Original article

Impact of routine intraoperative cholangiography during laparoscopic cholecystectomy on bile duct injury

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Background: The role of intraoperative cholangiography (IOC) in the diagnosis, prevention and management of bile duct injury (BDI) remains controversial. The aim of the present study was to determine the value of routine IOC in the diagnosis and management of BDI sustained during laparoscopic cholecystectomy (LC) at a high-volume centre.

Methods: A retrospective analysis of a single-institution database was performed. Patients who underwent LC with routine IOC between October 1991 and May 2012 were included.

Results: Among 11 423 consecutive LCs IOC was performed successfully in 95·7 per cent of patients. No patient had IOC-related complications. Twenty patients (0·17 per cent) sustained a BDI during LC, and the diagnosis was made during surgery in 18 patients. Most BDIs were type D according to the Strasberg classification. The sensitivity of IOC for the detection of BDI was 79 per cent; specificity was 100 per cent. All injuries diagnosed during surgery were repaired during the same surgical procedure. Two patients developed early biliary strictures that were treated by percutaneous dilatation and a Roux-en-Y hepaticojejunostomy with satisfactory long-term results.

Conclusion: The routine use of IOC during LC in a high-volume teaching centre was associated with a low incidence of BDI, and facilitated detection and repair during the same surgical procedure with a good outcome.

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Introduction

The incidence of bile duct injury (BDI) during laparoscopic cholecystectomy (LC) has not declined in the past few decades. BDI is a serious complication, often requiring assessment and treatment by experts[1,2]. Most patients referred to a tertiary centre have complex BDI, mainly as a result of late diagnosis or failed attempts at repair by inexperienced surgeons[3–5].

Intraoperative repair of BDI has recently been suggested as a useful therapeutic strategy. It is associated with low morbidity and the shortest path to achieve excellent long-term results[6]. However, immediate repair of BDI during LC is done infrequently because the diagnosis of BDI is often made after surgery[7,8].

The role of routine intraoperative cholangiography (IOC) during LC has been debated over the past 25 years[2,9–13]. It is still uncertain whether IOC prevents BDI or not. However, not much is known about the role of IOC in the diagnosis and subsequent treatment of BDI during the same surgical procedure. Some of the advantages of intraoperative diagnosis and definitive treatment of BDI include avoiding organic sequelae and the high treatment costs of late detection of cases, and reducing lawsuits[1,14].

A recent study[15] concluded that in a high-volume hepatobiliary centre it is possible to achieve an adequate scenario for the management of BDI: low incidence, less complex lesions, high rate of intraoperative diagnosis and repair by an experienced surgeon with excellent long-term results. The aim of this study was to determine the value of routine IOC in the diagnosis and management of BDI during LC at a high-volume centre.

Methods

A retrospective analysis of a single-institution LC database was carried out. All patients with a diagnosis of BDI sustained during LC at the Hospital Italiano de Buenos

Table 1 Strasberg classification[8] of bile duct injury

Type	Description
A	Bile leak from a minor duct still in continuity with the CBD
B	Occlusion of part of the biliary tree, mostly aberrant RHD
C	Bile leak from duct not in communication with CBD, mostly aberrant RHD
D	Lateral injury to extrahepatic bile ducts
E	Circumferential injury of major bile ducts as per Bismuth classification
E1	CBD lesion $\geq$ 2 cm from bifurcation
E2	CBD lesion $\leq$ 2 cm from bifurcation
E3	CBD lesion at bifurcation
E4	Separate left and right hepatic duct lesions
E5	Combined lesion to CHD and a right segmental bile duct

CBD, common bile duct; RHD, right hepatic duct; CHD, common hepatic duct.

Aires between October 1991 and May 2012 were included in the study.

