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Cholecystectomy Without Operative Cholangiography

Implications for Common Bile Duct Injury and Retained Common Bile Duct Stones

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Objective
This study evaluated the selective use of endoscopic retrograde cholangiopancreatography (ERCP) in the context of laparoscopic cholecystectomy (LC) while minimizing the use of operative cholangiography.

Summary Background Data
There has been a long-standing debate between routine and selective operative cholangiography that has resurfaced with LC.

Methods
Prospective data were collected on the first 1300 patients undergoing LC at McGill University. Preoperative indications for ERCP were recorded, radiologic findings were standardized, and technical points for a safe LC were emphasized.

Results
A total of 106 patients underwent 127 preoperative ERCPs. Fifty patients were found to have choledocholithiasis (3.8%), and clearance of the common bile duct (CBD) with endoscopic sphincterotomy was achieved in 45 patients. The other five patients underwent open cholecystectomy with common duct exploration. Intraoperative cholangiography (IOC) was attempted in only 54 patients (4.2%), 6 of whom demonstrated choledocholithiasis. Forty-nine postoperative ERCPs were performed in 33 patients and stones were detected in 17 (1.3%), with a median follow-up time of 22 months. Endoscopic duct clearance was successful in all of these. The incidence of CBD injury was 0.38%, and a policy of routine operative cholangiography might only have led to earlier recognition of duct injury in one case. The rate of complication for all ERCPs was 9% and the associated median duration of the hospital stay was 4 days. The median duration of the hospital stay after open CBD exploration was 13 days.

Conclusions
LC can be performed safely without routine IOC. The selective use of preoperative and postoperative ERCP will clear the CBD of stones in 92.5% of patients.

The introduction of laparoscopic cholecystectomy (LC) has led to many proven patient benefits, but has also brought about a re-examination of conventional practices. This is particularly true regarding operative cholangiography and the management of common bile duct (CBD) stones. Proponents of routine intraoperative cholangiography (IOC) claim that this practice will result in a lower risk of CBD injuries and fewer retained common duct stones.[1-6] The disadvantages of routine IOC include increased operating time and false-positive findings leading to unnecessary efforts to clear the common duct of stones. Moreover, such a policy precludes preoperative stone detection and endoscopic clearance, which had become increasingly common throughout the 1980s.[7-9]

This study reviews an alternative approach to the CBD in the era of LC. Patients thought to be at risk for choledocholithiasis were selected before surgery for endoscopic retrograde cholangiopancreatography (ERCP), and endoscopic duct clearance was attempted when stones were demonstrated. Rather than operative cholangiography, the risk of CBD injury was minimized by relying on meticulous surgical technique. IOC was rarely performed, and patients presenting with symptoms suggestive of retained common duct stones were referred for postoperative ERCP.

METHODS

From the first case of LC in May 1990 to February 1992, all patients who presented to four McGill University teaching hospitals for elective or urgent LC were included in a prospective, computerized data registry. Surgeons recorded information pertaining to patient clinical history, baseline characteristics, indications and results of perioperative ERCP, details of operative technique, intraoperative findings, as well as hospital course and postoperative follow-up. Patients with a clinical history or biochemical or ultrasonographic findings suggestive of choledocholithiasis were referred for consideration of an ERCP. Serum biochemical values closest to the time of ERCP were abstracted, and all ultrasound and radiographic findings were reviewed; the results were standardized across all hospitals. All ERCPs were performed by seven surgical, medical, and radiological endoscopists who collectively perform approximately 1000 cases yearly. A portable C-arm x-ray unit with static imaging was most often used when IOC was performed.

Patient Population

Over the period of this study, 1300 patients were included in the McGill Laparoscopic Cholecystectomy Registry; 71% of these patients were women, and the mean patient age was 49 years (age range, 7 to 98 years). In 13% of cases, the presentation was acute cholecystitis.

Preoperative ERCP

Of the 1300 patients described, 106 were thought to be at preoperative risk for a CBD stone and, as a result, underwent preoperative ERCP. Indications for ERCP included a history of jaundice (33%) or pancreatitis (22%), the presence of one or more abnormal liver function tests (87%), and the presence of a dilated CBD (30%) or the demonstration of choledocholithiasis on preoperative ultrasonography (23%).

