

# Identification and Management of Bile Leaks Post Cholecystectomy

# 22

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## Introduction

Post operative bile leaks, although infrequent, represent a significant complication following laparoscopic cholecystectomy that must be detected early and managed appropriately to prevent significant morbidity and rarely mortality.

## Prevalence and Aetiology of Post Cholecystectomy Bile Leaks

Post cholecystectomy bile leaks occur in 0.25–2% [1–3] of cholecystectomies. These occur due to an inadvertent injury to the biliary system in the course of the dissection. The anatomical location of where bile leaks most frequently arise is from the cystic duct stump (up to 80%), accessory hepatic ducts (Ducts of Lushka) (15%), small sub-segmental ducts on the surface of the gallbladder bed and less commonly from major hepatic injuries (Fig. 22.1, Table 22.1).

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## Cystic Duct Stump Leaks

### Aetiology

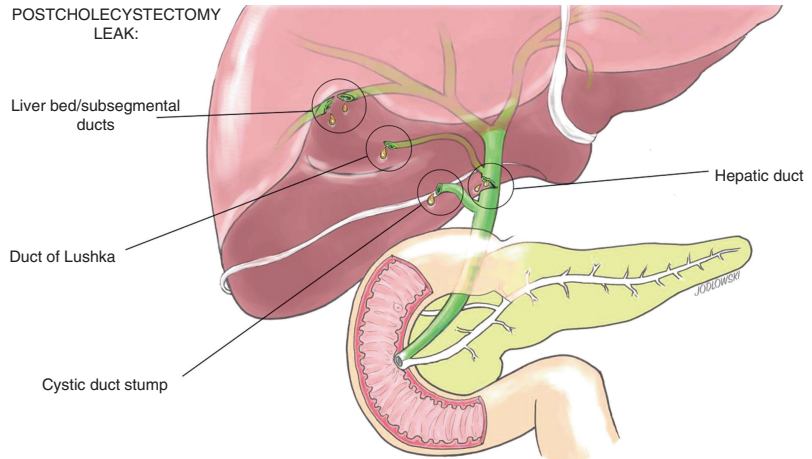
These occur when bile leaks from the cystic duct stump due to the inability to secure the cystic duct stump or Hartmann's pouch in the case of a subtotal cholecystectomy (Fig. 16.31a) or injury to the cystic duct proximal to where it has been controlled (Chap. 16) (Fig. 22.2).

Varying combinations of clip dysfunction or malposition may be responsible in some cases, highlighting the need for adequate dissection around the cystic duct to ensure visualisation of clips being applied to it and also that the clips applied have occluded the lumen of the duct without excessive surrounding tissue included within its ends. The clips need to be applied to the most distal part of the dissected cystic duct to ensure any unseen minor injury or possible thermal injury is excluded. Suction of the liver bed at the end of the operation may lead to inadvertent dislodgment of the clips and highlights the importance of both care when performing this and in inspecting the clips just prior to the end of the surgery (Chap. 16).

Excessive dissection, tension and electrosurgical injury of the cystic duct proximal to where it has been secured may be responsible for ischaemia and subsequent necrosis of tissue in the

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**Fig. 22.1** Sites of possible bile leak. Image courtesy of Dr. Tomasz Jodłowski



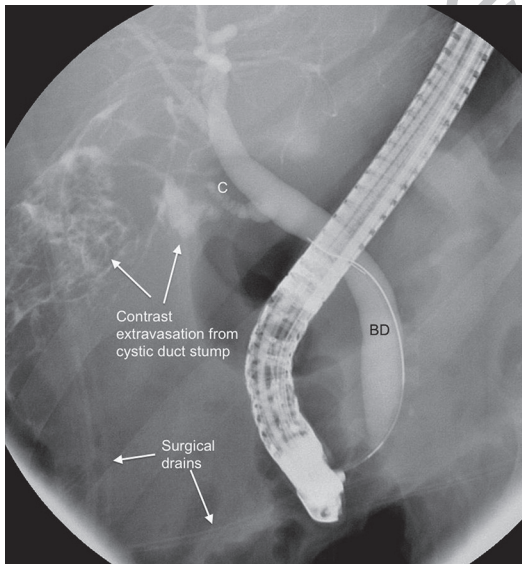
**Table 22.1** Location of post cholecystectomy bile leaks

Anatomical location of bile leaks	Frequency approx. (%)
Cystic duct stump	80
Accessory hepatic ducts (Ducts of Lushka)	15
Sub-segmental ducts	~2–3
Bile duct injuries	~2–3

wall of the cystic duct causing a delayed defect. This may present as a delayed bile leak and highlights the importance of judicious dissection of the cystic duct near the cystic duct and bile duct junction.

Other factors associated with cystic duct stump leaks include:

- **Coexisting unrecognised bile duct stones:** Identified in 20–35% of patients with post cholecystectomy bile leaks [4]. Their presence may increase intra-ductal pressure and potentiate a leak and as such should be identified and dealt expeditiously.
- **Emergency surgery:** May be associated with a threefold increase in the rate of cystic duct stump leaks when cholecystectomy is performed emergently [5]. This may be related to difficulty or inability to secure the cystic duct stump due to coexisting inflammatory changes in the vicinity of the cystic duct.
- **Intraoperative complications:** Such as bleeding, avulsing the cystic duct, opening of the inflamed gallbladder and spillage of stones.
- **Conversion to open**
- **A short and wide cystic duct** [6]: Can arise as a result of chronic inflammation and subsequent fibrosis, impaction of stones distally or recent passage of stone.



**Fig. 22.2** ERCP image of Cystic duct stump leak after a laparoscopic cholecystectomy for severe acute cholecystitis was converted to an open procedure. Note contrast leaking from proximal to the cystic duct stump (C) into the adjacent surgical drains

These factors are all surrogate markers for a difficult procedure that should increase the

degree of suspicion of a possible bile leak when the post operative course varies from the usual speedy recovery.

### Closure of Cystic Duct

Techniques of securing the cystic duct in laparoscopic surgery vary from metal clips, absorbable clips, Hem-o-lok® devices (Fig. 22.3) (Teleflex, Morrisville, NC, USA), Endoloop® ligature (Ethicon, Somerville, NJ, USA) and both intra and extracorporeal sutures and mechanical stapling devices. Whilst at open surgery, suture ligation, ties or clips are most commonly used.

There are no significant advantages between use of absorbable and non absorbable metal clips [7]. However, considerations include the possible decreased artefact on post-operative imaging and the extraordinarily rare occurrence of Post Cholecystectomy Clip Migration (PCCM) and stone formation—although this has been reported with both types of clips- and has been associated with the use of more than four clips [8].

