Emergency laparoscopic common bile duct exploration and analysis of risk factors for post-procedure leak: A seven years' experience

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ABSTRACT

Introduction: Laparoscopic common bile duct exploration (LCBDE) for choledocholithiasis in the emergency setting is challenging and technically demanding. This study aims to assess the safety and efficacy of emergency LCBDE and to analyze risk factors for post-operative bile leak.

Materials and Methods: A retrospective data collection was done over medical notes and electronic records of the patient for the period between January 2011 to October 2017. Merely the emergency LCBDEs were involved in this series. All of the emergency LCBDEs performed were on the index admission. Univariate and multivariate analysis were carried out for the risk factors of bile leak post-procedure.

Results: 78 patients were undergone emergency LCBDE in the given period. 76 patients had a laparoscopic cholecystectomy as well as emergency LCBDE; two patients had previously undergone laparoscopic cholecystectomy. While choledochotomy was performed in 62 patients, 16 patients had a transcystic approach. All emergency LCBDEs were initiated laparoscopically, three (4%) patients had to be converted to open procedure due to adhesions (one) and impacted stones (two). In 72 patients (%89), the CBD was cleared in 72 patients (89 %) and 9 patients were considered to be in need of post-operative ERCP (6 for retained stone, 2 showing clear ducts, and 1 for continuous bile leak). Normal CRP and bilirubin values were significantly associated with post-operative bile leak.

Conclusion: Emergency laparoscopic common bile duct exploration is safe, feasible, and efficient in the emergency management of common bile duct stones.

Keywords: Bile leak; common bile duct stones; emergency; laparoscopic.
feasible and effective management for acute presentation of CBD stone diseases. Choledochotomy and transcystic approaches in LCBDE are both valid options for treatment of CBD stones. Historically, a choledochotomy incision used to be drained via a T-tube; however primary choledochotomy incision closure without a T-tube has been shown to be safe and cost effective option. Bile leak following LCBDE and primary closure is one of the major potential complications of the procedure. One series has shown some potential risk factors of bile leak following LCBDE in the elective setting; this would help to predict patients at high risk of bile leak and may be used in considering other treatment options. Many series have published data from heterogeneous groups of elective and emergency LCBDE results. In our series we demonstrate the feasibility and safety of exploring the CBD laparoscopically in the emergency setting specifically and show the outcomes in terms of duct clearance, hospital stay, operative time and complications. This series also identifies potential risk factors for bile leak following LCBDE in the emergency setting.

Materials and Methods

Patients were identified retrospectively from our database that had an emergency LCBDE between January 2011 and October 2017. All patients were consented for the procedure and Caldicott approval obtained from the local governance team. All patients had been admitted as an emergency and were investigated with serum blood tests in forms of full blood count, Liver function test, urea and creatinine, Amylase and CRP. All patients had ultrasound imaging and all patients included were confirmed to have CBD stones via MRCP and/or CT-scan.

Our criteria for emergency LCBDE were that a patient was admitted as emergency with evidence of CBD stones and CBD diameter of 10 mm or more. All patients had a LC during their index admission.

Procedure: Patient position and port placement are as per standard for LC. Most of the patients had LC and LCBDE at the same time except for a few who had solely LCBDE due to previous LC. We adapted both transcystic and choledochotomy approaches depending on the diameter of cystic duct. When the transcystic approach failed, we converted to a choledochotomy if the anatomy was favourable. Exploration of the CBD was performed using a re-usable cholecdochoscope (3 mm in transcystic and 5 mm in choledochotomy) or disposable bronchoscope (Ambu Scope) (3.8 mm in transcystic and 5 mm in choledochotomy). We used normal saline to irrigate and distend the CBD. A Dormia® basket was used to retrieve any CBD stones. After transcystic exploration we clipped the cystic duct with Titanium or absorbable locking clips. We closed the choledochotomy incision using either PDS® or Vicryl® suture which could be of any size from 2/0 to 4/0, interrupted or continuous (depending on surgeons preference). LC was performed at the completion of the procedure; we always used two drains in the cholecystostomy group (one sub hepatic and other sub-phrenic) and one subhepatic drain in transcystic group.

Our definitions of a bile leak post emergency LCBDE are:

1- Drains continue to leak bile more than 100 mls /day for 3 days or more.
2- Evidence of abdominal pain and peritonism in the postoperative period necessitating the patient return to operating theatre.
3- Radiological evidence of large volume of intra-abdominal fluid collections.

We categorised factors which we thought they might associated with bile leak following emergency LCBDE into three groups:

1- Demographic (Age, sex, diagnosis)
2- Bio-chemical and radiological (Bilirubin, CRP, WBC levels and CBD diameter)
3- Operative (suture type, technique of closure, size of suture and T-tube usage).

Analysis of risk factors for bile leak was performed using uni-variance and multi-variance analysis via logistic regression methods using SPSS 16.0.

