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Original Research

Intraoperative cholangiogram during laparoscopic cholecystectomy: A clinical trial in rural setting

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Abstract

Objective: *The routine use of intraoperative cholangiogram (IOC) in laparoscopic cholecystectomy (LC) remains a contentious issue. IOC helps to delineate biliary tree anatomy, prevent bile duct injury and image stones in the common bile duct (CBD). It may prove to be a valuable alternative to ERCP or MRCP, especially in the rural setting with limited resources.*

Design/Setting/Participants/Interventions/Main outcome measures: *All patients undergoing laparoscopic cholecystectomy during a 12-month period were audited. For the first 6 months, patients were recruited for routine IOC and for the second 6 months, routine IOC was not performed. Cases were analysed with regard to patient demographics, operative details and clinical outcomes.*

Results: *A total of 75 patients were analysed within the 12-month period. The majority were women aged 41–50. Ultrasound suggested common bile duct stones in 6.7% of cases. IOC was attempted in 50.7% of cases. Of these, 29 (76.3%) were successful. IOC added an average of 28 min to total theatre time. A total of 75% (n = 22) of IOCs showed normal flow of contrast into the intra- and extra-hepatic biliary systems. In 17% (n = 5) of patients, stones within the CBD were suspected, and these were referred for further management. ERCP/MRCP confirmed CBD stones in 60% (n = 3) of these patients. There was poor correlation between pre-operative suspicion and confirmed CBD stones (two patients only with pre-operative suspected CBD stone confirmed on IOC and ERCP). There were no operative complications related to IOC. There were no post-operative complications in cases where no IOC was done.*

Conclusion: *The majority of patients treated in our centre were women, middle-aged patients booked for elective laparoscopic cholecystectomy. Although only 6.7% cases were suspicious for CBD stones pre-operatively, a total of 17% of patients with routine IOC suggested CBD stones. IOC was found to be safe, taking only an additional 28 min of total theatre time. Routine rather than selective use of IOC could be considered to improve patient safety and long-term results.*

KEY WORDS: *cholangiogram, cholecystectomy, rural medicine, rural surgery, service evaluation.*

Introduction

Laparoscopic cholecystectomy (LC) is the mainstay treatment for cholecystitis. Assessment of the biliary anatomy and visualisation of calculi within the biliary tree augments patient care, and can be done via ultrasonography (US), endoscopic retrograde cholangiopancreatography (ERCP), magnetic resonance cholangiopancreatography (MRCP) or cholangiography. Intraoperative cholangiography (IOC) is readily available in centres with an in-house radiology service via mobile x-ray image intensifier (XRII). IOC can therefore be a useful imaging modality in regional centres where ERCP or MRCP are not available.

Intraoperative cholangiogram is obtained by introducing a catheter into the cystic duct after Calot's triangle has been safely dissected and a critical view of safety has been achieved. A contrast medium is then injected into the biliary tree, and captured with an image intensifier to delineate biliary tree anatomy (Fig. 1). A distal filling defect can suggest an impacted CBD stone (Fig. 2). Extravasation of contrast or failure for the proximal biliary tree to image can suggest a bile duct injury.

The use of routine versus selective intraoperative cholangiography (IOC) remains controversial.[1–3] This study looks at outcomes of routine IOC in patients undergoing cholecystectomy in a rural setting. The

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***What is already known on this subject*:**
- *IOC is useful during LC to detect and remove CBD stones, confirm biliary tree anatomy and prevent BDI.*
- *Routine IOC is superior to selective IOC in finding minor BDI.*
- *Routine use of IOC maintains surgeon's experience and efficiency in performing this procedure.*

***What this study adds*:**
- *17% of routine IOC show stones within the CBD.*
- *ERCP confirmed CBD stones in 60% of cases with a positive IOC.*
- *IOC was found to be safe but time consuming.*
- *There were no significant complications of missed CBD stones in patients who did not undergo a routine IOC.*

Mount Gambier General Hospital services the majority of the Lower South East of South Australia, in both private and public sectors. Although ultrasonography and IOC are readily available, patients must travel to a tertiary hospital some 400 km away if ERCP is required.

