

## Management of Common Bile Duct (CBD) Stones and ERCP/ PTC Preparation - Full Clinical Guideline

Reference no.: CG-T/2014/193

### 1. Introduction & Purpose

Between 3-16% of patients with symptomatic gallstones have common bile duct (CBD) stones. They can result in a number of complications including pain, jaundice, cholangitis and acute pancreatitis. Extraction of CBD stones is recommended in patients without symptoms, however the evidence suggests the benefit is greatest in symptomatic patients. A number of different imaging modalities can be used to confirm them and management can be surgical, endoscopic or radiological. The following guidelines provide recommendations for the clinician when managing patients with CBD stones.

### 2. Definitions, Keywords

Royal Derby Hospital (RDH), Common bile duct stones (CBDS), Gallbladder (GB), Post ERCP Pancreatitis (PEP), Liver Function Tests (LFTs), Ultrasound Scan (USS), Magnetic Resonance Cholangio-Pancreatography (MRCP), Endoscopic Ultrasound (EUS), Laparoscopic Ultrasound (LUS), Intraoperative cholangiogram (IOC), Endoscopic Retrograde Cholangio-Pancreatography (ERCP), Laparoscopic Common Bile Duct Exploration (LCBDE)

### 3. Complications of CBD stones

- Pain
- Jaundice - Obstruction of the bile duct by a stone
- Ascending cholangitis- infection of partially or completely obstructed duct
- Pancreatitis - obstruction of biliopancreatic duct may lead to premature activation of enzymes in pancreas

### 4. Investigation for CBD stones ( Appendix: Figure 1)

Investigating CBD stones is recommended in all patients presenting with epigastric or right upper quadrant pain, particularly in those associated with jaundice, fever or acute pancreatitis. The following are the investigations available for identifying CBD stones:

- Liver function tests (LFTs) and transabdominal USS - Both are recommended in patients with suspected CBD stones, although normal results do not prevent further investigation, specifically in situations where the clinical suspicion remains high.
- MRCP and EUS - Both are highly accurate methods of identifying CBD stones when there is a moderate probability of disease.

EUS is superior to MRCP in detecting stones <5mm in size (MRCP sensitivity falls from 93 to 71% for stones <5mm).

There is comparable sensitivity/specificity of each investigation for stones >5mm in size, 95%/97% for EUS and 93%/96% for MRCP, respectively. The advantages of MRCP are that it is widely available, minimally invasive, allows for imaging of the intrahepatic ducts, cost effective and more suitable in patients with altered gastric or duodenal anatomy. Conversely, the advantages of EUS are that it can be used in patients where MRI is contraindicated or not tolerated due to claustrophobia. MRCP images may be equivocal in morbid obesity. MRCP is therefore the primary modality used with EUS reserved where there are contraindications to MRI or when the results of MRCP are equivocal.

EUS should also be considered in patients where a cause for pancreatitis has not been found, in order to look for evidence of microlithiasis. Meta-analyses show that in around 61% of cases, aetiology can be established by EUS. This includes the detection of microlithiasis or biliary sludge (41%), for which cholecystectomy is required to prevent recurrent pancreatitis.

- CT - Not routinely used for identifying CBD stones (sensitivity 69-87%, specificity 68-96%) but has an important role to play in identification and staging of malignant biliary obstruction. It's accuracy in diagnosing CBD stones falls considerably if the stone is small or has a similar density to bile. In patients older than 45 years where a CBD filling defect is identified with non-cross sectional imaging, CT is useful in differentiating between a stone, stricture and a polypoid lesion.

For a suggested pathway in diagnosing suspected CBD stones, please see **Appendix Figure 1**.

## 5. Management of CBD stones

CBD stones can be effectively treated via either ERCP or laparoscopic common bile duct exploration (LCBDE). When considering the preferred treatment for an individual patient, it is important to take into consideration whether they still have their gallbladder in situ and whether their age and/ or co-morbidity preclude general anaesthesia and surgery. Any patient in whom cholecystectomy would be planned following an ERCP, should be discussed with a surgeon with the ability to perform LCBDE to see whether single stage surgery as opposed to ERCP followed by cholecystectomy is preferred.

