# The Routine Use of Cholangiography for Laparoscopic Cholecystectomy in the Modern Era

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#### **ABSTRACT**

**Background and Objectives:** The use of routine versus selective intra-operative cholangiogram (IOC) for laparoscopic cholecystectomy (LC) remains an area of debate. In this study, we investigated the routine use of IOC in a single center, to determine whether it confers a reduced risk of common bile duct (CBD) injury and improved patient outcomes. We also identified several preoperative predictive factors for CBD stone detection on IOC to investigate the feasibility of a predictive model.

**Methods:** We identified 1005 LCs with routine IOC over a 2-year period at the Norfolk and Norwich University Hospital from October 1, 2013, to September 30, 2015. Outcomes measured included CBD stone detection on IOC, CBD injury, complication rates, readmission rate, and mortality. We also calculated sensitivity, specificity, and likelihood ratios for detection of CBD stones on IOC from preoperative biochemistry and radiological investigations.

**Results:** We identified a CBD stone detection rate of 10.1% and a readmission rate of 0.03%, with no reported CBD injuries and 1 reported mortality. Of the preoperative predictive factors investigated, the most specific for CBD stone detection on IOC was bilirubin at 89%. The most sensitive was preoperative MRCP at 77%.

**Discussion:** This study demonstrates that routine IOC is an effective method of detecting CBD stones and CBD injuries, resulting in improved patient outcomes and economic benefits for health services. We have also identified several predictive factors for CBD stones on IOC.

**Key Words:** Cholecystectomy, Common Bile Duct, Gallstone Laparoscopic.

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Disclosures none reported.

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#### INTRODUCTION

The use of intraoperative cholangiogram (IOC) during laparoscopic cholecystectomy (LC) is well established. 1-4 Its main uses include the detection of bile duct stones, defining biliary tree anatomy and the early recognition of iatrogenic common bile duct (CBD) injuries. 5-8

Although regarded as a safe procedure with a low risk of complications, the merits of routine IOC usage remain an area of debate. Some studies suggest that it adds significant operating time and cost, without reducing the risk of detection of retained CBD stones or bile duct injury.<sup>9–11</sup>

It is currently unclear whether IOC should be used routinely or selectively for the detection of CBD stones and whether preoperative predictors can be used to drive selectivity. This study was conducted primarily to investigate routine IOC usage for LC within a single center to determine whether it reduces the risk of CBD injury and improves the overall management of gallstone disease. We also explored CBD detection rates and identified several biochemical and radiological predictive factors of intraoperative CBD stones, to investigate the feasibility of a predictive model.

## MATERIALS AND METHODS

From a retrospective database, elective and emergency LCs were identified over a 2-year period from the October 1, 2013, to September 30, 2015, at the Norfolk and Norwich University Hospital, where IOC is performed routinely for LC. Cases where IOC was not performed were excluded from the study.

The main outcome measures investigated include CBD injury, CBD detection, elective versus emergency cholecystectomy, conversion rate to open cholecystectomy, complication rates (intraoperative and postoperative), mortality, readmission rates, and incidences requiring return to the operating room.

To investigate the role of preoperative predictive factors, cases were divided into those with an abnormal IOC (filling defect) and those with a normal IOC (no filling defect). These results were then grouped based on the following preoperative predictive factors for an intraoper-

ative CBD stone: elevated bilirubin (>25  $\mu$ mol/L), elevated alanine aminotransferase (ALT, >50 U/L), elevated alkaline phosphatase (ALP, >126 U/L), and abnormality detected by preoperative ultrasonography (US) (gallstone, CBD dilatation, CBD stone, sludge, and CBD abnormality) or by preoperative magnetic resonance cholangiopancreatography (MRCP) (CBD dilatation, CBD stone, CBD filling defect, and any other abnormality).

For each preoperative predictive factor, we calculated the sensitivity, specificity, positive predictive value, and negative predictive value for intraoperative CBD stones found on IOC. Positive and negative likelihood ratios (LRs) were then calculated for each preoperative predictive factor. The initial analysis of data was performed with Excel 2013 (Microsoft, Redmond, Washington, USA) and SPSS, version 24.0 (IBM, Armonk, New York, USA).

#### RESULTS

From the database, 1005 LCs with routine IOC were identified. The mean age of participants was 51 years (49 years for women and 59 years for men). There were 755 women and 250 men (3:1 female:male ratio).