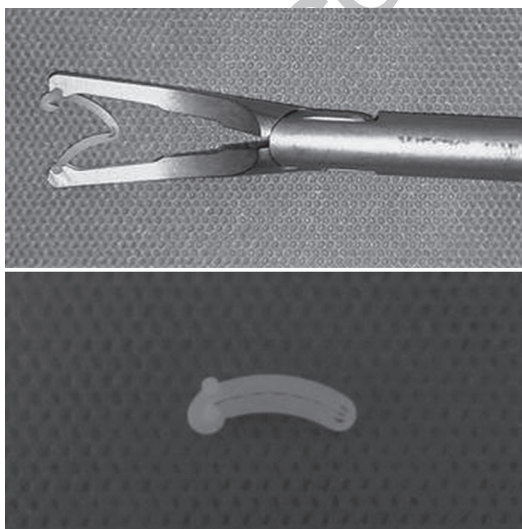
Despite a commonly mistaken belief that metal clips may not be as secure on the cystic duct as other options such as endoloops, when correctly applied, metal clips have a higher bursting pressure—as demonstrated in *ex vivo* animal

experiments—on the cystic duct (432 mmHg) compared to endoloops (371 mmHg) [9]. This difference is however redundant as intrabiliary pressure rarely rises above 25 mmHg [10].

Where the cystic duct is too large to be adequately secured with clips, endoloops should be used. A large duct may predispose clips to slip off or incompletely occlude the duct and thus fail. Following division of the cystic duct—an endoloop may be easily applied on the cut end of the cystic duct. Where the expertise exists, laparoscopic intracorporeal ligation of the cystic duct prior to division is extremely safe, cost effective and versatile in its ability to secure the cystic duct regardless of the size [11, 12].

Laparoscopic staplers can be used to divide a wide cystic duct or through the neck of the gallbladder. They pose the problem of difficulty in introducing a bulky stapler safely into the correct place, with good visualisation, without damaging the bile duct or possible anomalous right hepatic artery, in addition to the costs and so should not be used routinely.

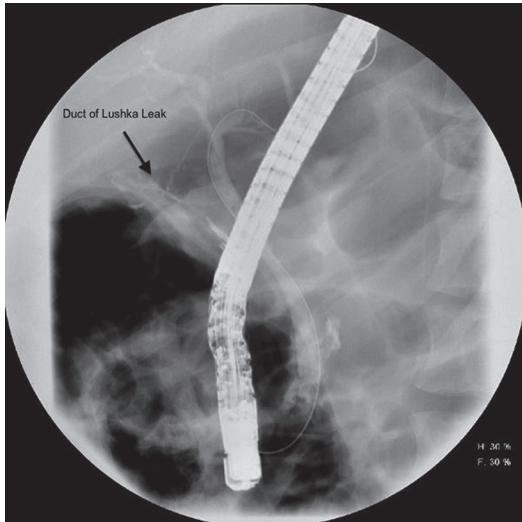
Increasing reports of the safety of use of the Harmonic ACE® shears (Ethicon, Somerville, NJ, USA) for sealing the cystic duct have been reported, however are not considered standard practice [13].



**Fig. 22.3** Hem-o-lok® used to secure the cystic duct

### Duct of Lushka (Fig. 22.4)

These tiny accessory 1–2 mm ducts originate in the right lobe of the liver and course along the centre or periphery of the gallbladder fossa eventually draining into, most frequently Right or Common Hepatic Ducts, either intra or extra-hepatically [14]. They do not drain an area of liver and are not accompanied by vessels. The risk of injury to them may be minimized by dissection in the subserosal plane when dissecting the gallbladder off the liver bed. This plane may be obscured by inflammation. Once divided, the volume of bile it leaks depends on the size and location of duct it communicates with. This combined with the pneumoperitoneum at laparoscopic cholecystectomy means that it may not leak bile intraoperatively to allow identification

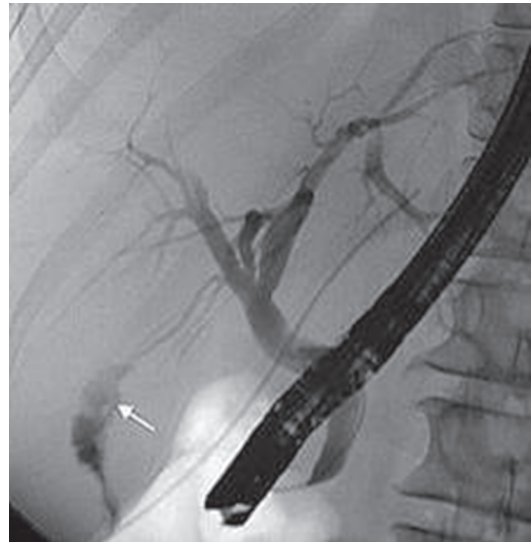


**Fig. 22.4** Duct of Lushka bile leak seen endoscopically at ERCP. Image courtesy of Mr. Michael Silva

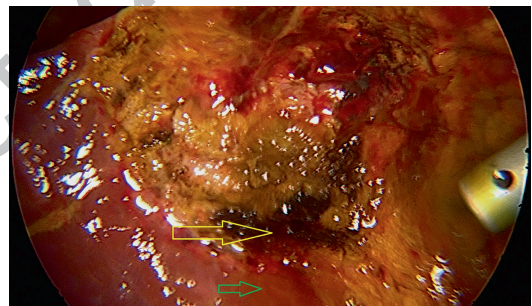
and either ligation or clipping of it. Intraoperative cholangiography does not detect it prior to the gallbladder being removed. The presence of bile duct stones or Sphincter of Oddi obstruction will raise transpapillary gradient and perpetuate a leak.

### Gallbladder Bed (Fig. 22.5)

Small sub-segmental biliary radicles within the substance of the liver parenchyma may be injured when the gallbladder is being dissected off the liver during cholecystectomy (Fig. 22.6). These are distinct from the anatomically identified and well recognized Ducts of Lushka (Chap. 1). They may leak bile but often it is of low volume, for a short period of time and some authors suggest that they may not be responsible for clinically significant bile leaks. Nonetheless, prevention of injury to these biliary radicles as well as bleeding during cholecystectomy is avoided by dissecting in the correct subserosal plane. In the case where the gallbladder is intrahepatic a subtotal cholecystectomy where the back wall of the gallbladder is left on is preferable to intrahepatic dissection which risks bleeding and bile leak.



