

Pathway for the Management of Acute Gallstone Diseases

What's in this document?

Pathways to encourage safer, faster and more cost effective management of acute gallstone (GS) disease by stratification and standardisation of treatment options.

Why do we need this?

- a) The average length of stay for acute GS (gallstone) presentations to laparoscopic cholecystectomy (LC) is approximately 7 days in some regions in England. In analogous health systems (Australia, France) it is 36 hours.
- b) GS related diseases account for around a third of emergency general surgery (EGS) admissions and referrals. Ineffective care is unaffordable as well as substandard.
- c) National Institute for Health and Care Excellence (NICE) guidelines published in October 2014 now advises that patients presenting with acute cholecystitis should have LC within a week, and the International Association of Pancreatology (IAP) / American Pancreatic Association (APA) guidelines (2013) recommend patients with gallstone pancreatitis to have LC on index admission. There are dangers associated with having an acute cholecystectomy more than 4 days after admission and the standard should ideally be within 3 days. With respect to acute pancreatitis the standard of care should be lap chole during index admission for all non-severe cases.
- d) Very few if any trusts have matched demand and capacity for acute biliary presentations and the wide variation in management strategies that exists by both trusts and surgeons (SWORD database) suggests that improvements could be made with standardisation of care. For example, emergency cholecystectomy rates for acute cholecystitis range from 0.2-35% in acute hospital trusts.

Why the problems?

Surgeons are mostly aware of the benefits of prompt LC during the index admission but are restricted by several constraints, including;

- a) Lack of rapid access to ultrasound scanning
- b) Restricted access to emergency theatre lists (a sense that cholecystectomy is not an emergency still prevails in most hospitals)
- c) Lack of predictable access to urgent theatre lists beyond the main emergency list
- d) Fear of the difficulty of acute LC especially when the disease process is several days old.
- e) Uncertainty with regard to the need for common bile duct imaging and usage of ERCP when liver function tests are deranged in gallstone disease or acute pancreatitis (AP)
- f) Variable skills with regard to intra-operative cholangiography and CBD stenting/ exploration. There are very low rates of both operative cholangiography (<10%) and laparoscopic bile duct clearance in the UK.

Why have a joint document?

Biliary disease is managed by most surgeons on the acute surgical take and LC is undertaken by many of them. The majority of surgeons providing the EGS (Emergency General Surgery) service are neither HPB surgeons nor have access to HPB colleagues on site. This document seeks to provide a concise management plan for the majority of cases of gallstone disease presenting to the EGS in any hospital rather than attempting to provide an exhaustive guide to every scenario. Facilities and skills vary between units and between individual surgeons on emergency duty. At times this will influence the best management and expert referral and transfer will be needed to deal with complex problems in a specialist HPB unit. In principle it should be an institutional responsibility to provide best practice care to all acute biliary disease patients presenting as acute admissions to a general surgical service

Initial assessment

In the management of acute biliary disease, a number of factors will dictate the optimum treatment pathway for any individual patient, including:

1. Severity and persistence of the biliary pain
2. Ultrasound findings
3. Results of blood tests
4. Overall fitness for surgery

History and examination

It is essential to establish the nature, severity and frequency of symptoms. Previous episodes of biliary pain should be identified to permit optimum management planning. An overall assessment of the patients' fitness and desire for surgical intervention should be assessed.

Ultrasound

For a patient with first presentation of biliary pain (i.e. pain in the epigastrium or RUQ, usually radiating round or through to the back, lasting for at least 20-30 minutes (often several hours or more)) ultrasound (US) is essential to establish the diagnosis of gallstone disease and exclude other diagnosis in the right upper quadrant. There is no correlation between the presence of, or severity of biliary pain, with the number nor the size of the gallstones, nor the thickness of the gallbladder wall. Patients who are already known to have gallstones do not routinely require further imaging.

The presence of dilated bile ducts with abnormal LFTs raises the possibility of CBD stones. Patients with dilated ducts alone (ie with normal LFTs) do not require further routine preoperative investigation of their bile ducts as stones in this group are no more common than in the non-dilated GS population (ie <5%).

