Biliary Leak After Laparoscopic Cholecystectomy; Incidence and Management
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ABSTRACT
Background: Biliary leak represent an unusual complication of laparoscopic cholecystectomy (LC). The origin of the biliary leak is multifactorial, which may arise from GB bed, cystic, or injuries of a major bile duct. Even with standardization and growing experience, LC still duct, involves the threat of damage of the biliary tree.
Patients and Methods: This retrospective study was achieved at the department of general surgery, Al-Azher University, Assiut between October 2015 to September 2020. The current study was a case series of 1000 cases who underwent LC. Twenty cases complaining of biliary leakage post-LC had been reported consecutively. The age of Patients was (14 - 65) years and sex was dispensed as 780 females and 220 males.
Results: In the current study there were 20 cases out of the 1000 patients that underwent LC complained from biliary leakage, 14 patients of the twenty patients were presented with bile leakage post LC which were attributed to gallbladder Bed, Duct of Luschka, and minor accessory duct, two case due to insecure or slipped ligature of the cystic duct, and a slipped clip and 2 cases due to injury to CHD and other two cases due to direct injury to CBD. The definitive treatment of biliary leakage was done. All cases were treated therefore with the use of endoscopy in 4 cases (plus percutaneous techniques in 3 patients) and surgical intervention in 1 patient and one patient died.
Conclusion: The endoscopic management proved very effective in cases with simple biliary leakage than patients with complex bile leaks.
Keywords: Laparoscopic cholecystectomy; bile duct; Bile leak; Percutaneous.

INTRODUCTION
Laparoscopy comes to be the preferred technique for the treatment of symptomatic cholelithiasis and an increasingly more approach performed for acute cholecystitis(1). Despite the brilliant effect of LC for the treatment of cholelithiasis, however, surgeons retain to stand challenges in the utility of LC in surgery(2). Nowadays Laparoscopic cholecystectomy may be a straight forward surgical procedure, however can also be a surgical procedure fraught with underlying complexities. The anatomic variations and the severity of underlying pathology make Laparoscopic cholecystectomy difficult in different situations. Many surgeons continue to be tremendously inexperienced in laparoscopy in regards to the technical nuances that permit for success and secure completion of a difficult LC(3).
LC remains a secure approach with a mortality rate of 0.22-0.4%(4). Major morbidity takes place in about 5% of cases(5). The most dreaded complication of LC is biliary injury and leakage. Biliary leakage is an infrequent disorder but critical. The causes of biliary leakage may be due to traumatic causes or most commonly iatrogenic(6). The tremendous causes occur following hepatobiliary surgical procedures and the remarkable causes always following LC or open cholecystectomy(7). Bile ducts injuries takes place in about 0.1% - 0.2% in open cholecystectomy and 0.3% - 0.8% at LC(8). The bile leak is commonly the end result of direct injuries to the bile duct, unsecure or slipped ligature or clip of the stump of the cystic duct, or bile leak from the liver bed and commonly induced with blockage of the distal part of the duct from residual stone or stricture(9).
A minor biliary leak can disappear spontaneously whilst a major leak can result in drastic effects on the patient(10). So that the cases presented with internal or external bile leak leading to localized or generalized biliary peritonitis(11). About 10% - 24% of bile duct injuries are identified during surgery whilst the remaining injuries are recognized after surgery or after discharge(12). Early treatment in a specialized center is the cornerstone for pleasant outcomes. Improper treatment commonly leads to critical co-morbidities and repair becomes more difficult(13).
Surgical intervention is associated with highly satisfactory results, however, it is related to severe co-morbidities and associated with a higher mortality rate(14). Preoperatively the treatment plan includes simple drainage and rapid transfer up to Bilio-enteric anastomosis(15). The minimal invasive endoscopy with evidenced outcomes identical to surgical results has become the management of choice(16). In comparison to surgical procedures, endoscopy can also additionally need multiple sessions and its efficacy is not satisfactory in all patients(17). The quality of treatment surgery versus endoscopy of biliary leakage remains one of the essential difficulties facing surgeons(18).
Furthermore, the prevalence of bile duct injuries related to LC does not appear to have diminished in more recent surveys, suggesting that the previously observed elevation is not always definitely the end result of a learning curve related to the laparoscopic approach.