**Fig. 22.5** An ERCP in a patient with an unexpected bile leak post laparoscopic cholecystectomy. The ERCP demonstrates a bile leak from the upper end of the gallbladder fossa from a small sub-segmental bile duct



**Fig. 22.6** A bile leak (yellow arrow) from the lateral edge of the cystic plate with bile (green arrow) flowing down over the segment 5. The pathology of this was a delayed leak related to diathermy to a subvscical duct. This had a similar presentation to Case C, with a sudden onset of pain 3 days' post LC

### Bile Duct Injury

Although rare, it must be excluded and not assumed that a post cholecystectomy bile leak results from either a cystic duct stump or Duct of Lushka leak. Bile duct injuries are classified according to the Strasberg classification (Chap. 23, Fig. 23.1, Table 23.2) and this chapter will deal with Type A (Minor) biliary injuries with major injuries covered in Chap. 23.

## Clinical Presentations

### Case A

A 74-year-old gentleman presented to the emergency department after referral from his General Practitioner with a 1-week history of Right Upper quadrant pain and fevers. He has a significant medical background of ischaemic heart disease, atrial fibrillation for which he is anticoagulated on warfarin, obesity and Type 2 Diabetes. His preoperative blood tests demonstrated a raised White cell count  $21.9 \times 10^9/L$  with a predominant Neutrophilia, a with normal Liver function test and INR 2.7. A preoperative Ultrasound and CT scan demonstrated acute cholecystitis, with a single 3 cm stone impacted in Hartmann's pouch, with a localized perforation into the liver parenchyma. He was commenced on intravenous fluids, intravenous antibiotics and his INR was reverse with vitamin K. Overnight he developed worsening epigastric pain and swinging fevers to  $38.5^\circ C$ . He was taken to theatre the next morning for a laparoscopic cholecystectomy. At laparoscopy, he had a large inflammatory phlegmon with the gallbladder encased in omentum and an unexpected fibrosed liver. Following extensive adhesiolysis, the gallbladder was identified, however was difficult to retract despite insertion of a further retraction port. Calot's triangle was impossible to dissect safely and a decision was made to perform a subtotal cholecystectomy. The anterior wall of the gallbladder was opened, the contents were decompressed and a large stone was removed from Hartmann's pouch. An intraoperative cholangiogram was attempted, however no meaningful images were able to be obtained and so abandoned. An endoloop was placed on Hartmann's pouch in an attempt to occlude it and a 20 Fr Blake's drain was left in the subhepatic space in anticipation of a post-

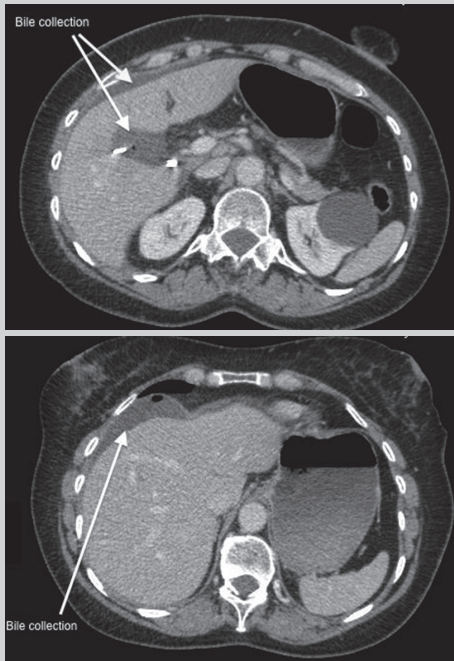
operative bile leak. Although not draining bile intraoperatively, bile started draining through the drain tube in recovery. Despite this he recovered well with no evidence of sepsis and underwent an ERCP on day 5 post operatively due to ongoing bile leaking through the surgical drain. At ERCP a leak from Hartmann's pouch was identified, an endoscopic sphincterotomy was performed and a 10 Fr Pigtail stent was inserted (Fig. 15.31). His drain slowed down on day 3 post ERCP and was removed the next day.

In this difficult case where the risk of a post operative bile leak is high, a drain left in situ has prevented this high risk patient from developing sepsis from an uncontrolled bile leak.

### Case B

A 68-year-old lady with an 18-month history of right upper quadrant pain, with progressively longer periods of pain in the last few months. An ultrasound demonstrated a distended and thickened gallbladder wall, with multiple stones in the gallbladder and a non dilated biliary tree. Her medical background included hypertension and depression with no previous surgery. She was planned for a laparoscopic cholecystectomy. At laparoscopy, the gallbladder had omental adhesions stuck to a tense, distended, thick-walled gallbladder that was difficult to grasp—necessitating decompression of the mucocele. Following dissection a short thick cystic duct was identified. An intraoperative cholangiogram was not possible due to the size of the duct. The cystic duct was clipped and cholecystectomy was performed.

A 10Fr Jackson Pratt suction drain was left, but removed 6 h later as no bile was draining and she remained pain free. She was admitted overnight, however the next



**Fig. 22.7** Post-operative CT detecting hyperdense fluid in the gallbladder fossa and adjacent to the right lobe of the liver Day 1 post cholecystectomy

*morning she appeared to be in significant discomfort with right upper quadrant abdominal pain, a tachycardia and a fever to 39.1 °C. A CT scan was performed (Fig. 22.6) which demonstrated fluid in the gallbladder fossa and the right subphrenic space. A bile leak was suspected and the patient was returned to theatre that day for re-laparoscopy. At laparoscopy a bile leak was confirmed and washed out with placement of a drain in the subhepatic space, without disturbing the gallbladder fossa. Post operatively, approximately 300 mL of bile per day drained through the surgical drain, but the patient had no evidence of sepsis, normal Liver function tests and White Cell count and only minor discomfort at the site of the drain. It had become apparent that this leak was ongoing and she was referred for ERCP day 4 post operatively. At ERCP (Fig. 22.7) a bile leak*

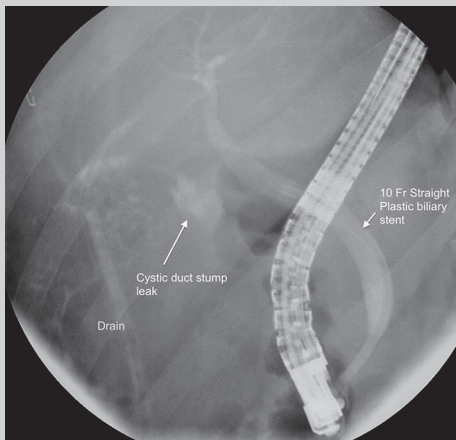
*arising from around the cystic duct was identified on the cholangiogram with no stones and otherwise normal biliary anatomy. A 10Fr straight plastic biliary stent was inserted. The procedure was uncomplicated and the drain stopped leaking bile on day 3 following the ERCP. The drain was removed on day 4 and the patient was discharged later on that day. She returned 6 weeks later for repeat ERCP and removal of the plastic biliary stent.*

In this scenario a post-operative drain was not left in for long enough. Bile does not always leak immediately after surgery. If there is concern about a possible bile leak the drain should be left in for at least 48 h to confirm there is no leak. Note that a drain will not always control a bile leak. Another possibility in this case is that the suction was not stopped by cutting the drain prior to removal. It is possible if suction is left on and a drain is removed that the clips may be dislodged in a similar fashion to disrupting them with a suction during the procedure. This clinical presentation is typical for a post operative bile leak with unexpected pain and a high fever following cholecystectomy. This correctly prompted investigation and confirmation of a bile leak with subsequent early return to theatre to control sepsis and subsequent ERCP occurring on a semi-urgent basis.

