ASSESSMENT OF RISK FACTORS AND TECHNICAL ERRORS INVOLVED IN THE OCCURRENCE OF IATROGENIC BILE DUCT INJURIES FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY

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INTRODUCTION

Laparoscopic cholecystectomy has become a standard method in the treatment of gallbladder lithiasis. In addition, the technique offers better aesthetic results thanks to the minimally invasive approach, it reduces the postoperative pain complaints and reduces hospitalisation of the patients, having a cost/benefit ratio higher than that of the classical technique.

The number of days of hospitalisation decreased from an average of 3.7 to 1.2 days, and postoperative recovery from an average of 43 to 8 days. (1,2) Nevertheless, studies indicate an increase in the incidence of these lesions from 0.1%-0.2% in the open period to 0.4%-0.7% in the era of laparoscopy (3-5).

PURPOSE

The purpose of this study is to identify the causes for the production of iatrogenic biliary lesions and to establish the responsible risk factors.

METHODS

21 patients with iatrogenic biliary lesions secondary to laparoscopic cholecystectomy were included in this study, lesions produced in a tertiary centre with experience in bile surgery.

RESULTS

There was a retrospective study and the data were collected during the period 2003-2008 in the Surgical Clinic No. 3 of Cluj-Napoca. The data were obtained by studying the patients’ observation charts, following the demographic data, the surgery details, the causes of the lesions, as well as the surgical management after their production.

The diagnosis was established either during surgery, by the identification of the biliary lesion, or post surgery on the basis of the clinical symptoms and of the paraclinical data.

The statistical processing was carried out by the use of the Chi-Square Test, where p<0.05 represented a significant difference.

The study analyses a group of 21 patients with iatrogenic biliary lesions produced in the Surgical Clinic No. 3 of Cluj-Napoca. The distribution per years of the lesions is presented in figure no. 1.
Figure no. 1. Distribution of the biliary lesions per years of study

The biliary lesions were distributed according to the Strasberg-Soper classification (table no. 1).

Table no. 1. Classification of biliary lesions

<table>
<thead>
<tr>
<th>Type</th>
<th>Definition</th>
<th>Number of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Minor bile leak (aberrant duct/cystic duct)</td>
<td>12</td>
<td>57.1%</td>
</tr>
<tr>
<td>B</td>
<td>The clipping of a segmental bile duct</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>C</td>
<td>Bile leak from accessory duct of the right lobe</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>D</td>
<td>Lateral injury of the CBD</td>
<td>6</td>
<td>28.5%</td>
</tr>
<tr>
<td>E1</td>
<td>Circumferential CBD lesion at &gt; 2 cm from the bifurcation</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>E2</td>
<td>Circumferential CBD lesion at ≤ 2 cm from the bifurcation</td>
<td>2</td>
<td>9.5%</td>
</tr>
<tr>
<td>E3</td>
<td>CBD lesion at the level of the bifurcation</td>
<td>1</td>
<td>4.7%</td>
</tr>
<tr>
<td>E4</td>
<td>Lesion involving the right and left hepatic duct</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>E5</td>
<td>Lesion of the right hepatic duct + major bile ducts</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

The lesions were divided into minor type A lesions (57.1%) containing cystic duct leak or certain aberrant ducts from the liver bed and major biliary lesions (42.9%) represented by stenoses or sections at the level of the main bile duct (figure no. 2).

Figure no. 2. Types of lesions

The annual incidence of lesions, as compared to the number of cholecystectomies carried out in the clinic, varies from 0.19% to 0.32% with an average of 0.22%. All the lesions were secondary to laparoscopic cholecystectomy, carried out in a retrograde or anterograde manner.

The demographic data show a predominance of the patients coming from urban areas (57.1%) and a higher frequency of the female gender (66.6% vs 33.3%), the average age of the patients being of 54.9 years old, with limits between 28 and 79 years old.

76.2% of the biliary lesions were produced as a result of an emergency surgical intervention. During surgery, they were associated with an inflammatory reaction in the area of the Calot’s triangle, with increased frailty of the tissues, haemorrhages during surgery which imposed rash haemostasis manoeuvres and the presence of dense fibroses which made it difficult to dissect and identify the biliary elements.

