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Biliary tract injury during open and laparoscopic cholecystectomy and management: An observational study at the tertiary care teaching hospital

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Abstract: Background: Bile duct injuries after laparoscopic cholecystectomy (LC), being one of the most commonly performed surgical procedures, remain a substantial problem in gastrointestinal surgery. The most important aspect regarding this issue is the prevention of bile duct injury during index cholecystectomy. Once it occurs, early and accurate diagnosis of bile duct injury is very important for surgeons and gastroenterologists, because unidentified bile duct injury may result in severe complications such as hepatic failure and death. Laboratory tests, radiological imaging, and endoscopy play an important role in the diagnosis of biliary injuries.

Material and Methods: This is a prospective, single-center, observational study including patients treated for a bile duct injury during a cholecystectomy at the tertiary care Teaching Hospital over a period of 1 year. All patients were older than 18 years and were informed of the study and gave informed consent. All types of iatrogenic injuries were included: minor or more complex, regardless of their management (endoscopic, radiological, surgical, or combined). Other biliary injury etiologies, mainly traumatic causes, were excluded. Minor wounds were defined as those affecting the cystic stump, the cystic duct, and the junction between the cystic duct and the MBD, and major wounds were defined as those affecting the MBD, the common hepatic duct, and the right hepatic branch.

Results: Out of 90 patients with bile duct injuries, 58 (64.4%) incurred the injuries during open cholecystectomy and 32 (35.6%) during laparoscopic cholecystectomy. No differences between the groups were observed concerning the time of bile duct injury diagnosis, type of injury, incidence of concomitant vascular and bile duct injuries, type of reconstruction procedure, or complication rates after the primary intervention. The latency of bile duct injury management was found to differ between the study groups. In the open cholecystectomy group, bile duct injuries were managed significantly later than in the laparoscopic one.

Conclusion: Bile duct injury after laparoscopic cholecystectomy requires a multidisciplinary approach with specialized physicians at tertiary hospitals. Imaging techniques and proper classification are required in order to prevent or treat sepsis, biliary leaks, and collections.

Keywords: Biliary tract; Laparoscopic cholecystectomy; Hepatobiliary surgeons.

1. Introduction

Cholecystectomy is one of the most frequently performed procedures in gastrointestinal surgery, and the laparoscopic approach is now the gold standard for symptomatic cholelithiasis as well as for chronic and acute cholecystitis [1]. Besides the advantages of a distinctly faster recovery and better cosmetic results, the laparoscopic approach bears a higher risk for iatrogenic bile duct injury and injury of the (right) hepatic artery. Bile duct injury is a complication associated with significant perioperative morbidity and mortality, reduced long-term survival and quality of life, and high rates of subsequent litigation [2].

Despite increasing experience and progress in laparoscopic skills of surgeons, the incidence of Bile duct injury is still elevated compared to open cholecystectomy [3]. The rate of clinically relevant bile leaks after conventional open cholecystectomy ranges between 0.1 and 0.5% [4]. In contrast, biliary leakages have increased in the era of laparoscopic cholecystectomy (LC) by up to 3% [5]. A variety of injuries can occur. Besides minor bile leakage of aberrant ducts, cystic stump or the main bile duct, complete occlusion of the main duct or a branch (often an aberrant right duct) can happen. In addition, bile duct strictures and biliary leakages are severe long-term complications after Laparoscopic cholecystectomy. These injuries are associated with high morbidity, mortality, and prolonged hospitalization [6].

Currently, endoscopic procedures are most frequently used in the management of postoperative Bile duct injury. There are several endoscopic techniques available, e.g. biliary stent placement, biliary sphincterotomy, and nasobiliary drainage [7]. In this respect, endoscopic therapy can reduce the transpapillary pressure gradient and improve the transpapillary flow, which decreases the extravasation out of the biliary tract. This reduction of bile leakage allows healing of duct lesion injuries without direct surgical repair. Nonetheless, if major Bile duct injury occurs, i.e. complete dissection of the common bile duct (CBD), surgical management is required to resolve this issue [8].

In an effort to reduce further complications and injuries in the hepatoduodenal ligament, surgical procedures should be performed in collaboration with skilled and experienced hepatobiliary surgeons, interventional radiologists, and gastroenterologists at a tertiary referral center.

2. Material and methods

This is a prospective, single-center, observational study including patients treated for a Bile duct injury during a cholecystectomy at the tertiary care Teaching Hospital over a period of 1 year. All the methodology was carried out in accordance with relevant guidelines and regulations. The protocol was approved by a named institutional Ethical committee.

2.1. Inclusion criteria

All patients were older than 18 years and were informed of such a study and gave informed consent.

2.2. Exclusion criteria

All types of iatrogenic injuries were included: minor or more complex, whatever their management (endoscopic, radiological, surgical, or combined). Other biliary injury etiologies, mainly traumatic causes, were excluded.