The most common indication for LC was gallbladder disease (84.6%), followed by pancreatitis (13.8%) and ductal stones (1.6%). The majority were elective cases (83.0% vs 17% emergency) with a 0.4% conversion rate to open cholecystectomy (4 elective cases and 2 emergency cases).

There were 8 failed IOCs that were excluded, leaving 997 successful IOCs. From this patient group, 101 (10.1%) showed a filling defect on IOC, and 896 (89.9%) displayed a normal IOC. Thirty underwent postoperative ERCP across both groups, 26 of which were performed for retained stones detected on IOC. Most of these ERCPs found retained stones (16 cases) and the patients underwent sphincterotomy, with or without balloon trawl. One case required stenting with repeat ERCP. Other indications for postoperative ERCP included 2 bile leaks, 1 gallstone-induced pancreatitis, and 1 cholangitis.

Of the 101 LCs with a filling defect on IOC, most (70.3%) underwent successful CBD exploration, with or without flushing/milking via the transcystic route (**Table 1**). The remainder either underwent failed CBD exploration (23.8%), had conversion to open (3.9%), or had no outcome documented in the operation note (2.0%). The patients in failed CBD exploration cases went on to have a postoperative ERCP.

Table 1. Outcomes of LCs with Filling Defect on IOC			
Outcome	Number	%	
Transcystic CBD exploration and direct CBD exploration through choledochotomy	52	51.5	
Failed CBD exploration and further post operative imaging suggested	24	23.8	
Flushing/milking of CBD, with or without buscopan	19	18.8	
Conversion to open	4	3.9	
Not stated	2	2.0	
$\overline{N = 101.}$			

Biochemical and radiological preoperative predictors of CBD stone on IOC were retrospectively analyzed for both the filling defect IOC group (**Table 2**, **Figures 1–3**) and the normal IOC group (**Table 3**, **Figures 1–3**).

In the filling-defect IOC group, 32.7% had elevated preoperative bilirubin, 49.5% raised ALP, and 49.5% raised ALT. In terms of preoperative imaging, 94.1% had US, and 25.7% had an MRCP. The most common abnormalities on US were gallstones (89.5%), followed by CBD dilatation (44.2%) and CBD stones (12.6%). The most common abnormalities on MRCP were CBD stone (57.7%) followed by CBD dilatation (53.8%).

In the normal IOC group 10.4% had an elevated bilirubin, 21.2% an elevated ALT and 17.1% an elevated ALP (**Table 3**, **Figure 1**). In terms of preoperative imaging, 86.9% had a US and 10.5% an MRCP. The most frequent abnormalities on US were gallstones (89.9%), followed by CBD dilatation (15.1%) and CBD stones (2.2%) (**Table 3**, **Figure 2**). The most frequent abnormalities on MRCP were CBD dilatation (31.9%), followed by CBD stones (19.1%) and CBD filling defect (3.2%) (**Table 3**, **Figure 3**).

Of the 896 patients in the normal IOC group, 8 eventually had a postoperative ERCP (2 emergency and 6 elective). Indications included 5 cases of retained stones, 1 case of gallstone pancreatitis, and 2 bile leaks.

For each preoperative predictor of CBD stones on IOC we calculated sensitivity and specificity, as well as positive and negative predictive values. From the sensitivity and specificity figures, we were able to calculate positive and negative LRs for each individual predictor to guide the selective use of IOC (**Table 4**).

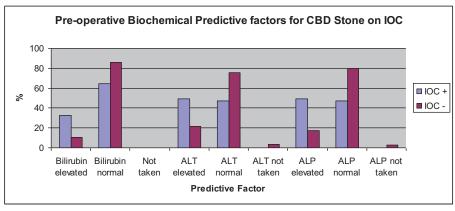
 Table 2.

 Preoperative Biochemical and Radiological Predictive Factors for CBD Stone in the Filling Defect on IOC Group

Investigation	Result	n (%)	Emergency LC, n (%)	Elective LC, n (%)
Bilirubin (n = 101)	Elevated	33 (32.7)	24 (23.8)	9 (8.9)
	Normal	65 (64.4)	13 (12.9)	52 (51.5)
	Not taken/available	3 (2.9)	0(0)	3 (2.9)
ALT (n = 101)	Elevated	50 (49.5)	30 (29.7)	20 (19.8)
	Normal	48 (47.5)	7 (6.9)	41 (40.6)
	Not taken/available	3 (3.0)	0(0)	3 (3.0)
ALP (n = 101)	Elevated	50 (49.5)	29 (28.7)	21 (20.8)
	Normal	48 (47.5)	8 (7.9)	40 (39.6)
	Not taken/available	3 (3.0)	0 (0)	3 (3.0)
Preoperative US $(n = 95)^*$	Gallstones	85 (89.5)	32	53
	CBD dilatation	42 (44.2)	21	21
	CBD stones	12 (12.6)	5	7
	Gallbladder Sludge	1 (1.1)	0	1
	CBD abnormality	43 (45.3)	21	22
	Normal CBD	52 (54.7)	-	-
	No report	1 (1.1)	0	1
Preoperative MRCP $(n = 26)^{\dagger}$	CBD dilatation	14 (53.8)	3	11
	CBD stones	15 (57.7)	4	11
	CBD filling defect	2 (7.7)	1	1
	Unable to perform	1 (3.8)	1	0