In 5 patients the lesion was produced in the conditions of chronic cholecystitis. These were produced due to the erroneous interpretation of the local anatomy and by the lack of attention and focus by the surgeon who considered the cholecystectomy an easy surgical intervention. 19% of the lesions belonged to young surgeons, who carried out less than 50 laparoscopic cholecystectomies per year. In their case, all the lesions belonged to the class A according to Strasberg-Soper.

The lesions could be explained by the deficient technique in the application of the clip on the cystic duct and the failure to recognize the aberrant ducts during surgery. In all cases, the postoperative evolution was favourable. 81% of the lesions were encountered with experienced surgeons, with a high frequency of the type D and E biliary lesions (9 vs 8).

Class E major lesions (E2, E3) were produced as a result of a misinterpretation of the local anatomy and having in view the fact that they were linked to experienced surgeons, with a good knowledge of the technique of cholecystectomy, they were not due to a deficient technique. The production scenario was that the surgeon mistook the main bile duct for the cystic one, dissected this anatomic element and then clipped or sectioned it, any structure encountered subsequently being interpreted as an aberrant bile duct. In type D lesions, the causes were represented by the surgeon's lack of attention, using the electrocautery excessively in the vicinity of the main bile duct, the biliary leak being secondary to the elimination of thermal eschars.

The ratio of biliary lesions from the number of cholecystectomies carried out by each of the experienced surgeons shows an incidence of up to 0.5% (table no. 2).

Table no. 2. The incidence of biliary lesions with experienced surgeons

<table>
<thead>
<tr>
<th>Experienced surgeon</th>
<th>No. of cholecystectomies</th>
<th>No. of lesions</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nr 1</td>
<td>1753</td>
<td>2</td>
<td>0.11%</td>
</tr>
<tr>
<td>Nr 2</td>
<td>1323</td>
<td>5</td>
<td>0.37%</td>
</tr>
<tr>
<td>Nr 3</td>
<td>1028</td>
<td>3</td>
<td>0.29%</td>
</tr>
<tr>
<td>Nr 4</td>
<td>767</td>
<td>2</td>
<td>0.26%</td>
</tr>
<tr>
<td>Nr 5</td>
<td>597</td>
<td>1</td>
<td>0.16%</td>
</tr>
<tr>
<td>Nr 6</td>
<td>595</td>
<td>3</td>
<td>0.50%</td>
</tr>
<tr>
<td>Nr 7</td>
<td>417</td>
<td>1</td>
<td>0.23%</td>
</tr>
</tbody>
</table>

In the case of patients with minor biliary lesions, the symptomatology was dominated by the presence of bile leak (exterorised through the wound or on the subhepatic drain tube at least 200-300 ml of bile daily, without a reduction tendency) and by choleperitonem (when the biliary fistula was not drained), confirmed by the paraclinical examinations. In these patients, fever, abdominal pain due to peritonitic manifestations (chemical and bacterial), abdominal distension due to gallstone ileus and abdominal collections were added. In the case of patients with major lesions, the clinical symptoms were dominated by pain, jaundice and angiolitic phenomena secondary to the obstruction of the biliary tree. In 3 cases, choleperitonem and local peritonitic manifestations were also
In order to accurately establish the diagnosis, we have carried out a biochemical balance to which we have added the data obtained through ultrasound and ERCP (table no. 3).

<table>
<thead>
<tr>
<th>Paraclinical explorations</th>
<th>Number</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukocytosis</td>
<td>12</td>
<td>57.1%</td>
</tr>
<tr>
<td>Increased bilirubin</td>
<td>8</td>
<td>38%</td>
</tr>
<tr>
<td>Hepatocytolysis</td>
<td>9</td>
<td>43%</td>
</tr>
<tr>
<td>Cholestasis</td>
<td>6</td>
<td>28.5%</td>
</tr>
<tr>
<td>Hypoproteinemia</td>
<td>5</td>
<td>23.8%</td>
</tr>
<tr>
<td>Anaemia</td>
<td>4</td>
<td>19%</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>17</td>
<td>81%</td>
</tr>
<tr>
<td>ERCP</td>
<td>5</td>
<td>14.2%</td>
</tr>
<tr>
<td>Intraoperatively diagnosis</td>
<td>4</td>
<td>19%</td>
</tr>
</tbody>
</table>

Table no. 3. Paraclinical explorations

Hypoproteinemia and anaemia had an impact especially in the patients where bilio-digestive anastomosis was used to solve the lesion and influenced the emergence rate of the fistula ($p<0.05$).