BDI was defined as any damage to the wall of the main biliary tree detected during LC or diagnosed after surgery as a result of a bile leak or biliary obstruction caused by stenosis. Intraoperative diagnosis was made by either direct view (bile leak or duct transection) or abnormal IOC findings (extravasation of radiographic dye or obliteration of a duct). Postoperative diagnosis was made when bile leakage, reoperation or bile duct imaging findings (endoscopic, transcatheter or magnetic resonance cholangiography) indicated a BDI. The Strasberg classification[8] (*Table 1*) was used to describe the type of BDI (based on surgical and cholangiographic findings) and the Clavien–Dindo classification[16] was employed to stratify the severity of complications. Patients with bile leak from the cystic duct or gallbladder bed (type A leaks), and patients who underwent open cholecystectomy, were excluded.

The American technique of LC was employed, as described previously[15]. IOC was used as a routine in all patients. Briefly, Calot's triangle was identified and dissected using monopolar electrosurgery energy (hook). Once the cystic duct had been recognized, a clip was placed at the cystic duct–infundibulum junction and a lateral incision was made just below the clip. A 5-Fr catheter was introduced in the cystic duct and fixed with an Olsen clamp. When the cystic duct could not be identified easily during dissection, cholangiography was performed by direct puncture of the gallbladder. After the biliary system had been filled with radio-opaque dye, the biliary anatomy was visualized dynamically using a mobile C-arm unit and an image intensifier with immediate print for documentation. Since 1995, the 'critical view of safety' (CVS) technique has been applied routinely before IOC[8]. The CVS was documented in the operative report, based on surgical team interobserver agreement of achievement during the procedure. In the presence of common bile duct (CBD) stones, laparoscopic CBD exploration was attempted under fluoroscopic control with the use of an extraction basket, either through the cystic duct or by choledochotomy.

All operations were performed or supervised by a member of the hepatopancreatobiliary surgery section (staff surgeon or senior fellow). Patients were followed up at 1 week, 1 month and 1 year after operation. Data for each patient were recorded prospectively from the date of index operation to a minimum of 12 months after surgery or death, whichever occurred first. Patients with a repaired BDI were assessed every 3 months during the first year and annually thereafter (with clinical evaluation and liver function blood tests). According to the findings and clinical judgement, additional imaging studies were employed to rule out biliary stenosis.

Patient demographics, indication for surgery, timing of the operation (elective or emergency), time of diagnosis of injury, mechanism and type of biliary injury, predisposing factors, results of IOC including the presence of gallstones in the CBD, type of repair, postoperative complications, and short- and long-term results were analysed in the group of patients with BDI. The following details on IOC were also analysed: percentage of successful cholangiograms (contrast seen in CBD), time necessary for IOC (time between placement of the first clip in the cystic duct and final placement of the second clip or endoloop after IOC and duct section), errors in the interpretation, and overall accuracy of IOC for the detection of BDI.

Results

Some 12 777 consecutive cholecystectomies were performed during the study interval, of which 11 423 were done laparoscopically (89·4 per cent); this cohort formed the study population. A total of 2184 patients (19·1 per cent) were operated on for acute cholecystitis. In 20 patients (0·17 per cent), a BDI secondary to LC was diagnosed. Ten patients had an emergency operation and in 18 patients BDI was diagnosed during surgery (*Table 2*). In two patients the diagnosis was made in the first week after surgery (postoperative days 4 and 7), and BDI was probably caused by thermal injury with late biliary perforation. According to the Strasberg classification of BDI, there were three type C, 15 type D and two type E2 lesions. Five patients had a type A leak (2 Luschka duct leaks and 3 cystic stump leaks), representing an overall incidence of BDI of 0·22 per cent (25 of 11 423). There were no associated vascular injuries.

The causes of BDI, contributing factors and direct mechanisms of injury are summarized in *Table 3*. All

Table 2 Characteristics, treatment and outcome of 20 patients with bile duct injury after laparoscopic cholecystectomy