Minor wounds were defined as those affecting the cystic stump, the cystic duct, and the junction between the cystic duct and the MBD, and major wounds were defined as those affecting the MBD, the common hepatic duct, and the right hepatic branch.

Data relating to cholecystectomy: all these data were noted on the operative report and extracted: the indication (emergency or elective surgery), whether the operation was to be performed as an outpatient; the approach; and the experience of the operator. The intraoperative risk factors were identified according to the literature on the subject and included the presence of bleeding; the presence of significant local inflammation (adhesions, hepatic pedicle inflammation) or chronic cholecystitis; and the detection of anatomical variations in the termination of the cystic duct or bile ducts (diagnosed intraoperatively or more remotely on the imaging data).

Data concerning Perioperative cholangiography: its achievement, its reading and interpretation (normal, incomplete hepatogram, leakage of contrast agent, suspicion of lithiasis in the MBD), and whether it had allowed early diagnosis of a biliary injury.

Data concerning the Bile duct injury: its type, specifying its location in relation to biliary convergence; its time of diagnosis [intraoperative, immediate postoperative (before 6 weeks) or late (more than 6 weeks) from the injury]; its mode of discovery (biliary leakage or retention symptoms); and the existence of an associated arterial wound, in particular of the right branch of the hepatic artery. The diagnosis of an arterial wound was made either on the basis of imaging data [injected abdominopelvic computed tomography (CT) scan, more rarely arteriography] or intraoperatively at resumption of surgery. In case of no formal data on the existence of

an arterial wound, the diagnosis was made by a radiologist on the basis of the data from the CT scan obtained at arterial time.

The initial management of the Bile duct injury: endoscopic with the performance of endoscopic retrograde cholangiopancreatography (ERCP), whether accompanied by the insertion of a biliary prosthesis or simply the extraction of residual lithiasis. The existence of an unsuccessful attempt to catheterize the MBD was recorded. The initial surgical management was noted: external drainage (by rubber corrugated drains or tube drains in contact with the vesicular bed), choledocholic suture on T-tube (Kehrs), simple suture of the biliary duct in case of a puncture wound, or Roux-en-Y hepaticojejunal anastomosis, whether early (within 6 weeks of the wound) or late (after 6 weeks).

Late complications linked to the management of the injury: morbidity related to secondary stenosis of a choledocholic suture or biliodigestive anastomosis was considered. The management of complications by radiological, endoscopic, or surgical means was specified. The other complications noted were the presence of a hernia on a laparotomy scar, the presence of acute pancreatitis postsphincterotomy in the case of ERCP, and postoperative hemorrhage requiring emergency reoperation. Mortality was taken into account in the case of patient death in the context of Bile duct injury inducing sepsis.

The final follow-up point was the date of the last consultation in digestive surgery at the university hospital or at the original peripheral hospital after the Bile duct injury. After conducting an observational study, the patients were divided into two groups: one group in which they had received POC (POC+) and one group in which POC had not been done (POC-).

2.3. Outcomes

Different outcomes such as the gravity of injuries, the diagnostic time, the delay to surgical treatment, and a composite variable called "morbimortality" encompassing cases of death and anastomotic stenosis were reported.

2.4. Statistical Analysis

The two groups were compared in terms of time to diagnosis, time to management, and postoperative morbidity and mortality using Fisher exact tests. A risk threshold α was determined at 0.05. Odds ratios were also calculated.

3. Results

Bile duct injury occurred in 58 (64.4%) patients who underwent open cholecystectomy and in 32 (35.6%) patients who underwent laparoscopic cholecystectomy. Out of 90 patients, 34 (37.8%) were male and 56 (62.2%) were female. The youngest patient was 23 and the oldest one 77, with the mean age of 56.3 ± 14.6 (see Table 1). The two groups did not statistically significantly differ with respect to age ($p = 0.115$).

Table 1. Distribution of patients according to age

Parameter	Laparoscopic cholecystectomy	Open cholecystectomy	Total	P
n	32 (35.6%)	58 (64.4%)	90	
Age (years)	53.4 ± 14.8	58.3 ± 13.9	56.3 ± 14.6	0.115

Table 2. Distribution of Gender

Parameter	Laparoscopic cholecystectomy	Open cholecystectomy	Total	P
Male	10 (29.4%)	24 (70.6%)	34 (37.8%)	0.10
Female	22 (39.3%)	34 (60.7%)	56 (62.2%)	

Table 3. Time of bile duct injurie diagnosis, type of injury, and concomitant vascular injury

