Prospective evaluation of a selective approach to cholangiography for suspected common bile duct stones

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ABSTRACT

INTRODUCTION Common bile duct (CBD) stones can cause serious morbidity or mortality, and evidence for them should be sought in all patients with symptomatic gallstones undergoing cholecystectomy. Routine intra-operative cholangiography (IOC) involves a large commitment of time and resources, so a policy of selective cholangiography was adopted. This study prospectively evaluated the policy of selective cholangiography for patients suspected of having choledocholithiasis, and aimed to identify the factors most likely to predict the presence of CBD stones positively.

PATIENTS AND METHODS Data from 501 consecutive patients undergoing laparoscopic cholecystectomy (LC) for symptomatic gallstones, of whom 166 underwent IOC for suspected CBD stones, were prospectively collected. Suspicion of choledocholithiasis was based upon: (i) deranged liver function tests (past or present); (ii) history of jaundice (past or present) or acute pancreatitis; (iii) a dilated CBD or demonstration of CBD stones on imaging; or (iv) a combination of these factors. Patient demographics, intra-operative findings, complications and clinical outcomes were recorded.

RESULTS Sixty-four cholangiograms were positive (39%). All indications for cholangiogram yielded positive results. Current jaundice yielded the highest positive predictive value (PPV; 86%). A dilated CBD on pre-operative imaging gave a PPV of 45% for CBD calculi; a history of pancreatitis produced a 26% PPV for CBD calculi. Patients with the presence of several factors suggestive of CBD stones yielded higher numbers of positive cholangiograms. Of the 64 patients having a laparoscopic common bile duct exploration (LCBDE), four (6%) required endoscopic retrograde cholangiopancreatography (ERCP) for retained stones (94% successful surgical clearance of the common bile duct) and one (2%) for a bile leak. Of the 335 patients undergoing LC alone, three (0.9%) re-presented with a retained stone, requiring intervention. There were 12 (7%) requiring conversion to open operation.

CONCLUSIONS A selective policy for intra-operative cholangiography yields acceptably high positive results. Pre-operatively, asymptomatic bile duct stones rarely present following LC; thus, routine imaging of the biliary tree for occult calculi can safely be avoided. Therefore, a rationing approach to the use of intra-operative imaging based on the pre-operative indicators presented in this paper, successfully identifies those patients with bile duct stones requiring exploration. Laparoscopic bile duct exploration, performed by an experienced laparoscopic surgeon, is a safe and effective method of clearing the bile duct of calculi, with minimal complications, avoiding the necessity for an additional intervention and prolonged hospital stay.

KEYWORDS

Bile duct stones – Intra-operative imaging – Pre-operative indicators – Cholangiography

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Common bile duct (CBD) stones remain a considerable source of morbidity and mortality, and their presence should be considered in all patients presenting with symptomatic calculi. Intra-operative cholangiography (IOC) has been shown to be a sensitive and specific method of demonstrating bile duct stones;¹ however, it is time consuming, has resource implications and may result in unnecessary bile duct explorations due to false-positive examinations.

Other methods for pre-operative assessment of the CBD have previously been evaluated. Magnetic resonance cholangiopancreatography (MRCP) is a sensitive, non-invasive method of imaging the biliary tree.^{2,3} However, it lacks the immediate therapeutic options available during IOC or endoscopic retrograde cholangiopancreatography (ERCP) and consumes the valuable MRI resource. ERCP, however, is an invasive procedure with morbidity and mortality rates

of up to 15% and 1%, respectively.^{4,25,26} Moreover, studies have demonstrated that even in patients suspected of having bile duct calculi, ERCP is only positive in 20–50% of cases,^{5,6} resulting in considerable numbers of unnecessary investigations. Those patients who have undergone a therapeutic ERCP still require a second invasive procedure to remove the gallbladder.

Some authors argue that patients suspected of CBD stones should routinely undergo pre-operative imaging of the bile ducts using MRCP/CT cholangiogram or endoluminal ultrasound (EUS) scanning. It is well known that gallstones can randomly migrate into the ducts, or can pass spontaneously; therefore, although acceptably sensitive, the results of these imaging modalities are only valid for a limited time period. Therefore, in order to use MRCP/CT/EUS to image the bile duct for the presence of calculi, surgical intervention would need to be carried out immediately. In an ever-burdened, publicly funded, NHS system, few institutions would have the resources available to provide such a service. In addition, a considerable number of patients suspected to have CBD stones will, in fact, be found to be clear of calculi on imaging (negative scan); thus, the considerable time and cost implications of this approach must be considered.