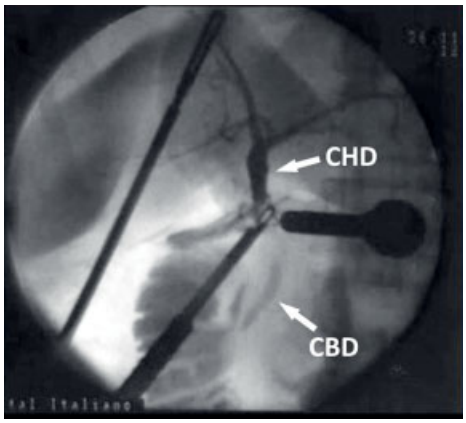
	No. of patients
Mean (range) age (years)	53 (18–81)
Sex ratio (M : F)	3 : 17
Indication for surgery	
Symptomatic cholelithiasis	9
Biliary pancreatitis	1
Acute cholecystitis	10
Emergency setting	10
Type of injury*	
C	3
D	15
E2	2
Intraoperative diagnosis	18
Type of repair	
Primary closure	11
End-to-end anastomosis	2
RYH	4
Transpapillary stent	1
Laparoscopic drainage†	1
Laparoscopic drainage + ERCP†	1
Morbidity‡	6
Grade I, bile leak	1
Grade II, acute pancreatitis	2
Grade IIIb, bile leak	1
Grade IIIb, CA pseudoaneurysm	1
Grade IIIb, choleperitoneum	1
Death	0
Stenosis	
Early	2
Late	0
Mean (range) follow-up (months)	75 (12–220)

*Strasberg classification[8]. †Management in patients with postoperative diagnosis of bile duct injury. ‡Clavien–Dindo classification[16]. RYH, Roux-en-Y hepaticojejunostomy; ERCP, endoscopic retrograde cholangiopancreatography; CA, cystic artery.

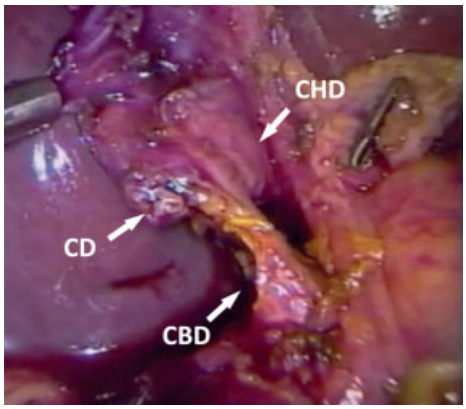
Table 3 Causes, contributing factors and mechanisms of bile duct injury in 20 patients

	No. of patients
Cause	
Inadequate dissection	9
Misidentification of anatomy	8
Inappropriate transcystic exploration	3
Contributing factor	
Cholecystitis	10
Anatomical variation	5
Inexperienced surgeon*	4
Mirizzi syndrome	3
Morbid obesity	2
Mechanism of injury	
Non-thermal section with scissors	12
Perforation with wire basket	3
Thermal	3
Devascularization + section with scissors	1
Main bile duct resection	1

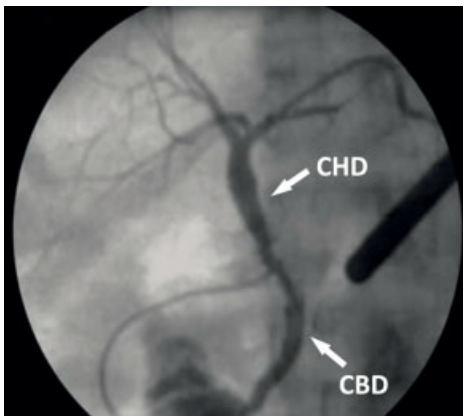
*Injury occurred during the learning curve at the start of the series.