Results

Seventy eight patients underwent emergency LCBDE. There were 55 female and 23 male patients; mean age for patients was 57±18 years. Seventy six patients had a laparoscopic cholecystectomy as well as emergency LCBDE; two patients (2.5%) had a previous laparoscopic cholecystectomy. Four patients (5%) had a previous gastric bypass surgery that was already not suitable for ERCP. Eight patients (10%) had unsuccessful ERCP and were referred for emergency LCBDE.

Patients presentations were primarily obstructive jaun-
dice in 24, cholangitis in 19, acute pancreatitis in 18 and acute cholecystitis in 17 patients (Table 1).

The mean time for patients waiting for surgery was 2.7±1.2 days. The mean overall hospital stay was 7.5±2.2 days, while the average post-operative stay was 4.6±1.5 days. A choledochotomy approach was performed in 62 patients, while a transcystic approach was followed in 16 patients. A transcystic approach was commenced in 23 patients and was successful in 16 patients. A transcystic approach was unsuccessful in seven patients because four had a large impacted stone, two anatomical difficulties and one when a 3mm choledoscopy was not available. The mean operative time for trans-cystic and choledochotomy approaches were 106 and 135 minutes respectively. In emergency LCBDE group, three patients (4%) had to be converted to an open procedure due to adhesions (one) and impacted bile duct stones (two). The CBD was cleared in 72/78 patients (89%). All the six patients who did not have the CBD cleared via laparoscopic CBD exploration proceeded to a post procedure ERCP (four of these patients had their CBD cleared from impacted stones with ERCP, one patient need laparotomy to clear the duct after failed attempt of ERCP and one his ERCP showed no stone).

Table 1. Shows demographic, hospitalisation, diagnosis and complications

| Sex | Approach | Hospitalisation | Mean age | Complications |
|-----|----------|-----------------|----------|---------------|
|     |          | 55 F versus 23 F | 62 Choledochotomy | 16 Transcystic |
| Time to operation | 2.7 days | 1 adhesion, 2 impacted stones |
| Post-operative stay | 4.6 days | 6 had already failed ERCP preop |
| Overall hospital stay | 7.5 days | 9 re-lap,1 ERCP, 3 conservative |
| Conversion rate | 3/78 | 3/78 death (medical reasons) |
| Bile leak | 13/78 | |
| Death and Re-admission | 3/78 re-admission | |

Sex 55 F versus 23 F Mean age 55 years

Obstructive jaundice 24/78 Deranged LFTs, normal inflammatory, thin wall GB
Cholangitis 19/78 Deranged LFTs, raise inflammatory markers
Acute pancreatitis 18/78 Raise amylase more than 400 regardless other finding
Acute cholecystitis 17/78 Thick wall GB with/out deranged LFTs and raise inflammatory markers

Five patients (6%) developed a post-operative chest infection. There was no surgery related mortality. Three patients (4%) were re-admitted within 30 days post-operatively; two were for a bile leak and one due to a post-operative pneumonia.

In univariate analysis, a normal bilirubin level p=0.009, OR 9.9 and CI 2.2–48), a normal CRP (p=0.021, OR 5.5 and CI 1.04–25) and PDS suture for choledochotomy closure (p=0.01, OR 5.6 and CI 1.4–23) were significant risk factors for bile leak. Gender (Male/Female), age (Above 70/less than 70), White cell count (more than 10 or less than 10*9, size of CBD (more than 12 mm/less than 12 mm), diagnosis (Biliary colic/non-biliary colic) and T-Tube usage had

Thirteen patients (16%) had a post-operative bile leak. All thirteen occurred after a choledocotomy was performed (9 needed re-laparoscopy for drainage and wash out, 3 were treated conservatively and 1 needed ERCP to drain the biliary system). There were no post-operative bile leaks following a transcystic approach. A T-tube was used in 12 patients. Most of the T tube insertions were during the early years of this series. The reasons for utilising a T tube were impacted and/or missed stones in five patients, a difficult procedure and/or unhealthy tissue for primary closure in four patients and preference of the surgeons as part of their routine practice in three patients. In patients who had T tube insertion due to concern about impacted/missing stones, four had impacted stones which were cleared by ERCP and one needed laparotomy to remove the stone after failed ERCP. T tube removal was after 4–12 weeks post procedure.
no significant effect on the rate of bile leak (P 0.45 OR 1.6, P 0.97 OR 1.0, P 0.48 OR 1.6, P 0.1 OR 2.7, P 0.1 OR 1.2 and P 0.1 OR respectively). Normal CRP and normal bilirubin were significantly associated with post emergency LCBDE bile leak on multivariate analysis (0.04 OR 4.1 and 0.009 OR 6.9 respectively) (Tables 2, 3).

