Surg Endosc (2006) 20: 868–874
DOI: 10.1007/s00464-005-0425-x

SURGICAL ENDOSCOPY
and Other Interventional Techniques

Routine versus selective intraoperative cholangiography during laparoscopic cholecystectomy

A survey of 2,130 patients undergoing laparoscopic cholecystectomy

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Received: 15 June 2005/Accepted: 18 December 2005/Online publication: 12 May 2006

Abstract
Background: Routine use of intraoperative cholangiography (IOC) during laparoscopic cholecystectomy (LC) is a matter of debate.
Methods: Data from 2,130 consecutive LCs and patients' follow-up during 9 years were collected and analyzed. During the first 4 years of the study, 800 patients underwent LC, and IOC was performed selectively (SIOC). Thereafter, 1,330 patients underwent LC, and IOC was routinely attempted (RIOC) for all.
Results: In the IOC group, 159 patients met the criteria for SIOC, which was completed successfully in 141 cases (success rate, 88.6%). Bile duct calculi were found in nine patients. All other patients with no criteria or failed SIOC were followed, and in nine patients retained stones were documented. Thus, the incidence of ductal stones was 1.1% and sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) for the detection of ductal stones were 50, 100, 98.6, and 100%, respectively. In the RIOC group, IOC was routinely attempted in 1,330 patients and was successful in 1,133 (success rate, 90.9%; $p = 0.015$). Bile duct stones were detected in 37 patients (including 14 asymptomatic stones). In two cases, IOC failed to reveal ductal stones (false negative). There was no false-positive IOC. Therefore, with RIOC policy, the incidence of ductal stones, sensitivity, specificity, NPV, and PPV were 3.3, 97.4, 100, 99.8, and 100%, respectively (significantly higher for success rate, incidence, sensitivity, and NPV; $p < 0.05$). Abnormal IOC findings were also significantly higher in the RIOC group. Common bile duct injury occurred only in the SIOC group [two cases of all 2,130 LCs (0.09%)].
Conclusion: RIOC during LC is a safe, accurate, quick, and cost-effective method for the detection of bile duct anatomy and stones. A highly disciplined performance of RIOC can minimize potentially debilitating and hazardous complications of bile duct injury.

Key words: Bile duct stone — Bile duct injury — Intraoperative cholangiography — Laparoscopic cholecystectomy

The rationale for performing intraoperative cholangiography (IOC) during traditional open cholecystectomy has undergone several revisions since it was first described by Mirizzi [1] in 1931. Since the introduction of laparoscopic cholecystectomy (LC) in the late 1980s, which has become the gold standard in the management of gallstone disease [2], there has been considerable controversy regarding the proper role of IOC for patients undergoing LC. IOC has been widely used for the detection of biliary tract anatomy as well as intraductal stones. However, there is no consensus regarding whether to use this technique routinely or selectively. Several reasons have been proposed for routine use of IOC (RIOC) in the era of LC. Whereas laparoscopic instrumentation allows only a two-dimensional view and limits tactile feedback, RIOC can help to clarify anatomy and therefore reduce bile duct injuries during LC [3–7]. In addition, it detects asymptomatic bile duct stones, which are estimated to be present in up to 5% of patients undergoing cholecystectomy [6–11]. Opponents contend this may cause a prolonged operative time and false-positive results, which can lead to more unnecessary common bile duct (CBD) explorations and their consequences, and they point to the fact that most small ductal stones pass spontaneously and the frequency of CBD injuries despite RIOC [6, 9, 12].

We retrospectively reviewed the results of 2,130 consecutive LCs in our community-based hospital.

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During the first 800 cases, IOC was performed selectively (SIOC), and thereafter it was performed routinely (RIOC). The statistical analysis of 1,274 successful IOC attempts has been reviewed, with emphasis on the role of RIOC to detect more ductal stones and to prevent major CBD injuries.

Materials and methods

In a retrospective study, data from hospital records, operative notes, cholangiographic studies, and follow-up of all patients who underwent LC from January 1992 to February 2001 were gathered and analyzed. Preoperative evaluation included abdominal ultrasonography, routine lab tests, and liver function tests (LFTs). In the first 4 years of study (until March 1996), 800 patients underwent LC and IOC was performed selectively (SIOC). The indications for performing SIOC were

- History of jaundice, cholangitis, or pancreatitis
- Abnormal LFTs
- Ultrasonographic evidence of CBD stone or dilatation
- Obscure anatomy during LC

From March 1996 to February 2001, 1,330 patients underwent LC and IOC was attempted in all of them routinely (RIOC).

