Bile leak following laparoscopic cholecystectomy, a prospective study
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Abstract
Bile leakage is a very dangerous condition after laparoscopic cholecystectomy and may lead to fatal complications and serious care should be taken to diagnose the cause as early as possible because it may be sign of bile duct injury which is a major concern to the surgeons as if it is not diagnosed early, it will lead to dangerous complications such as biliary peritonitis, hepatic failure and even death. Early diagnosis is important to decrease morbidity and mortality.

This study aimed to determine the incidence of bile leakage, its types of management and the outcome in patients with gall stone who are submitted to laparoscopic cholecystectomy.

This prospective study was done in Basrah Al-Sadr Teaching Hospital in a two-year period from October 2013 to October 2015 on 560 patients, they were 378 females and 182 males. All of them have symptomatic gall stones and underwent laparoscopic cholecystectomy. All converted cases to open cholecystectomy were excluded.

From the total number of 560 patients, nine patients developed bile leak in early post-operative period, 6 of them have drains and the other three have no drain and they were presented with signs and symptoms of intra-abdominal collection. The causes of leak were: common bile duct (CBD) injury in 2 cases, accessory duct in 3 patients, leak from the gall bladder bed in 3 cases and one case iatrogenic from intra-hepatic drain. All the patients were treated conservatively except the two patients with CBD injury who were treated; one with the aid endoscopic retrograde cholangio-pancreatography (ERCP) and the other by re-exploration.

In conclusion, bile leak is a serious complication after laparoscopic cholecystectomy, although it is not common but it is important to identify the site of leak and should be treated urgently especially by drainage to avoid more severe results which may lead to increased morbidity and mortality.

Key words: Bile, Leak, Incidence, Laparoscopic, Cholecystectomy, Complications

Introduction
Laparoscopic surgery is regarded as an effective and safe technique in hepatobiliary surgeries, especially in cholecystectomy which is regarded as a golden standard procedure especially if there is a clear anatomy with no severe adhesions or fibrosis in which open cholecystectomy is more safe, although incidence of bile duct injuries is higher in laparoscopic cholecystectomy than in open procedure.

Biliary system is very sophisticated and may carry wide variations, that’s why care must be taken in any hepatobiliary surgery to avoid serious complications especially CBD injury which was first discussed by Sprengel in 1891.

Bile leak incidence after laparoscopic cholecystectomy is about 0.3–2.7%, although it is not common, but it is important and should be taken seriously because it may be a sign of major duct injury with dangerous complications.

Bile leak is a continuous leakage of bile anywhere from biliary tree or liver bed for any reason, the most common cause is slipping of the clips of the cystic duct stump or the stump is not securely closed, other causes may include subvesical duct of Luschka or other accessory duct or from gall bladder bed, but the most serious cause of bile leakage is injury of CBD or common hepatic duct which may be partial or complete and can lead to
major complications such as subphrenic abscess, biliary fistula, peritonitis and even death. In the beginning of laparoscopic cholecystectomy, bile leak was managed by conservative way, if no response, a laparotomy may be done, but with the development of endoscopic retrograde cholangiopancreatography, improvement in laparoscopy skills and suturing techniques, nowadays bile leak management can be performed by minimal invasive technique which in turn leads to less morbidity and mortality.

The aim of this study is to evaluate the incidence of bile leakage, types of management and the outcome in patients with gall stone who are submitted to laparoscopic cholecystectomy.

Patient and methods
This prospective study was done in Basrah at Al-Sadr Teaching Hospital in the period from October 2013 to October 2015 on 560 patients with gall stones who underwent laparoscopic cholecystectomy. All open cholecystectomies were excluded. All patients were admitted to the surgical ward and a complete history and thorough examination were done for them with full preoperative investigations.

