

SAFETY AND OUTCOME OF SELECTIVE INTRA-OPERATIVE CHOLANGIOGRAPHY IN PATIENTS WITH SUSPECTED DUCT STONES

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Abstract

In an attempt to evaluate the selective intraoperative biliary imaging in patients with gall stone disease and suspected CBD stones., Patients with symptomatic gall stone disease presenting for laparoscopic cholecystectomy were prospectively studied for the safety and effectiveness of selective intraoperative cholangiogram (IOC) policy. 182 patients underwent laparoscopic cholecystectomy [140 females (77%) and 42 males (23%)]. Their age range was 19-72 years. 70/182 (34.5%) had suspicion of duct stones and required biliary imaging. Selection for IOC depended on radiological and biochemical evidence of suggestive duct stones. Patients who had IOC were studied for added operative time, results of IOC, operative and postoperative complications, and hospital stay. Mean follow up was for 18.4 months (range 7-38).

Of 182 patients, 21 required preoperative ERCP, 49 IOC and 112 neither. 41/49 (83.7%) had normal IOC, the rest 2/49 (4%) IOC failed, 6/49 (12%) had positive findings and required further imaging and/or treatment. Mean added operative time was 22 minutes (range: 15-35 minutes). 23/70 with suspicious duct stones had ERCP and 18/23 (87%) required sphincterotomy and stone retrieval. The mean hospital stay was 1.5 days (range: 1-4 days) and over the period of follow up there were no retained duct stones.

Conclusion: The selective policy of intra-operative cholangiography in suspected CBD stones saves many patients an additional preoperative or postoperative ERCP except in selected cases. IOC is safe, easy and adds little time to the procedure. It is reliable and accurate with high specificity and sensitivity in detection of common bile duct stones.

Keywords: Laparoscopic cholecystectomy, retained stones, missed stones, selective intraoperative, biliary imaging.

INTRODUCTION:

The use of intra-operative cholangiography has declined with the wide spread adoption of minimally invasive surgery for cholelithiasis. Prior to the advent of laparoscopic surgery, intraoperative cholangiography (IOC) was either routinely performed, or performed in patients suspected with choledochlithiasis, and if positive for common bile duct (CBD) calculi, open exploration of the CBD was undertaken¹.

The use of endoscopic retrograde cholangio-pancreatography (ERCP) reduces the need for operative management and exploration of the CBD. While less invasive than operative exploration of the CBD, ERCP is nevertheless associated with certain complications, such as pancreatitis, cholangitis and perforation².

In the last decade the clinical management of CBD stones has focused on pre-cholecystectomy detection with ERCP clearance in those with suspected stones³. This clinical algorithm successfully clears the stones in most patients, but no stones are found in 20% to 60% of patients⁴.

Currently, opinion is divided as to whether routine cholangiography should be performed in all patients undergoing laparoscopic cholecystectomy or a selective policy of cholangiography only in those considered to be at risk for choledocholithiasis should be adopted⁵.

The aim of this study was to evaluate the selective intraoperative biliary imaging in patients with gall stone disease and suspected CBD stones. Suspicion is based on clinical, biochemical, radiological and operative criteria.

PATIENTS AND METHODS:

The study was performed at MUST University hospital from January, 2003 till January, 2006 on 182 patients who underwent laparoscopic cholecystectomy for symptomatic gall stone disease, of which 49 patients were selected for IOC according to the selected criteria.

The study assesses the incidence of undiagnosed stones in this group using laparoscopic intra-operative cholangiography without performing diagnostic ERCP preoperatively.

Patients with high index of suspicion or hard evidence of CBD stones as clinical jaundice and/or radiologically proven CBD stones or patients with biochemical values beyond the selected range were excluded from the study and referred for preoperative ERCP. Other exclusion criteria include pregnancy and known allergy to iodinated contrast material.

Patients were selected to this study by having less than 3 of the following criteria (Table 1):

1. History of:

- Cholangitis, jaundice, or pancreatitis.

2. Laboratory investigations:

- Elevation of serum alkaline phosphatase or transaminases less than 2 folds of the normal range, Elevation of serum bilirubin less than 3 mg/dl.

3. Sonographic findings:

- Borderline dilatation of the CBD (6-9 mm).

4. Operative findings:

- Dilatation of the CBD (≥ 10 mm).