## 6. General consideration with endoscopic management of CBD stones (ERCP)

- Biliary sphincterotomy and endoscopic stone clearance is recommended as a primary form of treatment for patients with CBD stones post cholecystectomy. The exception is in those post bariatric or gastric surgery patients where ERCP would not be possible due to altered anatomy making the ampulla inaccessible. In these patients LCBDE should be considered.

- ERCP should also be considered when patients have evidence of acute cholangitis, as this is a relative contraindication to choledochotomy, or when the gallbladder is still present and due to significant co-morbidity the patient is not a surgical candidate.
- ERCP is an effective method of treating CBD stones with high rates of clearance, although there is also a potential for adverse events including acute pancreatitis, bleeding, perforation and biliary sepsis.

#### **Managing risk of bleeding prior to ERCP**

- Patients undergoing biliary sphincterotomy for ductal stones should have an FBC and INR performed pre-ERCP. Patients should have an INR < 1.4 and platelets  $\geq 70,000$  within 72 hours of the procedure before a sphincterotomy can be performed.
- If coagulation can't be corrected then initial therapy should involve a procedure that is inherently associated with a lower risk for bleeding such as endoscopic stenting.
- Warfarin should be stopped 5 days before the procedure and the INR repeated to ensure < 1.4 prior to the procedure. Direct oral anticoagulants – DOAC (e.g Rivaroxaban, Apixiban) should be stopped 48hrs prior to the procedure.
- In patients prescribed clopidogrel for a high risk heart condition, liaison with a cardiologist is advised prior to discontinuation.
- In patients on clopidogrel for other indications, then it should be stopped at least 7 days before ERCP to perform a sphincterotomy.
- Biliary sphincterotomy can be safely performed in patients taking Aspirin and prophylactic low molecular weight heparin.

#### **Endoscopic papillary balloon dilation (EPBD)**

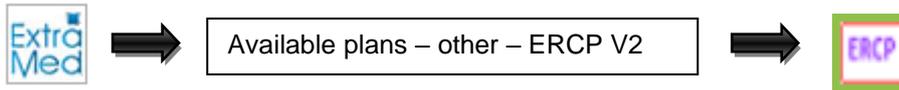
- EPBD is recommended as a technique to facilitate removal of large CBD stones.

#### **Role of Cholangioscopy (Spyglass ERCP)**

- Cholangioscopy or Spyglass ERCP guided electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL) should be considered in non-surgical candidates when other endoscopic treatment options fail to achieve duct clearance.
- Patients currently require referral to tertiary centre that provides Spyglass ERCP service. The closest tertiary referral centre to UHDB is Nottingham University Hospitals NHS Trust. The referring clinician should bear in mind that Spyglass ERCP for extraction of large CBD stones requires general anaesthetic.

## 7. Local RDH approach for ERCP (Appendix Figure 2)

- At present ERCP referrals can be made either via ICM or through the electronic whiteboard using the extramed icon on the flo website. The electronic white board request will be withdrawn when the ICM form moves to Lorenzo.  
(<http://extramed/pfm/Security/Authentication/login>)



- Indications
  - Removal of CBD stones. Primary form of treatment post cholecystectomy except in patients following bariatric or gastric surgery. It should also be considered when the gallbladder is still in place and the patient is not a surgical candidate.
  - Stenting of biliary strictures.
  - Biliary decompression in acute cholangitis (15-30% fail to respond to antibiotic therapy).
  - Acute severe (3 or more Glasgow/Ranson criteria) pancreatitis of suspected/proven biliary origin i.e. evidence of biliary obstruction (dilated CBD on trans-abdominal USS) or biliary sepsis (bilirubin > 90, Temperature > 39°C) and deterioration despite 48 hours of conservative management. Patients should undergo biliary sphincterotomy +/- stone extraction within 72 hours. Non-jaundiced patients with mild pancreatitis do not require ERCP (cholecystectomy within 2 weeks).
- Complications
  - Post-ERCP pancreatitis (1.3-6.7%). The risk is as high as 25% for patients undergoing ERCP for sphincter of oddi dysfunction (SOD).
  - Gastrointestinal haemorrhage (0.7-2%)
  - Cholangitis (0.5-5%)
  - Duodenal perforation (0.3-1%)
  - Miscellaneous, including cardiorespiratory (0.5-2.3%)