Operative Technique

At the time of LC, trocars were positioned according to patient body habitus. Open insertion of the periumbilical trocar was used in 45% of cases, and a 30-degree laparoscope was used more frequently in later cases. Most of the contributing surgeons were involved in teaching laparoscopic surgery. Technical emphasis was always placed on blunt thorough identification of all structures in the triangle of Calot before severing the cystic duct at its junction with the infundibulum. In particular, there was careful early mobilization of the posterior and anterior peritoneal folds, as well as caudad retraction of Hartmann's pouch in order to stretch out the triangle.

Statistical Methods

All continuous variables are expressed as mean ± standard deviation, or median and range (when the sample distribution is not normal). Categorical variables were expressed as percentages. A nonpaired t test was used to compare the duration of cholecystectomy in patients with and without IOC.

RESULTS

Among the 1300 patients, 6.2% required conversion to open cholecystectomy. There was a single postoperative death (0.08%). A postoperative bile leak was noted in 0.9%, and 1.3% had a cardiac or pulmonary complication. The overall incidence of postoperative complications was 4.8%. The median time to full activities after operation was 7 days.

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Preoperative ERCP

A total of 127 preoperative ERCPs were performed in 106 patients (8.2%). Cannulation failed in five, and these patients subsequently underwent IOC at the time of surgery. Fifty patients were found to have CBD stones (3.8%) at preoperative ERCP. The overall positive predictive value of the approach to detect choledocholithiasis in patients referred for ERCP was 47%. Successful sphincterotomy and clearance of the CBD was achieved in 45 of the 50 patients with choledocholithiasis (90%). When two successive ERCPs failed to clear the CBD of stones, the patient was considered to have "failed" ERCP and was referred for open common bile duct exploration (CBDE). All five patients whose CBDs could not be cleared by ERCP subsequently underwent successful open cholecystectomy and CBDE. All other patients subsequently underwent cholecystectomy, and the median time interval between ERCP and surgery was 9 days (range, 1 to 255 days).

IOC

IOC was attempted laparoscopically in 54 patients (4.2%). The most common indication was to develop familiarity with the technique; other indications included failed ERCP, a dilated cystic duct with multiple small stones, or unclear anatomy. IOC was successful in 40 cases, for a success rate of 74%, and most of the failures occurred early in the laparoscopic experience. Of these, 33 IOCs had normal findings, and abnormal findings were noted in the other 7 (17.5%). In one case, the IOC was performed to confirm the suspicion of a CBD injury, and did so. CBD stones were demonstrated in the other six cases. Five of these patients underwent postoperative ERCP and one had a CBDE. On average, performing an IOC added 24 minutes of operating room time to the LC (96.5 ± 34 *vs.* 72.7 ± 33.5 minutes, $p < 0.0001$).

Postoperative ERCP

Postoperatively, 49 ERCPs were performed in 33 patients (2.5% of total) because of the IOC findings or the suggestion of a retained stone (76%). The indication in the remaining patients was the suspicion of a postoperative complication (24%).

Retained CBD stones were confirmed in 17 patients (1.3% of total) and all underwent successful sphincterotomy and CBD clearance.

In the five patients where choledocholithiasis had been suspected by IOC, CBD stones were confirmed and cleared at postoperative ERCP. In five other patients who had upper abdominal pain after surgery (median, 91 days; range, 2 to 135 days), a CBD stone was confirmed. Two patients presented after surgery with a bile leak, and retained stones were demonstrated at ERCP. Two other patients in retrospect had presented with elevated liver function tests preoperatively, but had not undergone ERCP. In one patient, preoperative ERCP had been unsuccessful, but no intraoperative cholangiogram had been performed. In another, the preoperative ERCP had failed to demonstrate a CBD stone that was later found, possibly suggesting migration of the stone after the initial ERCP. That patient had originally presented with pancreatitis and the time interval between the ERCP and the cholecystectomy had been 7 days. In the final patient, a stone was demonstrated on T-tube cholangiography after open CBDE and subsequent ERCP allowed for definitive clearance of the duct. Six additional patients presented from 12 to 386 days after surgery with symptoms suggestive of retained CBD stones (presumed pancreatitis in four and jaundice in two). At ERCP, no stone was found.