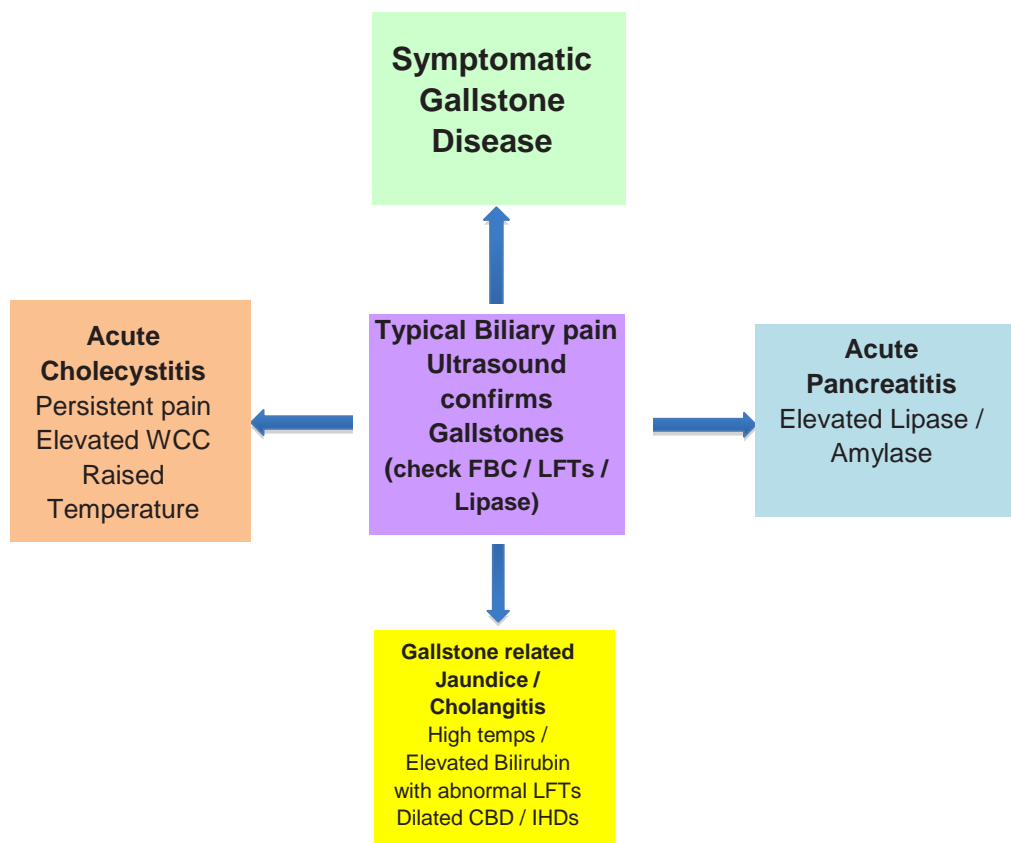
Blood Tests

A blood lipase (or amylase) will identify patients with acute pancreatitis. Elevated WCC and/or inflammatory markers may indicate patients with severe inflammation or infection of the gallbladder. Liver function tests may be elevated due to inflammation in the gallbladder or pancreas or may be due to CBD stones.

Management

Following clinical assessment, ultrasound and routine blood tests as outlined above, patients can be stratified into one of four groups

- **Symptomatic Gallstone disease (biliary colic, biliary pain)** – short duration of pain, minimal systemic upset, normal liver function tests (LFTs) and no biliary dilatation on ultrasound
- **Acute cholecystitis** – pain for over 24 hours, often with systemic upset (pyrexia, tachycardia), raised white cell count (WCC), often with ultrasound findings of an oedematous thick-walled gallbladder, or with stone stuck in Hartmanns pouch / cystic duct.
- **Gallstone pancreatitis** – peri-umbilical pain that radiates to the back, of variable duration and intensity, systemic upset, raised amylase or lipase. May have deranged liver function tests and inflammatory markers. US may reveal a dilated biliary tract. Should be stratified as severe or mild according to the presence or absence of persistent SIRS and organ dysfunction (*IAP/APA Acute Pancreatitis Guidelines, Pancreatology 2013*) or by a validated prognostic scoring system such as Glasgow, APACHE II or CRP.
- **Gallstone related Jaundice & Cholangitis** – variable duration of pain, systemic upset possibly including rigors, pyrexia, jaundice and deranged liver function tests and dilated biliary tract on ultrasound. High suspicion of gallstones being present in the common bile duct in addition to the gallbladder. May have had a previous ERCP for CBD stones or a biliary stent in situ.