Table (1) show the selective criteria for IOC

Indication for IOC	No of patients (Total no 49)	%
History of Jaundice	2	4
History of Pancreatitis	5	10
History of cholangitis	2	4
Alk ph. ↑	17	34.5
↑ in Bilirubin	16	32.5
U/S dilated CBD 6 - 9mm.	12	24
Intra-operative dilated CBD > 10 mm	5	10
More than 1 selection criteria	10	20

Routine 4 port Reddick laparoscopic cholecystectomy was performed using open method for induction of pneumo-peritoneum. After dissection of Calot's triangle, identification of the cystic duct and artery, clipping and division of the artery is performed. A distal clip is applied to the duct near the gall bladder neck securing the infundibulo-cystic junction. A small incision in the cystic duct is performed near to the clip using laparoscopic micro-scissors and the duct milked using the blades of Maryland forceps to ensure clearance of cystic duct from stones.

The cystic duct is cannulated using a front tipped, saline flushed, size 5 ureteric catheter introduced through a cholangioclamp (*Storz Endoscopy-America, Culver-city,*

California, U.S.A., fig.1). The latter is introduced through the same mid clavicular 5.5 mm port and the blades hug the canulated cystic duct to prevent leakage.

Fig.1. cholangiograsper



Prior to injection, the patient is turned back to the neutral position and slightly tilted (15-20°) to the right side to get the vertebral column out of the x-ray field.

10 ml of urograffin diluted with 10 ml normal saline in a 20 ml syringe connected to the free end of the catheter and injected in five c. c. boluses under fluoroscopic guidance.

The patient is screened with a C-arm during the injection and cholangiography is considered complete and negative if there is:

- a. Filling of the non-dilated extra and intrahepatic biliary radicles up to the second order divisions.
- b. No filling defects in the biliary tree.
- c. Free flow of the dye to the duodenum.

Local anesthetic (2.5% Bupivacaine) is infiltrated to the wounds at the end of surgery. Postoperative pain relief is achieved by morphine sulphate 5-10 mg given once during recovery and diclofenac 100 mg suppositories 12 hourly for 24 hours then daily for five days.

Postoperative intravenous fluid administration was limited to 1 liter of crystalloids mainly glucose 5% given over the first 8 hours. Oral fluids were started in the evening of the operation and if tolerated, light breakfast was allowed the following day. Drains were usually removed on the first postoperative day before leaving the hospital.

Surgery was performed electively under supervision of 2 consultant surgeons, trained and experienced (> 50 IOC\ five years) in the above technique before undertaking this study.

Data collected prospectively included added operative time, results of IOC, operative and postoperative complications and hospital stay (from the day of operation to the day of discharge).

Added operative time is calculated by recording the time from clipping the infundibulo-cystic junction till resuming the operation by double clipping of the proximal side of cystic duct.

Before hospital discharge, patients had to tolerate solids, be comfortable on oral analgesia, mobile around the ward, afebrile (Temp < 37.8°C) and with soft abdomen

RESULTS:

During the study period, 182 patients underwent laparoscopic cholecystectomy under the care of 2 consultant surgeons [140 females (77%) and 42 males (23%)]. Their age range was 19-72 years (mean 45 years). Three patients had their laparoscopic cholecystectomy converted to open (1.6%), one due to unclear anatomy and bleeding and two due to adhesions.

21/182 (11.5%) patients required ERCP preoperatively for strong evidence of common duct stones either by radiological confirmation or laboratory and/or radiological suspicion of stones beyond the set inclusion criteria. 16/21 (76%) had common duct stones and 5 negative examinations. ERCP, sphincterotomy, stone retrieval and clearance of the duct was achieved in 14/16 (87.5%). Stent insertion was done in the other 2 patients due to multiple stones and failure to achieve duct clearance.

49 (27%) patients had laparoscopic cholecystectomy with IOC for suspected CBD stones [34 females (69%) and 15 males (31%)], the mean age was 33 years ranging from 22-72 years. Mean post operative follow up was 18.4 months (range: 7-38 months), 5 (10%) were missed to follow up.

41/49 (83.7%) patients had multiple gall stones and the other 8 (17%) had single stone. All patients with single gallbladder stone showed normal IOC.

41/49 (83.7%) had normal IOC with normal biliary tree, no filling defect and normal duodenal show.

In 8/49 (16%) the IOC did not ensure CBD clearance either due to failure of completion of the test or due to an abnormality in the result, 2/49 (4%) patients with attempted IOC failed due to inability to cannulate the cystic duct. These patients subsequently had normal postoperative liver functions and magnetic resonance cholangiopancreatography (MRCP) before discharge. 6/49 (12%) of the study group had positive cholangiograms. 3 of them showed dilated biliary system and delayed duodenal

show but there was no filling defects with postoperative liver function tests and MRCP, done the next day were normal. 3/49 (6%) showed a small filling defect less than 1 cm, one was successfully removed transcystically by Dormia basket (size 5.5F), while in the other 2 the procedure failed due to migration of the stone up to CHD in one and narrow cystic duct (0.5cm) in the second. Postoperative ERCP was done the next day and stone retrieval with sphincterotomy was achieved in both patients.

