskey S, Thumma JR, Dimick JB, Norton EC, Sheetz KH. Patient Complexity and Bile Duct Injury After Robotic-Assisted vs Laparoscopic Cholecystectomy. JAMA Netw Open. 2025 Mar 25;8(3):e251705.

5. Strasberg SM, Brunt LM. The Critical View of Safety: Why It Is Not the Only Method of Ductal Identification Within the Standard of Care in Laparoscopic Cholecystectomy. Ann Surg. 2017 Mar;265(3):464.

Appendix A – data entry form for UK&I Bile Duct Injury Registry

Section A Patient Characteristics

1. Age at operation (whole years)
    a. Age in months in addition to age in years (whole months up to 11)
2. Sex at birth Male / Female
3. ASA Grade I / II / III / IV / V
4. Clinical Frailty Scale 1 (Very fit) / 2 (Well) / 3 (Managing Well) / 4 (Vulnerable) / 5 (Mildly Frail) / 6 (Moderately Frail) / 7 (Severely Frail) / 8 (Very Severely Frail) / 9 (Terminally Ill)
5. Comorbidities (please select all that apply)
   Myocardial Infarction (MI) / Other ischaemic heart disease / Congestive Heart Failure (CHF) / Peripheral Vascular Disease (PVD) / Cerebrovascular Accident (CVA) or Transient Ischaemic Attack (TIA) / Dementia / Chronic Obstructive Pulmonary Disease (COPD) / Connective Tissue Disease (CTD) / Peptic Ulcer Disease (PUD) / Hemiplegia / Leukaemia / Lymphoma / Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS) / Hypertension / Inflammatory Bowel Disease (IBD) / T1DM / T2DM / Solid Tumour / Liver Disease / Chronic Kidney Disease (CKD) / Other(s) / None of the above
    a. If "T2DM": Diet-Controlled / Medication (non-insulin) controlled / Insulin-controlled
    b. If "Solid Tumour": Localised / Metastatic
    c. If "Solid Tumour": Please specify type
    d. If "Liver Disease": Mild / Moderate or Severe
    e. If "Chronic Kidney Disease (CKD)": Stage I / II / IIIa / IIIb / IV / V / Dialysis
    f. If "Other(s)": Please specify

6. Prior intraperitoneal abdominopelvic surgery (Open / Laparoscopic / Robotic / None)
    a. If Yes Above Umbilicus / All below umbilicus
7. Weight
8. Height
9. BMI

Section B Pre-injury Biliary Pathology and Anatomy

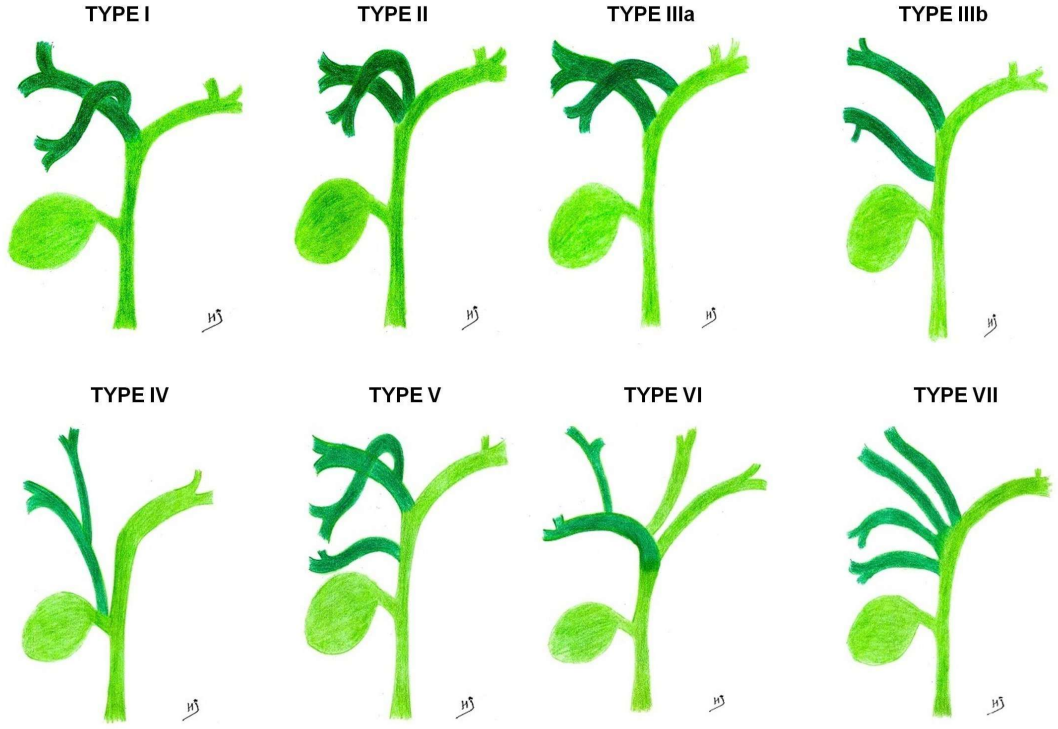
10. Number of acute admissions in past 12 months with biliary symptoms:
11. Any history of acute biliary pathology?
    a. Biliary colic
    b. Cholecystitis
    c. Choledocholithiasis
    d. Cholangitis
    e. Gallstone pancreatitis
    f. Polyp or other benign gallbladder pathology
    g. Acalculous cholecystitis
    h. Other (please specify)
12. Pre-operative Imaging?
    a. USS Y/N
    b. CT Y/N
    c. MRCP Y/N
    d. EUS Y/N
    e. ERCP Y/N
    f. Hepatobiliary Iminodiacetic Acid (HIDA) Y/N
    g. None
13. Imaging Findings
    a. Gallstones Y/N
    b. Thick-walled GB Y/N/Specific measurement
        i. Measurement (if provided)
    c. Pericholecystic fluid Y/N
    d. Dilated CBD Y/N/Specific measurement
        i. Measurement (if provided)
    e. CBD stones/debris Y/N
    f. No gallbladder imaging before surgery
    g. Other abnormality (please specify)
14. Indication for Surgery:

Cholecystitis (Tokyo I, II or III) / Biliary Colic / Pancreatitis / GB polyp / CBD Stones (including cholangitis) / Other (please specify)