The duration of follow-up for the patients in this study ranged from 13 to 34 months (median, 22 months). The total incidence of choledocholithiasis was 5.2% (Table 1).

ERCP Morbidity

Of the 176 ERCPs performed in 138 patients, there were 14 episodes of pancreatitis and 2 episodes of biliary sepsis for a complication rate of 9%. Post-ERCP complications led to 17 hospitalizations. The median duration of hospitalization was 4 days (range, 1–59 days). All but two patients stayed in the hospital for fewer than 6 days. Both remaining patients required parenteral nutrition and one had a pancreatic pseudocyst and remained in the hospital for 59 days. There were no deaths after ERCP.

CBD Injuries

Five CBD injuries occurred over the period of observation for an incidence of 0.38%. One of these was recognized at the time of operation and was repaired by pri-

Table 1. MANAGEMENT OF CBD STONES

	Prevalence of CBD Stones (1300 Patients)		
Detection	**No.**	**%**	**Treatment**
Preoperative	45	3.5	ERCP sphincterotomy
Operative	6	0.5	Open CBDE
Postoperative	17	1.3	ERCP sphincterotomy
Total	68	5.2	

mary ductal anastomosis. Another one of these patients presented a few days after operation with bile peritonitis. The injury was repaired by inserting a T-tube where a burn injury had caused a flute-hole in the side of the distal common hepatic duct. The other three patients presented at follow-up with biliary strictures. One of these patients had a normal IOC at the time of LC. Two of these patients have been managed endoscopically with a biliary prosthesis, and one underwent a Roux-en-Y biliary-enteric anastomosis. In only one case could routine IOC have possibly resulted in earlier recognition and different management of the injury.

CBDEs

Eight patients underwent open CBDE. In six cases, this was because of failure of preoperative ERCP (one failure of cannulation and five failures of stone extraction). In one of these, after a failed preoperative ERCP, a choledochoduodenostomy was performed to treat multiple CBD stones. In two other cases, the CBD had been successfully cleared at the time of preoperative ERCP, but conversion to open cholecystectomy was required because of a difficult dissection. In both cases, intraoperative cholangiograms were performed despite the normal preoperative ERCP. In each of these, false-positive IOC findings resulted in an unnecessary CBDE. The median duration of the hospital stay after open CBDE was 13 days (range, 10 to 25 days).

DISCUSSION

LC has brought many benefits to patients and these benefits have been convincingly demonstrated in controlled trials in the literature.[10,11] Along with these benefits, it has served to rejuvenate the debate regarding the practice of selective *versus* routine cholangiography. It has also challenged the traditional teaching on when and how to deal with CBD stones, as well as their reported overall prevalence.[2,5,9] This has led to a re-evaluation of the role of ERCP in cholecystectomy. Previously, in three randomized trials, ERCP followed by open cholecystectomy had not been shown to offer any advantages over traditional open CBDE.[12-14] This was mainly because the morbidities of ERCP and open cholecystectomy had been found to be cumulative, and not less than that of open cholecystectomy with CBDE. Given the very good results now obtained with LC, as again confirmed in this study, these findings need to be re-examined.

An approach to the CBD in patients undergoing LC, which has minimized the use of operative cholangiography and relied on preoperative ERCP both as a diagnostic and therapeutic modality in patients thought to be at risk for choledocholithiasis, is summarized in Figure 1. We will examine its advantages and disadvantages.

The practice of routine *versus* selective cholangiography has polarized general surgeons for many years. The perceived increased incidence (or reporting) of CBD injuries at LC and their severity have refocused the debate.[15,16] Proponents of routine IOC state a number of theoretical advantages. This policy allows a surgeon to become comfortable with the procedure, detect CBD stones, and demonstrate the biliary anatomy, thus helping to prevent biliary duct injury. If an injury occurs, it will be recognized and repaired more promptly, thus improving the chances of successful repair.