A literature review was carried out on PubMed using the search terms 'routine' 'intraoperative cholangiogram', and 'cholecystectomy'. There were 41 relevant articles published in English in the last 10 years. Surprisingly, five randomised clinical trials (RCTs)[2–6] were found, of which none compared routine IOC with no intraoperative imaging in patients undergoing LC. Three RCTs[2–4] looked at selective versus routine use of IOC, and one investigated the role of IOC in

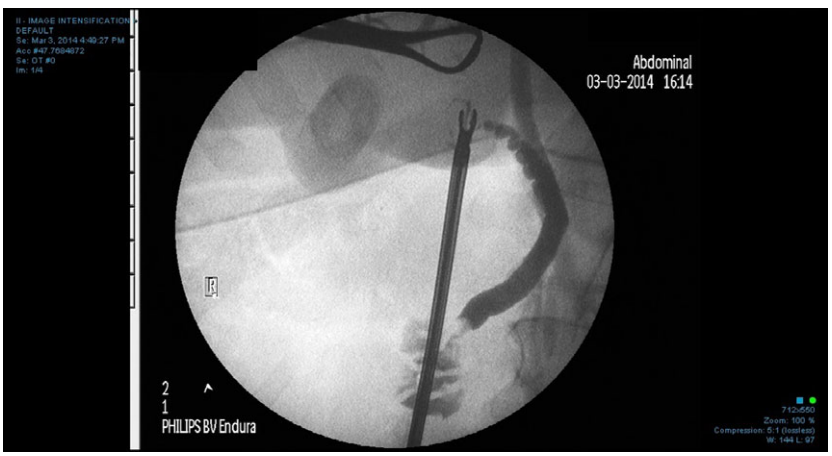

FIGURE 1: *Normal intraoperative cholangiogram showing contrast flow from cystic duct into CBD and duodenum.*

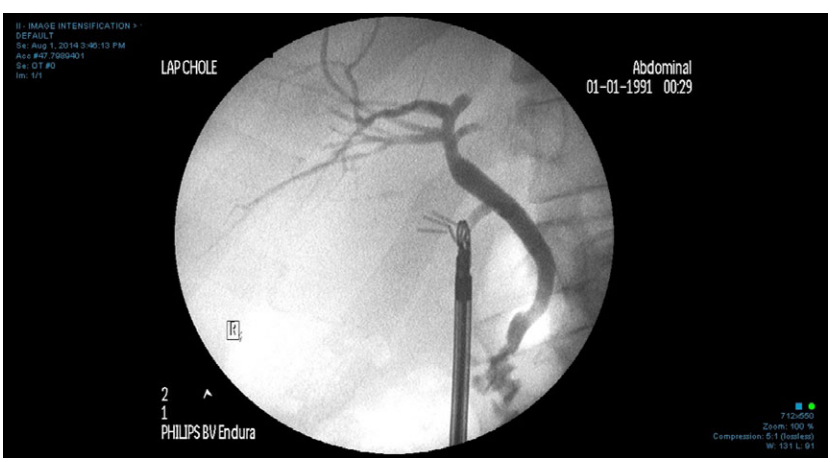

FIGURE 2: *Normal intraoperative cholangiogram showing contrast flow into intrahepatic ducts.*

patients only where stones were not suspected.[5] The fifth RCT looked at the Kumar and Olsen techniques of cystic duct cannulation.[6]

Materials and methods

Patients undergoing laparoscopic cholecystectomy between 1 November 2013 and 31 October 2014 (12 months) were analysed. For the first 6 months, patients booked for laparoscopic cholecystectomy had routine IOC. For the second 6 months, patients were offered IOC only selectively. That is, if CBD stones were suspected and ERCP was not possible. There were no such cases where selective IOC was warranted. Surgeries were carried out by one of three resident consultant surgeons. All three surgeons performed routine IOC during the study period.

The patients were audited with reference to their demographics, and whether choledocholithiasis was suspected pre-operatively. CBD stones were suspected based on clinical (jaundice or pancreatitis), radiological (common bile duct (CBD) dilatation) or biochemical (abnormal bilirubin, GGT or ALP) grounds. Intraoperative factors such as timing of operation and cholangiogram findings were also analysed, as were clinical outcomes of the patient including bile duct injury and the need for further treatment.

The impact of IOC on length of surgery was analysed by comparing the mean total theatre time of both study groups (time between patient entry and exit of operating theatre; mean ± SEM; *t*-test).