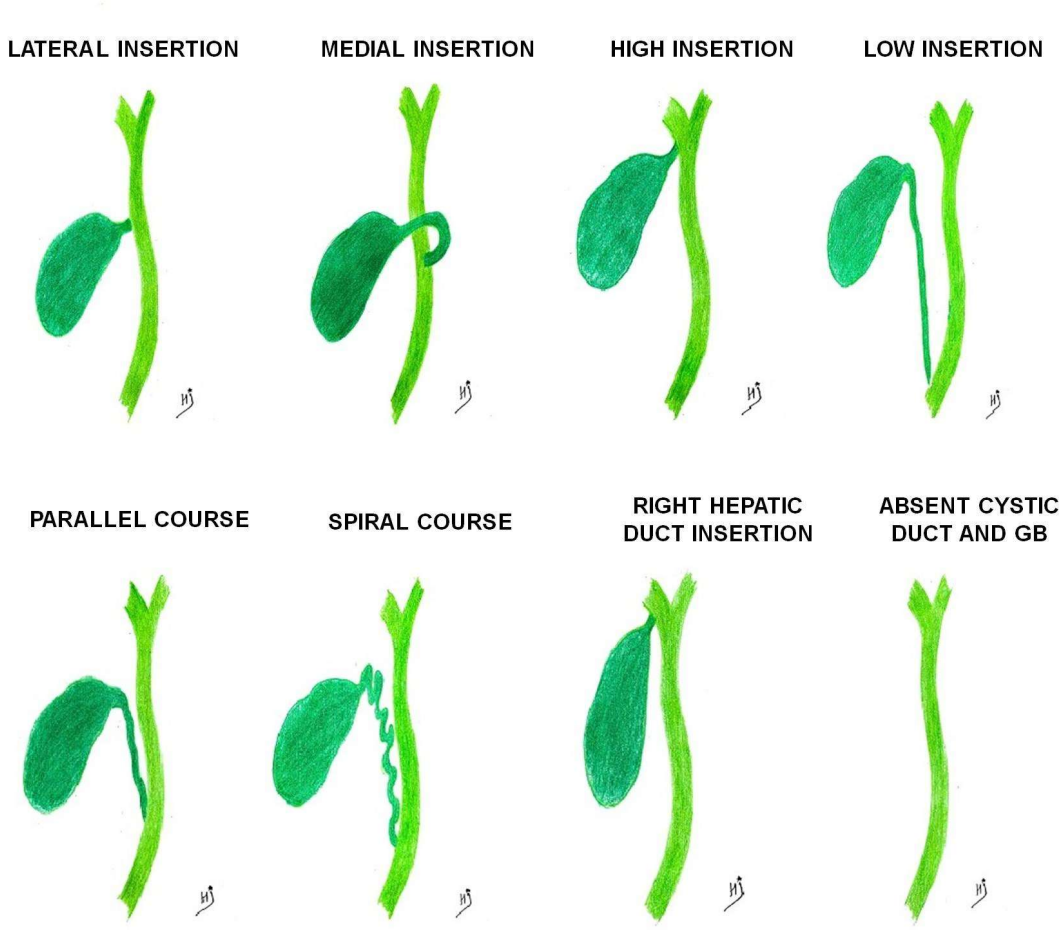
15. Days between decision to operate and surgery performed:
16. Pre-operative blood tests:
    a. Bilirubin
    b. Alkaline phosphatase
    c. Gamma glutamyl transferase
    d. White cell count
    e. C-reactive protein
    f. None of the above
17. Prior Biliary Procedures
    a. Cholecystostomy Y/N
    b. Subtotal cholecystectomy Y/N
    c. Endoscopic sphincterotomy Y/N
    d. Common bile duct stenting Y/N
    e. Other procedure Y/N (Please specify)
    f. None of the above
18. Use of pre-operative weight loss injections within 12 months

    None / Tirzepatide (Mounjaro) / Semaglutide (Wegovy/Ozempic) / Other (please specify) / Unknown

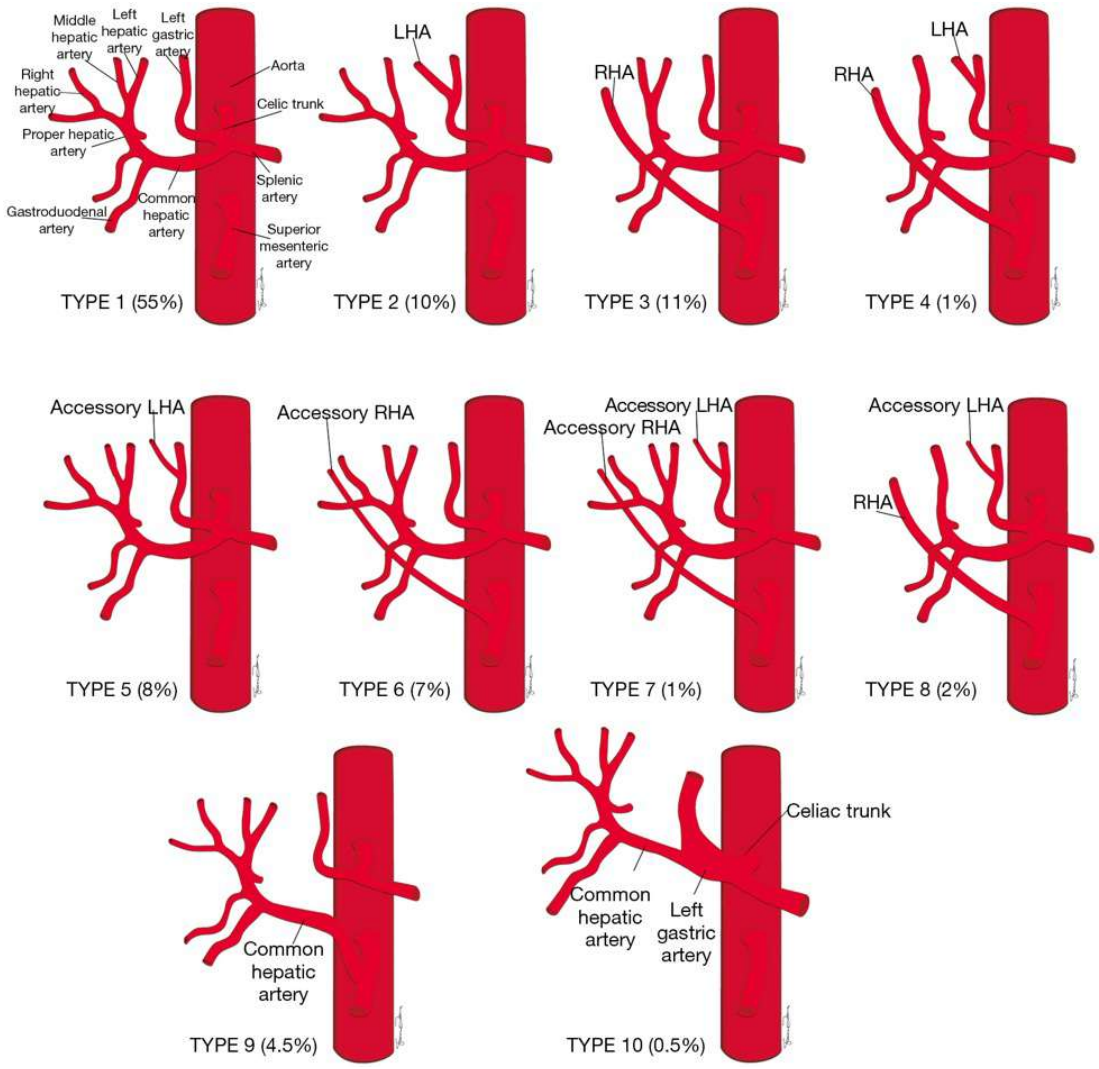
19. Please select pre-operative bile duct anatomical variant (or mark as not known)



