Proposed BBUGSS Guidelines on Common Bile Duct Stones

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Definition

Common bile duct stones (CBDS), also known as choledocholithiasis, is defined as the presence of stone(s) within the common bile duct (CBD) (1).

History

Diagnosis of CBDS

The first documented description of gallstone disease are those mentioned in Egyptian mummies (2000 BC) (2). In 1556, an autopsy performed on Saint Ignatius of Loyola by anatomist Realdo Colombo in Italy confirmed mortality by gallbladder disease. The post-mortem documented a large stone in the distal CBD eroding into the portal vein (3).

In 1840, General Francisco de Paula Santander, a hero during the independence of Columbia died from a likely case of acute cholangitis (4). The autopsy confirmed the presence of a 2.3cm CBD stone.

Cholangiography

In 1918, Adolph Reich, a radiologist injected petroleum paste and bismuth into a patient with a cutaneous fistula. To his surprise, the bile ducts were visible during fluoroscopy (5). These findings were corroborated by others that also found retained stones after injecting a lipid solution through a cutaneous fistula (6).

In 1924, the use of radiological examination of the gallbladder by intravenous injection of tetrabromophenolphthalein was introduced by Graham, Cole and Copher (7,8). They confirmed that the injected dye excreted slowly through the liver into bile and the cystic duct permitting visualisation of the gallbladder.

In 1931, an Argentinian surgeon called Pablo Luis Mirrizi recommended intra-operative cholangiography (IOC) to diagnose CBDS. The intended benefit was to avoid unnecessary exploration of CBD and to both confirm biliary anatomy and avoid inadvertent ductal injury (9,10).

Choledocholithotomies

The first documented successful common bile duct exploration was performed by Knowsley Thornton in London in 1889 (11,12). This was followed by the work of Ludwig Courvoisier and Hans Kehr, who both utilised T-tube for drainage and biliary tree decompression after CBD exploration. Early experience found the use of T-tube to reduce morbidity and mortality (13,14).

In the following decades, there were several important advancements in the management of CBDS. Amongst them included use of balloon catheters by Fogarty, et al (15), percutaneous removal of CBDS through T-tube tract by Mazzariello, et al (16), and introduction of endoscopic retrograde cholangio-pancreatography (ERCP) (17,18).

In the 1990's, with the utilisation minimally invasive surgery came laparoscopic CBD exploration (LCBDE) (19,20). Despite the emergence of LCBDE, there has been a slow adoption of this approach and recent guidelines have suggested encouragement of training to enable a wider implementation and in order take advantage of both significant economic and clinical benefits (21,22).

Epidemiology

- Between 3 – 16% of patients with symptomatic gallstones have concomitant CBDS (23,24).

Risk Factors

- Behavioural (diet, obesity, weight loss)
- Biological (age, gender, race, ileal resection and serum lipid level) (25).

Pathophysiology

Bile stored in the gallbladder can become saturated leading to formation of gallstones. In some cases, gallstones pass through the cystic duct (CD) and subsequently into the CBD. Most cases of CBDS are secondary to passage of stone from the gallbladder. Primary CBDS occur due to bile stasis in the bile duct, which cause intraductal stone formation (1). Less common causes of CBDS include complicated Mirrizi syndrome or hepatolithiasis (1).

Flow of bile is obstructed by CBDS, which can result in obstructive jaundice and/or ascending cholangitis. Furthermore obstruction of the biliopancreatic duct may lead to premature activation of pancreatic enzymes causing biliary pancreatitis (26).

Complications of CBDS

- **Pain**
- **Jaundice** - obstruction of CBD by stone
- **Ascending Cholangitis –** infection of partially or completely obstructed duct
- **Pancreatitis –** obstruction of biliopancreatic duct may lead to premature activation of enzymes in the pancreas

Investigation of CBDS

Investigating CBDS is recommended in all patients presenting with epigastric or right upper quadrant pain, particularly when associated with concomitant deranged LFTs, jaundice, pyrexia, or acute pancreatitis.

The following are the investigations available for identifying CBDS:

Liver Function Tests (LFTs) and Transabdominal Ultrasound Scan (US)

- Both are recommended in patients with suspected CBDS, although normal results should not prevent further investigations, especially when there is a high index of suspicion.