Like others, we think there is greater evidence to support the use of selective cholangiography.[17-20] The current study shows that in a large number of patients, even a very low rate of cholangiography is not associated with a greater risk of CBD injury. Indeed, the reported rate of IOC (4.2%) is among the lowest in the literature (Table 2), yet the reported rate of CBD injury (0.38%) is similar to that of most other series of laparoscopic and open cholecystectomy.[15,16,21,22] Although a longer follow-up time may be required until all bile duct injuries are clinically apparent, a large majority will already have been detected because our median patient follow-up time was 22 months.[23]

Careful dissection of the triangle of Calot is the best way to prevent bile duct injury.[18] This includes the early mobilization of anterior and posterior gallbladder peritoneal attachments, conclusive visualization of the junction between the infundibulum of the gallbladder and the cystic duct, and caudad retraction of Hartmann's pouch. If one adheres to strict technical principles, it is not necessary to perform IOC for the purpose of demonstrating aberrant anatomy.

In a recent randomized trial of routine *versus* no IOC in patients without obvious preoperative indication, Soper and Dunnegan found an abnormal communication between the gallbladder and the intrahepatic biliary

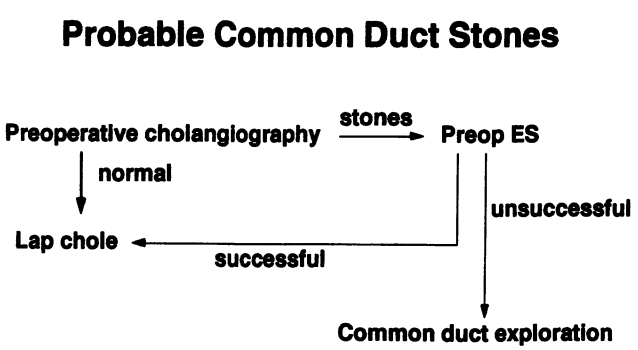

Figure 1. Algorithm for detection and management of CBD stones. ES: endoscopic sphincterotomy.

Table 2. CBD STONES AND INJURIES

Series	No. of Patients/ Follow-up (mo)	IOC (%)	CBD Injury (%)	Retained Stones (%)	Total Stones (%)
Flowers et al.[3]	384/3–15	45	0.3	1.4	4.7
Clair et al.[17]	514/NA	7	0.2	0.8	2.1
Lillemoe et al.[19]	400/NA	2	0	0.75	4.25
Soper and Dunnegan[28]	415/1–22	34	0.2	0.2	4.1
Sackier et al.[4]	516/NA	90	NA	NA	7 (+)
Current series	1300/13–34	4.2	0.38	1.3	5.6

NA: not applicable.

tree in only 3.8% of 115 cases.[18] They stated that prior knowledge of these abnormal communications did not alter the surgical approach. In one case in our series, a bile leak from the liver bed resulted in the need for reoperation. A good quality operative cholangiogram done at the time of the original LC did not show, even in retrospect, the abnormal communication. If the risk of damage to such structures were significant in the absence of routine IOC, one would have expected a greater incidence of bile leaks in our series. The rate of bile leak in this series is 0.9%, which is similar to that of other reported series.[21,24]

It might be reasonable to presume that a CBD injury would be detected earlier if IOC were performed routinely. In this series, however, 1300 cholangiograms would have been performed in order to have possibly changed the management of a single such case. It also must be appreciated that routine IOC results in a finite risk of inducing injuries by catheter perforation or cystic duct avulsion.[4,18,19] If complete dissection is performed before IOC, bile duct injury may have already occurred. If IOC is performed early in the procedure, before complete definition of the anatomy, the incision to place the catheter may inadvertently be made into the bile duct.

There is little question that the success rate of IOC increases with experience.[3,6] Our moderate success rate of cannulation (74%) probably reflects our early inexperience. In both this series and others, the individual ability to perform a cholangiogram improved with experience.