<sup>\*</sup>Of the total cases, 58 were elective (6 did not have an USS) and 37 were emergencies.

<sup>&</sup>lt;sup>†</sup>Of the total cases, 18 were elective and 8 were emergencies. Of the remaining 75 patients who did not undergo MRCP, 29 were emergency and 46 elective.



**Figure 1.** Comparison of preoperative biochemical predictive factors for CBD stone on IOC for CBD stone–induced filling defect in IOC (IOC+) and normal IOC (IOC-) groups.

The most sensitive preoperative predictor was preoperative MRCP (76.92%), followed by elevated ALT and ALP (both 51.02%), then preoperative US (45.26%) and finally elevated bilirubin (33.67%). The specificity of the preoperative pre-

dictors was much higher, with normal bilirubin being the most sensitive (89.27%) followed by normal preoperative US (84.60%), normal ALP (82.37%), normal ALP (78.11%) and finally normal preoperative MRCP (63.83%).

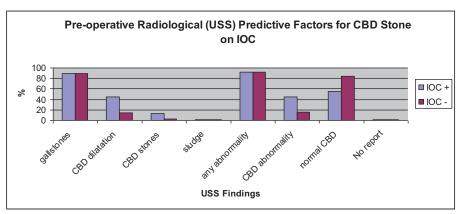
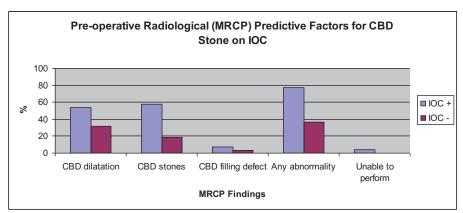


Figure 2. Preoperative radiological (US) predictive factors for CBD stone on IOC for CBD stone–induced filling defect on IOC (IOC+) and normal IOC (IOC-) groups.



**Figure 3.** Preoperative radiological (MRCP) predictive factors for CBD stone on IOC for CBD stone–induced filling defect on IOC (IOC+) and normal IOC (IOC-) groups.

The highest positive LR for CBD stones on IOC was elevated bilirubin at +3.14. The lowest positive LR was a positive preoperative MRCP at +2.13. None of the preoperative predictors examined scored a negative LR less than -1.00.

The incidence of postoperative complications were categorized according to the Accordion Classification System (**Table 5**). The most commonly occurring moderate complication was wound infection (0.8%). The most commonly occurring serious complication was bleeding (0.5%). There was 1 mortality identified as a consequence of surgery. This involved a patient with sepsis with recurrent cholecystitis who underwent choledochotomy because of the inability to retrieve all stones. The patient developed a postoperative bile leak and became septic with transfer to the critical care unit.

## **DISCUSSION**

In this study, we have demonstrated that the routine use of IOC for cholecystectomy plays a crucial role in the detection of intraoperative CBD stones and CBD injury. We report a CBD stone detection rate of 10.1% from 997 successful elective and emergency cholecystectomies (laparoscopic and open) over a 2-year period, which falls within the 2 to 12% detection rate reported in many studies. 7,12–14 Consequently, the majority (70.3%) of these cases were dealt with intraoperatively with CBD exploration, whereas the remainder were appropriately identified as requiring postoperative imaging.