a Type D BDI

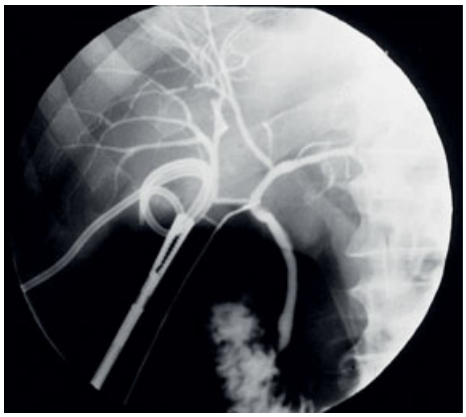


b Partial transection of the CBD

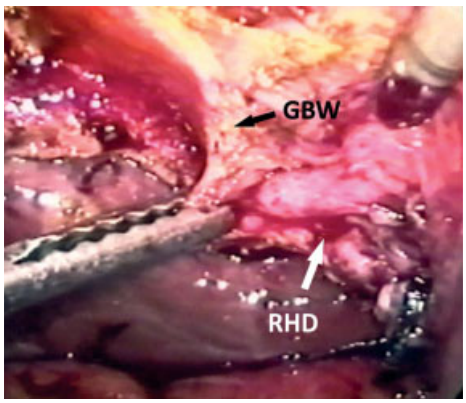


c Successful repair

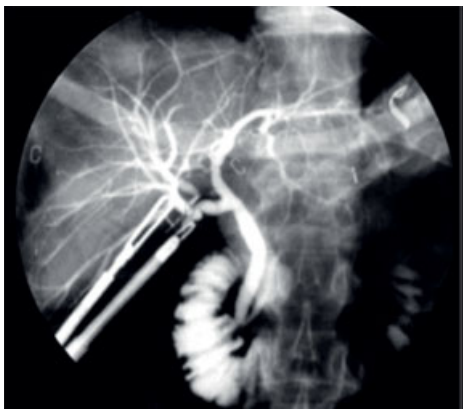
Fig. 1 **a** Type D lesion resulting from misinterpretation of the common bile duct (CBD) as the cystic duct (CD), diagnosed by intraoperative cholangiography (IOC). **b** Intraoperative photograph from the same patient showing the lateral partial transection of the CBD. **c** A successful repair is demonstrated by IOC after primary closure over a T tube. CHD, common hepatic duct



a RHD stuck to gallbladder bed



b RHD remains intact



c Ductotomy close to the RHD

Fig. 2 a Intraoperative cholangiography (IOC) in a patient with a cholecystostomy showing the right hepatic duct (RHD) stuck to the gallbladder bed. IOC prevented injury of the RHD during cholecystectomy in this patient with inflamed tissues. **b** Intraoperative photograph from the same patient demonstrates that the RHD below the gallbladder wall (GBW) was undamaged after partial cholecystectomy. **c** IOC shows a ductotomy placed close to the RHD in another patient with anomalous connection of a short cystic duct into the RHD. In this patient, IOC avoided partial clipping and stenosis of the RHD

Table 4 Diagnostic accuracy of intraoperative cholangiography for bile duct injury

	BDI present	BDI not present	Total
IOC abnormal findings	15	0	15
IOC normal findings	4	10 913	10 917
Total	19*	10 913	10 932

*In one of the 20 patients, intraoperative cholangiography (IOC) was not possible owing to a large inflammatory process. BDI, bile duct injury.

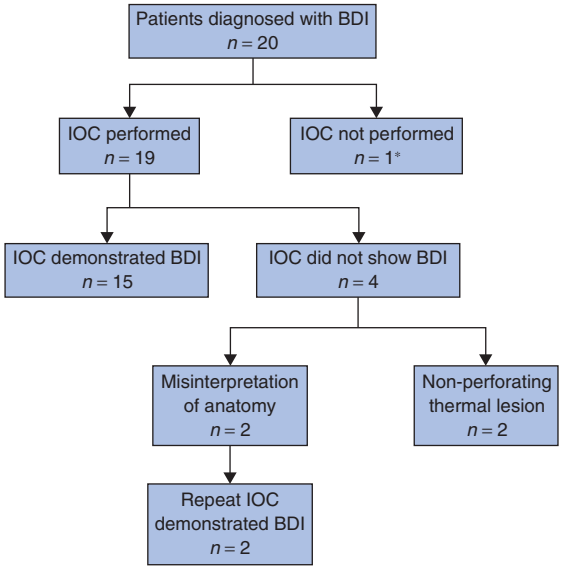
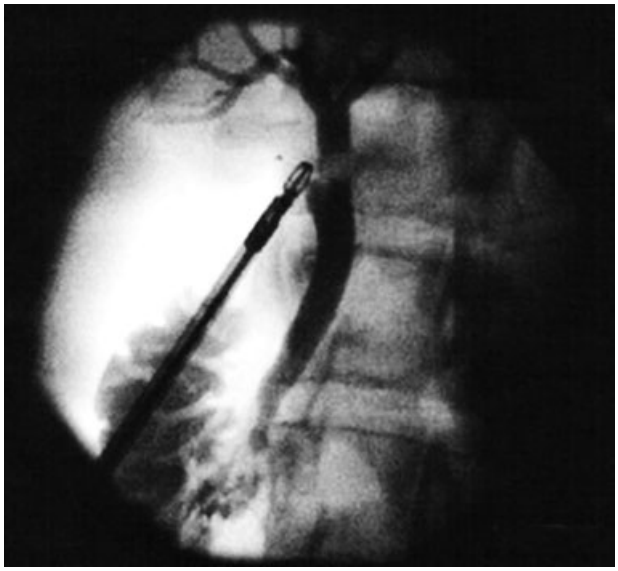