However, with the ability to perform CBD exploration in the presence of a positive intra-operative cholangiogram, patients can be cleared of their bile duct stones and gallbladder during a single procedure. In addition, surgical management of bile duct stones eliminates the requirement for sphincterotomy with its attendant risks of complications. The debate surrounding sphincterotomy-related malignancy continues unabated.^{7,8}

A selective cholangiogram policy could ration the use of this resource, for those patients most at risk of CBD stones. The aim of our study was to evaluate a policy of selective cholangiography prospectively, based on pre-operative indicators for the presence of bile duct stones, and to assess the safety of this policy.

Patients and Methods

Between January 2004 and June 2008, all patients undergoing a laparoscopic cholecystectomy under the care of a single laparoscopic surgeon were recorded in a prospective database. A policy of selective cholangiography was adopted with intra-operative cholangiography performed in all patients with clinical, biochemical or radiological indicators of a possible CBD stone. Patient demographics (age, sex, weight), intra-operative details, cholangiogram result, complications and outcomes were recorded.

Patients selected for on-table cholangiogram (OTC; based on one or more of the criteria) were listed for surgery on the next available list (usually 2–4 weeks). Jaundiced

Table 1 Pre-operative indicators for CBD calculi

- Previously deranged LFT
- Presently deranged LFT
- Previously jaundiced
- Present jaundice
- Dilated CBD on imaging
- History of acute pancreatitis
- CBD stone visualised on imaging

patients underwent surgery within one week of presentation, if the jaundice failed to settle. Patients showing signs of sepsis secondary to cholangitis underwent pre-operative ERCP, and were not considered to need IOC at subsequent cholecystectomy provided the ERCP was successful.

Patients with a biochemical diagnosis of gallstone pancreatitis underwent a pre-operative ERCP if they fulfilled the criteria outlined in the British Society of Gastroenterology guidelines for the management of acute pancreatitis,²⁷ in which case they did not undergo OTC at subsequent laparoscopic cholecystectomy. Patients with gallstone pancreatitis who did not require ERCP underwent laparoscopic cholecystectomy with OTC in all cases.

Pre-operative indicators of CBD calculi were identified and recorded prospectively (Table 1).

All indicators, both individually and combined, were analysed using standard statistical techniques to assess the positive predictive value for the presence of CBD calculi.

False-positive and negative cholangiogram results were recorded.

Results

Between January 2004 and June 2008, 501 patients undergoing biliary surgery for gallstone disease under the care of a single laparoscopic surgeon were prospectively recorded. Of these, 335 patients underwent laparoscopic cholecystectomy (LC) alone and 166 patients underwent LC with IOC. Male-to-female ratio was 1:1.3, median age was 64 years (range, 15–92 years) and median body mass index (BMI) was 29 kg/m² (range, 18–44 kg/m²).

IOC was attempted, but unsuccessful, in three cases (2%). Two patients had an occluded cystic duct, and one patient had complicated anatomy precluding safe cholangiography.

Of the remaining 163 IOCs, 64 cholangiograms were positive (39%) and the patients proceeded to LCBDE. Patients with positive cholangiograms were older (median, 66 years; $P = 0.005$) but no differences between sex and BMI were found.

Table 2 Positive predictive value of indicators for positive cholangiogram

Indication	Positive cholangiogram group (total)	Positive predictive value
Previously deranged LFT	15 (58)	0.26
Presently deranged LFT	33 (74)	0.45
Previously jaundiced	12 (33)	0.36
Present jaundice	6 (7)	0.86
Dilated CBD on imaging	38 (85)	0.45
History of acute pancreatitis	9 (35)	0.26
Stone visualised on imaging	28 (38)	0.74
Jaundice (past and present) + dilated CBD	14 (25)	0.56
Jaundice (past and present) + deranged LFT	3 (12)	0.25
Deranged LFT (past or present) + dilated CBD	18 (38)	0.47

Of the 335 patients undergoing LC alone, three (0.9%) who had no pre-operative indicators of bile duct stones, were re-admitted and required postoperative ERCP for retained stones. Sphincterotomy was performed and all patients recovered without complication.