### Discussion

Emergency LCBDE and ERCP have equivalent outcomes and are widely accepted procedures for urgent biliary system decompression and both treatments are recommended by published guidelines. The choice of the procedure depends on the endoscopic expertise in ERCP and...
the degree of surgeon’s experience performing LCBDE. LC+LCBDE have been shown to be more cost effective in comparison to LC+ERCP. Furthermore, ERCP has its own specific complications including damage to the sphincter of Oddi (SOD) which could have significant consequences to patients.

There is still no clear consensus about which modality is the best to treat CBD stones and specifically in the emergency setting. This series is one of very few which have investigated LCBDE in the emergency setting and probably the first one to analyse and predicted risk factors of bile leak following emergency LCBDE. In our study, the conversion rate to open surgery was 4%. This is in line with other published series. Duct clearance rate (89%) in this series is comparable to other emergency LCBDE series and elective LCBDE. CBD clearance was achieved in 6 patients who had impacted stones and had prior unsuccessful ERCP.

LCBDE may have serious potential complications. One of the important complications that can follow emergency LCBDE is post-operative bile leak. There is wide variability in the bile leak rate reported in the literature. Only a small number of series have defined bile leak post LCBDE. In our series, bile leak was reported in 13 patients (16%); this is higher than our large series of 300 patients. This is probably because in emergency setting we are doing more challenging cases which either had previous surgery or had unsuccessful ERCP due to impacted stones. One study on emergency LCBDE reported a 6% bile leak but it did not define bile leak clearly.

A published series has found possible associated factors with bile leak in the elective setting such as surgeon’s experience and size of bile duct. We found no relation for a bile leak in relation to the size of the CBD. We found a significant difference in relation to the type of suture for suturing the CBD. We found that PDS is associated with a post procedure bile leak. PDS suture has a memory that makes it difficult to manipulate during suturing in comparison to Vicryl this may affect the degree of suturing and knotting security. This is a potentially important finding and certainly warrants further investigation. As this technical choice could have a direct impact on procedural results.

In our analysis, a normal bilirubin and/or a normal C-reactive protein are associated with a post procedure bile leak. This is a difficult result to explain in that we would have expected raised inflammatory markers to indicate local inflammation of the CBD which could increase the risk of a bile leak. Likewise, a raised bilirubin would be conventionally expected to be a risk factor due to a high pressure biliary system. It can be speculated that normal bilirubin might reflect less dilated biliary system which lead to increased risk of bile leak, low CRP might indicates thin wall CBD which makes it less robust during suturing. As such, this finding is difficult to interpret. This warrants further investigation to investigate any preoperative risk factors.

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**Table 3. Shows results of multivariate analysis of bile leak risk factors**

| Risk factors                          | Univariable regression | Multivariable regression |
|--------------------------------------|------------------------|--------------------------|
|                                      | OR (95% CI)            | p                        | OR (95% CI)            | p     |
| Sex (male/female)                    | 1.6 (0.4–6.6)          | 0.45                     | 1.6 (0.4–6.6)          | 0.49  |
| Age (years) (≥70/<70)                | 1.0 (0.29–3.7)         | 0.97                     | 1.0 (0.29–3.7)         | 0.97  |
| Serum leukocytes (≥11×10⁸/L)         | 1.6 (0.43–6.0)         | 0.49                     | 1.6 (0.43–6.0)         | 0.49  |
| Total bilirubin (≥20/≤20 umol/L)     | 9.9 (2.0–48.9)         | 0.0009                   | 9.9 (2.0–48.9)         | 0.0009 |
| CRP (≥20/≤20)                        | 5.1 (1.0–25.6)         | 0.023                    | 5.1 (1.0–25.6)         | 0.023 |
| Diameter of CBD (≤12mm/≥12 mm)       | 2.78 (0.78–9.9)        | 0.1                      | 2.78 (0.78–9.9)        | 0.1   |
| Presentation (Cholangitis vs Non cholangitis) | 1.2 (0.37–3.9)        | 0.8                      | 1.2 (0.37–3.9)        | 0.8   |
| Method of suture (continuous/interrupted) | 1.3 (0.3–5)           | 0.7                      | 1.3 (0.3–5)           | 0.7   |
| Suture type (Vicryl/PDS)             | 5.7 (1.5–22.1)         | 0.01                     | 5.7 (1.5–22.1)         | 0.01  |
| T-Tube used/ T-Tube non-used         | 3.4 (0.9–9.9)          | 0.1                      | 3.4 (0.9–9.9)          | 0.1   |

CI: Confidence interval; CRP: C-reactive protein; PDS: Polydiaxonone suture.
Limitations
This is a retrospective series from a single unit. This limits the generalizability of our results. The study size is also relatively small (although comparable to other series). This also limits the range of our conclusions in this study.

Conclusion
Emergency LCBDE is a safe and feasible procedure for the treatment of emergency presentation CBD stones and it should be considered in the emergency management of bile duct stones.

Disclosures

Ethics Committee Approval: Northumbria healthcare foundation trust/2018 approval.

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Conflict of Interest: None declared.

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