To perform a static IOC, after the dissection of Calot's triangle and identification of the cystic artery and duct, a titanium clip is applied to the cystic duct close to the gallbladder infundibulum. Then a 4- or 5-Fr ureteral catheter, which is passed into the peritoneal cavity through an angiocath near the midclavicular trocar, is pushed into the cystic duct by a grasping forceps through a small transverse incision on the cystic duct made by scissors until its distal hole passes into the lumen and through the Heister's valve, if possible. The catheter is fixed in place by another titanium clip. Before administration of the contrast dye, the catheter is aspirated with a 10-ml syringe containing distilled water and then 2 or 3 ml of the distilled water is flushed into the lumen to examine the position of the catheter, its fixation, and the patency of the lumen. This can also push the sludge out of the cystic duct and into the CBD. If no water leaks, the anterior axillary grasper is removed to prevent its interference in the graphy. Following administration of 2 ml of contrast dye via a syringe into the catheter, a supine graphy is obtained with a portable radiological unit to visualize distal CBD and Oddi's sphincter. Then the patient is placed in the Trendelenburg position, and an additional 3 ml of contrast dye is administered to visualize the proximal CBD, right and left hepatic ducts, and the junction. Cholangiograms are routinely evaluated by the surgeon during the operation. The surgeon should focus on the following findings:

- CBD diameter
- Visualization of the proximal and distal CBD and hepatic ducts
- Passage of contrast media into duodenum
- Ductal stones
- Anatomic variations

Cholangiograms are kept with the patient's record. The first follow-up visit is 1 week postoperatively; then, follow-up occurs monthly up to 3 months and twice a year thereafter.

The chi-square test was employed for statistical analysis, and a p value of < 0.05 was considered significant.

Results

LC was performed in all 2,130 patients and conversion to open surgery was done in 61 patients (2.9%). The reasons for conversion are shown in Table 1. The female/male ratio was 1,558 to 572, and the median age of the patients was 54 years (range, 11–97). The mean LC duration was 45.5 min (range, 25–380) and the mean additional operative time for IOC during LC was 15 min (range, 7–45) (Table 2). Until March 1996, 800 patients underwent LC, and IOC was attempted in 159 cases selectively (SIOC) and was completed successfully in 141 cases (success rate, 88.6%). SIOC revealed ductal stones in nine patients (incidence, 1.1%). Follow-up of the rest of the group (659 patients)—no indications or failed IOCs—also revealed nine patients with retained stones. As a result, this approach was shown to have 50% sensitivity, 100% specificity, 98.6% negative predictive value (NPV), and 100% positive predictive value (PPV) in the detection of ductal stones. Since March 1996, IOC has been performed in all LCs routinely (RIOC). From this group of 1,330 consecutive LCs, RIOC was completed successfully in 1,133 cases, failed in 113 (success rate, 90.9%; $p = 0.015$), and was not attempted in a few cases for specific reasons (Table 3). Among the 1,133 successfully accomplished RIOCs, ductal stones were found in 37 cases, including 14 asymptomatic stones.

Table 1. Reasons for conversion to open

Reason	*n* (%)
Inflammation/fibrosis of Calot's triangle, or severely inflamed gallbladder	27 (1.3)
Impacted ductal stones	21 (1)
Bleeding	4 (0.19)
Gallbladder malignancy	3 (0.14)
Severe intraperitoneal adhesions	3 (0.14)
Difficulty with pneumoperitoneum	2 (0.09)
Ductal injuries	1 (0.05)
Total	61 (2.9)

Table 2. Patient demographics and operative times

Female/male ratio	1,558/572
Age (yr)	54 (14–97)[a]
Operative time for LC (min)	45.5 (25–380)[b]
Additional operative time for IOC (min)	15 (7–45)[b]

[a] Median (range)
[b] Mean (range)
IOC, intraoperative cholangiography; LC, laparoscopic cholecystectomy

Table 3. RIOC failed or not attempted

	n
RIOC failed	
Obscure anatomy (severe adhesions at Calot's)	35
Inability to cannulate cystic duct	37
Poor quality of cholangiograms	20
Unavailable radiology device or technician	12
Leakage of contrast dye	8
Morbid obesity	1
Total	113
RIOC not attempted	
Normal preop ERCP[a]	7
Pregnancy	2
Liver full of metastases	2
Total	11