Magnetic Resonance Cholangio-Pancreatography (MRCP) and Endoscopic Ultrasound (EUS)

- Both imaging modalities are highly accurate methods in identifying CBDS when there is a moderate probability of disease (Figure 1). There is comparable sensitivity/specificity of each investigation for stones >5mm in size (95%/97% - EUS; 93%/96% - MRCP) (27,28).
- EUS is superior to MRCP in detecting stones <5mm in size (MRCP sensitivity falls from 93% to 71% for stones <5mm) (27–29).
- The advantages of MRCP are that it is widely available, non-invasive, provides detailed images of the intrahepatic ducts, cost effective and more suitable in patients with altered gastric or duodenal anatomy (27,28).
- The advantages of EUS are that it can be performed in patients where MRI is contraindicated or not tolerated due to claustrophobia. Although EUS has the disadvantage of being invasive and therefore causing a risk of visceral perforation, aspiration, pneumonia and oral/dental injury.
- MRCP should be the primary modality used and EUS reserved when there are contraindications to MRI or when the results of MRCP are equivocal (27,28).
- EUS should also be considered in patients where a cause for pancreatitis has not been established. 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%) (30).

Computerised Tomography – (CT)

- CT is not routinely used for identifying CBDS (sensitivity 69-87%, specificity 68-96%) but has an important to role to play in identification and staging of malignant biliary obstruction. Its accuracy in diagnosing CBDS falls considerably when the stone is small or has a similar density to bile. In patients where a CBD filling defect is identified with US, cross sectional imaging (CT/MRCP) can be useful in differentiating between a stone, stricture, and a mass lesion (31).

For a suggested pathway in diagnosing suspected CBDS, see Figure 1.

Management of CBDS (Figure 2)

CBDS can be effectively treated via either ERCP or laparoscopic cholecystectomy and LCBDE (21). The benefits of LCBDE include an economic advantage by reducing the overall hospital stay and a significant lower risk of causing pancreatitis (32).

Surgical Management of CBDS

Pre-operative

- In patients with a gallbladder in-situ, LCBDE has been reported to be as effective as ERCP in achieving duct clearance (21). Furthermore, it is associated with a shorter hospital stay, reduced cost and lower incidence of pancreatitis (41).
- LCBDE has reported morbidity rate of 4 – 16% and mortality rates of 0 – 0.8% (42).
- Pre-operative MRCP in patients with a suspicion of CBDS can facilitate planning the operative approach for LCBDE by delineating the anatomy of the biliary tree including the cystic duct (important specifically for trans-cystic LCBDE) and size of the ductal stones.
- Although MRCP provides valuable pre-operative information, it is not mandatory particularly when there is a low index of suspicion for malignancy, LFTs are normalising and there is availability of intra-operative cholangiogram (IOC) and/or laparoscopic ultrasound (LUS).
- Intra-operative cholangiogram (IOC) provides real-time information of anatomy of both the cystic duct and CBD, and anatomical details of the bile duct stones. In experienced hands LUS may provide similar information to IOC.
- When available, IOC or LUS should be performed when CBDS are suspected (previously deranged LFTs, dilated CBD on USS or previous pancreatitis) or proven by preoperative imaging (MRCP/EUS/CT).
- Stone migration is a dynamic process and therefore pre-operative imaging should not be accepted as definitive. Intra-operative imaging with IOC or LUS are the most reliable means of confirming the real-time presence or absence of CBD stones.
- An equivocal IOC where the CBD is dilated and absence of contrast in the duodenum on the background of a patient with previous pancreatitis or altered GI anatomy then transcystic LCBDE should be attempted. Intravenous Buscopan (20mg) can be used to help relax the sphincter of Oddi in order to encourage the passage of a small stone at the papilla or flow of contrast into duodenum.
- LCBDE can take either a trans-cystic (via the cystic duct) or a transcholedochal (via the CBD) approach.

Trans-cystic LCBDE

- Trans-cystic CBDE is considered when there are ≤ 3 small, non-impacted stones in the distal CBD, favourable cystic duct anatomy with or without a non-dilated biliary system (< 8mm CBD).
- Trans-cystic route can be difficult in patients with a long, tortuous cystic duct. There are CBDE kits (Nathanson Transcystic Bile Duct Stone Exploration Pack Cook ® Medical) available with cystic duct balloon plasty devices that can be used to improve the chances of success. This procedure is performed under fluoroscopic guidance without direct visualisation of the CBD. There is always a risk of injuring the cystic duct with balloon-plasty increasing the chance of postoperative bile leak.
- Failure to clear the CBD via the trans-cystic route due to unfavourable cystic duct anatomy and thus failure to access the CBD, migration of the stones proximally into the common hepatic duct or large distal CBDS should lead to a transcholedochal CBDE when the CBD is dilated (≥8mm) or post-operative ERCP should be performed when the CBD is <8mm.