Fig. 3 Results of intraoperative cholangiography (IOC) for assessment of bile duct injury (BDI) in patients undergoing laparoscopic cholecystectomy who were subsequently diagnosed with a BDI. *In one patient, cannulation of the cystic duct was not possible owing to a large inflammatory process

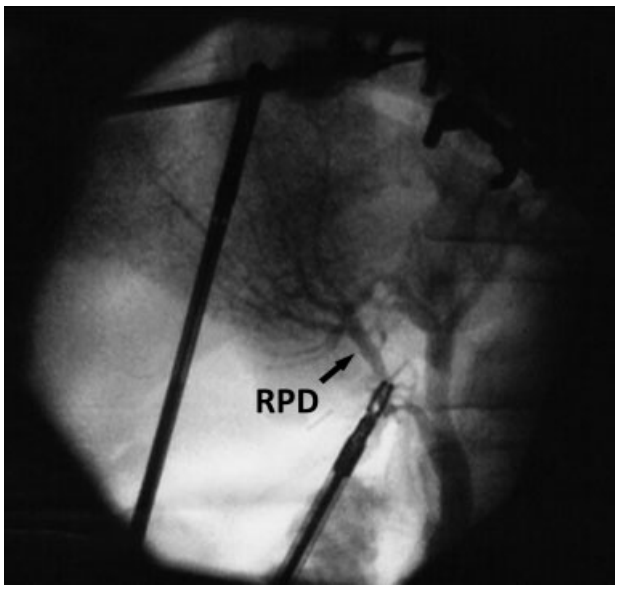
injuries diagnosed during surgery were repaired during the same surgical procedure (*Fig. 1*), following the algorithm described previously[15].

The overall success rate for IOC was 95·7 per cent (10 932 of 11 423). The duration of IOC was determined in 100 consecutive patients of the present cohort after the first 1000 cases, and showed a median duration and irradiation time of 6 (range 2–15) min and 44 (10–150) s respectively. No patient had complications related to the IOC. The sensitivity and specificity of IOC for BDI were 79 and 100 per cent respectively (*Table 4*). In some situations during this LC series, the findings at IOC indicated evidence of BDI prevention (*Fig. 2*).

Fig. 3 shows the results of the use of IOC in patients with BDI. In one patient it was not possible to cannulate the cystic duct owing to a large inflammatory process. In this patient the diagnosis of BDI was made by intraoperative



a Apparently normal biliary anatomy



b Lateral injury of the RPD

Fig. 4 a Intraoperative cholangiography (IOC) demonstrating an apparently normal biliary anatomy. **b** A second IOC was performed after slight withdrawal of the catheter because the surgeon suspected absence of the right posterior duct (RPD). A lateral injury of the RPD was finally diagnosed

findings and the procedure was converted to open surgery. In 15 patients, IOC facilitated the intraoperative detection of BDI when the surgeon did not suspect it (*Fig. 4*); thus the number of cholangiograms that needed to be performed in order to detect one lesion was 729. In the remaining four patients the injury was not detected during IOC. In two patients, initial interpretation of the anatomy was inadequate owing to anatomical variations of the right biliary tree; in both, after detection of a bile leak in the operative field, laparoscopic cannulation of the sectioned ducts confirmed the injury. Thus, 18 of the 20 BDIs were diagnosed during surgery.