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Finally, because of the increasing frequency of LC, it is expected that one in every two or three surgeons will create a bile duct injury throughout his or her career (19).

Aim of the work was to estimate the incidence and management options of post laparoscopic cholecystectomy biliary leaks.

PATIENT AND METHOD

This retrospective study was performed at the Department of General Surgery, Al-Azhar University Hospital, Assiut between October 2015 to September 2020. This article was a case series of 1000 cases that underwent LC. Twenty cases with a biliary leakage post LC had been reported consecutively.

Ethical Considerations:

After approval from the local ethical committee of Faculty of Medicine, Al-Azhar University and informed written consent was taken from all cases who accepted to participate in this research article.

The age of the cases varied from 14 to 65 years and sex was dispensed as 780 females and 220 males. A full history was taken, physical examination, laboratory investigations (complete blood count, liver function tests, coagulation profiles) and radiological investigations (ultrasonography) (Fig 1) were reported. Computed tomography (CT) (Fig 2) or magnetic resonance imaging (MRI) (Fig 3) were done in some selected cases in this study the period for follow up was 3 months. Twenty cases with cholecystitis (acute and chronic) who undergo LC and suffering from postoperative bile leak, were included in this study. This article didn’t include cases that had: Bile leakage following LC converted to open procedure, Bile leakage due to other procedures, and Bile leak discovered and definitively treated intraoperatively.

Also, the cases associated with biliary leakage due to traumatic causes, rupture, associated biliary malignancy, or vascular injuries were excluded. Biliary leakage was recognized clinically (abdominal pain, fever, distension, nausea, tenderness, jaundice) and radiological diagnosis (US and/or CT scan) and confirmed throughout cholangiogram. cases had been categorized actually in line with cholangiographic and operative findings into 2 groups; simple biliary leakage that consists of leakage at the liver bed, unsecure or slipped ligature or clip of the stump of the cystic duct, accessory duct leakage, and complex biliary leakage which consist of complete duct transaction.

The treatment of the cases started gradually with endoscopy (minimal invasive management). (Fig 5) alone or with percutaneous technique (Fig 7) to the more invasive surgery with planned endoscopic retrograde cholangiopancreatography, when a significant localized collection had been determined, a radiologically guided drainage was achieved, but when the collection had been massive and diffuse, drainage was carried out either laparoscopically or via open approach, either before or after the required approach. For simple biliary leakage, the cases underwent combined endoscopic sphincterotomy plus plastic stent (10F, 9 - 12 cm), straddling the site of the leakage (Fig 5).

For cases with biliary leakage and retained stones, an endoscopic sphincterotomy, removal of stone, and insertion of the stent were performed (Fig 4 and 5). For further evaluation and removal of the stent, the ERCP was repeated 2-3 months post the performed procedure. Cholangiography was carried out for confirmation of healing and lack of stricture or residual stone and as a result, they had been treated.

when ERCP failed, the percutaneous intervention was achieved either in the form of percutaneous transhepatic drainage (PTC) before the surgical intervention or a part of combined approaches (Rendezvous procedure). surgical intervention was achieved either urgently with a massive and diffuse collection not appropriate for percutaneous drainage or electively after failed or unsuitable nonsurgical management.

Follow up:

Third-generation cephalosporin antibiotics (cefoperazone), or quinolone, metronidazole infusion was prescribed for most cases. All cases were discharged from the hospital with clinical and radiological improvement and close follow-up in the outpatient clinic was achieved. Main outcome measurements: Successful treatment was obtained by the improvement of both clinical, laboratory, and radiological parameters and normal ERCP with the removal of the stent with no additional drastic effects.

Method of collection of data, operative and postoperative reports was scrutinized and data collected. In this article, clinical presentations following bile leakage, the time of detection of postoperative biliary leakage (< 24 hours or > 24 hours), acute or chronic cholecystitis at the time of the procedure, amount of bile leakage, duration of biliary leakage, postoperative investigation (MRCP, CT abdomen, USG) for biliary leakage, different modalities of treatment and their results, site of biliary leakage were noted.

Statistical analysis: was achieved using the Statistical Package for Social Sciences (SPSS) version 16. Descriptive data are expressed as mean - standard deviation or medians and ranges for continuous variables and as number and percent for categorical variables.
**Fig. (1):** Ultrasonography showing abdominal and pelvic collections.