- The risk of complications is increased if :
  - Age < 60 years
  - Female patient
  - Low probability of structural disease – normal bilirubin, non-dilated CBD, suspected SOD
  - Cirrhosis
  - Previous post ERCP pancreatitis
  - Coagulopathy
  - Biliary sphincterotomy or sphincteroplasty
- Preparation
  - Consent the patient (designated ERCP consent forms available)
  - FBC/INR within 72 hours of procedure. An INR  $\geq 1.4$  and/or platelets < 70,000 will need correcting pre-ERCP (biliary obstruction is associated with vitamin K malabsorption and any coagulopathy will usually correct within 12 hours of IV Vit. K)
  - Biliary sphincterotomy can be safely performed on patients taking Aspirin and prophylactic low-dose Heparin. Clopidogrel should be stopped for 7 days. The endoscopist should give guidance on when to restart anticoagulation/antiplatelet therapy post-sphincterotomy though in most cases this will not be before 48 hours
  - Prophylactic antibiotics (Ciprofloxacin 750mg orally 1hr pre-procedure) should be prescribed to all patients. If a patient is currently prescribed antibiotics for cholangitis then additional prophylactic antibiotics are not required
  - Diclofenac 100mg PR (1hr pre-procedure) should be given **except** in those with an eGFR <30 or where clear contraindications, in order to reduce incidence of post-ERCP pancreatitis
  - 500ml 0.9% saline should be given over 1hr prior to the procedure to reduce risk of dehydration and renal impairment post procedure.
- Procedural considerations
  - CBD stone clearance should be possible in >90% of cases (though up to 25% may require more than 1 ERCP).
  - A biliary stent as treatment for CBD stones should be seen as a bridge to definitive treatment and long-term stenting should be restricted to patients with a limited life expectancy.
  - Placement of a pancreatic stent may reduce the risk of ERCP related pancreatitis in patients at high risk (e.g. prolonged/pancreatic duct

cannulation, pre-cut, SOD patient). Early removal of the stent should be organised if it fails to migrate spontaneously (assessed on AXR at 2 weeks post-insertion).

## 8. Ultrasound guided decompression of the biliary system with percutaneous transhepatic cholangiography (PTC) – Appendix Figure 3

- At RDH PTC is preferred as first line approach in patients with hilar strictures. Cases should be discussed with an ERCP endoscopist and HPB radiologist.
- PTC should be offered to patients who are critically ill and are unable to undergo ERCP.
- It should also be offered to patients with cholangitis where ERCP would not be possible due to altered anatomy or where patients that have had an unsuccessful ERCP following discussion with the endoscopist.
- Patients should have stopped clopidogrel for 7 days, Warfarin for 5 days, Aspirin for 5 days, DOAC for 48hrs and therapeutic LMWH for 24hrs prior to the procedure. Ensure Hb > 80, Plts > 50 and INR ≤ 1.5. Patients should be Nil to eat for 6hrs and clear fluids only up until 3hrs before procedure. Patients will often benefit from the administration of iv fluids in the period before and after PTC. This should, however, be assessed on an individual basis following review of blood results and patients clinical stability, NBM status and how long the patient has not been taking diet and fluids (clinical condition and background). If needed please seek guidance from Hepato-Biliary Consultant or Interventional Radiology Consultant.
- Co-amoxiclav 1.2g (or Gentamicin 1.5 mg/kg and Metronidazole 500mg iv if penicillin allergic), cyclizine 50 mg and Diclofenac 100mg PR (provided eGFR > 60) 1hr pre-procedure. Add Teicoplanin 400mg iv if known MRSA carriage ([comprehensive antibiotic guidance for IR procedures is available via the trust guidelines page](#)).
- Patients should also receive oral loading dose of paracetamol:
  - Adult patients <65kg = 1500mg
  - Adult patients >65kg = 2000mg
  - In accordance with the [Guideline for Oral Loading Doses of Paracetamol in Adults prior to Theatre](#)
- Consent the patient for:
  - Bleeding
  - Bile leak
  - Failure
  - Infection/bacteraemia
  - Pancreatitis