Symptomatic Gallstone disease (Biliary colic, Biliary pain)

Most patients with biliary pain are suitable for early treatment in the ambulatory care setting or by early inpatient cholecystectomy. Once the pain has been treated or resolved, management options include:

- a) Ideally confirm the clinical diagnosis with ultrasound identification of gallstones during the index presentation. The patient should be offered a date for cholecystectomy, or reviewed in a surgical clinic pending a patient or surgical decision to operate. If surgery is declined or not appropriate (due to co-morbidities etc.) refer back to the GP with advice on a low fat diet which may reduce attacks of pain in a proportion of patients.
- b) All surgical triage units should develop the ability to offer diagnostic ultrasound scans within working hours. If ultrasound is not available within a few hours, the patient should be discharged from the surgical triage unit to have an early outpatient ultrasound with follow up in either a "hot" biliary or acute general surgical clinic. Most patients who are medically fit will be offered an elective laparoscopic cholecystectomy (within 6 weeks ideally) after one severe attack of biliary colic, as the likelihood of symptomatic recurrence is high.
- c) If pain is not controlled, or recurrent attacks occur at the index presentation, manage as acute cholecystitis and proceed to acute inpatient cholecystectomy.

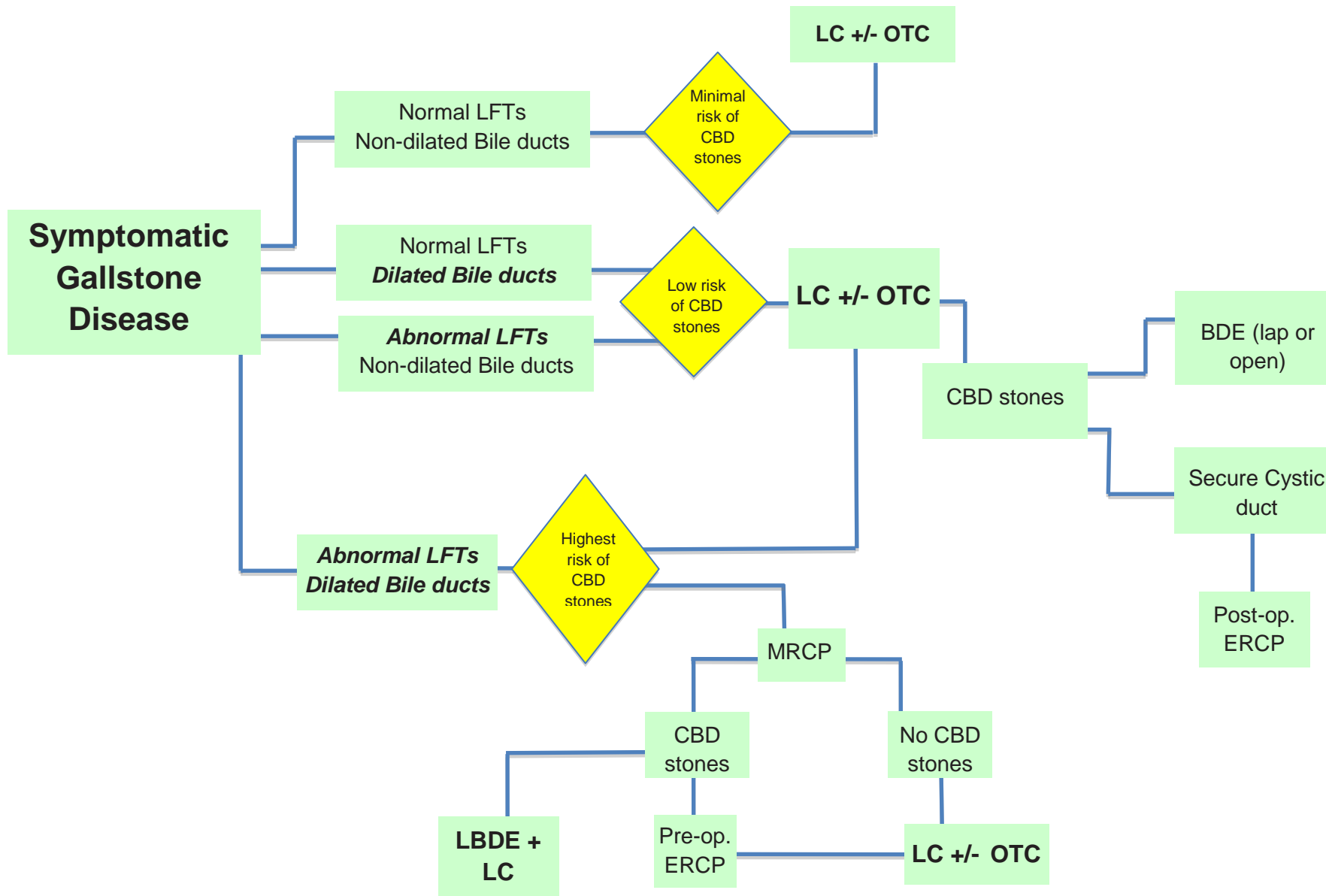
Management of abnormal LFTs