RIOC, routine intraoperative cholangiography; ERCP, endoscopic retrograde cholangiopancreatography
[a] 44 patients had been referred for preoperative ERCP

Table 4. Statistical analysis, RIOC vs SIOC

	SIOC	RIOC	p value
No. of cases	159/800	1,133/1,330	
Success rate (%)	88.6	90.9	0.015[a]
Incidence of ductal stones	9 (1.1%)	37 (3.3%)	< 0.01[a]
Inability to detect stones[b]	9/18 (50%)	2/39 (5%)	< 0.01[a]
Sensitivity (%)	50	97.4	< 0.01[a]
Specificity (%)	100	100	
Negative predictive value (%)	98.6	99.8	< 0.01[a]
Positive predictive value (%)	100	100	

RIOC, routine intraoperative cholangiography; SIOC, selective intraoperative cholangiography
[a] Statistically significant ($p < 0.05$)
[b] Ratio of false-negative cases to all documented ductal stones during follow-up in each approach

Asymptomatic stone means that the patient has no history, sonographic evidence, or lab tests indicating the presence of ductal obstruction. RIOC failed to detect ductal stones in two cases (false negatives). There were no false positives; that is, regardless of small asymptomatic stones that were simply followed, the presence of all IOC-detected ductal stones was documented later by CBD exploration, endoscopic retrograde cholangiopancreatography and endoscopic sphincterotomy (ERCP-ES), or another radiological modality (e.g., magnetic resonance cholangiopancreatography). Therefore, the RIOC approach increased the incidence of ductal stones to 3.3%, and its sensitivity, specificity, NPV, and PPV in the detection of ductal stones were 97.4, 100, 99.8, and 100%, respectively ($p < 0.01$ for incidence, sensitivity, and NPV) (Table 4).

Abnormal IOC findings are shown and compared between the two groups in Table 5. Abnormal IOC findings were collectively significantly higher in the RIOC group. CBD injury occurred only in the SIOC group ($p < 0.05$). Whether IOC was performed selectively or routinely, the approach toward the abnormal IOC findings remained the same.

Approaches and follow-up

Ductal stones (fig. 1)

Symptomatic ductal stones

From the total of 46 cases of ductal stones found by IOC, 32 (70%) were symptomatic. In 22 of these cases, LC was converted to laparotomy and exploration of the CBD. A T-tube was inserted in 10 patients and was removed after a satisfactory cholangiography within a mean of 7 days. In another 12 patients, choledochoenteric anastomosis was constructed (choledochoduodenostomy in 11 patients and Roux-en-Y choledochojejunostomy in one patient). ERCP-ES was performed in seven cases of symptomatic ductal stones within 1–20 days (mean, 12) postoperatively.

Finally, in three cases it was decided that expectant management should be done. All three patients had multiple small CBD stones. During follow-up, one patient developed symptoms of retained stone and underwent ERCP-ES. Another patient did not continue the follow-up, and follow-up for the third patient continued without any specific problems (22 months until the end of this study).

Asymptomatic ductal stones

As previously stated, RIOC revealed 14 cases of asymptomatic ductal stones (30% of all detected stones). One of these patients underwent ERCP-ES because of the size of the stone (7 mm) on postoperative day 10, and the patient stated that she found one 7-mm stone in her stool 1 month after the procedure. Thirteen other patients underwent expectant management; all were simply observed. Follow-up of these 13 patients continued without any problems reported by the end of this study (range, 11–55 months). Only one patient developed symptoms 51 months after the beginning of the observation; the patient underwent ERCP-ES and recovered without any complications. It is probable that this stone was a new primary CBD stone rather than the original stone found 51 months ago.

Dilated bile ducts without stones

CBD dilatation (8 mm) without stones was the most common finding during IOC (60 patients, 2.8%). Ten patients underwent preoperative ERCP followed by sphincterotomy for ductal stones. All patients were observed and seven of 60 developed symptoms. Five patients were managed conservatively. The sixth patient had cholangitis 19 months postoperatively. ERCP revealed a CBD stone and attempts to remove the stone endoscopically failed twice. The patient finally underwent laparotomy, CBD exploration, and choledochoduodenostomy. The seventh patient was admitted with fever, chills, jaundice, and abnormal LFTs with high amylase preoperatively. IOC revealed CBD dilatation without any obvious stone. The patient was readmitted 3 days after discharge for abdominal pain, underwent ERCP-ES, and was found to have a 1-cm retained stone. These two latter cases represent the only false-negative IOC results in our study, both in the RIOC group.