**Fig. (2):** MSCT abdomen and pelvis with contrast showing RT sub-phrenic, porta hepatis, umbilical regions peritoneal localized collections, and multiple inserted drains.
Fig. (3): MRCP showing biliary leak and stricture of CBD.
Fig. (4): ERCP showing stricture, leak, and missed stone.
Fig. (5): ERCP showing biliary leak which was managed with stenting.
RESULTS

Percutaneous drainage of a collection under US/CT guidance had been performed before ERCP in 3 cases and laparoscopic lavage in one patient before endoscopic retrograde cholangiopancreatography, in another case, laparoscopic lavage had been done immediately post-endoscopic retrograde cholangiopancreatography period. Common bile duct (CBD) cannulation and cholangiography at endoscopic retrograde cholangiopancreatography were succussed in most patients. In a single case, the cholangiographic finding showed complete transection of the right hepatic duct, and this case finally underwent Roux-en-Y hepaticojejunostomy. Leakage at the stump of the cystic duct was reported in two patients. In one patient CBD stone was documented (Figure 4): in this patient, choledocholithiasis was detected at intra-operative cholangiogram, and post-operative endoscopic retrograde cholangiopancreatography and sphincterotomy were made for its management. In this patient, the biliary leakage was unexpected and only reported at the time of ERCP.

Common hepatic duct (CHD) leakage was documented in two patients. Endoscopy was tried in 4 of the 6 cases (66.6%); the case with a complete division of the RHD (Strasberg type C injury) underwent open reconstruction.

Endoscopic sphincterotomy was performed in 3 patients, from the 4 patients that underwent ERCP with stent placement (Figure 5), while in a single case a stent was placed without sphincterotomy. As regard complications associated with endoscopy, only two cases were reported. In the first one, the affected persons developed a mild form of acute pancreatitis, which underwent conservative treatment after staying 7-day in the hospital. The second case presented with deep venous thrombosis throughout hospitalization without further complications.

<table>
<thead>
<tr>
<th>GB Pathology</th>
<th>Number of patients</th>
<th>Percentage %</th>
<th>Major bile duct injuries (Number of patients)</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Cholecystitis</td>
<td>13</td>
<td>65%</td>
<td>3</td>
<td>0.23%</td>
</tr>
<tr>
<td>Chronic Cholecystitis</td>
<td>7</td>
<td>35%</td>
<td>1</td>
<td>0.14%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Site</th>
<th>Number of patients</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gall bladder bed, Duct of Luschka, minor accessory duct.</td>
<td>14</td>
<td>70%</td>
</tr>
<tr>
<td>CBD</td>
<td>2</td>
<td>10%</td>
</tr>
<tr>
<td>CHD</td>
<td>2</td>
<td>10%</td>
</tr>
<tr>
<td>Cystic Duct</td>
<td>2</td>
<td>10%</td>
</tr>
</tbody>
</table>
Out of the twenty patients with bile leak, 2 cases the causes of the leak were due to cystic duct causes one from the slipped clip and another one from inappropriate ligation of cystic duct both 2 patients were managed via minimally invasive (endoscopic treatment). Alone in one patient and with percutaneous drainage in the second one. 85% (17 patients) of bile leakage were identified within 24 hours, and the last 3 patients were detected late. (Table 5) The amount of biliary leakage in most of the patients (15 out of 20) is more than 500 ml and the mean duration of biliary leakage in major bile duct injuries is 7.33 days and the duration of minor biliary leakage is 7.14 days. Almost all cases of post LC bile leakage manifested with abdominal distension (65%) and tachycardia (85%) due to bilomas. Manifestations of generalized biliary peritonitis with abdominal pain (30%), fever (20%), guarding (35%) are less common. Radiological assessment of the twenty patients with biliary leak consists of USG abdomen (90%) (18 cases), MRCP (30%) (6 cases), and CT abdomen (25%) (5 cases).