Patients with abnormal LFTs but normal bilirubin and a non-dilated biliary tract on ultrasound may proceed to directly to LC. Although some surgeons may prefer to have pre-operative identification of CBD stones (by MRCP or EUS) and duct clearance by ERCP prior to LC, further investigation introduces unnecessary delay in management, increases costs and impacts upon MRI / EUS resources. The presence of CBD stones is around 10% in this group of patients and the status of the CBD should where possible be clarified by intra-operative cholangiography (IOC) or Laparoscopic Ultrasound. Where IOC has not been performed if LFTs remain abnormal post-operatively they should be investigated by MRCP or EUS.

If CBD stones are found at LC the surgeon has several options. Ideally patients will have duct clearance in a single staged procedure by LBDE (laparoscopic bile duct exploration). This may not always be possible and securing of the cystic duct with subsequent post-operative ERCP either during the same admission or within 1-2 weeks post LC is an alternative approach in non-obstructed biliary ducts. Intra-operative ERCP, antegrade stenting of the CBD (with subsequent post-operative ERCP) and Open BDE are viable alternatives.

Patients with a CBD >10mm and abnormal LFTs with an elevated bilirubin represent those at highest risk of CBD stones and pre-operative (MRCP or EUS) assessment of the CBD will yield a CBD stone rate of around 30% permitting CBD clearance pre-operatively. However, the most cost effective algorithm for treatment in centres with the appropriate skill mix remains to proceed to LC & OTC without pre-op investigation, as the majority of patients will not have CBD stones, and the treatment options for managing CBD stones listed above may still be applied.

There should be a locally agreed patient pathway for managing patients in these various scenarios dependent upon local skills and facilities.