No passage, no obstruction

In 12 patients (0.6%), dye did not enter the duodenum in the absence of a ductal stone and/or dilatation. Only one patient in this group developed pancreatitis on postoperative day 2, which was managed medically. Follow-up of the rest of the patients revealed no problem.

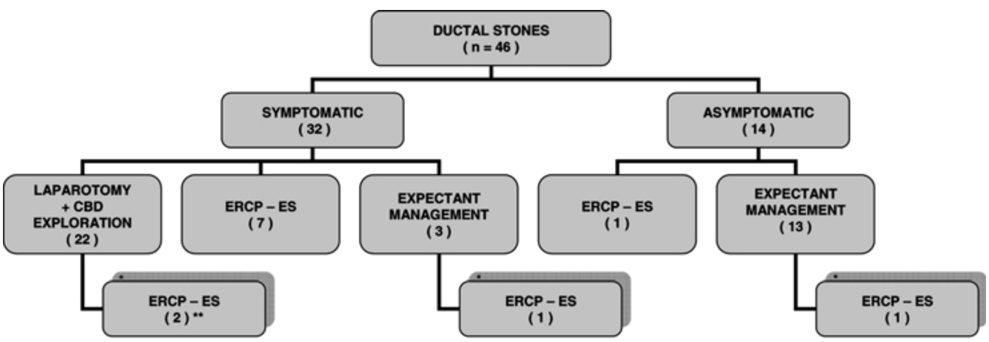
Ductal injury

In our series, CBD injury occurred in two patients (0.09%), the 239th and the 740th patients in 2,130 con-

Table 5. Abnormal IOC findings

	RIOC (n = 1,330)	SIOC (n = 800)	Total (n = 2,130)	p
Dilated duct (>8 mm), no stone	42 (3.2%)	18 (2.2%)	60 (2.8%)	0.1
Symptomatic bile duct stones	23 (1.7%)	9 (1.1%)	32 (1.5%)	0.2
Asymptomatic bile duct stones	14 (1.2%)	0	14 (0.7%)	0.02
Bile duct stones (total)	37 (2.8%)	9 (1.1%)	46 (2.2%)	0.01
No passage, no obstruction	10 (0.9%)	2 (0.3%)	12 (0.6%)	0.1
Anatomic variations	5 (0.4%)	1 (0.1%)	6 (0.3%)	0.3
Common bile duct injury	0	2 (0.3%)	2 (0.09%)	0.07
Total	94 (7.1%)	32 (4.0%)	127 (6%)	0.005[a]

IOC, intraoperative cholangiography; RIOC, routine intraoperative cholangiography; SIOC, selective intraoperative cholangiography
[a]Abnormal IOC findings were detected significantly more in RIOC group



*** The shadowed boxes represent the number of patients that underwent ERCP-ES during the follow-up.**
**** One patient underwent ERCP-ES on postop day 10 because stone removal failed during CBD exploration, and the other 2 years after choledochoduodenostomy due to Sump syndrome.**
ERCP-ES: Endoscopic Retrograde Cholangiopancreatography – Endoscopic Sphincterotomy
IOC: Intraoperative Cholangiography

Fig. 1. Management of ductal stones found with IOC (n = 46).

secutive LCs, both in the SIOC era of our study. The former had acute cholecystitis and met no criteria for IOC. Following closure of a slender duct that had been recognized as the cystic duct and before cutting it, an incision was made distal to the clip to perform IOC because the surgeon did not feel comfortable about his judgment. Because the proximal CBD was not visualized, it was concluded that the CBD must have been ligated. Therefore, the procedure was converted to open laparotomy with subsequent completion of cholecystectomy and T-tube insertion via the same incision. Postoperative T-tube cholangiography was normal and the patient recovered without any problems. The second patient had Mirizzi syndrome (documented in retrospect). Following ligation and cutting of the duct identified as the cystic duct, and later in the course of LC, the procedure was converted to open because of technical difficulty with pneumoperitoneum, lack of proper visualization, and bleeding. Only then did IOC reveal the transection of the CBD. The course was completed with cholecystectomy and a choledochoenteric anastomosis. Follow-up is to be continued for both patients, the first for 7 years and the second for 5 years, and there have been no problems to date.

IOC-related ductal complications were minor and occurred in 3 patients (0.14%). In all three cases, attempts to cannulate the cystic duct resulted in the disruption of the cystic duct and therefore the IOC failed. In all cases, the cystic duct was clipped and a Nelaton drain inserted and removed after a mean of 3 days with no further complications. There was no IOC-related mortality.