These results further emphasize the utility of routine IOC in the intraoperative diagnosis of CBD stones and subsequent postoperative planning when it is not possible to remove gallstones.<sup>15</sup> The success of this method is reflected in the low readmission rate with CBD stones of just

**Table 3.**Preoperative Biochemical and Radiological Predictive Factors for CBD Stone in the Normal IOC Group

Investigation	Result	n (%)	Emergency LC, n (%)	Elective LC, n (%)
Bilirubin (n = 896)	Elevated	93 (10.4)	32 (3.6)	61 (6.8)
	Normal	774 (86.4)	100 (11.2)	674 (75.2)
	Not taken/available	29 (3.2)	0 (0)	29 (3.2)
ALT $(n = 896)$	Elevated	190 (21.2)	75 (8.4)	115 (12.8)
	Normal	678 (75.7)	57 (6.4)	621 (69.3)
	Not taken/available	28 (3.1)	0 (0)	28 (3.1)
ALP (n = 896)	Elevated	153 (17.1)	63 (7.0)	90 (10.1)
	Normal	715 (79.8)	69 (7.7)	646 (72.1)
	Not taken/available	28 (3.1)	0 (0)	28 (3.1)
Preoperative US finding $(n = 779)^*$	Gallstones	700 (89.9)	101	599
	CBD dilatation	118 (15.1)	35	83
	CBD stones	17 (2.2)	6	11
	Gallbladder Sludge	9 (1.2)	2	7
	CBD abnormality	120 (15.4)	35	85
	Normal CBD	659 (84.6)	_	_
	No report	6 (0.8)	0	6
Preoperative MRCP finding $(n = 94)\dagger$	CBD dilatation	30 (31.9)	12	18
	CBD stones	18 (19.1)	8	10
	CBD filling defect	3 (3.2)	0	3
	Unable to perform	0 (0)	0	0

<sup>\*</sup>Of the total cases, 666 were elective and 113 were emergency; 117 patients did not include a preoperative US (19 emergency and 98 elective).

<sup>†</sup>Of the total cases, 72 were elective and 22 were emergency; 802 patients did not have a preoperative MRCP (110 emergency and 692 elective).

Table 4. Preoperative Predictors of CBD Stones on IOC						
Preoperative Predictor of CBD Stones	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)	Positive Likelihood Ratio	Negative Likelihood Ratio
Bilirubin	33.67	89.27	26.19	92.25	+3.14	-0.62
ALT	51.02	78.11	20.83	93.39	+2.33	-0.63
ALP	51.02	82.37	24.63	93.71	+2.89	-0.59
Pre-op USS	45.26	84.60	26.38	92.69	+2.93	-0.65
Pre-op MRCP	76.92	63.83	37.04	90.91	+2.13	-0.36

0.03% and suggests that IOC plays a crucial role in reducing intraoperative and postoperative complications. The result has positive implications in terms of reducing financial burdens and bed-availability pressures on the NHS

overall. All data were collected from a single center that acts as the sole upper gastrointestinal surgery referral center within a 70-mile radius; therefore, it is unlikely that any readmissions for postoperative complications present

**Table 5.**Postoperative Complications per Accordion Classification

Complication	Cases		
Moderate complications			
Wound infection	8		
Sepsis	3		
Pancreatitis	2		
Pneumonia	1		
Post op abscess	1		
Severe complications			
Bleed	5 (3 returns to OR)		
Bile leak	3 (1 return to OR)		
Umbilical port hernia	1 (return to OR)		
Small bowel obstruction	1 (return to OR)		
Blocked drain needing reinsertion	1 (return to OR)		
Death			
Bile leak and sepsis	1		

to other hospitals within the local geographical area. Of all the patients studied, none was lost to follow-up at 30 days after surgery.

We have also demonstrated a 0% incidence of CBD injury over the 2-year period overall. This result compares favorably with a reported CBD injury incidence of 0.2 to 0.4% in other studies where routine IOC was employed.<sup>5,10</sup> There are studies that suggest that the routine IOC increases recognition of CBD injury at the time of the operation, which in turn influences the success of repair and long-term outcomes.5 There are also studies that suggest that routine employment of IOC does not lead to a reduced risk of CBD injury or better outcomes.<sup>9,16</sup> This retrospective cohort study is limited by the fact that there was no comparison arm where routine IOC was not employed; therefore, it is possible that other factors may be responsible for the low CBD injury rate observed. These factors could be investigated further with a randomized controlled trial.

During the study, we also collected data on the incidence of intraoperative complications, the most common being bile leak with an overall incidence of 3.3%. Most of these were minor and dealt with during surgery. In one reported case, a return to the operation room (OR) was necessary, and there was 1 death associated with a postoperative bile leak. That case involved a patient who had many irretrievable stones necessitating a choledochotomy and draining of the subhepatic space. The patient was treated in the

critical care unit and became septic after surgery, with an ongoing bile leak.