The other rationale proposed for routine IOC is the identification of choledocholithiasis. If stones are identified only at the time of surgery, the options for management include conversion to open CBDE, laparoscopic duct clearance, or postoperative ERCP. Open CBDE, albeit in a select group, was associated with a prolonged hospital stay in this study. Laparoscopic techniques for duct clearance are not yet widely available and are still being developed in selected centers.[4,25] Relying on postoperative ERCP to clear the CBD implies a risk of failure and the possible need for a second operation to clear the duct.

The perceived benefits of routine IOC not only seem overrated, but the technique itself may occasionally have drawbacks. These include the frequency and consequences of false-positive findings, the increased operating time, and the increased cost. The false-positive rate of IOC in our study was 2.5%, and this is representative of the literature.[4,26] It is also important to assess the outcomes of all patients who are found to have positive cholangiograms. Flowers et al. have recommended routine IOC at LC.[3] In their series of 364 cases, there were 16 abnormal cholangiograms (11% of cholangiograms). Four of these had "aberrant" anatomy (2.7%) and six had equivocal findings leading to observation in three and negative postoperative ERCPs in three (false-positive). Of the other six, who were thought to have choledocholithiasis, one patient refused postoperative assessment. Even if one assumes that IOC was of crucial importance in the first 4 cases, these numbers show that despite a positive IOC, there was no change in the management of at least 44% (7 of 16) of patients with abnormal cholangiograms.

We found that IOC was associated, on average, with a 24-minute increase in operating room time, and others have identified a $700.00 (U.S. dollars) increase in cost.[18] Although these financial considerations should not dictate the policy to be followed, surgeons have a responsibility to ensure that the utilization of IOC be clearly justifiable. As a consequence, we conclude that there is not sufficient evidence to support a policy of routine IOC at elective LC. Nevertheless, clear indications remain to perform IOC, and these include failure of preoperative ERCP, familiarization with the technique, and unclear anatomy.

The incidence of choledocholithiasis at the time of cholecystectomy has long been thought to be near 10%.[27] In our series, it was 5.2% with a median follow-up time of 22 months. The discrepancy with historical series may be due to the limited follow-up time or to other factors related to the selection of laparoscopic patients. The paucity of open cholecystectomies now being performed, however, makes a patient selection bias less likely. Inter-

estingly, these findings are in keeping with most laparoscopic series published to date.[4,17,19,21,28]

The approach described is based on the identification of choledocholithiasis and clearance of the CBD preoperatively. Because of the well documented 1% to 3% risk of pancreatitis and cholangitis of diagnostic ERCP,[8,29] it is not appropriate to routinely investigate all patients presenting for LC.[30] Therefore, a categorization of patients must first be performed regarding their risk of harboring a CBD stone. Unfortunately, preoperative clinical, biochemical, and sonographic information has traditionally yielded poor accuracy. This was borne out in our patients where "traditional" individual predictors led to a positive predictive value of only 47%. Using multiple regression techniques, we are now changing our criteria for use of preoperative ERCP to optimize diagnostic accuracy,[31] as has been done successfully by others.[26,32]

The use of preoperative ERCP in the current report (8.2%) is similar to that of others.[3,17,19] Although the overall rate of complication with our ERCP approach (9%) may seem high, this is similar to endoscopic sphincterotomy results reported in the literature.[8,29] Furthermore, the morbidity of these complications is limited, as evidenced by the associated 4-day median duration of the hospital stay. These results are favorable when compared to morbidity and hospital stay in patients having open CBDE who are described in recent series.[12–14,33] The success rate of CBD clearance before surgery with this approach is 90%, which is also in keeping with reported series.[29] This implies that of 1300 patients, only 6 will require open CBDE.