Follow-up

All patients in whom IOC was not done or failed were followed. These included 641 of the first 800 patients without indications for cholangiography, 18 patients with failed SIOC, 11 of the next 1,330 patients for whom RIOC was not done for specific reasons, and 113 cases of failed RIOC (Table 3), for a total of 856 patients. Fifteen patients (1.7%) developed symptoms during follow-up. All were referred for postoperative ERCP. The time between the development of symptoms and referral for ERCP ranged from 6 to 540 days. In 11 patients, ERCP documented the retained stones and endoscopic sphincterotomy was performed. The others had normal ERCP, one of whom sustained serious complications after ERCP. Therefore, of these 15 patients, retained stones were documented in 11 patients, nine of whom were among the 641 patients who had not met the indications for cholangiography before March 1996.

Case report

A 26-year-old woman underwent LC for cholelithiasis in August 1993. IOC was not done because she did not meet the indications for IOC at that time. During follow-up, she complained of right upper quadrant pain, abdominal distension, and constipation. Conservative medical therapy did not resolve the symptoms. Abdominal sonography, LFTs, barium enema, and gastroscopy were all normal. She was referred to a gastroenterologist and underwent ERCP for suspected retained stone. ERCP was normal but resulted in severe post-ERCP acute pancreatitis. She was admitted, underwent laparotomy twice, and sustained a very critical medical condition. Fortunately, she recovered and was discharged home after approximately 1 month.

Discussion

The definitive management of CBD stones in the era of laparoscopic surgery is still controversial. Approaches include conversion to open laparotomy and exploration of the CBD, various sequences of LC and ERCP-ES, and laparoscopic bile duct exploration (LBDE) depending on the surgeons' preference and the level of expertise, as well as the availability of the desired technique. A 1999 European Association for Endoscopic Surgery multicenter prospective randomized trial showed equal efficacy in terms of ductal stone clearance for the two-stage ERCP-ES/LC and the single-stage LC/LBDE, as well as similar rates of morbidity and mortality [6]. Other authors have shown that LC followed by postoperative ERCP-ES for the management of ductal stones found intraoperatively minimizes cost and morbidity [14]. Management of the unexpected ductal stones found by IOC during LC also presents a dilemma. Two approaches can be undertaken: routine postoperative ERCP for all patients in whom IOC has detected ductal stones or observing of these patients and reserving ERCP for those who develop symptoms during follow-up [5, 15]. Although ERCP is quite efficient in the management of ductal stones, it has a morbidity rate of 7–11% and a mortality of $<1\%$ [16, 17], especially if accompanied by ES [18]. Our approach toward ductal stones found during RIOC was to refer patients with stones >5 mm for endoscopic intervention (i.e., ERCP and also sphincterotomy if needed). Because LBDE has not been our policy, for most stones >8 mm, conversion of LC to open laparotomy and CBD exploration was performed, with subsequent T-tube insertion and T-tube cholangiography. For multiple or impacted stones, especially in a dilated CBD (>8 mm diameter), choledochoenteric anastomosis was performed. Asymptomatic stones with a diameter <5 mm were followed, and if patients developed symptoms, they were referred for ERCP-ES. This "expectant management" was employed without any problems in 86.7% of patients with asymptomatic stones (follow-up, 11–55 months until the end of the study).

According to our results (Table 4), routine versus selective use of IOC can lead to significant increases in the incidence (3.3 vs 1.1%), sensitivity (97.4 vs 50%), and NPV (99.8 vs 98.6%) in the detection of ductal stones ($p < 0.01$). These findings have also been demonstrated by other authors [9, 12, 19]. It is necessary to note that if IOC is to be performed selectively on the basis of some criteria (as we did in our initial 4 years of study), these asymptomatic stones will be missed. However, most of these stones will not develop symptoms, and if they do, the surgeon can refer the patient for ERCP [15]. The point is that the statistically significant higher NPV for RIOC in the detection of ductal stones means that a normal cholangiogram almost always implies a clear duct. This is contrary to when a patient in the SIOC group does not meet the criteria to undergo IOC. The absence of any indications for cholangiography does not mean that the patient has a clear duct, at least in 50% of cases. This may lead to problems such as those mentioned in our case report and expose the patient to the potential hazards of unnecessary ERCP for the lack of a definitive image of the biliary tree that could have been taken easily during LC.