## 9. Surgical management of CBD stones (Appendix Figure 4)

- In patients with a gallbladder insitu, laparoscopic common bile duct exploration (LCBDE) has been reported to be as effective as ERCP in achieving duct clearance. Furthermore it is associated with a shorter hospital stay and reduced cost.
- LCBDE has reported morbidity rate of 4-16% and mortality rates of 0-0.8%. LCBDE mitigates the risk of pancreatitis seen in patients following ERCP.
- The Derby Pancreaticobiliary Unit is a high volume centre for LCBDE. Our approach is to offer a single stage surgical approach in all patients fit for surgery when there is no evidence of cholangitis.
- LCBDE can take either a trans-cystic (via the cystic duct – non dilated CBD with < 3 mobile distal CBD stones) or a transductal (via the CBD) approach (Figure 3).
- Pre-operative MRCP in patients with confirmed CBD stones can facilitate planning the operative approach for LCBDE by delineating the anatomy of the biliary tree including the cystic duct (important for cases that require transcystic LCBDE) and anatomy of the ductal stones.
- Although MRCP provides valuable preoperative information it is not mandatory in patients below the age of 45 and in those with improving LFTs when malignancy is unlikely. In this group of patients IOC will provide the necessary information about anatomy of the CBD and bile duct stones.
- Cross sectional imaging (CT scan) should still be performed in patients with symptoms that may have clinical concerns of malignancy, independent of age.
- Patients with <3 small, non-impacted stones in the distal CBD and a non-dilated biliary system (<8mm CBD), CBD exploration should be approached via transcystic route.
- The trans-cystic approach is difficult in patients with long, tortuous cystic ducts. There are common bile duct exploration kits (Nathanson Transcystic Bile Duct Stone Exploration Pack Cook® Medical) available with cystic duct balloon plasty devices that can be used to assist in manoeuvring through tortuous cystic duct. This procedure is performed under fluoroscopic guidance without direct visualisation of the CBD. Appropriate training and experience would be required before use of this specialist equipment.
- Failure to clear the CBD via the transcystic route due to unfavourable anatomy of the cystic duct and therefore failure to access the bile duct, migration of the stones proximally into the common hepatic duct or large distal CBD stone/s should lead to a transductal CBDE when the CBD is dilated (>8mm). Post-operative ERCP should be performed when the CBD is <8mm.
- Patients with a dilated CBD (>8mm) and a high stone load/several large (>1cm)/ impacted stones should be managed by a transductal approach for LCBDE.

- The most important factor for transductal exploration is the presence of dilated CBD (>8mm). This is to prevent CBD stricture post closure. At RDH our routine practice is to perform a vertical choledochotomy using a choledochotome. Closure of the duct is performed by continuous suturing with a 4/0 Vicryl (braided absorbable) suture.
- Assessment of CBD size can be made by either preoperative MRCP or intraoperative on-table cholangiogram (IOC). With experience assessment of CBD size can be assisted by direct visualisation during laparoscopy.
- IOC is performed in all patients with suspected CBD stones (previously deranged LFTs, dilated CBD on USS or previous pancreatitis) or proven stones on preoperative imaging (MRCP). Stone migration is a dynamic process and imaging with IOC performed during the operation is the most reliable means of confirming the presence or absence of CBD stones.
- IOC confirming absence of CBD stones when preoperative imaging (MRCP/CT scan) demonstrated presence of CBD stones can avoid unnecessary CBD intervention.
- IOC which is equivocal where the CBD is dilated +/- absence of contrast in the duodenum on the background of a patient with previous pancreatitis or roux en y reconstruction (at level of stomach/oesophagus) then transcystic LCBDE should be performed where the cystic duct anatomy is favourable.
- Completion IOC should be performed via cystic duct in cases where there is a significant stone load, there has been use of a lithotripter (concerns of proximal migration of stone fragments into the intrahepatic ducts) or in patients with Roux-en-y gastric reconstruction to increase confidence of CBD clearance. In cases where the IOC is positive this should lead to further choledochoscopy and clearance. If subsequent IOC remains equivocal then T-tube should be placed for percutaneous access to the CBD.
- T-tube should also be placed when patients return to theatre with biliary peritonitis following LCBDE, where the dominant cause of bile leak is via the suture line.
- Patients with preoperative imaging (MRCP) confirming a CBD stricture should be discussed at the HPB MDT with a view to confirming benign nature (ERCP and brushings) and remodelling of CBD with ERCP guided placement of covered metal stents before considering cholecystectomy.
- Primary duct closure without T-tube insertion is superior to planned T-tube insertion with reduction of hospital stay. In addition primary duct closure is associated with a shorter operative time and a faster return to work.
- Patients that have had a previous cholecystectomy should proceed to ERCP except in those patients that are post bariatric surgery where the option of LCBDE should be considered. If patients are unfit for surgery then Spyglass ERCP should be considered.
- Advancing age is associated with increased mortality from LCBDE in contrast to ERCP where age does not appear to impact on complication rates. This is likely due