Our results were compared with findings from the existing literature. This research was granted exemption from the Ethical Review process by the Flinders University Institutional Review Board as it was viewed to be of negligible risk.

Results

Patient demographics

There were a total of 75 patients within the 12-month period. Of these, the majority (69.3%) were women and 30.6% were men. The age of the patients ranged from 22 to 83 years, with most in the 41- to 50-year-old age group (Fig. 3). The majority (86.6%) of cases were elective. The cases were shared between the three consulting surgeons, at 26.7%, 30.7% and 40%. The remaining 2.7% of cases were completed by visiting locum surgeons. A registrar was present in 54.6% of cases. Common bile duct stones were suspected on clinical grounds in 20% of cases, on biochemical testing in 16% of cases and on ultrasonography only in 6.7% of cases (Fig. 4). There were two cases with pre-operative suspicion of CBD stones on US and bloods, but in both cases there was improvement in liver function parameters, indicating passage of a CBD stone. Both cases were therefore treated with laparoscopic cholecystectomy rather than ERCP. Both cases underwent IOC which showed further CBD stones, and thus were arranged for ERCP post-operatively.

Timing of surgery

Most cases (97.3%) were done within working hours (8 am to 4 pm, Monday to Friday). The total time in theatre ranged between 45 min and over two hours, with the majority of cases between 60 and 120 min (Fig. 5). This is the time recorded from when the patient enters theatre until they leave for recovery. The average operative time for laparoscopic cholecystectomies without IOC was one hour 30 min, and with IOC was one hour 58 min, suggesting an additional time of 28 min for IOC (±7.46 min standard error,

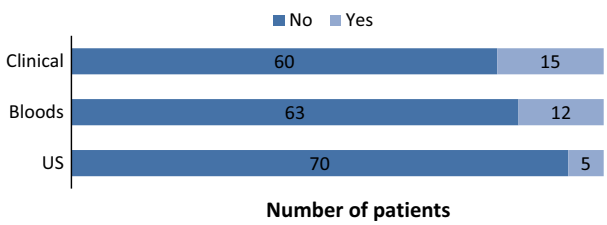

FIGURE 4: *Pre-operative suspicion of CBD stones.*

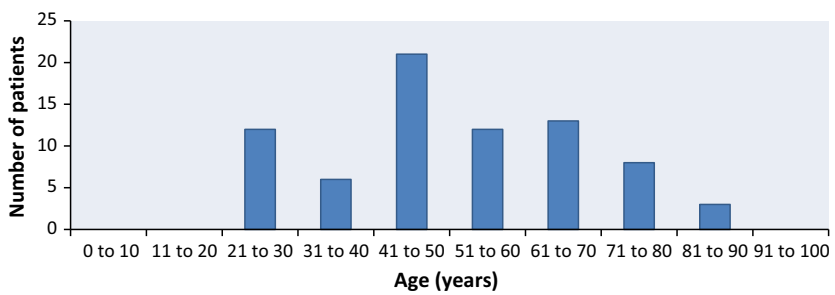

FIGURE 3: *Age range of patients.*

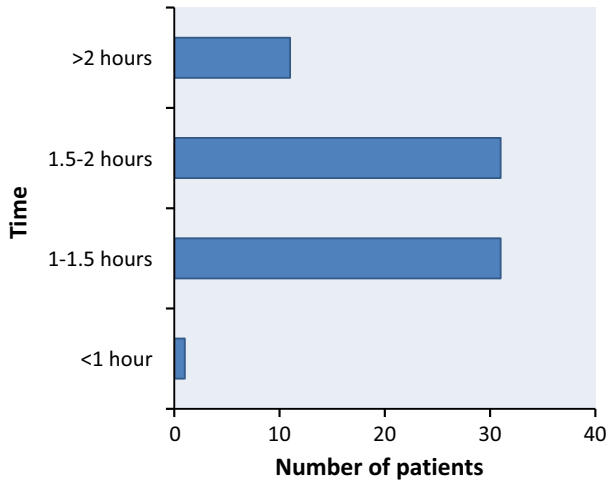

FIGURE 5: *Total time in theatre.*

$P = 0.0032$). This is the total theatre time, and includes anaesthetic time, patient positioning and other peri-operative set-up. All patients were admitted overnight.