During the 1990s, a higher rate of iatrogenic biliary tract injuries was reported, and this was attributed to the learning curve for LC [20]. Stewart and Way [21], in a review of patients who were referred to their tertiary center with iatrogenic biliary tract injuries during a 7-year period, identified the two most important reasons for ductal injury during LC as (a) false identification of CBD as the cystic duct and (b) aggressive efforts to stop bleeding. They outlined 14 principles to avoid nearly all ductal injuries, the two most crucial of which are the liberal use of IOC and to cautiously interpret the lack of opacification of the proximal CBD as a sign of its closure. Several other studies have shown that RIOC can detect significantly more biliary injuries as well as unexpected biliary anatomy, many of potential surgical relevance. Although it has not been shown to prevent all injuries, RIOC has enabled surgeons to limit and correct biliary injuries earlier, leading to significantly reduced costs and fewer overall operative procedures to correct injuries [7, 10, 11, 22]. A meta-analysis of 327,523 LCs with 405 registered major CBD injuries showed a significantly lower rate of injuries for RIOC vs SIOC (0.21 vs 0.43%, $p < 0.05$), a higher rate of intraoperative detection of such injuries with RIOC compared to SIOC (90 vs 44.5%, $p < 0.05$), and the complete transection of CBD as the most common type of injury when IOC was not performed [22]. This should make sense at least from a liability standpoint. Olsen [23] reviewed 177 cases of ductal injuries and determined that IOC had been performed only in 32 of these cases (18%). In all cases of complete transection of CBD, cholangiogram had revealed the closure of the lumen but the surgeon had not interpreted the unopacification of the proximal ducts as a sign of the CBD closure. This emphasizes the importance of visualization of the right and left hepatic ducts and the junction during IOC. If the surgeon had noticed the closure of the duct (just as it had been revealed by IOC), its transection could have been avoided. Then, only suturing of the small incision on the CBD would have been necessary. In our series, CBD injury occurred in two patients (0.09%), the 239th and 740th patients, both among the SIOC group and neither met the criteria for IOC. In the first case, had the surgeon not suspected the problem, he would have mostly missed it. In the second case, lack of a routine policy of performing IOC during LC resulted in the complete transection of CBD. As stated previously, RIOC has been our routine during every LC since the 800th consecutive case.

It has been suggested that RIOC can cause ductal complications [24]. In our series, the complications attributable to the performance of IOC were minor and only caused RIOC not to be accomplished. One can hypothesize that IOC can increase the possibility of postoperative pancreatitis. However, a 5-year study conducted by Traverso et al. [25] showed that in their center, where the routine performance of IOC is a policy during LC, postoperative pancreatitis is rare, as in our institution, and has no statistic relevance to the performance of RIOC.

There are also arguments that RIOC wastes time and money [6, 18, 19]. It has been estimated that if one severe bile duct injury is prevented in every 1,000 LCs, the cost of all "unnecessary" IOCs will be saved [26]. A cost-effectiveness analysis estimated that RIOC would cost $100 more per LC. However, it would save $390,000 per death avoided and $87,143 per CBD injury avoided [27]. The extra charge for a static IOC during LC in our center in Tehran is approximately $45 and includes radiology department fees (including the fee for a portable radiological device per single use, radiology technician, two cassettes, and development of two radiological films) and operating room instruments used (one ureteral catheter, one angiocath, and 10 ml of contrast dye). Although it has been stated that digital fluoroscopic IOC is less time-consuming than static IOC [18], the mean additional time of operation in our series with static IOC was only approximately 15 min, and it was much cheaper compared to the fluoroscopic technique. Considering the various and valuable information obtained in this way so that injury to the CBD and its potentially hazardous consequences can be prevented, RIOC is cost-effective and is recommended in all LCs.

RIOC is a safe, accurate, quick, and cost-effective method for the detection of bile duct anatomy and stones. A highly disciplined performance of RIOC, especially in the hands of an experienced laparoscopic surgeon, can well minimize the potentially debilitating and hazardous complications of bile duct injury.

A normal cholangiogram, routinely performed, almost always means a clear bile duct and can prevent unnecessary postoperative ERCP and its potential complications for the symptoms that can be attributed to retained ductal stones. Also, the routine use of IOC seems reasonable and is recommended.

Bile duct stones are detected more frequently when IOC is employed routinely rather than selectively. It seems that an expectant management for these stones, which are often small and asymptomatic, is safe and cost-effective. Postoperative ERCP can be reserved for those who become symptomatic during the follow-up period.

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