20. Please select pre-operative cystic duct insertion (or mark as not known)



21. Please select hepatic vascular variant (or mark as not known)



Section C Operative Details

22. Please select the hospital in which the initial cholecystectomy was performed (list full hospital name, city and country if not in drop-down list) (this data is only to be used for assisting with follow-up – this data WILL NOT be used in publication)
23. Urgency of surgery
    a. Emergency (Immediate) / Emergency (Urgent) / Semi-Elective (Expedited) / Elective
    b. If Emergency, was patient on elective WL Y/N
24. Date and time of initial operation
25. Type of Hospital – DGH / Teaching / Private / Treatment Centre (Or Waiting List Hub)
26. Operating Surgeon – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Core Trainee / Other
27. Most senior surgeon in theatre – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Other
28. Most senior Surgeon Specialty – HPB / UGI / Colorectal / Vascular / Endocrine / Breast / Emergency / General / Transplant
29. Setting – Elective Day case / Elective main theatre / Emergency / Semi-Elective
30. Operative approach – Open / Laparoscopic / Robotic / Laparoscopic converted to open / Robotic converted to open.
    a. If relevant, reason for open conversion – Adhesions / Unable to show Critical View of Safety / Bowel injury / Bleeding / Suspected BDI / Other (Please specify)
31. Critical view of safety
    a. Description in operation note of "critical view of safety" or similar term – Yes-explicitly stated / No-operation note states such a view not possible / Not documented.
    b. Is there a description of only two structures clearly seen to be connected to the gallbladder. Y/N
    c. Is there a description of the lower one third of the gallbladder being separated from the liver to expose the cystic plate.

   d. Is there a description of the hepatocystic triangle being completely cleared of all adipose and fibrous tissue.
   e. Photographs available from initial operation Y/N
      i. If Y, are these consistent with all three elements of "critical view of safety" prior to application of clips or division of cystic artery and cystic duct? Y/N
   f. Is there a description of a "time-out" performed prior to clipping ductal structures? Y/N
32. Intraoperative cholangiogram – Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
33. Intraoperative ultrasound Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
34. Cholangioscopy Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
35. Incisionless fluorescent cholangiography Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
36. Intra-operative ERCP Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
37. Was a stone identified in the common bile duct?
   a. Not assessed
   b. Duct clear of stones
   c. Stone(s) seen in duct but cleared intra-operatively
   d. Stone(s) seen in duct and not cleared by end of procedure
38. Intra-operative variation
   a. Subtotal cholecystectomy (reconstituting)
   b. Subtotal cholecystectomy (fenestrating)
   c. Transcystic bile duct exploration
   d. Choledochotomy
      i. If choledochotomy method of closure: T-tube / primary closure / Other (please specify)
   e. T-tube
   f. Pharmacological sphincter relaxation
   g. Fogarty catheter trawl
   h. Basket trawl
   i. Fundus first approach
   j. Placement of abdominal drain
   k. Other notable variation to standard procedure (please describe)
39. Called for help – Y / N

a. Who came to help – Consultant / Post-CCT fellow / Specialist Registrar / Trust Grade / Other (please specify)
b. Specialty of above - HPB / UGI / Colorectal / Vascular / Endocrine / Breast / Emergency / General / Transplant

40. Injury recognised on table? Y/ N
41. Were HPB centre contacted intra-operatively? Y / N / Not applicable (already in HPB centre)

Section D Bile duct injury and management

42. Was the bile duct injury managed at the tertiary HPB unit? Y / N

    a. If Yes, Please select HPB centre (Hospital-specific data WILL NOT be published)

    b. If No, Please enter the name, city and country of the hospital in which the patient was managed in. (this data is required to improve follow-up and the hospital WILL NOT be published)

    c. If No, Was the bile duct injury managed with involvement of the tertiary HPB unit?

43. Presentation of BDI: Intraoperative / Bile leak from abdominal drain / Pain due to uncontrolled bile leak/ Obstructive jaundice or cholangitis / Intra-abdominal collection or biloma / Other (please specify)

    a. Days from index cholecystectomy to bile duct injury diagnosis:

44. BDI Classification – Strasberg B / C / D / E 1-5

45. Referral to HPB?
    1, Referral to HPB centre on recognition of BDI + transfer to HPB
    2, Referral to HPB centre but managed locally without transfer

3, Injury occurred at same site as HPB centre
4, BDI managed without any involvement of HPB centre

a. If 1 or 2, how many days after surgery was referral made?

46. Concomitant vascular injury – Y / N / Unknown
    a. If yes – Right hepatic artery / Common hepatic artery / Right portal vein / main portal vein / Other (please specify)
47. Imaging modality to confirm BDI – On-table Cholangiogram / USS / CT / MRCP / ERCP / PTC / Tubogram / Other (Please specify) / None (no imaging necessary)
48. Did the patient undergo an attempted surgical repair of the BDI during the primary cholecystectomy?
    a. Yes - attempt made initially without HPB input
    b. Yes - attempt made with input of HPB centre
    c. No - injury in HPB centre with repair delayed to second procedure
    d. No - patient referred to HPB specialist after injury recognised
    e. No - injury not recognised at time of surgery
49. Did the patient undergo any form of surgical management of the BDI (either at the time of cholecystectomy or in a subsequent procedure)? Yes / No – no procedure was required / No – procedure deemed inappropriate (e.g. palliation)
    a. Initial management of BDI? Primary suture repair / Primary suture repair over T-tube / Duct ligation / End-to-end bile anastomosis / Side-to-side duct anastomosis / Roux-en-Y HJ / Drain / Stent / Other (please specify) placement
        i. (For each repair method attempted) Repair successful / repair unsuccessful
        ii. Operating surgeon specialty for each type of repair HPB / UGI / Other (please specify)
        iii. Number of days after cholecystectomy for each repair (Day 0 is date of initial cholecystectomy)
50. Vascular repair – Y / N (If Y please describe repair)
51. Did the patient undergo percutaneous transhepatic biliary drainage? Y / No (not available) / No (contraindicated) / No (not indicated)

Section E 30-day outcomes

52. Admission to critical care – Y / N
    a. Total length of stay in critical care

53. Total length of hospital stay from index cholecystectomy?
54. Mortality during index admission or within 30 days? Y/N
    a. If yes, list day of death with day 0 being day of index procedure:
55. Highest 30-day Clavien Dindo Complication Grade: I, II, IIIa, IIIb, IVa, IVb, V
56. Specific complications (select relevant CD grade):
    a. Surgical site infection
    b. Post-operative pulmonary complication
    c. Bile leak
    d. Bleeding
    e. Intra-abdominal collection
    f. Acute pancreatitis
57. Unplanned re-admission within 30 days of surgery Y/N
    a. If so, readmission length of stay (whole number of days)

Section F Long-term Follow-up

58. Mortality during 1-year follow-up
    a. If yes, list day of death with day 0 being day of index procedure:
59. Please give number of readmissions within first year from index procedure
60. Complications within 1 year (select all the apply) – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / re-operation / Acute pancreatitis / None
61. Highest LFT value within 1 year
    a. Bilirubin
    b. Alkaline Phosphatase
    c. Gamma glutamyl transferase
62. Mortality during 2-year follow-up
    a. If yes, list day of death with day 0 being day of index procedure:
63. Please give number of readmissions within two years from index procedure (include all admissions within first two years)
64. Complications within 2 years (select all the apply) – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / Re-repair / None
65. Highest LFT value from 12-24 months after bile duct injury
    a. Bilirubin
    b. Alkaline Phosphatase
    c. Gamma glutamyl transferase
66. Mortality during 3-year follow-up

a. If yes, list day of death with day 0 being day of index procedure:

67. Please give number of readmissions within three years from index procedure (include all admissions within the first three years)
68. Complications within 3 years (select all the apply) – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / Re-repair / None
69. Highest LFT value from 24-36 months after bile duct injury
    a. Bilirubin
    b. Alkaline Phosphatase
    c. Gamma glutamyl transferase

Appendix B – Data Dictionary

Section A Patient Characteristics

1. **Patient age**: Years (Whole years at the time of operation)
    a. [If "Patient age" less than or equal to 17]
    Age in months in addition to age in years (whole months between 0 and 11 in addition to age in years above)
2. **Patient sex at birth**: Male / Female
3. **ASA grade**: I / II / III / IV / V (Appendix C for definitions)
4. **Clinical Frailty Scale**: 1 to 9 (Appendix C for definitions)
5. **Co-Morbidities** - (Select all that apply)
    Myocardial Infarction (MI) / Other ischaemic heart disease / Congestive Heart Failure (CHF) / Peripheral Arterial Disease (PAD) / Cerebrovascular Accident (CVA) or Transient Ischaemic Attack (TIA) / Dementia / Chronic Obstructive Pulmonary Disease (COPD) / Connective Tissue Disease (CTD) / Peptic Ulcer Disease (PUD) / Hemiplegia / Leukaemia / Lymphoma / Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS) / Hypertension / Inflammatory Bowel Disease (IBD) / T1DM / T2DM / Solid Tumour / Liver Disease / Chronic Kidney Disease (CKD) / Other(s) / None of the above
    a. If "T2DM": Diet-Controlled / Medication (non-insulin) controlled / Insulin-controlled
    b. If "Solid Tumour": Localised / Metastatic
    c. If "Solid Tumour": Please specify type
    d. If "Liver Disease": Mild / Moderate or Severe
    e. If "Chronic Kidney Disease (CKD)": Stage I / II / IIIa / IIIb / IV / V / Dialysis
    f. If "Other(s)": Please specify

    Definitions:

    Other ischaemic heart disease: Angina pectoris, requirement for percutaneous coronary intervention, requirement for coronary artery bypass grafting

Peripheral arterial disease: Diagnosis of arterial insufficiency, intermittent claudication, requirement for vascular or endovascular intervention in the absence of trauma.
eGFR for CKD stages: I≥ 90; II = 60-90; IIIa = 45-59; IIIb = 30-44; IV = 15-29; V <15
Liver Disease: Mild defined as chronic hepatitis or cirrhosis without portal hypertension; Moderate defined as cirrhosis and portal hypertension but no variceal bleeding history; Severe defined as cirrhosis and portal hypertension with variceal bleeding history.

6. **Prior intraperitoneal abdominopelvic surgery**

   Open Any open procedure where peritoneum is opened including laparoscopic and robotic cases in which conversion to open is required.

   Laparoscopic Any intraperitoneal procedure using one or more port sites where procedure was not converted to open. Incision for specimen extraction or extracorporeal anastomosis not considered conversion and should be recorded as laparoscopic. Extraperitoneal hernia approaches should not be considered in this category.

   Robotic Any intraperitoneal procedure using any robotic platform where procedure was not converted to open. Incision for specimen extraction or extracorporeal anastomosis not considered conversion and should be recorded as robotic.

   None

   a. If Yes Above Umbilicus / All below umbilicus

   Considered above umbilicus if any incision is performed above the umbilicus or surgery is performed on organs typically lying above or partly the umbilicus (gallbladder, stomach, diaphragm, pancreas, liver, kidneys, spleen, adrenals, aorta, duodenum, jejunum, hepatic flexure, transverse colon or splenic flexure.

7. **Weight** Please enter value in kilograms. Set to 0 if unknown and not possible to estimate from historical patient records.
8. **Height** Please enter value in centimetres. Set to 0 if unknown and not possible to estimate from historical patient records.
9. **BMI** (calculated field)

Section B Pre-injury Biliary Pathology and Anatomy

10. **Number of acute admissions in past 12 months with biliary symptoms**
    Please record total number of admissions with acute symptoms in any hospital within the 12 months prior to the operation date. Please do not include the admission for the operation in which BDI occurred.
11. **Any history of acute biliary pathology?** Select all that apply
    a. Biliary colic
    b. Cholecystitis
    c. Choledocholithiasis
    d. Cholangitis
    e. Gallstone pancreatitis
    f. Polyp or other benign gallbladder pathology
    g. Acalculous cholecystitis
    h. Other (please specify)
12. **Pre-operative Imaging?** Any pre-operative imaging undertaken at any time prior to the operation in which BDI occurred. This can be in any hospital.
    a. USS Y/N
    b. CT Y/N
    c. MRCP Y/N
    d. EUS Y/N
    e. ERCP Y/N
    f. Hepatobiliary Iminodiacetic Acid (HIDA) Y/N
    g. None
13. **Imaging Findings**
    a. Gallstones Y/N
    b. Thick-walled GB Y/N/Specific measurement
        i. Measurement (if provided) Where differing imaging modalities provide different values, please use the thicker of the two measurements
    c. Pericholecystic fluid Y/N
    d. Dilated CBD Y/N/Specific measurement
        i. Measurement (if provided) Where differing imaging modalities provide different values, please use the larger of the two measurements
    e. CBD stones/debris Y/N
    f. No gallbladder imaging before surgery
    g. Other abnormality (please specify)

14. **Indication for Surgery**:

    Cholecystitis (Tokyo I, II or III) / Biliary Colic / Pancreatitis / GB polyp / CBD Stones (including cholangitis) / Other (please specify)

    Please see Appendix C for definitions of the Tokyo criteria.

    Please select the most accurate diagnosis based on available documentation from the patient notes.

15. **Days between decision to operate and surgery performed**: Number of days. Day 0 is same day as surgery. For elective cases this should be the day the patient was seen in the outpatient clinic. For delayed cases this is the day the patient was LAST discharged from hospital with biliary disease. For emergency cases this should be the day the decision was made to perform an acute cholecystectomy in that emergency admission. If the patient was previously on an elective waiting list for surgery, please still use the date it was decided to perform the operation as an emergency.
16. **Pre-operative blood tests:**
    a. Bilirubin
    b. Alkaline phosphatase
    c. Gamma glutamyl transferase
    d. White cell count
    e. C-reactive protein
    f. None of the above