Transcholedochal LCBDE

- Patients with a dilated CBD (≥8mm) and a high stone load/ large stones (>1cm)/impacted stones should be managed by transcholedochal approach.
- The most important factor for transcholedochal exploration is the presence of dilated CBD (≥8mm) in order to prevent postoperative CBD stricture (21).
- Assessment of CBD size can be made by either pre-operative MRCP, IOC or LUS. MRCP is the least reliable as there is often a delay in surgery and both IOC and LUS are performed real-time.
- A vertical choledochotomy is best performed using a choledochotome to provide a linear clean incision. Laparoscopic scissors can be used instead of the choledochotome although use of diathermy should be avoided to reduce the risk of thermal injury.
- Closure of the duct can be performed by using a continuous suturing technique with a 4/0 Vicryl suture. Acceptable methods of closure include interrupted suturing with a monofilament absorbable thread (PDS). Non-absorbable sutures should be avoided due to the risk of the suture material acting as a nidus for stone formation.
- Primary duct closure without T-tube insertion is superior to planned T-tube insertion with reduction of hospital stay (43). In addition, primary duct closure is associated with both a shorter operative time and patient recovery (43).
- Completion IOC can be performed via cystic duct in cases where there is a significant stone load, there has been use of a lithotriptor giving rise to proximal migration of stone fragments into the intrahepatic ducts or in patients with altered GI anatomy. In these circumstances completion IOC will allow to increase confidence in 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 placement should be considered to allow for percutaneous access to the CBD.

- T-tube placement should be considered where patients return to theatre for biliary peritonitis following LCBDE, in which the dominant cause of bile leak is due to technical failure in the suture line (21).

Other considerations:

- Patients that have had previous cholecystectomy should proceed to ERCP
- 15 – 37% of patients with a gallbladder in-situ post-clearance of CBD stones at ERCP will require a cholecystectomy within 5 years (21).
- In those with altered GI anatomy, unless in a centre with experience of laparoscopic transgastric assisted or push enteroscopy ERCP (the disadvantage of these approaches being the duration of procedure with variable success rate), LCBDE should be considered.
- EUS-guided ERCP is an evolving alternative option in patients with Roux-en-Y gastric bypass but due to publication of small case-series its success and risks have not been understood comprehensively (44)
- In 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 or consider spyglass ERCP in patients with severe co-morbidity.
- A biliary stent placed as an intermediate step to surgery should be removed at LCBDE and sent for microscopy, culture, and sensitivity.
- Evidence suggests that biliary stents removed during LCBDE will culture resistant strains of bacteria which require discussion with a specialist microbiologist to initiate appropriate antibiotics (45).

Special Considerations

Pregnancy

- Laparoscopy has become the preferred treatment modality for many surgical diseases in the gravid patient (46).
- Guidance suggests that laparoscopy can be carried out safely during any trimester of pregnancy without increased risk to mother or foetus (46).
- Both IOC and ERCP expose the mother to a minimal amount of radiation and may be used selectively during pregnancy with shielding of the lower abdomen.
- A safer alternative would be the use of LUS during LCBDE (47).
- Pregnant patients when in the second trimester should be placed in left lateral decubitus position to minimise compression of the vena cava.
- CO_2 insufflation pressure of 10-15 mmHg can be used safely in pregnant patients; however, CO_2 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 high quality randomised studies in these patient groups are lacking (46).
- Early involvement of an Obstetrician is critical and foetal heart rate monitoring should take place both pre and post operatively.

Bariatric or Oesophago-Gastric Resectional Surgery

- When cholecystectomy is performed prior to or following bariatric/oesophago-gastric surgery, routine IOC or LUS should be performed irrespective of LFTs, size of common bile duct or previous pancreatitis, as accessing the papilla postoperatively would be technically difficult.
- In these patients, the primary choice of treatment should be LBCDE (33).
- If this fails then a forward viewing scope, push enteroscopy assisted ERCP (post oesophago-gastric resectional surgery), EUS guided ERCP or laparoscopic assisted ERCP (post Roux-en-Y gastric bypass) can be performed through the remnant stomach, although success of these methods are variable (33).