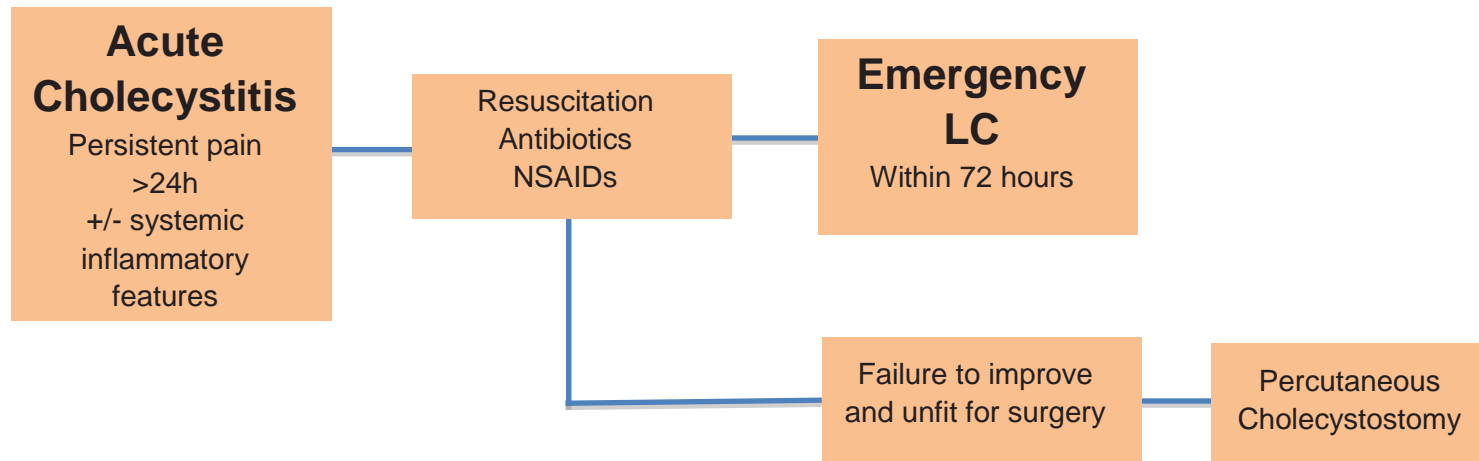
Acute Cholecystitis

Patients with acute cholecystitis should be admitted to hospital to have fluid resuscitation, antibiotics and analgesia. The diagnosis of acute cholecystitis is a clinical one with a consistent history of ongoing pain and tenderness in the RUQ, usually accompanied by a raised temperature and inflammatory markers. Ultrasound features may underestimate disease severity (a thickwalled gallbladder and pericholecystic fluid when present are suggestive diagnostic indicators) and overall the patient's systemic symptoms and inflammatory markers, together with response to therapy are a better guide to severity.

Patients diagnosed with acute cholecystitis should have their LC on the same admission within 72 hours (NICE guidelines, Oct 2014 state 1 week but 72 hours is preferable). Surgery for this sub-group of patients may be very challenging and is associated with a higher incidence of complications (particularly beyond 96 hours) and a higher conversion rate. These patients should be operated on by surgeons with experience of operating on patients with acute cholecystitis or if not available locally should be transferred to a specialist unit. This is preferable to leaving them for a delayed procedure.

Patients with persistent and / or increasing biliary pain, but without systemic inflammatory response, should be managed in the same way as patients with AC i.e. by early LC.

Patients with signs and symptoms of AC who are unfit for general anaesthesia and surgery who do not improve with antibiotics, may be treated by percutaneous cholecystostomy. This treatment however is not recommended for patients who are fit for surgery since it may not be therapeutic in patients with necrotic gallbladders causing delay in definitive management.