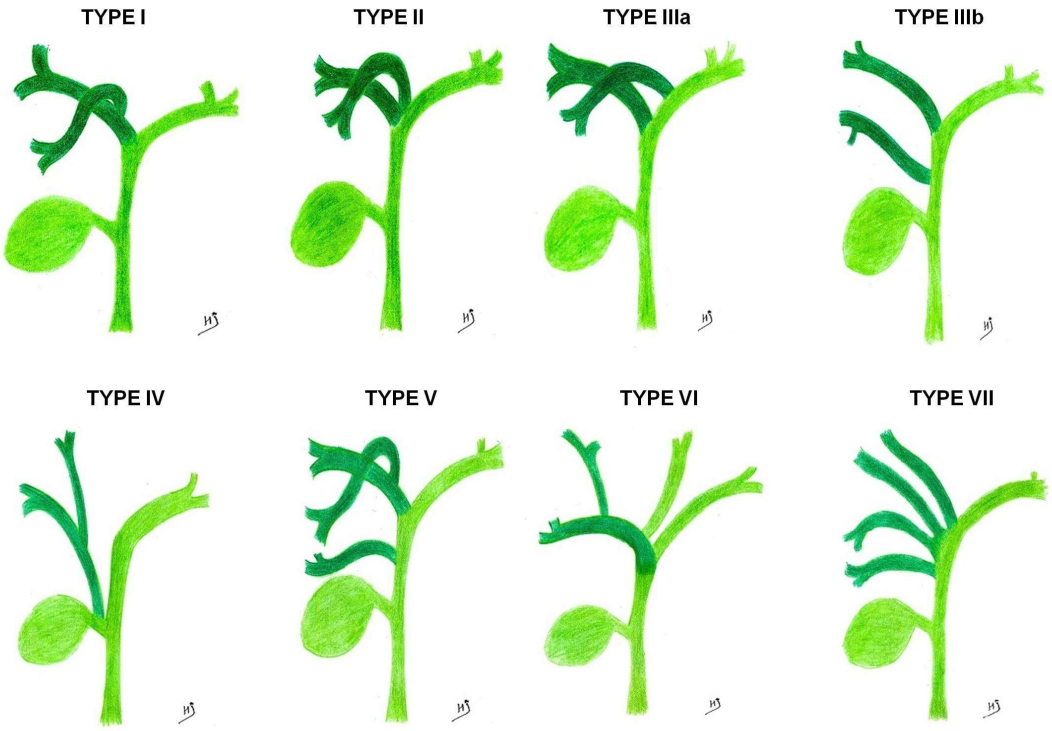
    For all cases, please use the most recent result available even if this is several weeks or months earlier for elective cases.
17. **Prior Biliary Procedures**
    a. Cholecystostomy Y/N (include any percutaneous drainage whether performed for cholecystitis or abscess regardless of the radiological method used for insertion)
    b. Subtotal cholecystectomy Y/N (any case in which a subtotal cholecystectomy was previously documented or any case in which further resection of the gallbladder or cystic duct stump has been undertaken regardless of whether the earlier procedure was listed as subtotal or total cholecystectomy)
    c. Endoscopic sphincterotomy Y/N
    d. Common bile duct stenting Y/N
    e. Other procedure Y/N (Please specify)
    f. None of the above

18. **Use of pre-operative weight loss injections**

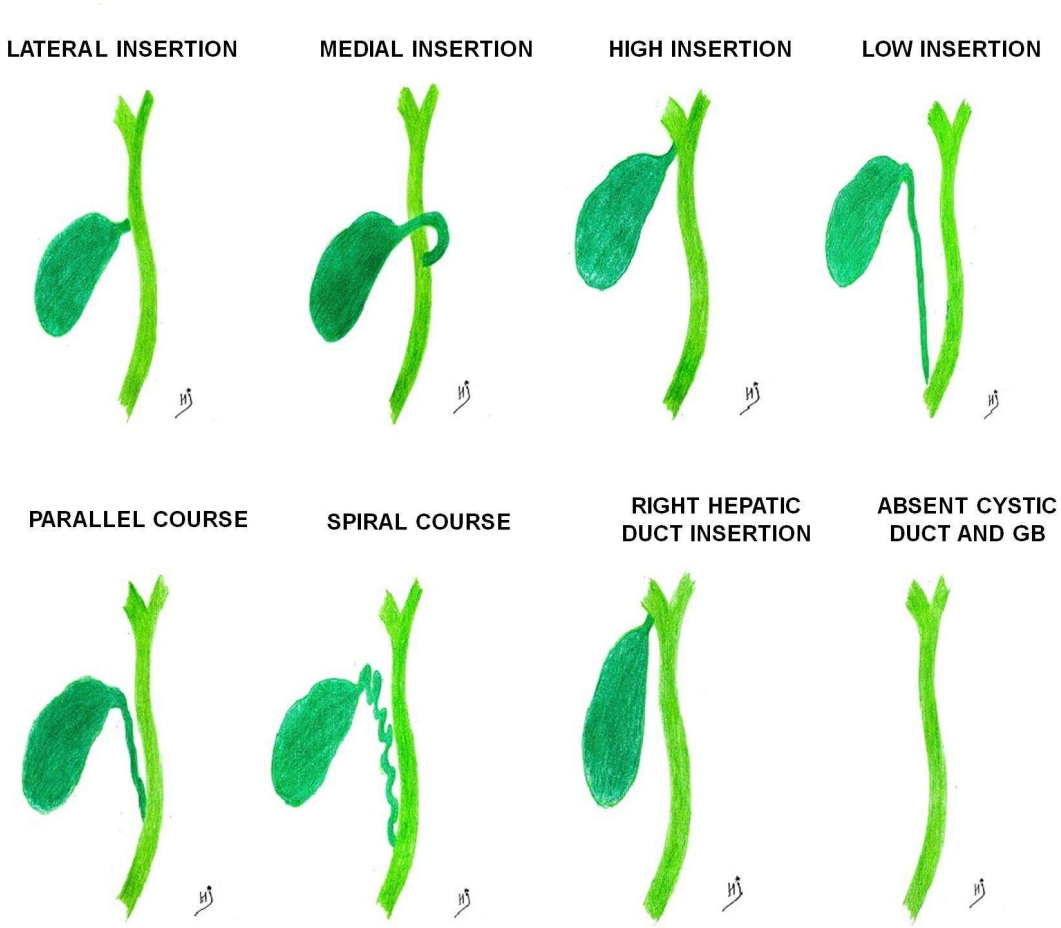
    None / Tirzepatide (Mounjaro) / Semaglutide (Wegovy/Ozempic) / Other (please specify) / Unknown

    Please include any use whether this was prescribed by a doctor, obtained through an online pharmacist or taken without prescription (e.g. supplied relative). Tick all that apply. Please include any use within previous 12 months.