Findings of IOC

Calot's triangle was clearly dissected in all cases. An IOC was attempted in 50.7% ($n = 38$) of cases. Of these, 29 (76.3%) were successful, and nine cases were abandoned. Failure of IOC was due to inability to advance the catheter ($n = 4$), leakage ($n = 3$) and equipment issues ($n = 2$). Of the cases where an IOC was completed, 83% showed clear flow of contrast into the intra and extra hepatic duct systems. The remaining 17% ($n = 5$) of cases found stones within the CBD, and these cases were referred for ERCP. These cases did not correlate with pre-operative suspicion of extra-biliary stones.

Patient outcomes

In three cases of acute cholecystitis, severe inflammation prevented IOC from being attempted. Two of these cases were converted to open cholecystectomy (of which one was complicated by haemorrhage) and in the third a laparoscopic, subtotal cholecystectomy was performed. There were no complications related to IOC. There were also no peri- or post-operative complications in cases where no IOC was performed. In our study, therefore, there were no clinically significant 'missed CBD stones' detected in patients who did not have an IOC. Patients were followed up for a median of 15 months. There were no patients who were readmitted with complications of their cholecystitis or of missed CBD stones.

Discussion

Delineating biliary tree anatomy is a crucial aspect to diagnosis and management of patients with hepatobiliary disease. Tools for imaging the biliary tree include US, ERCP, MRCP and IOC. Of these, only ERCP and IOC allow removal of any stones within the CBD.[7] In cases of laparoscopic cholecystectomy, IOC is the only investigation that allows intraoperative delineation of biliary tree anatomy.[3]

The shift from open to laparoscopic cholecystectomy has been associated with an increase in the rate of BDI from 0.2 to 0.5%.[8] Tornqvist *et al.*[9] found the rate of BDI in laparoscopic cholecystectomy to be as high as 1.5%. BDI is associated with a mortality rate of 12.5%,[10] and increased the mortality rate of patients undergoing LC (3.9% compared with 1.1% at one year).[9] Achieving the 'critical view of safety' via dissection of Calot's triangle and IOC have both been advocated as gold standard for preventing BDI in LC.[11,12] Routine IOC was found to reduce the incidence of BDI by up to 50–70%.[13–15] For example, one retrospective audit[16] describes IOC highlighting the misinterpretation of the CBD as the cystic duct. Minor BDI, especially, was better detected with routine rather than selective IOC.[17] The benefit of IOC in prevention of BDI has been found to be greater in cases where there is presence or history of acute cholecystitis.[18] Early detection of BDI via IOC was associated with 62% reduction in mortality.[9] If routine IOC for all patients appears to be not practical, this investigation should be strongly considered in all cases where there is current or previous acute cholecystitis.[18]

Buddingh *et al.*[2] found that routine IOC in LC was associated with lower rates of BDI and increased intraoperative management of CBD stones. Nickkholgh *et al.*[3] also found that routine IOC resulted in lower BDI rates, and had a higher detection rate of unsuspected CBD stones. The significance of these CBD stones is discussed below. Conversely, Khan *et al.*[5] found no difference in outcomes with the implementation of IOC, and cases with IOC were significantly longer. Arnott *et al.*[4] showed that routine IOC became more time-efficient compared to selective IOC, as staff could anticipate and prepare for IOC regularly.

The incidence of CBD stone detection pre-operatively ranges from 5.4%[19] to 13.6%.[20] If pre-operative US suggested CBD stones (based on a dilated CBD), 40% of operators recommended LC with IOC, 23% recommended pre-operative MRCP, and the remainder recommended ERCP.[21,22] Pre-operative ERCP allowed CBD stone removal and was found to be an effective mode of treatment.[23] However, ERCP involves a separate procedure, and is not available at all treating hospitals.[7] Transcystic exploration of the CBD has also

been described as a method for retrieving CBD stones. As this is not routinely done in our centre, it was not included in the study.