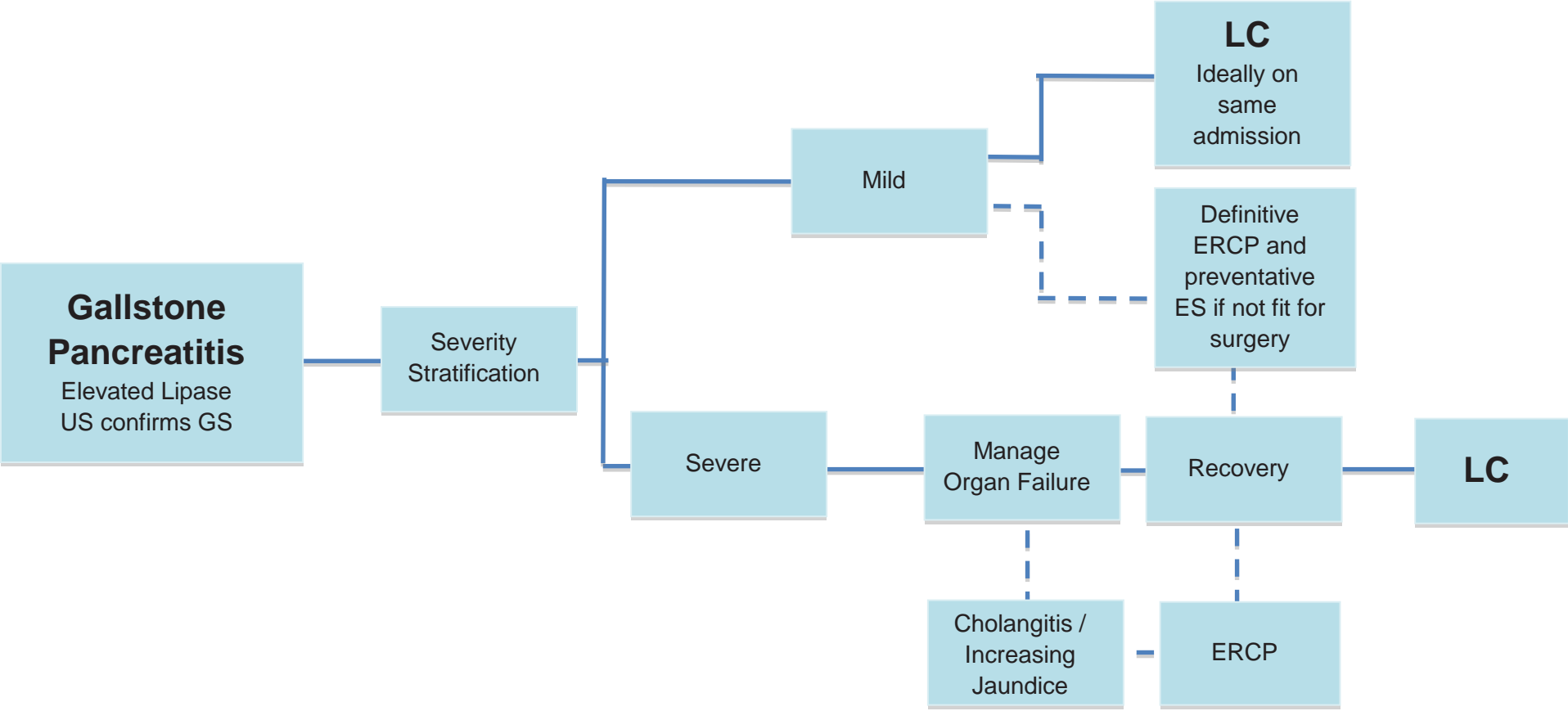


Gallstone Pancreatitis

Patients with gallstone pancreatitis should be admitted and resuscitated with intravenous fluids, oxygen and analgesia. Those with predicted mild disease can be managed on a general ward, and should be allowed to eat and drink as tolerated with adequate analgesia and anti-emetics as required. Patients can be discharged once pain is controlled and they are able to eat adequately. LC should be arranged ideally during the same admission once the pancreatitis has resolved. Current BSG guidelines suggest LC within 2 weeks of the admission to prevent further episodes of AP but this is less than standard of care in other countries.

Patients with severe or predicted severe disease should be carefully monitored for development of organ failure with early input from critical care teams and admission to a critical care unit when necessary.

- Early Ultrasound should be performed to confirm the presence of gallstones to guide subsequent management
- Those with predicted severe disease will require a CT between 7 – 10 days of admission, or if the CRP is rapidly rising, to determine the presence of pancreatic necrosis.
- Early ERCP should be considered where there is co-existing cholangitis or significant ongoing biliary obstruction.
- When the patient is constitutionally and physiologically well, they should undergo LC and OTC. A CT of the pancreas may sometimes be helpful to look for peri-pancreatic fluid collections or complications that may make early LC more difficult. In this scenario surgery may need to be deferred until symptoms and inflammatory markers are settling. Recurrent acute pancreatitis before full recovery in the setting of severe acute pancreatitis is rare and it is reasonable for the cholecystectomy to be delayed.