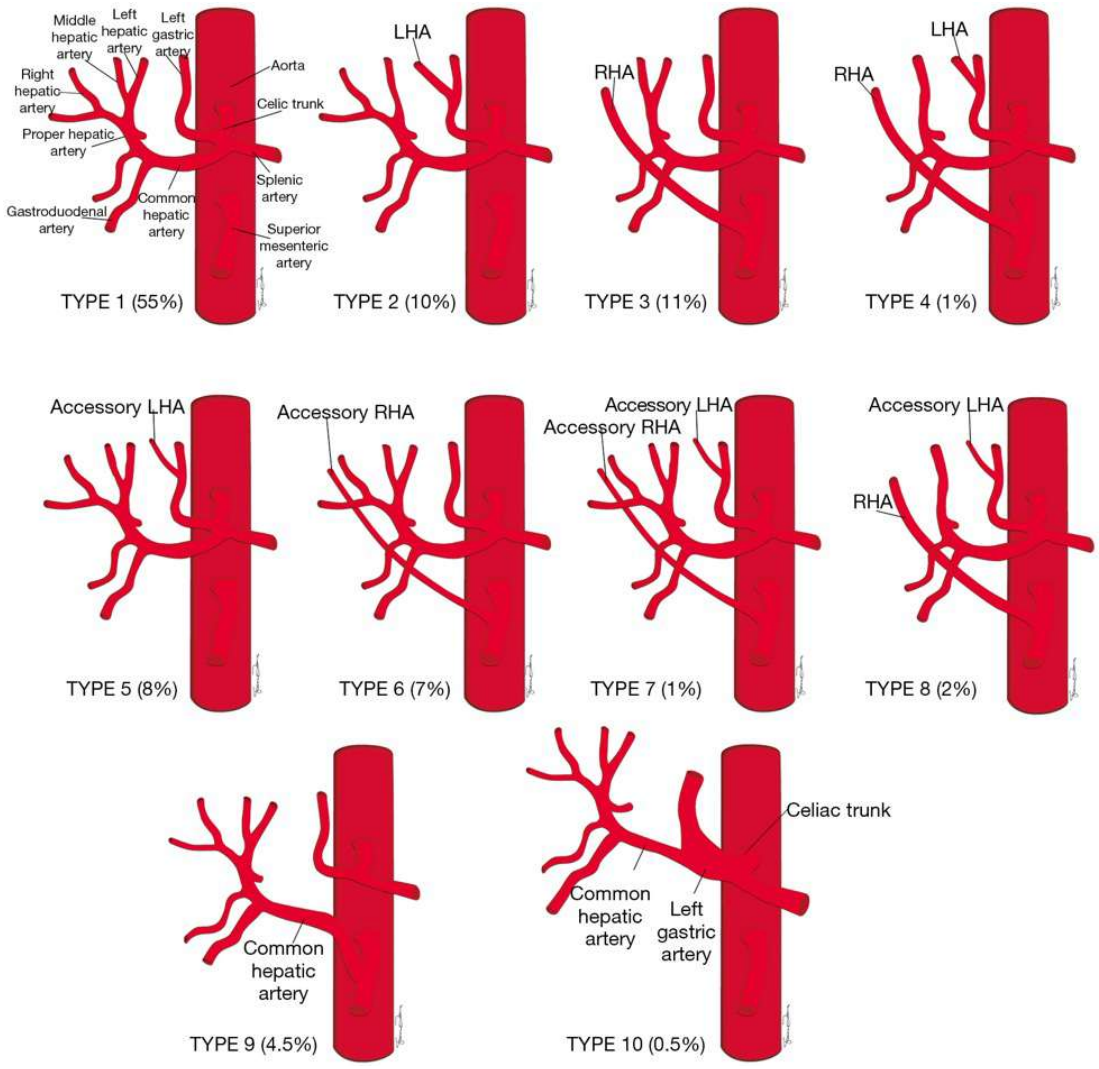
19. Please select pre-operative bile duct anatomical variant (or mark as not known)



20. Please select pre-operative cystic duct insertion (or mark as not known)



21. Please select hepatic vascular variant (or mark as not known)



Section C Operative Details

22. **Please select the hospital in which the initial cholecystectomy was performed (list full hospital name, city and country if not in drop-down list) (this data is only to be used for assisting with follow-up – this data WILL NOT be used in publication)**
    This should be the hospital in which the bile duct injury occurred in. In cases where a cholecystectomy is attempted but abandoned before transfer to another centre in which the cholecystectomy is performed, please list the centre in which the bile duct injury is believed to have been sustained.
23. **Urgency of surgery** (Appendix C for definitions)
    a. Emergency (Immediate) / Emergency (Urgent) / Semi-Elective (Expedited) / Elective
    b. If Emergency, was patient on elective WL Y/N
24. **Date of initial operation**
    Date on which primary operation, during which BDI sustained, commenced.
25. **Type of Hospital** – DGH / Teaching / Private / Treatment Centre (Or Waiting List Hub)
    Type of hospital in which the bile duct injury occurred regardless of where subsequently managed
26. **Operating Surgeon** – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Core Trainee / Other
    Consultant Senior doctor on UK or Republic of Ireland Specialist Register
    Post-CCT Fellow (Fellow who has completed UK / ROI training or equivalent and holds a valid Certificate of Completion of Training)
    Specialist registrar (trainee in general surgery with a national training number)
    Trust Grade (Locally appointed trust doctor, not on a formal training program, also including Fellows without a Certificate of Completion of Training from UK / ROI level)
27. **Most senior surgeon in theatre** – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Other
28. **Most senior Surgeon Specialty** – HPB / UGI / Colorectal / Vascular / Endocrine / Breast / Emergency / Transplant
    List the specialty of the consultant present in theatre. Where no consultant was present list the specialty of the most senior operating surgeon.

29. **Setting** – Elective Day case / Elective main theatre / Emergency / Semi-Elective
30. **Operative approach** – Open / Laparoscopic / Robotic / Laparoscopic converted to open / Robotic converted to open.
    a. If relevant, reason for open conversion – Adhesions / Unable to show Critical View of Safety / Bowel injury / Bleeding / Suspected BDI / Other (Please specify)
31. **Critical view of safety**
    a. Description in operation note of "critical view of safety" or similar term – Yes-explicitly stated / No-operation note states such a view not possible / Not documented.
    b. Is there a description of only two structures clearly seen to be connected to the gallbladder. Y/N
    c. Is there a description of the lower one third of the gallbladder being separated from the liver to expose the cystic plate.
    d. Is there a description of the hepatocystic triangle being completely cleared of all adipose and fibrous tissue.
    e. Photographs available from initial operation Y/N
        i. If Y, are these consistent with all three elements of "critical view of safety" prior to application of clips or division of cystic artery and cystic duct? Y/N
    f. Is there a description of a "time-out" performed prior to clipping ductal structures? Y/N
    See Appendix C for description of critical view of safety.
32. **Intraoperative cholangiogram -** Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
33. **Intraoperative ultrasound** Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
34. **Cholangioscopy** Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
35. **Incisionless fluorescent cholangiography** Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
36. **Intra-operative ERCP** Yes – bile duct injury suspected / Yes – bile duct injury not suspected / No
37. **Was a stone identified in the common bile duct?**
    a. Not assessed
    b. Duct clear of stones
    c. Stone(s) seen in duct but cleared intra-operatively

d. Stone(s) seen in duct and not cleared by end of procedure

38. **Intra-operative variation**
    a. Subtotal cholecystectomy (reconstituting)

Less than complete resection of the gallbladder leaving a cuff of gallbladder in addition to the cystic duct in which the open end of gallbladder is reconstituted through an Endoloop, V-loc suture or other form of closure.

    b. Subtotal cholecystectomy (fenestrating)

Less than complete resection of the gallbladder leaving a cuff of gallbladder in addition to the cystic duct in which the open end of gallbladder is left open and potentially controlled through placement of an abdominal drain.

    c. Transcystic bile duct exploration
    d. Choledochotomy (direct incision over the common bile duct or common hepatic duct, please do not include opening of the cystic duct)
        i. If choledochotomy method of closure: T-tube / primary closure / Other (please specify)
    e. T-tube
    f. Pharmacological sphincter relaxation
       Including glucagon, buscopan and any other pharmacological attempt to induce sphincter relaxation and stone passage.
    g. Fogarty catheter trawl
    h. Basket trawl
    i. Fundus first approach
    j. Placement of abdominal drain
    k. Other notable variation to standard procedure (please describe)

39. **Called for help – Y / N**
    a. Who came to help (list most senior if multiple surgeons came to help) – Consultant / Post-CCT Fellow / Specialist Registrar / Trust Grade / Other (please specify)
    b. Specialty of above - HPB / UGI / Colorectal / Vascular / Endocrine / Breast / Emergency / General / Transplant
40. **Injury recognised on table? Y/ N** Injury recognised during index cholecystectomy and not post-operatively due to complications.
41. **Were HPB centre contacted intra-operatively?** Y / N / Not applicable (already in HPB centre)

Section D Bile duct injury and management

42. **Was the bile duct injury managed at the tertiary HPB unit? Y/N**
    a. If Yes, Please select HPB centre (Hospital-specific data WILL NOT be published) – if patient had immediate management such as drain placement at the referring hospital and then transferred to the HPB unit for definitive surgery then please select "Yes"
    b. If No, Please enter the name, city and country of the hospital in which the patient was managed in. (this data is required to improve follow-up and the hospital WILL NOT be published)
    c. If No, Was the bile duct injury managed with involvement of the tertiary HPB unit?