As regards the condition of cases, 6 cases out of 20 cases were assessed for the site of bile duct injuries. The origin of bile duct injuries was identified to be the common hepatic duct in 20% (two cases), common bile duct in 20% (two cases), cystic duct in 20% (two cases). 70% (14 patients), bile leakage was discovered to be either from the bed of gall bladder, duct of Luschka, or injury of minor accessory ducts. Biliary leakage that was recognized to be from both the bed of gall bladder, duct of Luschka, or accessory duct injury was spontaneously resolved after controlled external biliary fistula. Conservative management consists of control external biliary fistula which was taken into consideration in 70% (14 cases) which underwent spontaneous resolution in more than one day. Surgical intervention in the form of hepaticojejunostomy in one case (5%). Another patient (5%) died from bad sequels after bile leakage because not in time referral to the hospital. Out of twenty patients, 19 (95%) cases recovered without major drastic effects and follow up for one month without any complaint. Another patient (5%) died due to biliary peritonitis who had been presented late.

**DISCUSSION**

Generally, cholecystectomies are the most achieved abdominal operations everywhere in the world. Bile leakage following either LC or open cholecystectomy due to bile duct injuries is a probably devastating problem of this otherwise secure surgical approach. The drastic outcomes of bile duct injuries can vary from minor clinically inconsiderable biliary leakage, bilomas, and biliary ascites to biliary peritonitis marked sepsis or even loss of life of the patient in the acute condition and stricture of the bile duct, secondary biliary cirrhosis, portal hypertension and end-stage liver disease which required liver
transplantation in long term. Adequate and early interventions can commonly salvage the condition and saving the affected person from major morbidity and mortality. Many researches have proven that the incidence of biliary injury has decreased over time\(^{(21,22)}\) and in line with a few authors, the patients referred with iatrogenic bile duct injury have also declined\(^{(23,24)}\).

However numerous modern studies have recommended no big difference in the occurrence of BDI over time\(^{(22)}\) and the variety and complexity of patients referred for repair have remained fixed at few specialized centers\(^{(24)}\). However, continuity of appearance BDI by inexpert surgeons has been maintained\(^{(25)}\). LC has replaced the open procedure, as the LC is accompanied with much less discomfort, rapid recovery and short hospitalization, and better cosmesis. However, LC has been related to a higher occurrence of BDI than the open procedure, which varies from 0.5% to 2.0%\(^{(9)}\). As regards the study of Adamsen et al.\(^{(26)}\) BDI is more reported after LC\(^{(26)}\), which includes a fistula, which was recorded in 1.3% to 5.5% of patients\(^{(10)}\). Ali et al.\(^{(27)}\) and Karvonen et al.\(^{(9)}\) additionally reported that BDI is often recoded more in the LC (0.2% to 0.7%) than in open cholecystectomy (0.1% to 0.4%).

Minor bile duct injuries were frequently reported problems of LC and were recorded at an incidence of approximately 1.2%\(^{(6,8)}\). If the management were unsuitable, those injuries constitute an iatrogenic catastrophe that decreasing the quality of life of the patients and leading to critical morbidity and mortality\(^{(28)}\). Currently, using endoscopy in the treatment of minor biliary tree injury has been associated with a high success rate with a marked reduction in morbidity. ERCP can be used for diagnosis of the anatomical site of bile leak and overcoming the pressure gradient at the ampulla of Vater which will permit bile to flow into the duodenum and away from the leakage site. This facilitates rapid healing of the injured site\(^{(29)}\).

In the current study, we’ve discovered that the mean duration of biliary leakage was 7.33 days that was agreed to the study achieved by Chen et al.\(^{(30)}\) (9 days), at the present study, ultrasound and CT scan of the abdomen and pelvis were the commonly performed investigations in post-operative bile leakage\(^{(9)}\), in our study the MR cholangiopancreatography was performed for delineation of the anatomy of biliary tree and detection of the site of injury which was agreed to the study performed by Mungai et al.\(^{(31)}\) which record that MR cholangiopancreatography combined with hepatobiliary contrast-enhanced MR imaging is a beneficial method that offers comprehensive data about the biliary tree and can locate the site of bile leakage and differentiate it from different postoperative complications. In our study, the commonest sites of the biliary leak were documented to be originated from the bed of the gall bladder, Duct of Luschka, and minor accessory bile duct. Type A (Leak from the cystic duct or bile duct of Luschka) was the most frequently reported bile duct injury in this study that was agreed with the study performed by Strasberg et al.\(^{(32)}\). When the continuity of biliary-enteric is present, and bile flow distal to the origin of the fistula not obstructed, a prolonged period of conservative management is recommended since spontaneous closure of the fistula is usual. Recently conservative management in the form of external drainage of bile has proven tremendous outcomes in the treatment of biliary leakage. However, in the presence of major bile duct injury, a surgical intervention must be taken into consideration\(^{(33)}\).