to the association of increasing age with co-morbidity. Limitations in performing a LCBDE should be based on fitness and whether or not cholangitis is present.

- Patients with acute cholangitis secondary to a common bile duct stone who have failed to respond to antibiotic therapy or have signs of septic shock require urgent decompression via ERCP. In this setting endoscopic CBD stone extraction +/- biliary stenting or biliary stenting alone is recommended. If the patient is considered too unwell for ERCP then percutaneous transhepatic cholangiogram (PTC) should be considered (Section 8).
- In young patients with cholangitis where the endoscopist believes ERCP will be unsuccessful due to complexity of the stone disease or would like to avoid sphincterotomy then placement of a straight stent is preferred as a bridge to definitive LCBDE.
- A biliary stent placed as an intermediate step to surgery should be removed at LCBDE and sent for microscopy, culture and sensitivity.
- Local RDH audit has confirmed that biliary stents that are removed during LCBDE will often culture bacteria which will culture resistant strains of bacteria which require discussion with Microbiologist.
- 15-37% of patients with a GB left post-clearance of CBD stones at ERCP will require a cholecystectomy within 5 years. Cholecystectomy at the time of the initial presentation is preferred due to a lower risk of complications compared with patients undergoing the operation following a subsequent presentation with complications of gallstones.

Special considerations:

Pregnancy

- Laparoscopy has become the preferred treatment modality for many surgical diseases in the gravid patient.
- IOC and ERCP exposes the mother to minimal amount of radiation and maybe used selectively during pregnancy with shielding of the lower abdomen.
- Evidence suggests that laparoscopy can be carried out safely during any trimester of pregnancy without increased risk to mother or foetus.
- Pregnant patients from the second trimester should be placed in left lateral decubitus position to minimise compression of the vena cava.
- CO2 insufflation pressure of 10-15 mmHg can be used safely in pregnant patients, however CO2 monitoring should take place with capnography during the procedure.
- CBDS can be managed safely during pregnancy with preoperative ERCP followed by laparoscopic cholecystectomy, laparoscopic cholecystectomy and LCBDE or laparoscopic cholecystectomy followed by ERCP. Comparative studies in this patient group are lacking.
- At RDH the primary approach is surgery and ERCP would only be offered if surgery is contraindicated (cholangitis).
- Foetal heart rate monitoring should take place both pre and post operatively.

Previous Bariatric Surgery

- When cholecystectomy is performed prior to bariatric surgery, routine IOC should be performed irrespective of LFTs, size of common bile duct or previous pancreatitis.
- Post roux-en-y gastric bypass (RYGB), sleeve gastrectomy or any oesophogastric resectional surgery- The primary choice of treatment is LBCDE. If this fails then a forward viewing scope, push enteroscopy assisted ERCP or laparoscopic assisted ERCP can be performed through the remnant stomach, although success of this method is poorly reported.

Biliary Immunofluorescence Cholangiography (BIC)

- Use of Immunofluorescence cholangiography in biliary operations lacks evidence by way of improving safety although it is in our view a promising new technology.
- Early experience at RDH with BIC has confirmed inconsistent visualisation of the CBD, usually making it difficult in cases where the CBD is thickened.
- Additional advantage may be present in visualising small ductal bile leaks (Lushka) from the liver bed.