#### Case C

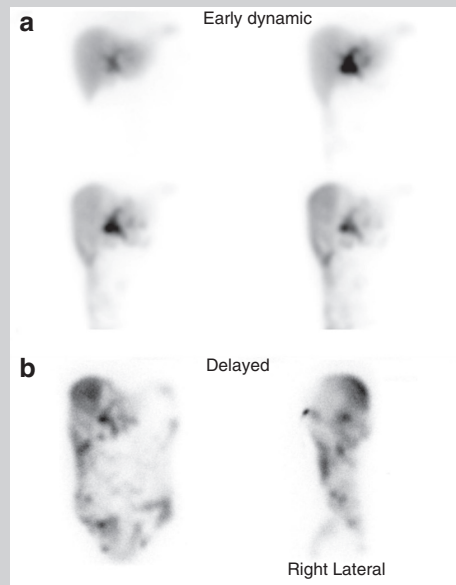
*30-year-old man with no other health problems presented to hospital with a 6-month history of typical biliary colic. A preoperative Ultrasound and MRCP confirmed cholelithiasis and he underwent an elective day case laparoscopic cholecystectomy recovering well. An intraoperative cholangiogram was performed and found to be normal. On day 4 post*

operatively he developed a sudden onset of upper abdominal and represented to the hospital. Clinical examination detected RUQ tenderness with normal observations, whilst his blood tests demonstrated a raised White cell count  $15 \times 10^9/L$  with a predominant Neutrophilia  $12.32 \times 10^9/L$ , abnormal Liver function tests (Serum Bilirubin  $28 \mu\text{mol/L}$ , raised Alanine aminotransferase (ALT)  $102 \text{ IU/L}$  and  $\gamma$  glutamyl transpeptidase ( $\gamma\text{GT}$ )  $329 \text{ IU/L}$ ) and a raised C Reactive Protein  $156 \text{ mg/L}$ . There was clinical suspicion of a bile leak and so he underwent an Ultrasound of the abdomen which demonstrated a small fluid collection in the gallbladder fossa and confirmed on subsequent CT scan on that day. A HIDA scan (Fig. 22.8) was performed which confirmed the presence of a bile leak. He returned to theatre for a laparoscopy that evening where a bile leak originating from the cystic duct stump proximal to



**Fig. 22.8** ERCP image from cystic duct stump leak. Note the extravasation of contrast on the cholangiogram draining into the abdominal drain. 10Fr Straight Plastic stent insertion

where the clips were applied was identified. A repeat intraoperative cholangiogram was performed which confirmed the anatomy and excluded distal obstruction (Fig. 22.9). The cystic duct was then re-clipped to occlude the defect. Bile was aspirated and lavaged from the peritoneal cavity and drains were inserted into the subhepatic, right subphrenic spaces and in the pelvis. There was no ongoing bile leak post operatively and by Day 4



**Fig. 22.9** HIDA Scan Demonstrating Biliary Leak—Hepatobiliary IminoDiacetic Acid (HIDA) labelled with  $99 \text{ m-Tc}$  Technetium given by intravenous injection to the right upper limb. All images are anterior, unless described. (a) Initial image shows hepatobiliary uptake and excretion to give hilar cholangiogram. Subsequent images show activity increasing in the right iliac-fossa, flank and over the liver, not compatible with movement through bowel. Some passage of activity into duodenum is also demonstrated. (b) Three-hour delayed images show activity pooled anterior to liver, in the right paracolic gutter and pelvis, in keeping with leak. (Artefact from injection-site on lateral.) Images courtesy of Dr. Nick Morley

*post his return to theatre all drains were removed and the patient was discharged with an uneventful recovery subsequently (Fig. 22.10).*



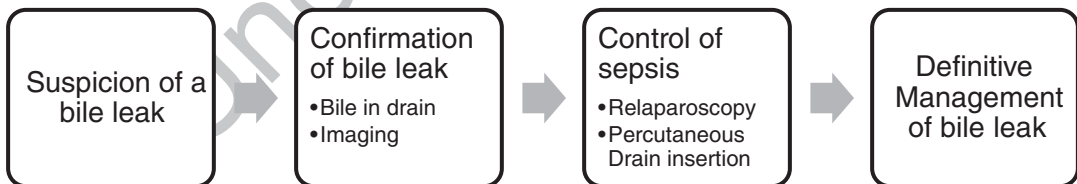
**Fig. 22.10** The operative cholangiogram at the re-laparoscopy to determine there was no other site of leak and no stones in the CBD contributing to the cystic duct leak

This case demonstrates a delayed bile leak presenting due to possible thermal injury to the cystic duct. This may have been avoided by placement of the clips on the distal most portion of the dissected cystic duct (Figs. 16.22 and 16.34). Despite the delay in presentation and reassuring cholangiogram at the time of the cholecystectomy, appropriate investigations were performed early on presentation which allowed a return to theatre and management of the bile leak without the need for an ERCP.

## Management of the Post Cholecystectomy Bile Leak

### Suspected Bile Leak

The presence of a post operative bile leak is usually heralded by excessive postoperative pain, nausea, malaise, abdominal distention, tachycardia and usually a fever [15]. Rarely bile may drain through the cannula sites or result in cutaneous bile staining [16]. Clinical features progress to those of peritonitis and sepsis if the bile leak remains undrained with serious morbidity resulting. The management of a suspected post-operative bile leak is summarized in Fig. 22.11.