The sensitivity of our selective cholangiogram policy for the detection of CBD stones is, therefore, 96%.

Two (3%) LCBDEs were abandoned due to technical difficulties. Three (5%) LCBDEs failed to demonstrate any abnormalities of the biliary system (false-positive cholangiogram), giving a specificity for IOC of 95%.

All individual criteria investigated revealed some positive cholangiograms. In patients with a single pre-operative criterion, jaundice at the time of surgery and a stone visualised on pre-operative imaging yielded the highest number of positive cholangiograms (positive predictive values [PPVs] of 0.86 and 0.74, respectively). Patients with combined pre-operative indicators were more likely to have a positive cholangiogram, with a history of jaundice and a dilated CBD being the combination with the highest PPV (0.56). Two patients had a biochemical diagnosis of pancreatitis but lacked any other indicators of CBD stones. In both patients, IOCs were normal. A further two patients had pancreatitis and a stone visualised on imaging; however, these also had a negative cholangiogram at the time of surgery.

Thirty-eight patients had stones visualised on pre-operative imaging, but only 28 of those had a positive cholangiogram at operation (PPV 0.74).

In total, 12 (7%) procedures required conversion to open operation (8 from CBDE group vs 4 from no CBDE). Eleven conversions were for dense adhesions and difficulty in identifying anatomy, while one conversion was for uncontrolled bleeding from the gallbladder bed. One patient was returned to theatre for repeat laparoscopy and haemostasis.

Of the 64 patients who underwent LCBDE, four (6%) required a postoperative ERCP for retained stones and one

(2%) required ERCP for control of a persistent bile leak. There were three (5%) further bile leaks, which settled with drainage and conservative management.

In the series of 163 IOC cases, there was one (0.6%) mortality. The patient underwent a LC with a negative cholangiogram. However, the patient developed sepsis and died within 48 h. A post-mortem revealed a long-standing retroperitoneal abscess and a gallstone which had eroded through the CBD. Complications were recorded in 17 further patients (morbidity rate 10%). The complications included six bile leaks managed conservatively, superficial port site infections, subhepatic abscess, acute urinary retention and respiratory tract infections. Of the 335 patients undergoing LC alone, six (1.8%) patients developed postoperative bile leaks requiring ERCP and stent insertion for persistent bile leaks.

Delay from decision-to-operate to procedure in the positive cholangiogram group had a median 28 days (range, 1–140 days) compared with 47 days (range, 1–224 days) in the negative IOC group.

Discussion

This study evaluated a policy of selective cholangiography, using clinical, biochemical and radiological selection criteria, for the detection of CBD stones in patients undergoing laparoscopic cholecystectomy for symptomatic gallstones.

It is well known that CBD stones are present in 10–15% of patients presenting with symptomatic gallstones.²⁸ CBD stones are responsible for considerable morbidity and mortality from complications including pancreatitis, cholangitis and hepatic dysfunction. To prevent such complications, some authors recommend routine intra-operative cholangiogram to exclude unsuspected CBD stones, while undertaking laparoscopic cholecystectomy.^{1–3} Proponents of routine IOC also argue that the use of the procedure is associated

with a lower incidence and earlier recognition of bile duct injury, which is associated with an improved outcome.⁴

However, intra-operative cholangiography itself has a number of disadvantages. The technique is time consuming, adding an average of 20 min per case (range, 7–30 min)^{5,6} and results in operator, patient and theatre personnel exposure to radiation. In addition, IOC has a success rate of 86–94%,^{2,7} failures resulting from technical difficulties with cannulation of the cystic duct. IOC has been found to have a sensitivity and specificity ranging between 93–99%,⁴ with inevitable false-positive examinations.

False-positive cholangiograms commonly result from misinterpretation of filling defects and artefacts (air bubbles), which have the radiological appearance of gallstones, resulting in unnecessary choledochotomy. In addition, routine cholangiography will identify a number of patients with asymptomatic CBD stones, which may subsequently pass spontaneously or may never have become symptomatic and, therefore, a CBD exploration would be unnecessary.