### Laparoscopic US (LUS)

- LUS is essential to a department that is performing advanced laparoscopic pancreaticobiliary surgery. It is required to improve safety and correct identification of the CBD when performing LCBDE in special cases.
- LUS should be used in patients allergic to contrast, in those having revisional LCBDE surgery, complex history of liver abscess/ choledochoduodenostomy/ hepaticojejunostomy or post laparoscopic/open cholecystectomy where there will be inflammation/scarring/thickening expected in the hepatoduodenal ligament.
- Following exposure and confirmation of the CBD with LUS. The CBD should be aspirated with a long abocath to confirm aspiration of bile before making a choledochotomy.

### Medical treatment of CBD stones

- Ursodeoxycholic acid (UDCA) is licensed for treatment of gallstones but there is no evidence it reduces symptoms in the majority of patients with stones. The exceptions are:
  - During rapid weight loss (>1.5Kg/week) post bariatric surgery for 6 months
  - Patients with low phospholipid associated cholelithiasis (LPAC) due to mutation of ABCD4 gene. These patients typically develop cholesterol gallstone disease before the age of 40 years, have 1<sup>st</sup> degree relatives with gallstone disease, have recurrent symptoms post cholecystectomy and are prone to intrahepatic duct stones.
  - Patients on somatostatin analogues

## 10. References (including any links to NICE Guidance etc.)

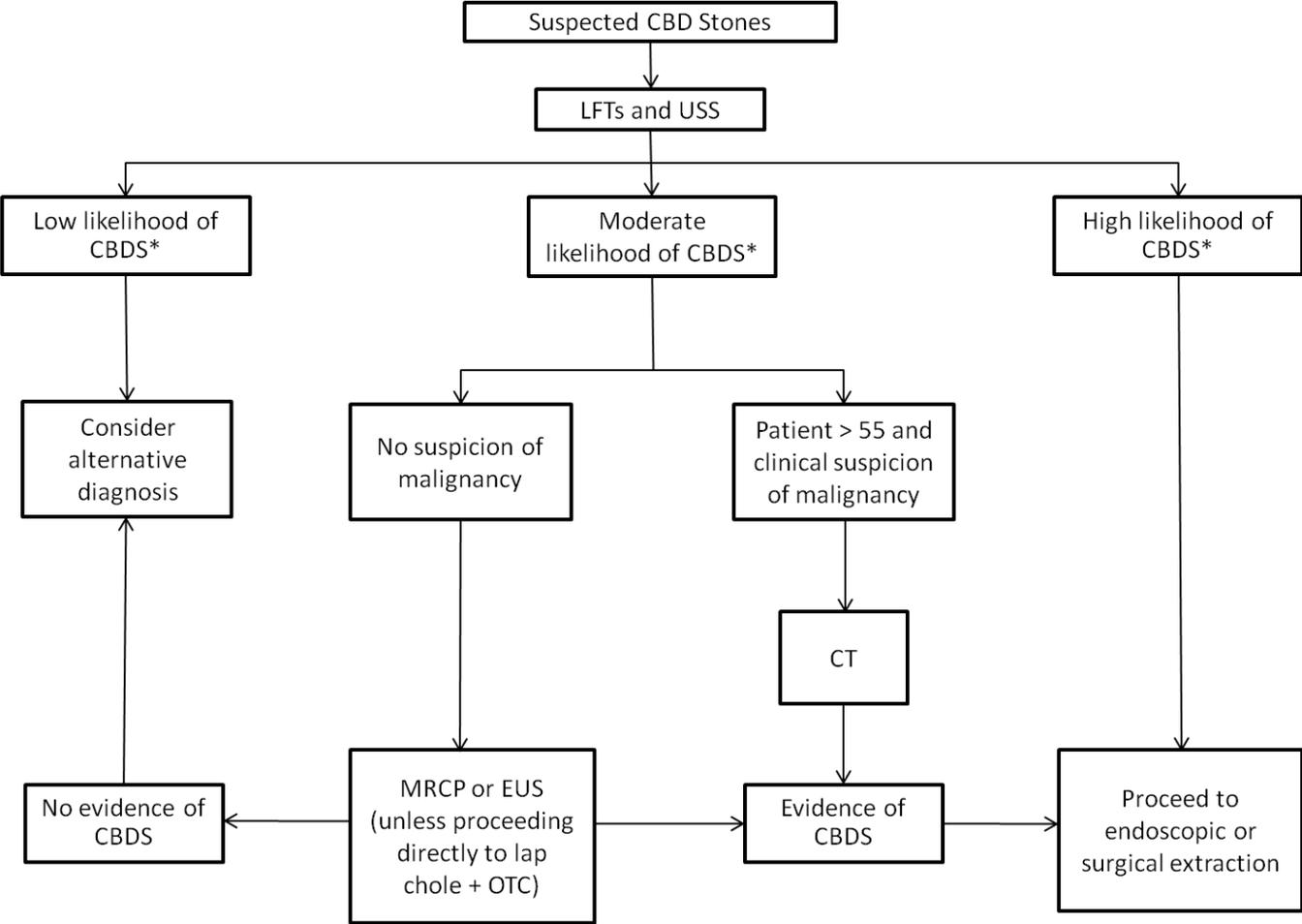
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**11. Documentation Controls**