In 4 cases (19%), the lesion was recognised during surgery, being then solved (3 D type lesions and one E2 type lesion). In 14 cases, the lesions were solved during the first 7 days from its production and in 3 cases after more than 2 weeks from production. The average duration of hospitalisation in our study was of 14.6 days.

6 type A lesions were represented by bile leak from the aberrant bile duct and were solved by laparoscopic clipping. The rest of the lesions were due to the skidding of the clip from the cystic stump, the solution consisting of kehr’s drainage in 2 cases, and respectively the clipping/ligation of the cystic duct in the rest of the cases. In 3 D type lesions, the recognition of the lesion during surgery allowed solving it by suture laparoscopically, one case was solved by kehr’s drainage, and 2 cases by side-to-side Roux-en-Y hepatojunostomy. For the E class lesions, the solution consisted of end-to-side Roux-en-Y hepatojunostomy.

Complications were encountered in 4 cases: 1 death by septic shock in a type A lesion, with the necrosis of the cystic stump and biliary peritonitis, 2 anastomotic fistulas (in a type D and a type E lesion), solved by the reconstruction of the bilioleral anastomosis and one case (type D lesion) where initially the suture of the biliary lesion with kehr’s drainage was carried out, subsequently a bilio-digestive anastomosis being carried out for the stenosis of the main bile duct.

Postoperative complications were more frequently associated with major biliary lesions, with the number of reparatory attempts, the presence of intra-abdominal sepsis and antecedents of acute cholecystitis ($p<0.01$).

**DISCUSSIONS**

Biliary lesions are characterised by a high degree of severity, with a proximal localisation tendency of the lesions, often being associated with vascular lesions. Moreover, 15% of the reparation interventions on the bile ducts need a new intervention.(6) In our study we have used the Strasberg Soper classification of biliary lesions.(7,8) The factors involved in the lesions of the bile ducts are multiple and may be grouped into three categories: factors related to the surgeon, factors related to the patient and factors related to the surgical act. Of the factors related to the surgeon, an important part is played by the surgical experience of the surgeon. The probability of emergence of biliary lesions is higher during the first 10 cholecystectomies carried out (48.4%), after 50 surgeries it is of around 9%.(9,10) Bismuth affirms that the incidence of lesions is of 3.4% up to 500 cholecystectomies (11,12), and in another study, carried out on 1518 laparoscopic cholecystectomies, an incidence of 2.2% of lesions of the bile ducts is found during the first 13 cholecystectomies carried out.(13) The higher incidence of these lesions was initially explained by “the learning curve” attributed to any new surgical technique. The lesions are the result of the false confidence the young surgeon has after carrying out a few successful cholecystectomies, to which the insistence to close the surgery by the intermediary of the laparoscopic technique is added.