Intraoperatively diagnosed	Laparoscopic cholecystectomy n = 32	open cholecystectomy n = 58	Total	P
Strasberg classification				
C	0	2 (3.4%)	2 (2.2%)	0.750
D	5 (15.6%)	6 (10.3%)	11 (12.2%)	
E1	4 (12.5%)	7 (12.1%)	11 (12.2%)	
E2	10 (31.2%)	17 (29.3%)	27 (30%)	
E3	7 (21.9%)	5 (8.6%)	12 (13.3%)	
E4	5 (15.6%)	7 (12.1%)	12 (13.3%)	0.210
Concomitant vascular injury	11 (32.4)	10 (17.2%)	21 (23.3%)	

Bile duct injury were intraoperatively diagnosed in five (15.6%) patients operated by Laparoscopic cholecystectomy and in 12 (20.7%) patients during open cholecystectomy. This difference was not statistically significant ($p = 0.214$). Moreover, no statistical difference in the type of Bile duct injury (Strasberg classification) was found between patients operated by Laparoscopic cholecystectomy or open cholecystectomy ($p = 0.750$). Additionally, there was no difference in the incidence of concomitant vascular injuries and Bile duct injury between the two groups ($p = 0.210$). The overall incidence of vascular injury was 23.3% (Table 3).

Table 4. Time of bile duct injurie management and reconstruction types

Time of Bile duct injury management	Laparoscopic cholecystectomy n = 32	Open cholecystectomy n = 58	Total	P
Within 24 hours	8 (25%)	10 (17.2%)	18 (20%)	0.008
1–5 days	6 (18.7%)	0	6 (6.7%)	
6–40 days	14 (43.8%)	16 (27.6%)	30 (33.3%)	
Late reconstruction	4(12.5%)	32 (55.2%)	36 (40%)	
Type of reconstruction				
Primary suture and T drainage	5 (15.6%)	10 (17.2%)	15 (16.7%)	0.730
Roux-en-Y HJA	11 (34.4%)	17 (29.3%)	28 (31.1%)	
Roux–Hepp	15 (46.9%)	21 (36.2%)	36 (40%)	
Hepatectomy	1 (3.1%)	10 (17.3%)	11 (12.2%)	

A comparison of the latency of post-cholecystectomy Bile duct injury management revealed a statistically significant difference. Open cholecystectomy patients were managed significantly later, with almost 55.2% of them being treated more than 40 days after the primary surgery ($p = 0.008$; Table 4). The most commonly performed bile duct reconstruction procedure in both groups was Roux–Hepp. There was no statistical significance regarding the frequency of the reconstruction type between the groups ($p = 0.730$). The incidence of complications (sepsis, thrombo-emboly, infections, etc.), abscess, biliary fistula, bile collection, and hepatic necrosis were not statistically significantly different between the groups ($p = 0.675$).

Table 5. Types of complication after primary surgery and mortality rate

Complications	Laparoscopic cholecystectomy n = 32	Open cholecystectomy n = 58	Total	P
General complications	7 (21.9)	11 (18.9)	18 (20)	0.675
Abscess	5 (15.6)	10 (17.2)	15 (16.7)	0.328
Biliary fistula	14 (43.7)	19 (32.8)	33 (36.7)	0.915
Biloma	13 (40.6)	13 (22.4)	26 (28.9)	0.275
Liver necrosis	8 (25)	6 (10.3)	14 (15.6)	0.180
Mortality	0	3 (5.2)	3 (3.3)	

The median patient follow-up time was 117.6 months, with a range of 12–168 months. During the follow-up period, satisfactory results were achieved after the primary reconstruction in 57 (89%) patients. Benign stenosis, as a late complication of the reconstruction, occurred in six (9.4%) patients. In those six patients, a secondary reconstruction was performed due to biliary stenosis. In two of the patients, the secondary reconstruction was performed two years after T tube placement. In the other four patients, the secondary reconstruction was performed two to seven years following the primary reconstruction, which was done within 24 hours of the injury. One lethal outcome was observed (mortality rate 3.3%), which was due to the consequences of purulent cholangitis, subhepatic abscess, and biliary peritonitis. Actually, the patient

developed signs of severe septic shock, liver, and multiorgan failure 10 days after the primary reconstruction in the primary referring institution.

4. Discussion

The most common BIs include biliary leakage, biliary fistula, and hemobiliary. There have been several proposals recently to classify postoperative strictures and bile duct injuries. The Corlette-Bismuth classification made a proposal which is based on the length of the proximal biliary stump, however; not on the nature and length of the lesion. McMahon has proposed a detailed subdivision into minor and major bile duct injuries. Minor injuries are considered when laceration of the cystic to CBD junction and laceration of the CHD is <25% of the duct diameter. Major injuries are considered when laceration is >25% of the bile duct diameter, also, if transection either of the common hepatic or CBD occurs or if there is a development of postoperative stricture. There is also the Strasberg classification which is considered the most detailed classification as it includes all types of injuries [10].