All patients underwent laparoscopic cholecystectomy without peroperative cholangiogram. All operations were done under general anaesthesia. Four ports were inserted in the abdomen with CO₂ insufflation, then the Callot’s triangle, cystic duct and artery were identified. Clipping and division of cystic artery and duct were done, then the gall bladder was extracted from the epigastric port. Drain was not always being inserted but only in certain cases when there was large amount of bile leak or an oozing raw area especially in difficult dissection. Drains were not inserted routinely.

In all cases, the gall bladder was sent to histopathological examination. All patients were discharged within 48 hours if they are stable.

Results
This study included a total number of 560 patients with gall stones, they were 378 females and 182 males. The age of most of the patients was in a range from 25 to 60 years. There was a history of previous jaundice in 18 patients, biliary colic in 158, chronic cholecystitis in 480, and empyema in 17 cases. The characteristics of the patients participating in this study are shown in Table I.

Table I: The parameters of patients participating in this study

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>25-60 (52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (range, mean)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>378 (67.5%)</td>
</tr>
<tr>
<td>M</td>
<td>182 (32.5%)</td>
</tr>
<tr>
<td>History and clinical presentation</td>
<td></td>
</tr>
<tr>
<td>Previous jaundice</td>
<td>18 (3.21%)</td>
</tr>
<tr>
<td>Biliary colic</td>
<td>158 (28.21%)</td>
</tr>
<tr>
<td>Chronic cholecystitis</td>
<td>480 (85.7%)</td>
</tr>
<tr>
<td>Empyema</td>
<td>17 (3.03%)</td>
</tr>
</tbody>
</table>

Nine patients (1.6%) developed bile leak in early post-operative period, 6 of them have drain insitu and were discovered in the first 48 hours while they were in the hospital. The other 3 were presented with abdominal pain and distension few days after discharge. Initially, urgent investigations were done for all the nine patients in form of blood investigations and abdominal ultrasonography. When there is a leak, the patient was sent for magnetic resonance cholangiopancreato-
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...graphy (MRCP) to identify the exact site of the leak, which revealed CBD injury in 2 patients, one of them had complete cut and the other had partial injury, 3 patients have leak from gall bladder bed, 3 cases from accessory ducts while one case developed leak as a result of drain inserted in the liver tissue as shown in Table II.

Table II: The causes of bile leak

<table>
<thead>
<tr>
<th>Causes of bile leak</th>
<th>Number</th>
<th>% of 9 patients</th>
<th>% of the total patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBD injury</td>
<td>2</td>
<td>22.2%</td>
<td>0.35%</td>
</tr>
<tr>
<td>Accessory duct</td>
<td>3</td>
<td>33.3%</td>
<td>0.53%</td>
</tr>
<tr>
<td>Gall bladder bed</td>
<td>3</td>
<td>33.3%</td>
<td>0.53%</td>
</tr>
<tr>
<td>Liver parenchyma</td>
<td>1</td>
<td>11.1%</td>
<td>0.17%</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>100%</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

In the 3 cases who have no drain and diagnosed as collection from bile leak, drains were inserted under ultrasound guide. All the patients with leak were kept in the hospital under close observation with good hydration, covered with broad spectrum antibiotics and daily checking of the amount of bile leak.

Patients with CBD injury were referred to Gastrointestinal Tract Center, the patient with partial CBD injury was managed by endoscopic retrograde cholangiopancreatography (ERCP) with stent. The patient with complete CBD injury was kept for few weeks with drain insitu and was covered with antibiotic then re-exploration was done for definitive surgery by Roux-en-Y hepatocojejunostomy and he run uneventful condition after surgery.

All other cases were managed conservatively and discharged well after few days. The case with drain inside the liver tissue became well after pulling the drain small distance under ultrasound guide and discharged home in a good condition. The types of management are demonstrated in Table III.

Table III: The types of management.

<table>
<thead>
<tr>
<th>Patients</th>
<th>No.</th>
<th>Conservative</th>
<th>Stent</th>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBD injury</td>
<td>2</td>
<td>0</td>
<td>1 (11.2%)</td>
<td>1 (11.2%)</td>
</tr>
<tr>
<td>Accessory ducts leak</td>
<td>3</td>
<td>3 (33.4%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gall bladder bed leak</td>
<td>3</td>
<td>3 (33.4%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Injury by intra-hepatic drain</td>
<td>1</td>
<td>1 (11.2%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

It is clear from the above results that most patients were managed by conservative measures, while intervention was needed in only two cases with CBD injury.