43. **Presentation of BDI**:
    Intraoperative / Bile leak from abdominal drain / Pain due to uncontrolled bile leak/ Obstructive jaundice or cholangitis / Intra-abdominal collection or biloma / Other (please specify)
    a. Days from index cholecystectomy to bile duct injury diagnosis:
    For intra-operative diagnoses select "0"
44. **BDI Classification** – Strasberg B / C / D / E 1-5 (see Appendix C for Strasberg Classification)
45. **Referral to HPB?**
    1, Referral to HPB centre on recognition of BDI + transfer to HPB
    2, Referral to HPB centre but managed locally without transfer
    3, Injury occurred at same site as HPB centre
    4, BDI managed without any involvement of HPB centre
    a. If 1 or 2, how many days after surgery was referral made?
46. **Concomitant vascular injury** – Y / N / Unknown
    a. If yes – Right hepatic artery / Common hepatic artery / Right portal vein / main portal vein

47. **Imaging modality to confirm BDI** – On-table Cholangiogram / USS / CT / MRCP / ERCP / PTC / Tubogram / Other (Please specify) / None (no imaging necessary) select all that apply
48. **Did the patient undergo an attempted surgical repair of the BDI during the primary cholecystectomy?**
    a. Yes - attempt made initially without HPB input
    b. Yes - attempt made with input of HPB centre
    c. No - injury in HPB centre with repair delayed to second procedure
    d. No - patient referred to HPB specialist after injury recognised
    e. No - injury not recognised at time of surgery
49. **Did the patient undergo any form of surgical management of the BDI (either at the time of cholecystectomy or in a subsequent procedure)?** Yes / No – no procedure was required / No – procedure deemed inappropriate (e.g. palliation)
    a. Initial management of BDI? Primary suture repair / Primary suture repair over T-tube / Duct ligation / End-to-end bile anastomosis / Side-to-side duct anastomosis / Roux-en-Y HJ / Drain / Stent / Other (please specify) placement
        i. (For each repair method attempted) Repair successful / repair unsuccessful
        ii. Operating surgeon specialty for each type of repair HPB / UGI / Other (please specify)
        iii. Number of days after cholecystectomy for each repair (Day 0 is date of initial cholecystectomy)
50. **Vascular repair** – Y / N
51. **Did the patient undergo percutaneous transhepatic biliary drainage?** Y / No (not available) / No (contraindicated) / No (not indicated)
    Select "No (not available)" if the procedure was not possible at the time the patient required this intervention (either due to no availability at the managing centre or due to no availability at the specific time the patient required intervention e.g. out of hours).

Section E 30-day outcomes

52. **Admission to critical care** – Y / N

   a. **Total length of stay in critical care** (count day of admission as day 1)

53. **Total length of hospital stay from index cholecystectomy?** Stay in days where day 0 is the day of the index cholecystectomy.
54. **Mortality during index admission or within 30 days?** Y/N
    a. If yes, list day of death with day 0 being day of index procedure:
55. **Highest 30-day Clavien Dindo Complication Grade**: I, II, IIIa, IIIb, IVa, IVb, V (Appendix C for Clavien Dindo Complication classification)
56. **Specific complications (select relevant CD grade):**
    a. **Surgical site infection**
    b. **Post-operative pulmonary complication**
    c. **Bile leak**
    d. **Bleeding**
    e. **Intra-abdominal collection**
    f. **Acute pancreatitis**
57. **Unplanned re-admission within 30 days of surgery** (list any unplanned admission regardless of cause) Y/N
    a. If so, readmission length of stay (whole number of days)

Section F Long-term Follow-up

58. **Mortality during 1-year follow-up**
    a. If yes, list day of death with day 0 being day of index procedure:
59. **Please give number of readmissions within first year from index procedure**
60. **Complications within 1 year (select all the apply)** – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / Re-repair / None
61. **Highest LFT value within 1 year**
    a. Bilirubin
    b. Alkaline Phosphatase
    c. Gamma glutamyl transferase
62. **Mortality during 2-year follow-up**
    a. If yes, list day of death with day 0 being day of index procedure:
63. **Please give number of readmissions within two years from index procedure** (include all admissions within first two years)
64. **Complications within 2 years (select all the apply)** – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / Re-repair / None

65. **Highest LFT value from 12-24 months after bile duct injury**
    a. Bilirubin
    b. Alkaline Phosphatase
    c. Gamma glutamyl transferase
66. **Mortality during 3-year follow-up**
    a. If yes, list day of death with day 0 being day of index procedure:
67. **Please give number of readmissions within three years from index procedure (include all admissions within the first three years)**
68. **Complications within 3 years (select all the apply)** – Stricture / Cholangitis / Anastomotic leak / intra-abdominal collection or biloma / Re-repair / None
69. **Highest LFT value from 24-36 months after bile duct injury**
    a. Bilirubin
    b. Alkaline Phosphatase
    c. Gamma glutamyl transferase

Appendix C – Study definitions

1. American Society of Anesthesiologists (ASA) Classification ASA Classification

Definition Examples

Grade I: A normal healthy patient Healthy, non-smoking, no or minimal alcohol use.

Grade II: A patient with mild systemic disease Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease

Grade III: A patient with severe systemic disease Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.

Grade IV: A patient with severe systemic disease that is a constant threat to life Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis

Grade V: A moribund patient who is not expected to survive without the operation Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction.

2. Indication for Surgery Definitions

Biliary colic The presence of colicky right upper quadrant pain associated with gallstones or sludge on an USS, but no signs of acute cholecystitis.

Acute calculous cholecystitis Clinical (right upper quadrant pain, with or without fever, WCC > 11 × 109/l) OR ultrasound evidence (thick-walled gallbladder (≥ 3mm), OR USS tenderness over the gallbladder, the presence of gallstones)

Acute acalculous cholecystitis Clinical OR ultrasound evidence (thick-walled gallbladder and/or pericholecystitis, USS tenderness over the gallbladder) in the absence of gallstones

Chronic calculous cholecystitis Previous clinical or ultrasound evidence (thick-walled gallbladder and/or pericholecystitis, OR USS tenderness over the gallbladder OR the presence of gallstones) of cholecystitis

Common bile duct stone Common bile duct stones, as confirmed by before or at the time of surgery.