In total 23/182 (12.6%) patients required ERCP either pre or postoperative with positive result in 18/23 (78%).

The mean added operative time (from the time of applying the distal clip to the cystic duct to the conclusion of the cholangiogram) was 22 min (range: 15-35 min).

There was no operative mortality or any major common duct injuries or any missed stones during the follow up period. The over all morbidity was 8% (4/49). One had minor biliary leakage (Bile leakage in the absence of major ductal injury, from the liver bed or cystic duct remnant) that settled after 3 days and did not require ERCP. One patient developed subphrenic collection one week after surgery for acute cholecystitis. Percutaneous ultrasonographic guided drainage was successful. One patient developed port site infection and another presented 6 months after the operation with umbilical port site hernia. Mean hospital stay was 1.5 days (range: 1-4).

Discussion

Prior to 1975, treatment of suspected stones in common bile duct was open cholecystectomy and exploration of common bile duct. In mid 90's preoperative ERCP became standard for patients with suspected stones in CBD to avoid CBD exploration with its added morbidity and mortality^{6, 7}. However this policy had many problems as, preoperative prediction of CBD stones is imprecise; about 25-50% of preoperative ERCP studies were negative for CBD stones⁸. Also, the complication rate of ERCP is about 10% and about 50% of these complications were of major clinical importance like, cholangitis, pancreatitis, CBD perforation and hemorrhage⁹.

The Society of American Gastrointestinal Endoscopic Surgeons (SAGES), stated that, preoperative E.R.C.P. should not be used routinely in patients with suspected stones in C.B.D and should be reserved only for specific patients with suppurative cholangitis at poor risk and postoperatively for suspected bile leakage, ductal injury or missed stones¹⁰.

The management of choledocholithiasis has changed. Many centers practice selective intra-operative cholangiography only in those patients in whom common bile duct calculi are suspected^{11, 12, 13, 14, 15}. ERCP is often used pre-operatively in patients at

high risk of CBD stones, for example patients presenting with obstructive jaundice, cholangitis and gall stone pancreatitis.

In our study 70/182 (38%) had clinical suspicion of duct stones of which only 18/182 (9.9%) proved to have common duct stones. This marked discrepancy is the main issue addressed in our study. Only 21 the index of suspicion was high or in actual fact there was hard evidence of common bile duct stones dictating preoperative imaging and possible stone clearance. This latter group had a high yield at ERCP 16/21 (76%) especially compared to patients selected to IOC 2/49 (4%). This concurs well with other studies^{16,17}. Using our selection criteria 47/70 (67%) with suspicious common duct stones were saved an unnecessary ERCP with its added potential complication risk. There is no evidence based agreeable selection criteria for IOC and our criteria were based on other experiences¹⁷ but obviously it needs further evaluation and validation in a larger study.

The mean added operative time was 22 minutes (range: 15-35 minutes) which is not far and comparable to other group results¹¹. This added extra time is justifiable if compared with preoperative ERCP with its added risk, operative time and cost.

The results of IOC in our study were both sensitive and specific with no false negative or false positive. This was based on the absence of any clinical manifestations of missed or retained stones during mean 18.4 months (range: 7-38 months) follow up. Other groups had similar data with very low rates of retained stones (0-1.17%)^{14,18}. Other studies showed 2% false positive rate¹⁹.

There was no mortality in this study group and the complications rate was low (8%) . There was a single case (2%) of minor biliary leakage which was not known to be IOC related nor method-specific. The gall bladder was acutely inflamed with edematous friable cystic duct. Similar results (0.2-3%) were shown by other groups^{12,20}.

The mean hospital stay in our study was 1.5 days (range: 1-4 days) which is a universally accepted level compared to 2.25 days (range: 1.5-3 days) reported by others^{9,16}.

Finally, Centers committed to management of patients with gall stones should have access to all diagnostic and therapeutic modalities for CBD stones. CBD stones should be suspected, diagnosed and treated with the safest, economic, minimally invasive modalities. IOC is safe, easy and adds little time to the procedure. It is reliable and accurate with high specificity and sensitivity in detection of common bile duct stones.

The selective policy of per-operative cholangiography in suspected CBD stones saves many patients the potential risk of ERCP and even more patients, the added anaesthetic time, cost and low yield in picking unsuspected CBD stones if IOC is done routinely.

The selection criteria need to be tested and validated in larger multi-centric studies. The current role of MRCP is not clear yet probably diagnostic before embarking on ERCP if the index of suspicion is still low and results of other tests as ultrasound and per-operative cholangiography are still questionable.

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