Nevertheless, surgical training alone cannot prevent the occurrence of lesions, fact proved by their emergence with surgeons with experience in biliary pathology. The fact is also added here that some biliary lesions appear in the absence of local anatomical modifications and in the absence of acute cholecystitis, shaping the idea that there is an incorrect exposure and dissection of the bilo-vascular elements from the area of the Calot’s triangle. Riggs and Bowder affirm that over 50% of the iatrogenic biliary lesions emerged with experienced surgeons, often being major biliary lesions.(14,15) In our study, 81% of the lesions were linked to experienced surgeons. The favouring factors in the emergence of biliary lesions are the surgeon’s fatigue, lack of attention, indisposition, as well as the haste of the surgeon to limit the duration of the intervention. The patient related factors are represented by: obesity, gender, age, biological status and the local anatomic variants. Obesity by the presence of perivisceral adiposity may favour the emergence of iatrogenic lesions, because it makes it difficult to dissect and identify the biliary ducts. The age of the patients represents a risk factor by the fact that often these lesions emerge in the patients aged between 30 and 40 and where the diameter of the main bile duct is of less than 5 mm. The anatomic variants represented by anomalies of the cholecyst, of the cystic duct, vascular anomalies, as well as of the cystic duct stump, may create difficulties in the identification of the area’s anatomy. Acute cholecystitis (76.2% of the cases) determined an intense inflammatory syndrome at the level of the Calot’s triangle, so the cystic duct was incorporated in this inflammatory mass and the lesion was due to the erroneous anatomic interpretation, the surgeon thinking that the cystic duct was correctly identified. The uncertain anatomy during the cholecystectomy represents a risk factor with a frequency of almost 59%. (16) The junction between the cystic duct and the main bile duct represents the most frequent location of biliary lesions (Glenn). The electrocautery must be used with precaution, because one of the mechanisms involved in the emergence of late biliary stenoses is its excessive use in the area of the Calot’s triangle with the reduction of the blood support from the level of the common hepatic duct. The presence of metallic clips determines the concentration of the thermal energy at their level, subsequently predisposing to fistulas by the elimination of the eschars. The emergence of biliary lesions is influenced by the modifications brought by the laparoscopic technique: the bidimensional image, the disappearance of the tactile sense, the approach of the hepatic pedicle from the inferior and lateral side and not from the anterior as in open surgery, the dependence on the optical image, the use of the electrocautery in the area of the Calot’s triangle, as well as the relatively little experience of the surgeons with the laparoscopic instruments. In our study, the major risk factors, in the lesions of the bile ducts can be systematised as follows:

- the surgeon’s lack of experience (4 cases ),
- for the experienced surgeons, the lack of concentration, lack of attention and the trivialisation of the cholecystectomy (17 cases),
- the local anatomy modified by the inflammatory remains,
the oedema at the level of the hepatic hilus and of the Calot’s triangle or the anatomic variants (16 cases),
- the excessive use of the electrocautery in the area of the Calot’s triangle (6 cases).

We can systematise the causes of biliary lesions as follows:
- the inadequate clipping of the cystic duct with subsequent bile leak or choleperitonemus,
- lesions of the bile ducts from the liver bed as a result of an electro-dissection carried out in a too deep cleavage plane,
- lesions secondary to the inadequate use of the electrocautery in the vicinity of the biliary tree with the elimination of eschars and secondary bile leak,
- the exaggerated traction on the gallbladder with the angulation of the cystic duct and the secondary clipping of the main bile duct,
- the mistaking of the bile duct with the cystic duct, followed by its sectioning or clipping.

Studies have shown an incidence of type A lesions of 1.1% up to 2.1% (17,18) where more than 50% are due to the leak from the cystic stump, the rest coming from the level of the Luschka bile ducts. In our study, as compared to the number of cholecystectomies carried out, type A lesions were encountered in 0.13% of the cases and major lesions in 0.1%.

It appears that the emergence of biliary lesions is secondary to an accumulation of factors leading initially to minor incidents during surgery and then as they accumulate, to major incidents with biliary lesions. In our study the minor incidents were represented by:
- the accidental perforation of the gallbladder with the loss of the cleavage plane,
- thermal lesions and haemorrhages from the hepatic capsule which affected the operative field,
- the incomplete clipping of the cystic duct with secondary bile leak,
- lesions of some branches of the cystic artery with rash haemostasis,
- dissection of the vesicular bed in a deeper plane, with secondary haemorrhage,
- traction on the surrounding tissues with subsequent haemorrhages,
- the loss of the pneumo-peritoneum through the lack of tightness at the level of the trocars with the narrowing of the operative field.

The best approach method in biliary lesions is to prevent them. In order to do so, an excellent knowledge of the region’s anatomy and of the possible anatomic variants is necessary. In addition, a surgical technique is necessary which offers a good exposure of the hepato-duodenal space, avoids haemorrhages during surgery and avoids the excessive use of electrocoagulation in the area of the Calot’s triangle. No anatomic element shall be sectioned without its exact identification.(19,20)

CONCLUSIONS

The multidisciplinary approach and addressing the case in due time is essential in order to get optimal results in biliary lesions.

The best treatment is prevention, by optimal surgical access, adequate exposure of the Calot’s triangle, the exact identification of all anatomic elements, adequate dissection and the careful use of the electrocautery.

Any time such a lesion emerges, the surgeon must make an honest evaluation and address the case urgently to a surgeon with experience in hepatobiliary surgery.

REFERENCES