Biliary Immunofluorescence Cholangiography (BIC)

- Use of BIC in biliary operations lacks evidence by way of improving safety. The intensity of fluorescent detection can be poor in inflamed thickened tissue or structures with significant overlying adipose tissue (48,49).
- An advantage of BIC may be in early visualisation of small ductal bile leaks (Lushka/sectoral) from the liver bed during the cholecystectomy.

Laparoscopic Ultrasound (LUS)

- LUS can be used routinely for identification of CBDS as an alternative to IOC.
- LUS should be used in patients allergic to contrast, in those having a history of choledochoduodenostomy/ hepaticojejunostomy or post laparoscopic/open cholecystectomy where there will be inflammation/scarring/thickening expected in and around the hepatoduodenal ligament.
- In the above scenarios scarring can lead to distortion/displacement of the portal structures. Here LUS can differentiate between structures by use of colour flow Doppler.
- Following exposure and confirmation of the CBD with LUS, once dissected the CBD should be aspirated with a long Abocath needle to verify aspiration of bile before performing a choledochotomy.

General Consideration with Endoscopic Management of CBDS – Endoscopic Retrograde Cholangio-Pancreatography (ERCP)

- Biliary sphincterotomy and endoscopic stone clearance is recommended as a primary form of treatment for patients with CBDS post cholecystectomy (21).
- The exception is in post bariatric or gastric surgery where ERCP would not be possible due to altered anatomy making the ampulla inaccessible. In such cases, LCBDE should be considered (21,33).
- Double balloon enteroscopy assisted ERCP has been used in patients with altered gastric anatomy although the technical success has been less than 90% (34).
- There has been the emergence of laparoscopic assisted transgastric ERCP but the reported outcomes have shown significant complications related to the laparoscopy and the technique has not been evaluated in large randomised studies (35–37). The procedure related complications include:
    - Conversion to open (5%)
    - Access site infection (5%)
    - Bowel injury (5.9%)
    - Intra-abdominal haematoma (5%)
- ERCP should also be considered when patients have evidence of acute cholangitis, as this is a relative contraindication to choledochotomy (21).
- ERCP is also preferred when the gallbladder is still present but due to significant co-morbidity, surgery is not feasible (21).
- ERCP is an effective method of treating CBDS with high rates of clearance, although there is also a potential for adverse events including (38):
    - acute pancreatitis (3.5%)
    - bleeding (1.3%)
    - perforation (0.6%)
    - biliary sepsis (1.5%)

Role of Cholangioscopy (Spyglass ERCP)

- Approximately 10-15% of CBDS cannot be treated using the standard stone removal techniques such as the basket or balloon catheter (39). Cholangioscopy or Spyglass ERCP guided electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL) should be considered in non-surgical candidates when other standard ERCP treatment options fail to achieve duct clearance (40).
- Spyglass-EHL cannot be effectively used in circumstances where there is a distal CBD stones and a water column cannot be maintained. The water column is critical to keep the CBD distended and avoid thermal injury to the wall of the bile duct.
- Most encountered complications of Spyglass-EHL are cholangitis, pancreatitis, and bleeding. Rarely, perforation of the duodenum can occur (50,51). The overall procedure success rate in clearing the CBD with Spyglass ERCP is 89% (51).

Ultrasound Guided Decompression of the Biliary System with Percutaneous Transhepatic Cholangiography (PTC)

- PTC should be offered to patients who are critically ill and 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 have had an unsuccessful ERCP.
- Complications include bleeding, bile leak and infection and with right sided biliary puncture there is an increased risk of pneumothorax.
- Inpatient mortality of patients that have undergone PTC has been reported as high as 21% (52). However, it is to be appreciated that the physiological burden of disease process has a profound influence on the mortality rate.