Development of Guideline:	Mr Imran Bhatti, Dr Adam Lawson and Mr Altaf Awan
Consultation with:	HPB medical and surgical teams
Approved By:	<i>Discussed at Derby and Burton HPB operational meeting 11.12.19 Revision of ERCP guidance agreed 23.4.20 (Dr A Lawson, Dr A Austin, Dr N Taylor) Medical Division 04/05/2020</i>
Review Date:	May 2023
Key Contact:	Dr Adam Lawson

Appendices

Figure 1- Investigation of suspected CBD stones

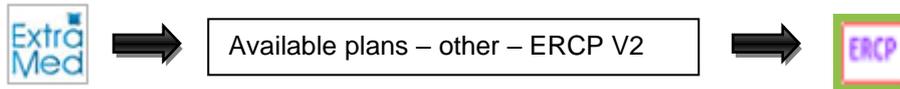


\*low likelihood= normal USS/LFTs and low clinical suspicion; moderate likelihood= CBD dilatation on USS with normal LFTs or abnormal LFTs with normal CBD on USS; high likelihood= CBD stone on USS, feature of cholangitis or pain/duct dilatation/jaundice in a patient with a history of gallstones

## Figure 2- Preparation and considerations for ERCP

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(<http://extramed/pfm/Security/Authentication/login>)



### Preparation

- Consent the patient (designated ERCP consent forms available)
  - Post-ERCP pancreatitis (1.3-6.7%). The risk is as high as 25% for patients undergoing ERCP for sphincter of oddi dysfunction (SOD).
  - Gastrointestinal haemorrhage (0.7-2%)
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  - Miscellaneous, including cardiorespiratory (0.5-2.3%)
- FBC/INR within 72 hours of procedure. An INR  $\geq 1.4$  and/or platelets  $< 70,000$  will need correcting pre-ERCP (biliary obstruction is associated with vitamin K malabsorption and any coagulopathy will usually correct within 12 hours of IV Vit. K)
- Biliary sphincterotomy can be safely performed on patients taking Aspirin and prophylactic low-dose Heparin. Clopidogrel should be stopped for 7 days, DOAC for 48hrs and warfarin for 5 days with repeat INR. The endoscopist should give guidance on when to restart anticoagulation/antiplatelet therapy post-sphincterotomy though in most cases this will not be before 48 hours
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- Diclofenac 100mg PR (1hr pre-procedure) should be given **except** in those with an eGFR  $< 30$  or where clear contraindications to reduce incidence of post-ERCP pancreatitis
- 500ml 0.9% saline should be given over 1hr prior to the procedure to reduce risk of dehydration and renal impairment post procedure.