Despite its widespread and well-established use for many years,1,2 the routine versus selective use of IOC remains controversial. Advocates of routine use argue that IOC reduces the incidence of symptomatic CBD stones.7 However, the successful detection of CBD stones on routine IOC in an otherwise asymptomatic patient raises the possibility that some patients pass undetected CBD stones spontaneously without any symptoms. Some surgeons report that the incidence of CBD stones in patients undergoing LC is as low as 1 to 4% and that more than one-third of these patients will pass the stone spontaneously within 6 weeks after surgery. 12,17 In a literature review, Metcalfe et al18 estimated the true incidence of silent CBD stones to be as low as 4%, with only 0.6% going on to cause any problems. The number of routine IOCs needed to detect 1 CBD stone that will eventually be symptomatic in a patient with no predictive factors for ductal stones is 167. Consequently, Metcalfe et al did not advocate the routine use of IOC and advised selectivity based on the presence of acute pancreatitis, obstructive jaundice, or radiological evidence of filling defect from MRCP or ERCP.

To add to the debate on the merits of routine versus selective IOC use, we also investigated the possibility of a predictive model for detecting CBD stones on IOC by identifying several preoperative biochemical and radiological predictive factors. The predictive factor with the highest sensitivity was positive findings on a perioperative MRCP at 76.92%. The highest specificity was elevated bilirubin at 89.27%. None of the predictive factors examined scored highly for positive predictive value, but all displayed a negative predictive value greater than 90%.

These results are consistent with those in studies of factors predictive of the presence of CBD stones on IOC. <sup>14,19</sup> In a meta-analysis, Abboud et al <sup>19</sup> identified 10 common indicators of CBD stones, including dilated CBD on US [96% specificity, LR+ 6.9, LR- 0.77], raised bilirubin (88% specificity, LR+ 4.8, LR- 0.54), and raised ALP (86% specificity, LR+ 2.6, LR- 0.65). These results correlate closely with our findings of high specificity and low sensitivity. We therefore conclude that no single indicator can confidently predict the presence of a CBD stone on IOC. The absence of a positive result from any of the predictive factors investigated suggests a low likelihood of CBD stones and is therefore more useful as a "rule out" test when considering selective IOC.

The cases of most patients included in this study were elective, with symptomatic gallstones and a low risk of

CBD stone presence during surgery. However, a significant proportion of high-risk patients with previous pancreatitis, cholangitis, or cholecystitis were included. It is accepted that this group of high-risk patients may exaggerate the need for routine IOC. A suggestion for further study would be to investigate patients with normal liver function transferases who undergo IOC to investigate the utility of routine IOC use in patients with a low risk of CBD stone detection.

The proposal of a predictive model of detection of a CBD stone during IOC based on our study findings has several limitations, however. We did not include any clinical predictive factors, such as acute pancreatitis, cholangitis, or biliary colic/acute cholecystitis (including number of previous episodes). The time from the most recent liver function tests and imaging to IOC was not standardized for all patients. Most patients had these investigations performed at a clinic before having an elective LC, and hence the time scale ranged from weeks (as in the case of most emergency cases) to months. The length of the time frame may be significant, in that it allows more time for a CBD stone to be passed before IOC, thereby affecting sensitivity and specificity.

Finally, when evaluating the benefits of routine or selective IOC one must also consider cost efficacy. The health economic benefits of selective IOC are based on reduced operating time and cost of equipment and imaging, among others. In a cost–benefit analysis, Flum et al<sup>20</sup> showed a 50% reduction of bile duct injury with routine IOC, with a higher incidence in complex cases with multiple comorbidities. Routine IOC was estimated to cost \$13,900 per life-year saved (well within the <\$50,000 threshold at the time of the study). The cost per CBD injury avoided was estimated at \$87,100.

In Germany, where selective use of IOC is favored, Ludwig et al<sup>21</sup> estimated the number needed to prevent 1 CBD injury at 500–700, with a cost per CBD injury in the region of \$8,000–20,000. Both studies<sup>20,21</sup> concluded that routine IOC is a cost-effective method of reducing the risk of bile duct injury.

# **CONCLUSION**

Our study suggests that high-volume routine cholangiography is associated with a low risk of bile duct injury and can be performed safely in emergency and elective cases. We have demonstrated that the routine use of IOC is an effective method of detecting CBD stones and CBD injury, resulting in improved patient outcomes. We have also identified several predictive factors that can be used to estimate the likelihood of detecting CBD stones by using IOC during LC. The result of this study could be further strengthened by researching factors that influence the course of symptomatic versus asymptomatic CBD stone disease and the rate of spontaneous resolution.

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