Gallstone related Jaundice & Cholangitis

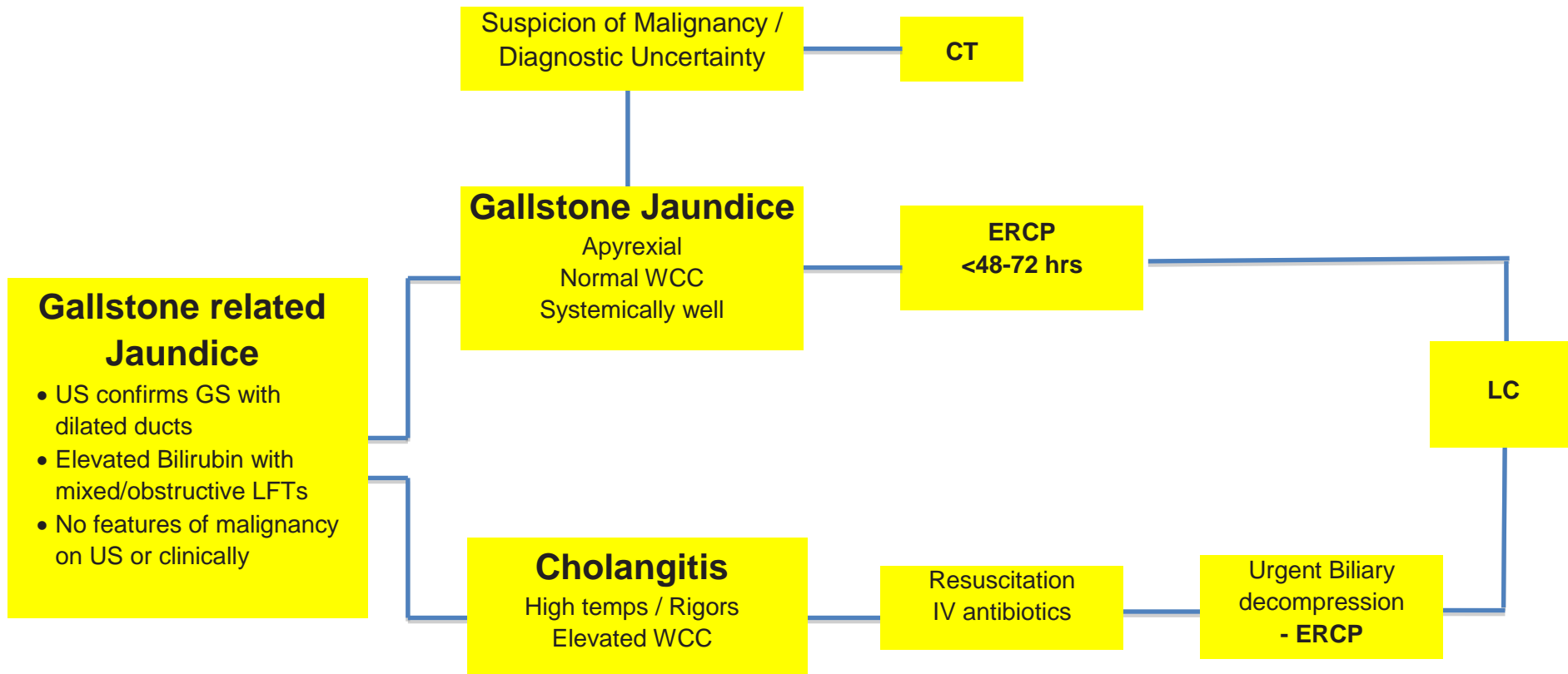
Patients with abnormal LFTs, dilated bile ducts and sepsis have cholangitis and should start immediate IV antibiotics and undergo urgent ERCP and decompression of the bile duct.

Patients with jaundice and an obstructive or mixed picture of elevated LFTs should undergo US to confirm the presence of gallstones and dilated bile ducts. A careful history and examination for signs and symptoms of malignant disease are important. A CT scan is indicated to diagnose malignant disease where suspected or when US shows no GB stones.

Patients with jaundice and suspected CBD stones should proceed to ERCP and stone extraction within a few days of diagnosis. In-patient admission is not necessarily required if systemically well, drinking freely and without signs of sepsis.

Patients who have had previous ERCP for CBD stone disease +/- have a biliary stent in situ should be treated with antibiotics and proceed to urgent ERCP for stent change or duct clearance as the incidence of residual stones/debris is high even when the duct was thought to be cleared.

Cholecystectomy is recommended after ERCP for jaundice or cholangitis secondary to CBD stones. This may be done during the index admission or delayed. Laparoscopic cholecystectomy after cholangitis is usually a very challenging procedure and should be undertaken by an experienced biliary surgeon.



Summary

This document provides a guide to pathways for the management of Acute Gallstone related diseases.

It is recognised that there are other alternative management algorithms that may be more applicable in individual centres dependent upon local resources and available skills.

The algorithms presented here seek to set a standardised approach which is considered acceptable amongst a reasonable body of General Surgeons practising within the UK. It also serves as a template to which future research and audit studies can refine and improve upon and allow the development of performance related outcome measures (PROMs) to be established.