Flum *et al.*²⁰ found that the average cost of an on-table cholangiogram in their institution amounted to US\$100 per case. They, however, argued that the additional cost of the investigation could be offset against the considerable costs associated with a common bile duct injury, which may have been avoided.²⁰ Flum *et al.*²⁰ concluded that a rationing of the use of OTC to less experienced surgeons and high-risk cases was the most cost-effective approach.

Many surgeons, therefore, favour a rationing approach to IOC, withholding the investigation only for those patients who are suspected of having CBD stones. Methods of predicting the presence of CBD stones, however, remains controversial. Peng *et al.*²¹ evaluated the role of liver function tests in predicting CBD stones and found a raised γ -glutamyl transpeptidase level to be the most sensitive test. However, Sheen *et al.*²² found that alkaline phosphatase levels were the best predictor. Many authors agree that IOC can be safely avoided in patients with no clinical, biochemical or radiological indications of CBD stones.^{6,9}

In our series, 98% of intra-operative cholangiograms attempted were completed successfully, comparing favourably with previously published data.⁵ We found no complications directly related to IOC.

Using our criteria, 40% of patients suspected of choledocholithiasis were indeed found to have bile duct stones at time of surgery. Our data concur with Tranter and Thompson's findings that up to 80% of patients with suspicion of CBD stones (including a history of pancreatitis and jaundice) had passed their stone spontaneously prior to surgical intervention.²⁹ Putting this together with the 10 patients who had had stones visualised on pre-operative imaging, but subsequently had normal cholangiograms, leads us to conclude that a significant number of stones passed spontaneously between presentation and surgery.

This has implications for the optimum timing of surgery: it may be preferable to delay the surgery to allow spontaneous passage of the CBD stone.

Of the 64 patients undergoing laparoscopic bile duct exploration, four (6%) required postoperative ERCP for retained stones (clearance rate 94%) and four (6%) patients developed a bile leak. Once again, our results compare favourably with previously published data⁹ leading us to conclude that laparoscopic CBD exploration, by an experienced laparoscopic surgeon, is a safe and highly effective method of clearing calculi from the bile duct.

Of the 335 patients undergoing laparoscopic cholecystectomy without OTC (*i.e.* not suspected of CBD stone), only three patients (0.9%) re-presented with symptomatic CBD 'retained' stone requiring endoscopic intervention. This gives our policy of selective cholangiography a sensitivity of 96%. In our series of selective cholangiograms, we found a false-positive rate of 5%, giving our policy a specificity of 95%. Assuming this false-positive rate would be replicated in unselected cholangiograms, a routine cholangiogram approach in all our patients would have resulted in 17 false-positive cholangiograms. These may have resulted in unnecessary CBD explorations, with their inevitable additional morbidity and operative time, to prevent three patients re-presenting with symptomatic retained bile duct stones, requiring ERCP. We believe this calculation supports our choice of a policy of selective cholangiography in preference to routine cholangiography.

All criteria, when present independently, yielded numbers of positive cholangiograms which we considered acceptable. Jaundice at the time of surgery, and a stone visualised on imaging, were the most sensitive criteria. The presence of multiple predictors further increased the positive yield for IOC.

Conclusions

Our policy of selective cholangiography is a highly effective and practical method of identifying patients with choledocholithiasis, who require bile duct exploration at the time of cholecystectomy. All of our inclusion criteria yielded at least some positive cholangiograms, with a high rate of successful surgical clearance of the bile duct with minimal morbidity. Our reported number of positive cholangiograms in patients with a history of pancreatitis is considerably higher than has been reported in previous studies and warrants further evaluation.

Although other authors advocate alternative policies for patients with suspected bile duct stones (routine cholangiography, pre-operative MRCP, CT, EUS, *etc.*), our policy of selective cholangiography we believe to be preferable due to fewer false-positive examinations, lower utilisation of costly and over-stretched imaging modalities and the considerable benefits of a single-staged procedure.

Combined with laparoscopic CBD exploration, selective intra-operative cholangiography offers a safe and effective method for managing CBD calculi, avoiding (in most cases) the need for endoscopic intervention.

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