The CBD stone rate in the present series of patients undergoing LC was 10·3 per cent (1176 of 11 423 patients): 376 (32·0 per cent) were unsuspected and 800 (68·0 per cent) were suspected before operation. Of the 1176 patients with CBD stones, 953 (81·0 per cent) were managed successfully by a laparoscopic transcystic approach, 175 (14·9 per cent) were treated successfully by laparoscopic choledochotomy and 12 (1·0 per cent) required a laparoscopic biliodigestive anastomosis to resolve the cholelithiasis. Thus, the final success rate for CBD stone clearance during LC was 96·9 per cent (1140 of 1176). The remaining 36 patients either had conversion to an open procedure (27 patients, 2·3 per cent) or required postoperative endoscopic retrograde cholangiopancreatography (9 patients, 0·8 per cent) to remove the stones.

Discussion

The mortality rate for LC associated with a BDI is six times greater than that following an uneventful LC[17]. A recent editorial from the Society of American Gastrointestinal and Endoscopic Surgeons places the issue at a national priority level and advocates an aggressive campaign to achieve the 'duct injury mitigation era'[18]. The European Association for Endoscopic Surgery[19] has proposed a new classification (ATOM) to determine the true incidence of BDI, and to aid in the adoption of correct preventive and therapeutic measures. Despite the potential benefits of IOC, there is a debate over whether it should be considered a standard of care or an optional procedure according to the surgeon's judgement.

Arguments that support the routine use of IOC are: a decreased incidence of BDI, prevention of serious injuries, increased intraoperative detection of BDI and improvement of patient outcome[20–23]. Overall prevention of BDI is the most controversial topic. It is suggested that a proper dissection technique would prevent injuries. However, in the Netherlands, where the CVS is recommended rather than IOC, the incidence of BDI is 0·7 per cent[21,24–27]. Buddingh and colleagues[22] demonstrated that the BDI rate dropped from 1·9 to 0 per cent after the application of routine IOC, and large cohort studies[1,18,23,26,28,29] have shown that routine IOC reduces the incidence of BDI by

40–70 per cent. Furthermore, a recent study[30] using data from the Swedish GallRiks registry found a BDI rate as high as 1·5 per cent, and demonstrated that the intention to use IOC, whether successful or not, significantly improved survival. In contrast, a recent systematic review[10] could not find any evidence to support or abandon the routine use of IOC. However, this study gathered heterogeneous randomized clinical trial data and did not have the power to detect differences in BDI. In addition, a recent retrospective study[31] using Medicare data found that IOC was not associated with a significant reduction in BDI. However, this study was criticized[32] for including only patients older than 65 years undergoing either open or laparoscopic cholecystectomy and for using a 'pseudorandomization' method for statistical analysis[32]. In the Hospital Italiano, routine IOC is used for both open and laparoscopic cholecystectomy, as BDI rates are similar for the two approaches (0·19 and 0·17 per cent)[15,20]. The performance of routine IOC does not mean that a proper dissection (as provided by the CVS) should be abandoned, because the techniques are complementary in helping to reduce the rate of BDI[33].

Intraoperative diagnosis of BDI is also a major advantage of routine IOC. Immediate diagnosis prevents damage progression leading to more complex injuries. Furthermore, it allows appropriate measures for delayed definitive correction or immediate on-table repair if an experienced surgeon is present[15]. The evaluation by the Swiss Association of Laparoscopic and Thoracoscopic Surgery[34] of 12 111 LCs showed an intraoperative diagnosis rate of BDI of 80·6 per cent, and IOC allowed the diagnosis of BDI in 64 per cent of these patients. In the present series, IOC diagnosed unsuspected BDI in 15 of 19 patients. In two other patients, IOC confirmed the injury after surgeon suspicion, so that IOC was able to confirm BDI in 17 of 19 patients. In two patients the diagnosis of BDI was established during the postoperative course, most likely associated with a thermal insult (sustained either before or after IOC). These lesions were minor, with lateral leakage of the biliary system, and both were managed successfully by laparoscopic drainage.