Gallbladder polyp Hyperechoic lesions on USS imaging which have no acoustic shadow and do not move with positional changes, with no overt features of malignancy.

3. Tokyo Guidelines 2018 for Grading of Acute Cholecystitis

Grade I (mild): No organ dysfunction and mild inflammatory changes in the gallbladder.

Grade II (moderate): o Elevated WBC count (>18,000/mm3) o Palpable tender mass in the right upper abdominal quadrant o Duration of complaints >72 hours o Marked local inflammation (gangrenous cholecystitis, pericholecystic abscess, hepatic abscess, biliary peritonitis, emphysematous cholecystitis)

Grade III (severe): o Cardiovascular dysfunction: hypotension requiring treatment with dopamine ≥5 μg/kg per min, or any dose of norepinephrine or Neurological dysfunction: decreased level of consciousness o Respiratory dysfunction: PaO2/FiO2 ratio <300 o Renal dysfunction: oliguria, creatinine >2.0 mg/dl o Hepatic dysfunction: PT-INR >1.5 o Haematological dysfunction: platelet count <100,000/mm3

4. Urgency of Surgery

The urgency of index cholecystectomy is defined as:

Elective: planned elective admission for cholecystectomy via a routine surgical waiting list from the outpatient department only. Patients on an elective waiting list treated as an emergency should be classed as 'acute' cases.

Delayed: all other planned cholecystectomies; for example, patients who have had one or more acute admissions with biliary symptoms but then discharged for a planned procedure on an elective operating list.

Emergency: emergency admission with biliary disease through the Emergency Department or primary care, and cholecystectomy performed during that emergency admission.

5. Critical View of Safety

I) Clear Cystohepatic Triangle (borders: common hepatic duct, cystic duct and inferior service of liver):

The triangle must be completely cleared of all fat and fibrous tissue.

II) Two structures entering the gallbladder:

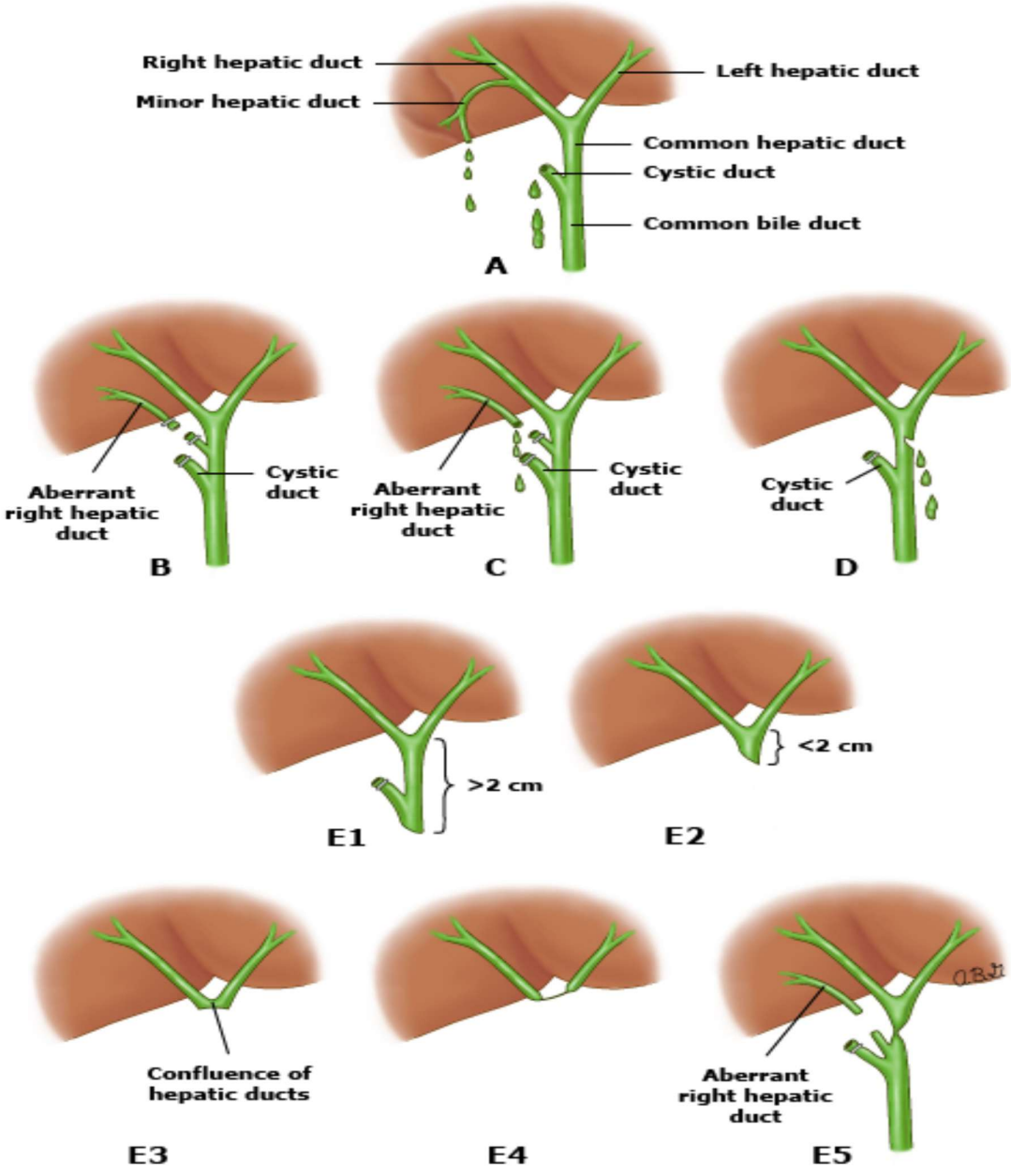
Only two structures attached to the gallbladder, which are the cystic duct and the cystic artery.

III) Gallbladder dissected from the Cystic Plate:

The lower one third of the gallbladder should be completely separated from the underlying liver's cystic plate.

6. Common bile duct injury: Any injury to the main biliary tree will be classified using the Strasberg Classification System (see diagram below):

In this registry we will only include patients with Strasberg grade B to E injuries.



Description of injury grades:

A – leak from cystic duct or small duct in liver bed

B – occlusion of an aberrant right hepatic duct

C – leak from an aberrant right hepatic duct

D – lateral injury to the common hepatic or bile duct (<50% of circumference)

E1 – transection or stricture of common hepatic or common bile duct >2cm from the hilum.

E2 - transection or stricture of common hepatic duct <2cm from the hilum.

E3 – Transection of the common hepatic duct at the level of the bifurcation without loss of contact between left and right hepatic duct.

E4 – Transection of the common hepatic duct at the level of the bifurcation with loss of communication between the left and right hepatic duct.

E5 – injury of a right segmental duct combined with an E3 or E4 injury.

7. Clinical Frailty Scale:

i) Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

ii) Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.

iii) Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.

iv) Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up", and/or being tired during the day.

v) Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

vi) Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.

vii) Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

viii) Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

ix) Terminally Ill - Approaching the end of life. This category applies to people with a life expectancy

8. Clavien Dindo Complications

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TABLE 1. Classification of Surgical Complications

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions
	Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications
	Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix "d"	If the patient suffers from a complication at the time of discharge (see examples in Table 2), the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks.
CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.