**Fig. 22.11** Pathway for management of the post cholecystectomy bile leak



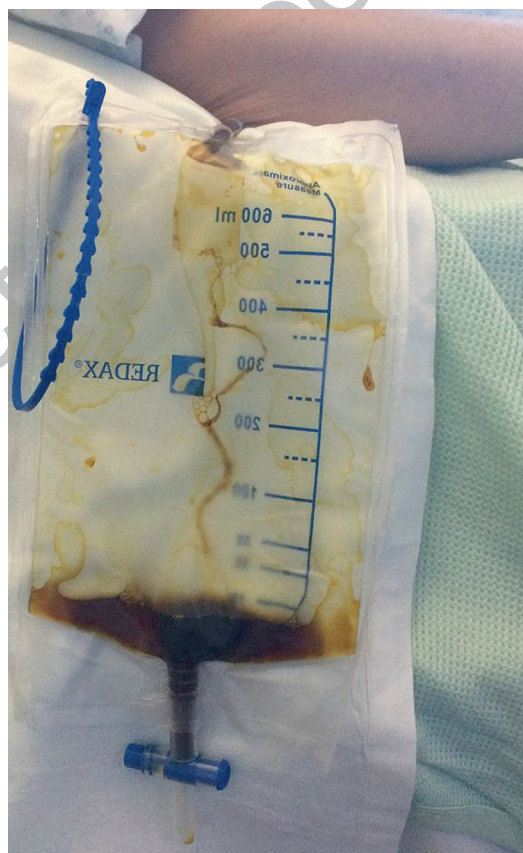
Laboratory tests may demonstrate a raised white cell count and inflammatory markers with abnormalities in the liver function tests including hyperbilirubinaemia—which relates to the reabsorption of bile within the peritoneal cavity. The degree of hyperbilirubinaemia may be relatively mild and often may be dismissed. Early signs of presentation can be quite mild and dismissed as expected post-operative pain. It is essential that there is a high index of suspicion of a possible bile leak should be kept in any patient that is “not right”. This allows for an early diagnosis, treatment and avoidance of serious morbidity due to delayed treatment of biliary peritonitis. As a rule, it is rare that a patient exhibits significant pain—in anywhere other than port sites—or a fever in the immediate post operative period following laparoscopic cholecystectomy and should not be dismissed without consideration that this may represent a complication. Another reliable guide is if the patient is unable to be discharged within 24 h due to severe pain or another clinical problem, a bile leak needs to be considered and investigations performed accordingly.

The consequences of delay in diagnosis and management of undrained bile collections involve exposing patients to high rates (21–62%) of serious morbidity (sepsis and multi-organ failure), increasing length of stay [17] as well as risking litigation [18]. The risk of developing serious complications is associated with a longer duration of undrained bile and it also confers a much higher risk that the bile becomes infected. Despite this mortality from delay in diagnosis and control of sepsis however remains rare (1.5%) [19].

Once a bile leak is suspected imaging should be used to confirm this and measures taken to place a drain in order to establish a controlled biliary fistula and control sepsis.

Where a bile leak is expected post operatively; where the liver bed has been entered,

there is concern about the cystic duct closure or a subtotal cholecystectomy has been performed a drain should be placed in the gallbladder fossa in anticipation of a bile leak after such a difficult case (Chap. 16). This may drain bile (Fig. 22.12), confirming a bile leak and creating a controlled fistula and preventing biliary peritonitis and associated sepsis. This must be balanced out with the fact that routine placement of a drain leads to increased postoperative pain, increased hospital stay and does not prevent intra-abdominal complications [20] and is therefore not recommended routinely.



**Fig. 22.12** Controlled biliary fistula post laparoscopic cholecystectomy

## Imaging

The appropriate imaging modality selected for investigation of the patient will depend on a number of factors. Specifically:

- Clinical scenario presented to the clinician
- Diagnostic question that needs to be evaluated
- Local availability and expertise in the investigation.

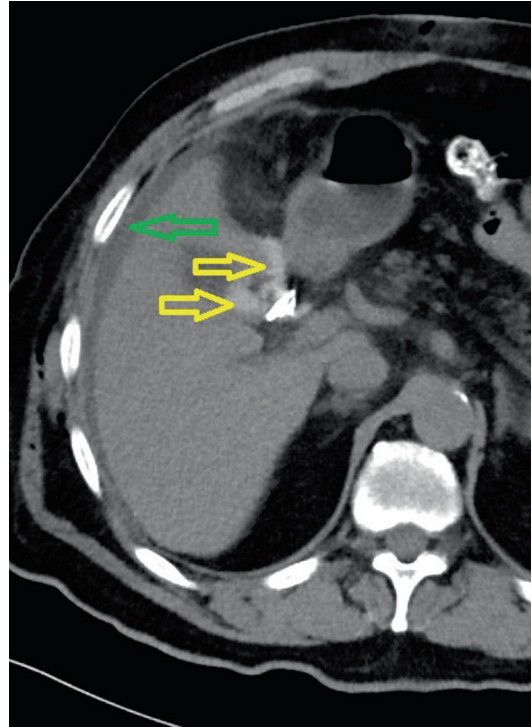
**Ultrasound (US)**—may detect free or loculated fluid but is not able to distinguish between the nature of the fluid. In general, it may be limited due to body habitus and pain and may not exclude a leak (Chap. 2). With those limitations it may be a cheap, non invasive adjunct to assessment of the patient in detecting a post operative fluid collection.

**Computerized Tomography (CT)**—is widely available and very sensitive in detection of post operative fluid collections to allows diagnosis (Fig. 22.7). The images need to be interpreted in the correct clinical scenario—that is it will show post operative fluid, but not the nature of it—blood, bile, enteric content. Neither US or standard CT will define the dynamics of a leak, the site, the presence of a major duct injury of the presence of a CBD stone that may be contributing to the leak (Fig. 22.7).

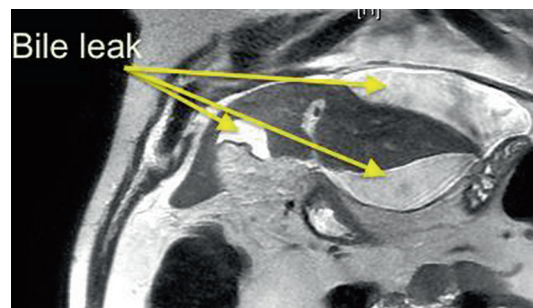
### CT Cholangiography

Where available CT Cholangiography, not only demonstrates the dynamic bile leak (Fig. 22.13) but delineates the biliary anatomy, the possible site of leak and the presence of any stones that will aid in ongoing management. There are limitations however in the availability of this modality and the sensitivity of this in the presence of co-existing biliary obstruction with variable excretion of contrast and subsequent cholangiogram acquisition.