Medical Management of CBDS

- Ursodeoxycholic acid (UDCA) is licensed for treatment of gallstones but there is no evidence it reduces symptoms in many patients with stones (52).
- The exceptions are:
    - During rapid weight loss (>1.5Kg/week) post bariatric surgery for 6 months (52).
    - Patients with low phospholipid associated cholelithiasis (LPAC) due to mutation of ABCD4 gene. Typically develop cholesterol gallstone disease < 40 years, have 1st degree relatives with gallstone disease, recurrent symptoms post cholecystectomy and prone to IHD stones (53).
    - Patients on somatostatin analogues (54)

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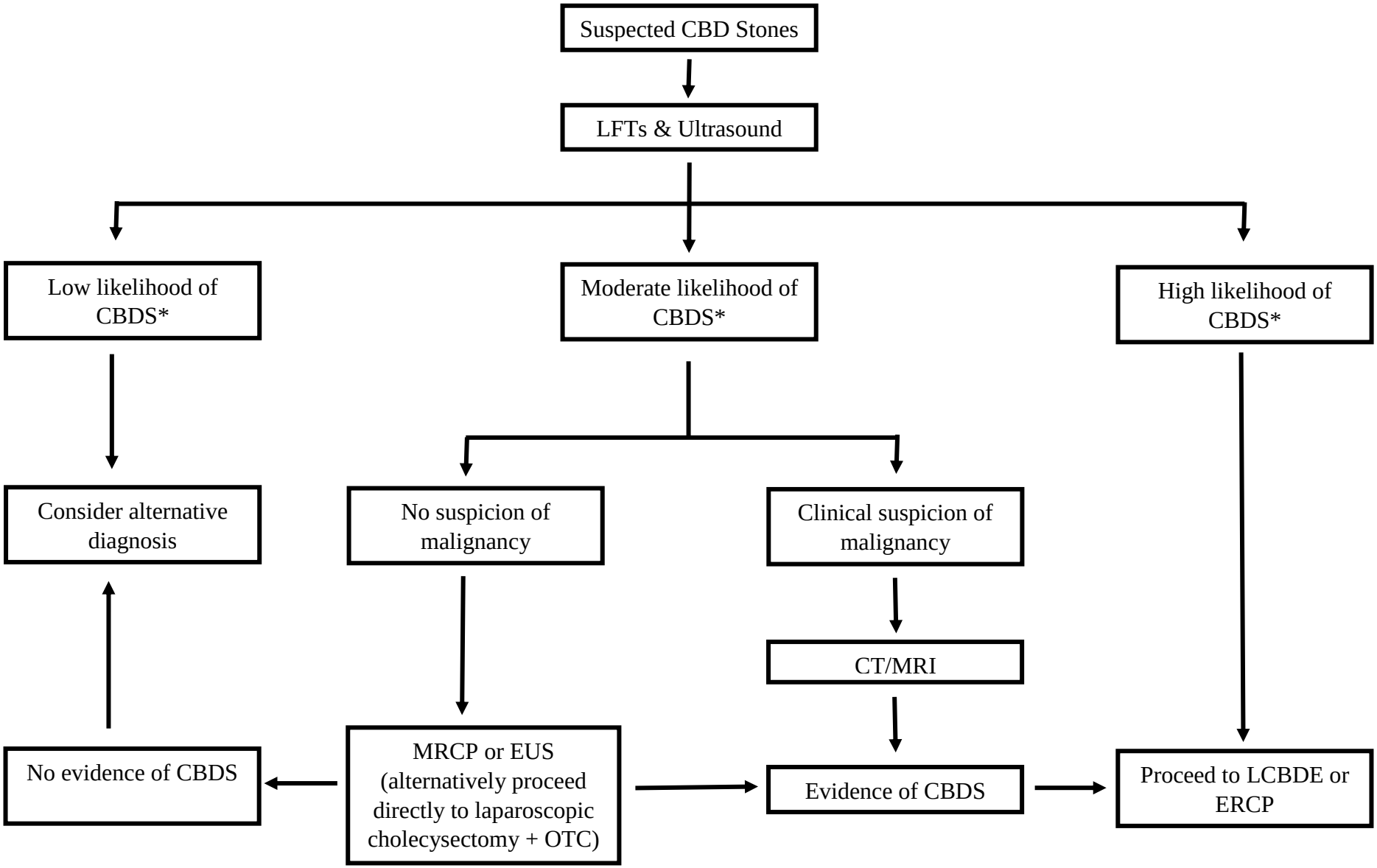