Prevention of serious injury is a topic of great importance[35]. In most published series on LC without IOC, intraoperative diagnosis is made in only 20–30 per cent of the patients, and mainly for severe injuries[30]. By contrast, 19 of 20 patients in the present series had IOC, 18 of which were diagnosed during surgery. Most injuries were mild and could be repaired during the same surgical procedure with successful outcomes. Eight of the 15 type D lesions in the present series were partial transections of the hepatic duct to insert the cholangiography catheter. If IOC had not been performed, these patients would have sustained complete transectional injuries. In the only case of biliary tract resection, IOC was performed after the BDI occurred in a patient with a type 2 Mirizzi syndrome.

The routine use of IOC has a short surgical and institutional learning curve, enables team planning, and improves surgical dexterity and bile duct exploration skills. It also increases the surgeon's knowledge of anatomical variations, thus decreasing misinterpretation, especially during surgical residency training[21,22,36–38]. As up to 30 per cent of BDIs result in malpractice claims[2], IOC may also have possible use in defensive medicine. In the present study, none of the BDIs resulted in litigation.

Despite the potential benefits of routine IOC, there are some drawbacks to its application, such as the expertise needed to interpret the cholangiogram, lengthening of the operating time, associated costs, and the infrequency of BDI when an appropriate surgical technique (CVS) is followed[2,12,39]. The increased duration of surgery is related closely to the level of training and availability of technology[40]. In the present study, the mean time for IOC was 6 min, which is similar to the time reported by other experienced groups and is not clinically significant[40,41]. Furthermore, there is evidence indicating that routine IOC is cost-effective by reducing the severity of BDI and the treatment cost of patients with retained stones[2]. The cost of routine IOC must be balanced against the costs generated by the resolution of an inadvertent BDI. Savader and colleagues[42] from Johns Hopkins University defined BDI as 'a health and financial disaster'. The long duration of the present study (1991–2012) did not allow a cost-effectiveness analysis of routine IOC, owing to variations in costs over time. However, the current cost of IOC at the Hospital Italiano is €16, and the procedure is included in the surgical package covered by health insurance. However, the average cost of a BDI in a patient with postoperative complications after late diagnosis during 2012 was €27 368 ($37 508; exchange rate 17 February 2014) (16 times higher than the cost of immediate on-table repair)[6]. Thus, from these data, it can be seen that in the authors' setting IOC is a cost-effective practice, justifying the performance of 729 IOCs to avoid one undetected BDI.

Misinterpretation of cholangiograms is one of the most important considerations against IOC. A study by Way and colleagues[43] found that fewer than 25 per cent of cholangiograms were interpreted correctly when a BDI occurred. However, these data were from patients who had been referred from centres where IOC was not always performed routinely. In the present series, only two of 17 cholangiograms showing the injury were misinterpreted. Only a few reports have analysed the accuracy of IOC as a diagnostic method, and these involved mainly the

detection of biliary stones[10,44]. The present study analysed the sensitivity and specificity of IOC for detecting BDI. The high sensitivity and specificity found in this series (79 and 100 per cent respectively) might be associated with the routine use of IOC and the wide experience gained by a single surgical team over 20 years in a teaching environment. The only two BDIs not shown by IOC were energy-driven secondary injuries. These thermal lesions, without immediate tissue loss, are the type of injury that IOC is unable to detect because they manifest only as late stenosis or perforation.

The main limitation of the present study is its retrospective nature. In addition, the early introduction of the CVS technique might have contributed to the low BDI rate found in this series, and thus the present results may not be related solely to the routine use of IOC. As it is almost impossible to perform a randomized clinical trial with sufficient power to determine whether routine IOC can prevent BDI, population-based studies remain as important evidence to clarify this aspect.

It has been proposed recently that the different perceptions of the BDI problem might bias the decision of whether or not to perform IOC[21]. Like other accidental injuries, BDIs are unexpected and unpredictable events; therefore, the value of IOC as a safety measure for primary and secondary prevention of BDI relies on its systematic application.

Disclosure

The authors declare no conflict of interest.

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