Magnetic Resonance Cholangiopancreatography (MRCP)—exhibits a high sensitivity 84–100% of detecting biliary injuries. Specificity is

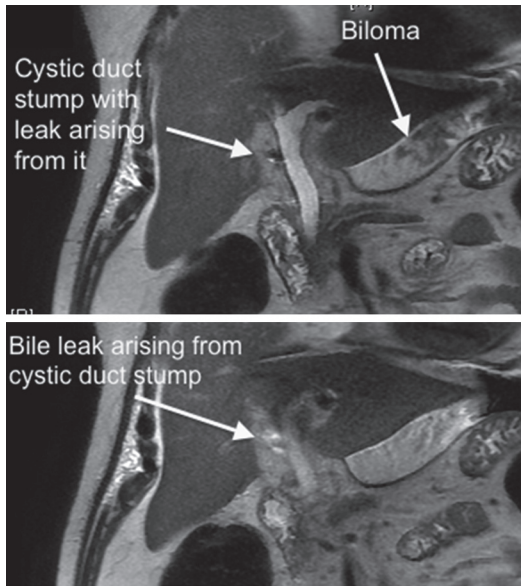


**Fig. 22.13** A CT Cholangiogram after a difficult laparoscopic cholecystectomy where there was a post-operative bile leak. The leak is demonstrated in a dynamic fashion; the site is identified as the cystic duct. There is no major biliary injury and no CBD stone exacerbating the leak

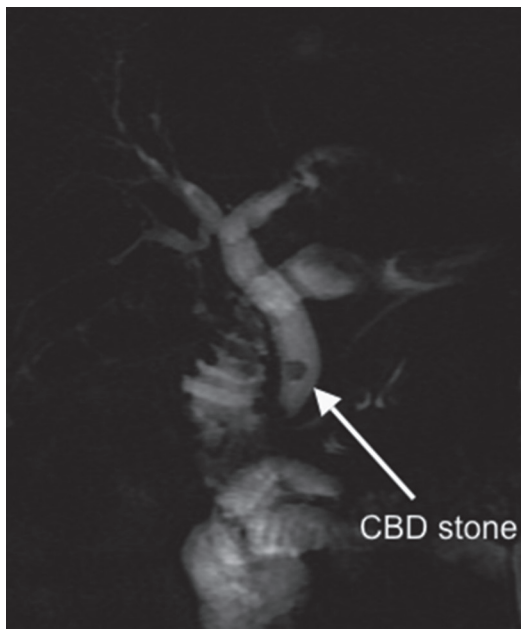


**Fig. 22.14** Bile leak as detected by MRCP from the Gallbladder fossa collecting around the left lobe of the liver

100% [21]. It provides structural confirmation of a bile leak, a bile duct injury and can detect the presence of choledocholithiasis (Figs. 22.14, 22.15 and 22.16).



**Fig. 22.15** Bile leak arising from the cystic duct stump as detected on MRCP



**Fig. 22.16** Bile duct stone detected as a filling defect on MRCP reconstruction following a bile leak post laparoscopic cholecystectomy

## Hepatobiliary Scintigraphy

Hepatobiliary scintigraphy is a radionuclide diagnostic imaging study, utilizing Hepatobiliary IminoDiacetic Acid (HIDA) labelled with  $^{99m}\text{Tc}$  given by intravenous injection which evaluates hepatocellular function and the biliary system by tracing the production and flow of bile from its formation in the liver, and its passage through the biliary system into the small intestine [22]. It detects active bile leaks, both free intraperitoneal and contained intrahepatic leaks by progressive accumulation of radiotracer in the abdominal cavity that does not conform to the morphologic appearance of the bowel is characteristic of bile leak (Fig. 22.9). The HIDA scan is considered the gold standard investigation to detect a bile leak with a sensitivity and specificity close to 100% for detection of a bile leak. Its limitation lies in the fact that although it confirms the presence of a bile leak, it does not localize or provide structural information.

## Establishing a Controlled Biliary Fistula

Once the diagnosis of bile leak has been made, options for drainage of bile include:

- (a) Image guided percutaneous drainage
- (b) Re-laparoscopy, aspiration of bile, lavage of the peritoneal cavity and placement of an operative drain in the gallbladder fossa.

Although a combined approach of percutaneous image guided drainage of post cholecystectomy bile leaks and ERCP has been shown to be successful in resolution of the problem in a number of series [17, 23] re-laparoscopy has a number of significant and important advantages:

1. It allows adequate aspiration and lavage of all bilomas within the peritoneal cavity that may

be loculated or inaccessible by percutaneous routes. This ensures adequate surgical treatment of the biliary peritonitis with a reduction in subsequent abscess formation.

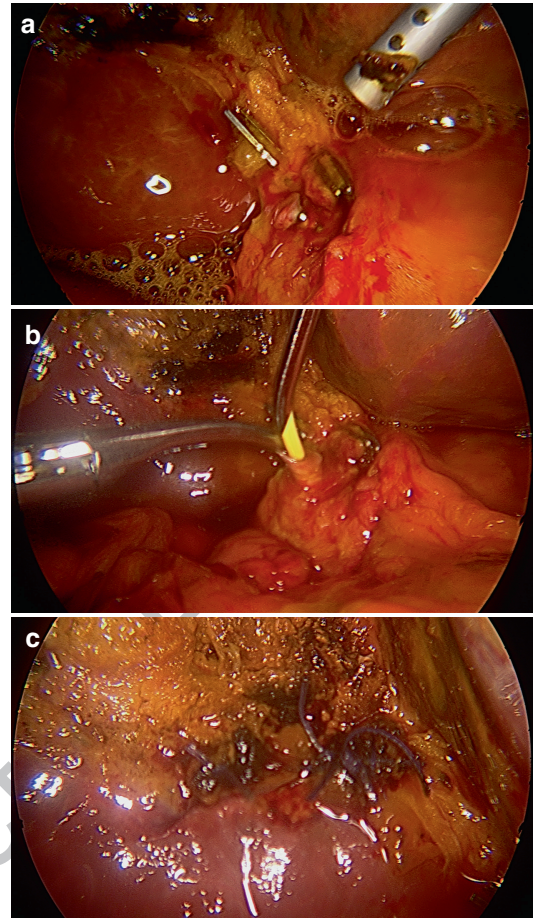
2. It permits placement of a larger drain in the gallbladder fossa to control any subsequent bile leak and create a controlled fistula. This prevents the recurrence of biliary peritonitis or the re-accumulation of bilomas
3. It allows the possibility of performing an intraoperative cholangiogram (Fig. 22.17)
4. It does not significantly increase the morbidity for a patient that has already undergone laparoscopy very recently.
5. It can provide further information as to the source of the bile leak but also the possibility of successful definitive treatment of the bile leak (>90%) [24–26] at the time of surgery in the case of cystic duct stump leaks (Case C), Duct of Lushka leaks or gallbladder fossa leaks (Fig. 22.17).

We would therefore advocate that a re-laparoscopy and washout of a suspected bile leak is the procedure of choice and that clinicians should have a low threshold to proceed.

### Definitive Management of the Bile Leak

While the definitive management of the bile leak may occur at the re-laparoscopy due to either the associated pathology or the experience of the surgeon the bile leak may persist. However, this shall now be a controlled bile leak or biliary fistula. Once control of sepsis has been obtained and physiology normalized, endoscopic therapy with Endoscopic Retrograde Cholangiopancreatography (ERCP) is the cornerstone of management of ongoing biliary leaks. Although a small group of patients may resolve without the need for intervention from ERCP [16, 27], the vast majority of patients require endoscopic intervention.