### Figure 3- Preparation and considerations for PTC

- Patients should have stopped clopidogrel for 7 days, Warfarin for 5 days, Aspirin for 5 days, DOAC for 48hrs and therapeutic LMWH for 24hrs prior to the procedure.
- Ensure Hb > 80, Plts > 50 and INR ≤ 1.5
- Patients should be Nil to eat for 6hrs and clear fluids only up until 3hrs before procedure. Patients will often benefit from the administration of iv fluids in the period before and after PTC. This should, however, be assessed on an individual basis following review of blood results and patients clinical stability, NBM status and how long the patient has not been taking diet and fluids (clinical condition and background). If needed please seek guidance from Hepato-Biliary Consultant or Interventional Radiology Consultant.
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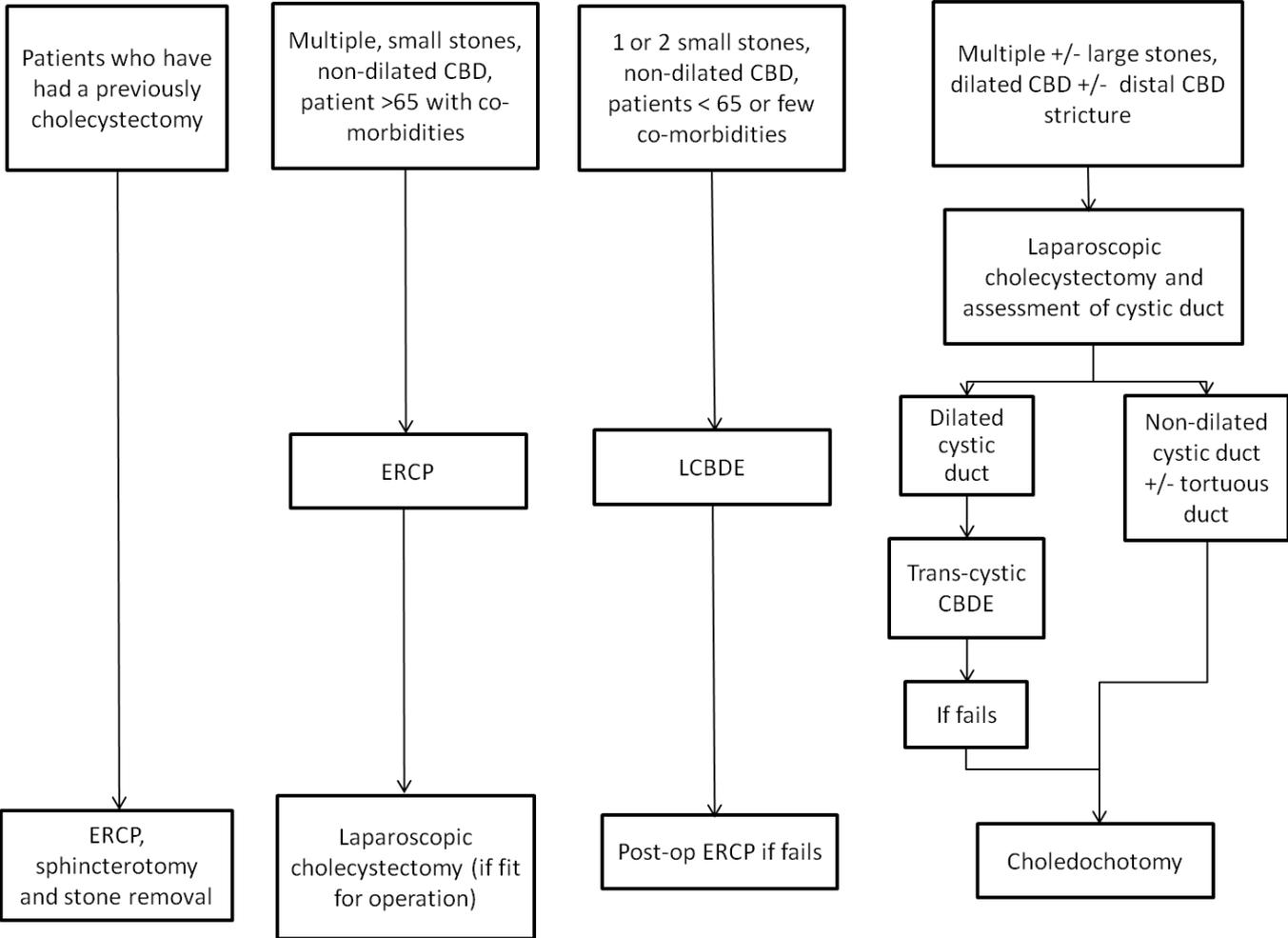
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Adult patients >65kg = 2000mg

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- Consent the patient for:
  - Bleeding
  - Bile leak
  - Failure
  - Infection/bacteraemia
  - Pancreatitis

Figure 4- Management of CBD stones



LCBDE – laparoscopic common bile duct exploration, CBDE – common bile duct exploration