Unfortunately, it is almost impossible to obtain the exact incidence rate of iatrogenic bile duct injuries because bile duct injuries could be attributed to the negligence of surgeons or anatomical abnormalities or even agenesis of the gallbladder [11]. When a Bile duct injury after laparoscopic cholecystectomy occurs it is difficult to treat the problem and depends on the time of diagnosis after the initial injury and the type, extent and level of the injury. Immediate management is necessary to avoid fistulas, sepsis, and obstruction of the biliary system [12]. Bile duct injury identification and categorization of the type is necessary in order to identify the next steps. After classification, repair of the injury should be performed. Furthermore it has been reported that the incidence of Bile duct injury after laparoscopic cholecystectomy is higher than that after open cholecystectomy [13]. There are risk factors such as; dangerous anatomy, dangerous pathology, and dangerous surgery [14].

There is a great chance that Bile duct injury is missed during laparoscopic cholecystectomy [15]. There are anatomical structure variations of Calot's triangle which are not very clear because of congestion, edema, and fragility of the tissues surrounding the cystic duct in acute suppurative or gangrenous cholecystitis. Therefore, the exposure of peritoneal attachments in Calot's triangle is necessary in order to identify anatomical variations, and the cystic duct should not be separated at the junction of the common hepatic, and cystic ducts are positively identified. In some cases, fibrous tissue scars are identified in Calot's triangle in atrophic cholecystitis. Nowadays injuries to the bile duct system during laparoscopic cholecystectomy are not associated only with the experience of the surgeon and is also not related to the "learning curve" of the operating surgeon as suggested in the past [16].

Recent studies demonstrated that the in one-third of all bile duct injuries, the basic cause use of a nonproper approach to the fundamental structures of the extrahepatic biliary tree. In specific because of a visual perceptual illusion [17]. Another issue is inflammation or chronic fibrosis at the time of the initial procedure which does not allow the proper evaluation of the situation. Currently, the role or use of Intraoperative laparoscopic ultrasonography and cholangiography in prevention of Bile duct injury during laparoscopic cholecystectomy is a matter of ongoing debate [18]. Upon referral, all patients with suspected Bile duct injury should undergo Ultrasound and CT of the abdomen so that any dilatation of the bile duct system or fluid collection can be observed. In most cases those techniques must be combined with magnetic resonance cholangiopancreatographies (MRCP), ERCP or even percutaneous transhepatic catheterizations (PTC) in order to identify the biliary anatomy [19].

In cases where patients do not recover after cholecystectomy then these patients are considered candidates for having a Bile duct injury. In the case of Bile duct injury the patient should be transferred to a tertiary care center with expertise in biliary surgery, by doing this we limit further operations, complications, time to definitive repair, and finally mortality [20]. Surgery treatment should be performed only when the patient is stabilized and the Bile duct injury has been properly classified because the success of the operating procedure depends on the proper and accurate identification of the Bile duct injury. In the case of the early postoperative period (2 to 7 days), which involves a relatively distal lesion below the bifurcation and there is no biliary leakage, sepsis or abscess formation then early reconstruction can be considered. In the case of bifurcation, then percutaneous biliary drainage is preferred with an elective repair after 6 to 8 weeks [21].

Association of the level of injury and the outcome of the surgical procedure has been proposed. There are also other factors that foresee the surgical outcome such as; the performance of preoperative cholangiography, include the timing of the repair, the expertise of the surgeon performing the repair, the choice of surgical procedure, and the presence of concomitant vascular injury [22]. It has been reported in the literature that the outcome of surgical reconstruction for major lesions or failure of endoscopic treatment depends on the timing of the reconstruction [23]. It is proposed that postoperatively the transhepatic catheters should stay for external gravity drainage until day 5, and a cholangiogram should be performed. It is also proposed that upon follow-up cholangiograms should be obtained at 1 month and 3 months postoperatively, if necessary, more often or earlier. Moreover, catheters should be removed between 3 and 6 months postoperatively, this depends on the level of the injury, as well as the appearance of the cholangiogram [24]. Recurrent biliary stricture has been observed in 10–30% of cases, after open cholecystectomy [24]. It has been also noted that patients with recurrent stricture develop more frequently restenosis. Additionally, previous surgical attempts also greatly influence the outcome, because repeated attempts make the stricture even greater, leading to an even more challenging next repair and the result not always favorable.

5. Conclusion

Bile duct injury after laparoscopic cholecystectomy requires a multidisciplinary approach with specialized physicians at tertiary hospitals. Imaging techniques and proper classification is required in order to prevent or treat sepsis, biliary leaks, and collections. Rouxen-Y hepaticojejunostomy should be considered in these cases, since it presents excellent results. In some cases, life threatening complications can occur if the referral to an expert center is delayed or, rarely, after surgical repair. It has been observed that complications are frequent, however; almost all can be managed non-operatively.

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Conflicts of Interest: The authors declare that they do not have any conflict of interests.

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