Of cases where no CBD stone was suspected pre-operatively, one was revealed on routine IOC in 1–4% of cases.[7,17,20] In contrast, 22.4% of patients with a suspected CBD stone had this confirmed on IOC.[20] Missed CBD stones were associated with a 15% readmission rate.[17] Routine IOC resulted in peri-operative CBD stone detection, thereby allowing either intraoperative or post-operative (ERCP) removal of the stone.[15,24] Specifically, routine use of IOC prevented missing CBD stones in patients wrongly classified as 'low risk'.[2,25]

Of interest in our study is that there were no clinical sequelae of missed CBD stones in the patient group who did not have a routine IOC. This may suggest that although routine IOC did pick up previously unsuspected CBD stones, these may have not caused clinical complications. This supports the observation that 85% of missed CBD stones never become clinically relevant.[17]

In IOC cases where a CBD stone was found, it may be possible to explore the CBD laparoscopically, negating the need for follow-up ERCP.[14] Laparoscopic CBD exploration (LCBDE) was advocated by 61% of surgeons, whereas 25% recommended post-operative ERCP. In the same paper, LCBDE was found to have similar long term outcomes to post-operative ERCP.[14] The use of a flexible choledochoscope and wire basket for laparoscopic transcystic stone removal has been described.[5,26] Intraoperative cholangiogram (with or without CBD exploration) did not seem to change outcomes in patients with gallstone pancreatitis undergoing LC.[27]

Barriers to routine IOC have found to include operator experience, time restraints, radiation exposure and financial cost.[22] A survey of surgeons found that accurate interpretation of IOC was poor among both junior and senior operators.[22] Successful IOC procedure improved with operator experience.[28] Better training of general surgeons in IOC techniques and interpretation may be useful in optimising the value of this investigation.[29]

Another barrier identified against routine IOC was time. El Shallaly *et al.*[30] found the average time for the radiographer to attend theatre was 9 min from being called. The radiographer was present in theatre for on average 15 min,[30] and the average time for IOC to be completed was 4.3 min.[31] Routine IOC was not found to be associated with longer operating times or increased risk of bile duct injury.[2,3,5,32] Our data, however, indicate that IOC adds on an average of 28 min to total operative time. This information is limited by small case numbers but it appears that with routine use of IOC a significant reduction of operating time can be possible as staff would be used to preparing for the procedure and operator skills in IOC would improve as well.

We observed a rate of successful IOC of 76%, which was significantly lower than the 91–93% that has been reported by others.[33,34] This indicates scope for further improvement with routine use of IOC.

CBD stones were suspected based on pre-operative ultrasound in 6.7% of cases, which was consistent with the literature. During the follow-up after completion of the study there were no readmissions related to missed CBD stones. This follow-up period with a median length of 15 months after surgery is reassuring. Cox *et al.*,[35] however, recently reported that a follow-up of up to 10 years may be necessary to reliably exclude the potential of missed CBD stones.

Radiation exposure during IOC was found to be of minimal dose, and the procedure is deemed safe with regard to this.[36] The financial cost of IOC has been reported to be approximately US$720.[36,37] Assuming an average incidence of BDI of 0.5%, the cost of routine IOC would be more than US$370 000 to possibly prevent one BDI.[36] This is a significant cost which must be seen against the background of the potential psychosocial, medical and legal costs of an avoidable BDI. These figures, however, can only be speculated upon.

Conclusion

The majority of patients treated in our centre were women, middle-aged patients booked for elective laparoscopic cholecystectomy. We found that 17% of routine IOC showed stones within the CBD, which were subsequently confirmed by ERCP in 60% cases. IOC was found to be safe but time consuming, usually adding 28 min to the total theatre time. There were no complications of clinically significant missed CBD stones in patients who did not undergo a routine IOC. It could therefore be argued that IOC did not, in our study, prevent any complications of unsuspected CBD stones.

Routine IOC allows delineation of biliary tree anatomy, detection of CBD stones and diagnosis of BDI. Routine IOC has been shown to be superior to selective IOC in finding minor BDI.[13–15] Routine use of IOC allows operators to maintain experience and comfort in performing this procedure. Furthermore, operating times may be further reduced with routine IOC as operating equipment is predictable for staff to prepare. However, in our study, there were no cases where patients suffered adverse outcomes because they did not have an IOC. Although safe, the benefits of

routine IOC cannot be convincingly argued either way.

Routine IOC can be considered in patients undergoing LC to detect and remove CBD stones, confirm biliary tree anatomy and prevent BDI. Routine rather than selective use of IOC could be recommended in teaching centres to improve operator technique and efficiency.

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