With this approach, retained stones were diagnosed in 17 patients (1.3%). Two of these patients should have been evaluated by ERCP preoperatively according to the algorithm in Figure 1. Six other patients had stones found on IOC, three of whom would also have been candidates for preoperative ERCP because of elevated liver function tests. If these five patients had been evaluated preoperatively and their ducts successfully cleared (as they were), the rate of retained CBD stones would have been 0.9% (12 of 1300). This compares favorably with other reports associated with greater rates of cholangiography and shorter follow-up times (Table 2). Although the number of retained stones in our series was small, we were not able to detect greater morbidity in these patients than in those who had successful preoperative duct clearance. A longer follow-up time is required to ensure an accurate assessment of the true incidence of symptomatic retained stones.

We have described an approach to the CBD in patients undergoing LC that emphasizes preoperative detection and treatment of CBD stones, while minimizing the use of IOC. Careful attention to operative technique is associated with a rate of CBD injury comparable to other laparoscopic and open cholecystectomy series. We have found that the overall morbidity and retained stone rates with this approach support its validity. It would seem that the successful treatment of biliary lithiasis reflects the qualities embodied by the modern laparo-endoscopic general surgeon.

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Discussion

DR. FRANK G. MOODY (Houston, Texas): I thought that when laparoscopic cholecystectomy emerged, the way we take out a gallbladder and the chronic discussion about whether one does perioperative cholangiography or not would be put to bed. I've always been an advocate of routine perioperative cholangiography, even when I could see the junction of the bile duct and the cystic duct. With this technology you don't usually get a good view of this particular junction. But it didn't take us long to find out in our own unit that there are problems with perioperative cholangiography, not the least of which is misidentifying the cystic duct.

I agree with the approach of doing the endoscopic clearance of the bile duct perioperatively. It makes sense. You get a good cholangiogram, you see your anatomy. That makes a lot of sense. In terms of the cholangiogram, I believe that once you use it routinely, you can really do it when you need to, because it is not a simple matter. As you have seen here, they only had a 74% success rate in gaining a cholangiogram.

Therefore, I ask the authors to address the issue of the indications, if they're going to use it selectively. It didn't come out clearly when I read the paper. Also, shouldn't it be used in the teaching institutions where those who are going to go out into practice really should know how to do this very, very important procedure?

DR. RICHARD A. PRINZ (Maywood, Illinois): Cholangiography is standard with all of our laparoscopic biliary procedures. I would agree that a selective approach, as the authors have demonstrated, is compatible with a low incidence of common bile duct injury. We do routine cholangiography because we are at a teaching institution and we have an obligation to instruct our residents to do this. I do not think a 74% success rate with intraoperative cholangiography is what we should expect from our trainees. With greater experience, a surgeon should be able to do this well over 90% to 95% of the time, and that is what our experience is.

The authors' use of selective ERCP preoperatively is based on the supposition that this will decrease the rate of open common bile duct exploration. There is obviously another alternative at this time to deal with common bile duct stones (e.g., laparoscopic exploration of the common bile duct). Unless you are skilled with cholangiography, you will never be able to perform laparoscopic exploration of the common bile duct.

With the authors' approach, 17 patients had retained stones. In other words, 25% of the common bile duct stones that were present in their patients were not identified by selective preoperative ERCP. I wonder what ways they are exploring to improve this. Second, they had successful clearance of stones from the common bile duct preoperatively in 45 of 50 patients. The five patients in whom the stones were not cleared went on to open cholecystectomy. I question whether overall morbidity would have been less if they would have tried laparoscopic cholecystectomy and laparoscopic common bile duct exploration in these five patients.

DR. JACK PICKLEMAN (Maywood, Illinois): Like Dr. Prinz, I am also from Loyola. However, I don't want the membership to think this is some Jesuit plot.

With the advent of laparoscopic cholecystectomy, there are obviously multiple options now for dealing with suspected common duct stones and it's obvious that there will be no one algorithm that is clearly superior.

It is really too bad that the Association limits discussants to one slide. What I would like to do is to run through each of the authors' slides and use their own data to justify an opposite view, namely, that cholangiography should be performed, albeit on a very selective basis. Being denied access to their carousel, let me summarize their data.

The authors performed 53% of their ERCPs on patients with no common duct pathology and had a 9% ERCP complication rate, similar to our own published rate of 10%, and a 0.38% common duct injury rate.