Discussion

It is a well-known fact that patients with gall stones are mostly females and above 40 year of age which is also proved by the results of this study.

In this study, 18 patients have history of jaundice, 17 patients presented with empyema, while most other patients presented as chronic cholecystitis with many attacks of pain and colic, so in this study only symptomatic patients underwent surgery in form of laparoscopic cholecystectomy, while all open surgeries were excluded.

Laparoscopic cholecystectomy is regarded as gold standard for symptomatic gall stones and it is completely replaced the old open technique and many centres did it as a day case surgery, this in turn with development of ERCP affect the management of bile leak, but still the early drainage of bile is the corner stone in
management because delay or inadequate drainage may lead to serious complications including sepsis and peritonitis which necessitates laparotomy in most cases and may cause more morbidity and mortality. Early drainage makes management more successful and with more laparoscopic experience and development of ERCP for diagnostic and therapeutic purpose decreases the need for laparotomy and decreases serious complications.

After bile leak for any cause, bile will accumulate in the abdomen, and sometimes results in fistula or may present with bile ascites, and if not treated it will result in serious complications, but there is no predicting factor for who will develop peritonitis and serious outcome, but in general, every patient with no drain is regarded as risky patient.

The drain is not always dependable regarding bile leak, because it may be non-functioning, that’s why CT scan must be done if any suspicion of bile collection inside the abdomen and to decide next step in management. Some authors discussed conservative management in undrained patients with bile leak depending on re-absorption from the abdominal cavity, but this is not true if collection is more than 4 cc, and many studies showed more morbidity and mortality in undrained patients with bile leak.

Clinical data reveals that bile never absorbed unless very little amount, this in turn is complicated by superadded infection leading to worse results. The toxicity of bile salts, large amount of bile, in addition to superadded infection can lead to lethal outcome. As much as delay in drainage of bile, the worse illness develops which ends in sepsis and more mortality.

If the patient is presented with features of bile leak but have no drain, CT scan should be done to confirm the diagnosis of the collection, and once confirmed, it should be drained under guide of ultrasonography or CT scan. After drainage, the site of the leak should be confirmed by MRCP or ERCP and then treated according to the cause.

In this study there are 9 (1.6%) cases who developed bile leak, 2 (0.35%) of them have bile duct injury, and 7 (77.8%) due to other causes. All were treated conservatively except the 2 cases of CBD injury who were treated by intervention, one by stent and the other by surgery. The mean duration of the leakage was 10 days, these results are similar to the study done by Chen XP et al (9 days).

Bile leak in this study was mostly managed by conservative measures in form of controlled external drainage, cover with broad spectrum antibiotics, and good hydration. This management gave excellent results in about 77.8%, and was almost similar to a study done by Strasberg SM, et al.

The percentage of CBD injury in this study was 0.35% which is similar to Ali et al, and Karvonen et al who discussed bile duct injuries and their results were 0.2% to 0.7% respectively, and they see more injuries among laparoscopic than open cholecystectomy.

**Conclusion**

Bile leak is not common after laparoscopic cholecystectomy but it is very important if occur and should be taken seriously.

The diagnosis should be confirmed as early as possible, because bile leak may indicate biliary ducts injury anywhere in the biliary tree which is a serious complication and should be treated urgently. While other causes of bile leak including injury of gall bladder bed, luschka duct and other small accessory ducts which are more common in this study, are usually stopped by conservative measures.

In all cases, drainage of the bile is the cornerstone of management to protect the patient from developing serious sequelae.
of bile leak including septicaemia and even death, so every surgeon performs laparoscopic cholecystectomy should put in mind bile leak with high index of suspicion and urgent management should be done without any delay.

References