While pre-operative CT cholangiogram or MRI are important prior to the re-laparoscopy pre ERCP biliary imaging with either CT cholangiogram or MRCP has a very limited role. ERCP



**Fig. 22.17** Vision of the cystic duct and cystic artery clips in the same patient as Fig. 22.6. (a) The cystic duct clips were removed and a cholangiogram catheter inserted. The leak was demonstrated with a saline flush and then confirmed with a cholangiogram. The cholangiogram excluded any other leak or CBD stone. (b) The site of the gallbladder bed was sutured with 3/0 PDS. The closure of the leak was confirmed with the saline flush and cholangiogram. A drain was placed, but there was no post-operative bile leak. The drain was removed 48 h later and the patient discharged well

provides both diagnostic and therapeutic capabilities and so remains the preferred management pathway. The goals of ERCP involve:

- confirmation of the diagnosis
- classification of the site of injury
- removal of any distal obstructing calculi
- decompression of the biliary system by insertion of a biliary stent, with or without a sphincterotomy.

The aim of the ERCP intervention is to decrease the transpapillary gradient across the sphincter of Oddi and promote drainage of bile through this preferred route rather than extravasation through the site of injury, which would allow sufficient time for the injury to heal. This may be achieved by a combination of either sphincterotomy and or stent insertion across the papilla, without the need to cover the defect.

The general principles when performing ERCP involve:

- Cannulation of the Ampulla
- Cholangiogram to confirm the presence of a leak, anatomy and presence of stones/strictures
- Possible Sphincterotomy (as treatment or for removal of bile duct stones)
- Insertion of Biliary Stent (Figs. 22.8 and 16.31)
- Removal of surgical/radiologically placed peritoneal drain once bile leak dried up
- Removal of Biliary Stent with repeat ERCP and check cholangiogram between 6 and 8 weeks later.

Following either sphincterotomy and/or insertion of a biliary stent, resolution of the bile leak occurs within 3–6 days in over 90% of cases with a single ERCP (Table 22.2).

Stents do carry a small risk of migration which may be problematic and may become occluded—especially if left in place for a long time or patients fail to have them removed.

**Table 22.2** Rates of resolution of bile leaks as reported in the literature

n	Successful ERCP	Re-intervention
178	162	16 6 required third intervention
48	44	0
21	19	1
72	–	–
90	65	0
207	–	11
127	115	12
96	89	7
52	52	0
36	27	0

## Sphincterotomy

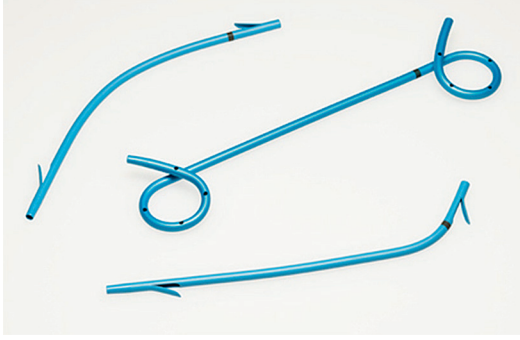
A sphincterotomy may need to be performed for access to the bile duct in the form of a precut or needle knife sphincterotomy or in order to allow retrieval of stones—if there are no contraindications to performing this such as coagulopathy. Endoscopic sphincterotomy is however associated with not insignificant risks of developing complications (Table 22.3).

In addition to these early complications there has been a widely held belief and concern that performing a sphincterotomy has long term implications for young patients—in particular a risk of cholangiocarcinoma. The association appears to be extrapolated from the observation that biliary—enteric anastomoses carry a long-term risk of cholangiocarcinoma secondary to reflux of pancreatobiliary and duodenobiliary reflux causing chronic inflammation and bacterial overgrowth of the biliary tree which induces hyperplasia, dysplasia and atypia of the epithelium which can lead to carcinogenesis. There have been two large population-based studies recently that did not demonstrate a causal association between sphincterotomy and cholangiocarcinoma [29, 30].

It does make sense to try and preserve the ampulla if possible and it is the authors' preference to attempt cannulation without sphincterotomy and insertion of a straight plastic stent held in place by the ampulla. When a sphincterotomy has not been performed we use plastic pigtail 7 Fr stents (Fig. 22.18). This decreases the possibility

**Table 22.3** Risks of early complications from Endoscopic Sphincterotomy in cohort of 2347 patients of 16 North American Institutes [28]

Early complications	Rate (%)
Pancreatitis	5.4
Severe pancreatitis	0.4
Haemorrhage	2.0
Severe haemorrhage	0.5
Perforation	0.3
Cholangitis	1.0
Severe cholangitis	0.1
Miscellaneous	1.1



**Fig. 22.18** Boston Scientific Biliary stents—both straight and pigtail stents demonstrated

of stent migration of a straight plastic stent with a non-intact ampullary sphincter. Although not evidence based a 2nd pigtail stent is occasionally inserted, where possible to encourage better drainage of the biliary tree.

### Sphincterotomy Alone vs. Stent

There is clear evidence that biliary stent insertion is far superior to sphincterotomy alone in resolution of bile leaks. This is reflected in multiple series which report significantly higher rates of re-intervention after sphincterotomy alone [4, 31, 32]. Interestingly, a multivariate logistic analysis of a series of bile leaks identified that insertion of a stent was 71 times more likely to be successful in drying up the bile leak than in sphincterotomy alone [33].

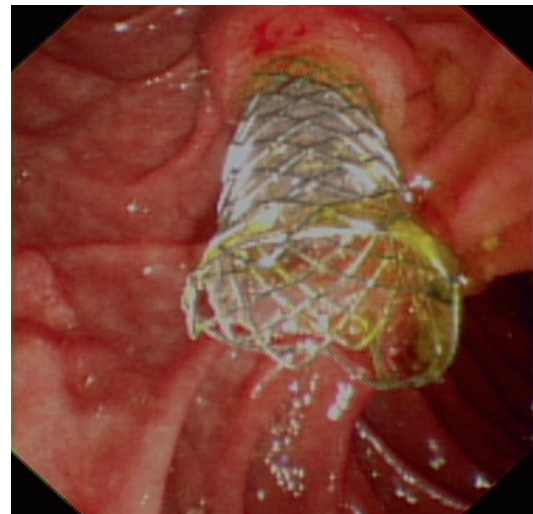
### Stent Size

The commonest used stent sizes are either 10Fr or 7Fr plastic biliary stents. Despite the theoretical benefit of a larger stent, two randomized controlled trials comparing the two sizes have addressed this issue and have not identified a significant difference [33, 34]. It appears that for most patients these does not appear to be a significant difference between the stent sizes, in fact the possibility of a larger stent causing pancreatitis has been suggested by some groups due to the obstruction of the pancreatic orifice [35].