Conservative management in the form of the controlled external biliary fistula was performed in up to 80% of cases in this research article. Out of which 70% of the patients presented with biliary leak spontaneously resolved in two days with controlled external biliary fistula. That was agreed with the study of Chen et al.\(^{(30)}\) in which the non-surgical management of biliary leak was effective 82.5% of cases. In the current study, only one patient (5%) underwent surgical intervention in the form of hepaticojejunostomy, cases associated with a biliary leak but without considerable major duct injury usually not in need of intervention, but percutaneous external drainage of the bilomas, ERCP with ES, or placement of temporary stent may be mandatory. Major bile duct injury with or without significant biliary leakage needs more invasive treatment, such as biliary reconstruction\(^{(29)}\). Other 5% (1 case) died from complications after bile leakage because of marked sepsis.

ERCP and percutaneous transhepatic cholangiography (PTC) can determine the continuity of the biliary tree, find the actual site of the biliary leak, and consequently, permit for the correct management of injury by appropriate decompression or dilation of the biliary system. However, those procedures are invasive, using a significant quantity of X-rays and related to the hazards of complications like severe acute pancreatitis particularly following ERCP, bleeding and cholangitis following PTC. Other negative aspects encompass the inability to detect the extra biliary anomalies and no visualization of ducts upstream or downstream from an obstructing lesion (stricture, stone). Moreover, occasionally PTC may be technically difficult as intrahepatic bile ducts are commonly not dilated\(^{(29)}\). ERCP does not usually display the actual site of a leak in minor biliary injury; but, the most reported sites are the cystic duct stump and gallbladder fossa. This is showed through both the modern study and formerly posted data. If a major biliary injury is recognized at ERCP, the patient needs to be referred for the attention of biliary reconstruction. If the actual site of the leak cannot be identified after ERCP, the patient has to be referred for
further investigations. An excluded biliary segment following transection during LC will not be visible in ERCP and these cases can be identified with MRCP or CT-IVC.

Most reported studies focus on the value of ERCP in the treatment of bile leakage following LC, but in many patients, the use of endoscopy can manage the original cause of the leak, because it stops the leakage. For dealing with the localized or diffuse biliary collections secondary to the leakage Supplementary measures may be required. In these studies, a successful combination of endoscopy and radiology or laparoscopy was used, making all efforts to avoid the requirement for open intervention in all patients. These studies are complementary to preceding evaluations that verify the safety and efficacy of minimally invasive techniques in the treatment of symptomatic biliary leakage after minor bile duct injury-related LC. Endoscopic management by using endoscopic retrograde cholangiopancreatography is the cornerstone of treatment, with the aid of using either a radiological intervention or laparoscopic approach.

CONCLUSION

Bile leak following LC due to major bile duct injuries is infrequent though not usual. Biliary leakage takes place either from the accessory bile duct, duct of Luschka, fossa of the gall bladder that underwent conservative treatment, and cautious observation. Only biliary leakage from major bile duct injury needs to be treated promptly and required well trained and skilled surgeon.

Endoscopic management has been alternative to surgical intervention in all simple cases presented with postoperative biliary leakage as equal definitive management. Surgical intervention has been the definitive management of complicated postoperative biliary leaks, but Endoscopic treatment was an obligatory complementary tool in the preliminary treatment. Early referral to tertiary care centers with expertise in hepatobiliary surgery, results in limitation of morbidity and mortality.

Abbreviations:
LC Laparoscopic cholecystectomy
IOC Intraoperative cholangiography
CT Computer tomography
ERC Endoscopic retrograde cholangiography
MRC Magnetic resonance cholangiography
EPT Endoscopic papillotomy
PTC Percutaneous transhepatic cholangiodrainage
IDD Intraductal dilatation
US Ultrasonography
GB gall bladder

REFERENCES