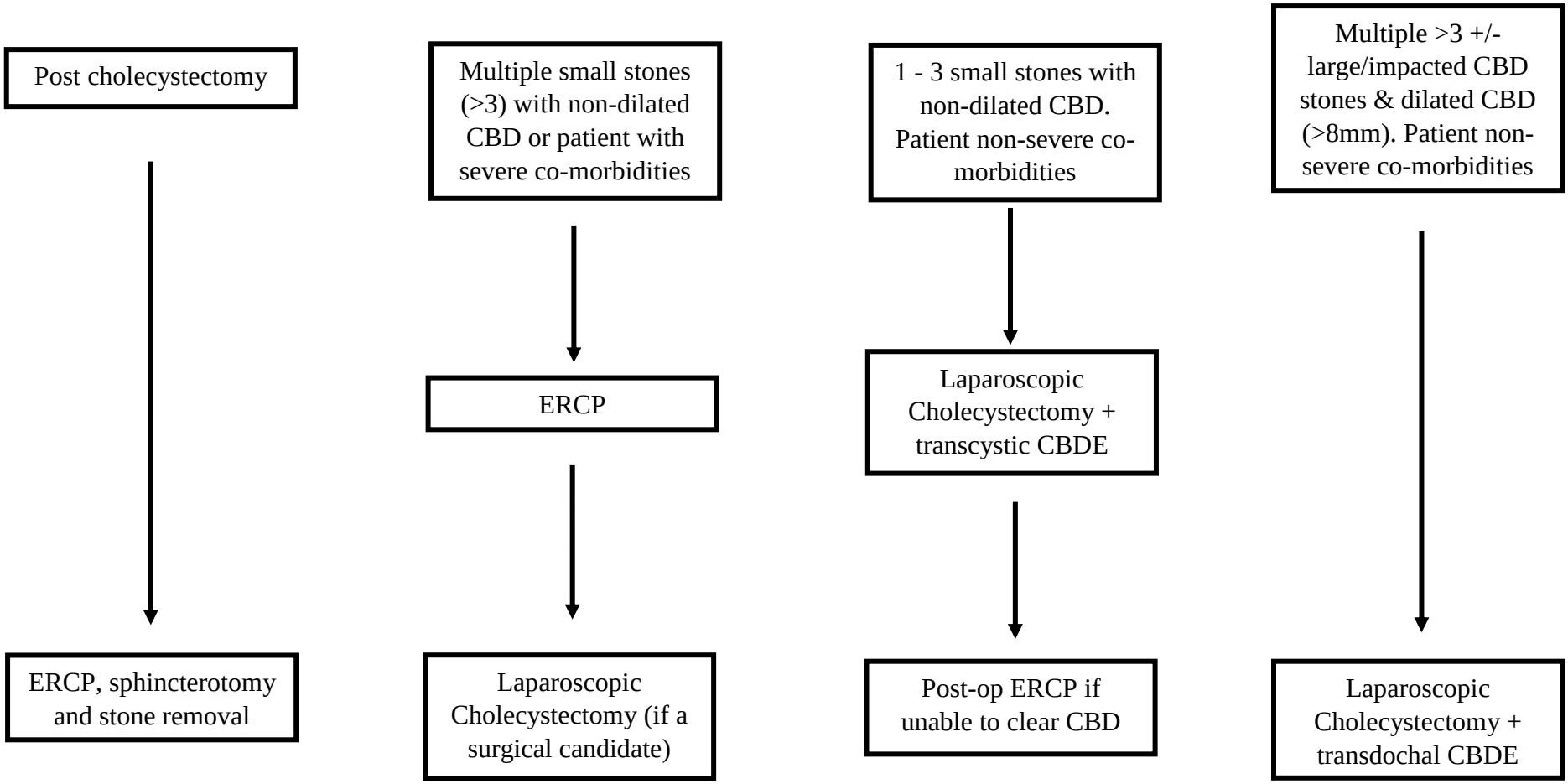
Figure 1 (21)



*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 US, features of cholangitis or pain/duct dilatation/jaundice in a patient with history of gallstones

Figure 2


Post cholecystectomy
ERCP, sphincterotomy and stone removal
Multiple small stones (>3) with non-dilated CBD or patient with severe co-morbidities
ERCP
Laparoscopic Cholecystectomy (if a surgical candidate)
1 - 3 small stones with non-dilated CBD. Patient non-severe co-morbidities
Laparoscopic Cholecystectomy + transcystic CBDE
Post-op ERCP if unable to clear CBD
Multiple >3 +/- large/impacted CBD stones & dilated CBD (>8mm). Patient non-severe co-morbidities
Laparoscopic Cholecystectomy + transdochal CBDE