### Refractory Bile Leaks

Although the initial intervention of ERCP appears to have a high success rate of over 90% in resolution of bile leaks there remains a small group of treatment failures, where standard insertion of a plastic stent has not sufficiently decreased the transpapillary gradient to allow closure of the bile leak. This may relate to stent obstruction or may be associated with a high grade leak. Options for treatment of refractory bile leaks following initial successful cannulation and stent insertion include repeating the ERCP and inserting a further plastic stent or covered Self Expanding Metal Stent (SEMS) (Figs. 22.19 and 22.20).

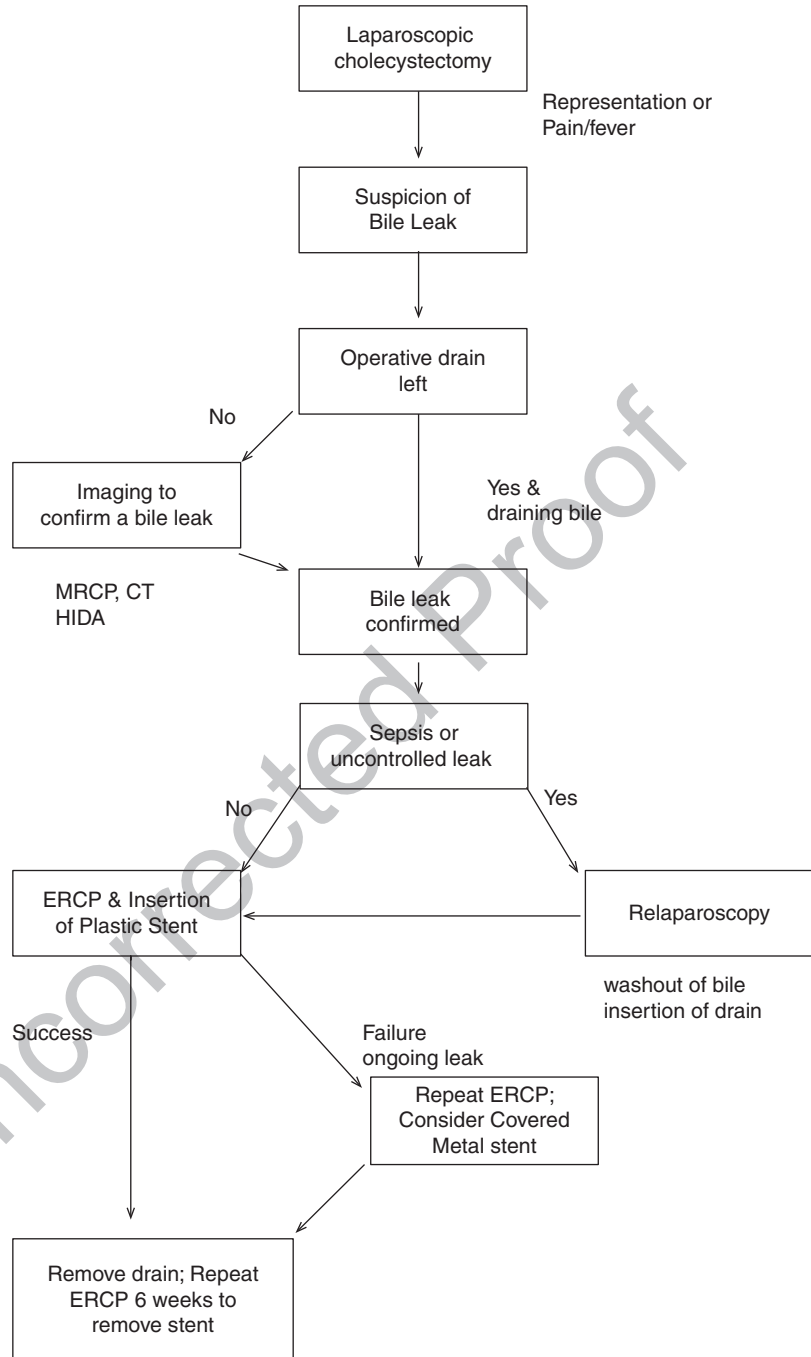
Replacing the plastic stent may be useful in the situation where the existing plastic stent is clogged or blocked and thus inadequately decompressing the biliary tree. This may result in resolution in a number of patients. In a recent a retrospective multicenter series from Portugal of 178 post cholecystectomy bile leaks, Canena et al. report their experience of resolution of refractory bile leaks 10/16 patients with repeat ERCP and insertion of further plastic stents. Failures of this treatment then went on to have SEMS inserted with resolution of bile leak at a median of 6 days.



**Fig. 22.19** Endoscopic view of Boston Scientific Wallflex Covered Biliary Self Expanding Metal Stent (SEMS) in situ in the bile duct

**Fig. 22.20** SEMS  
Mr. Nosworthy MRC to  
get. Suggested algorithm  
for management of post  
cholecystectomy leaks

[AU3]



Univariate analysis from this series suggested that a high-grade leak was associated with further interventions [36].

SEMS appear to have a role in refractory bile leaks, where they provide a high level of resolu-

tion between 90 and 100%. The SEMS need to be fully covered to allow removal which needs to occur within 6–8 weeks following insertion, to allow ease of removal. They presumably allow a very high level of decompression of the biliary

tree with stent diameters of 10 mm. In addition, they may be deployed to cover the leak site completely -i.e. cystic duct origin and thus further aid drying up of the bile leak (Fig. 22.20). They are however expensive—approximately \$3000AUD per stent compared to \$82 AUD per straight plastic stent- and can only be recommended where previous plastic stents have failed to seal the leak.

## Summary/Keypoints

- Post cholecystectomy bile leaks most often arise from the cystic duct stump or accessory hepatic ducts.
- A high index of suspicion is necessary to allow early detection and management to prevent a sepsis from an undrained bile leak
- CT or MRCP appears to be initial investigation of choice to detect a bile leak post cholecystectomy
- Where a bile leak is suspected, relaparoscopy enables adequate washout and provides an opportunity to correct the problem
- ERCP and biliary stent insertion remains the cornerstone of management if there is an ongoing bile leak.

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# Author Queries

Chapter No.: 22      0003182560

Queries	Details Required	Author's Response
AU1	Please check and confirm if the affiliation is presented correctly.	
AU2	Please check the hierarchy of the section headings and confirm if correct.	
AU3	Please check and confirm if the caption of "Figure 22.20" is fine.	
AU4	We have relabeled Figs 22.1, 22.9. Kindly check and provide better quality figures if any.	

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