Ending the debate

Routine or selective cholangiography during gallstone surgery?

The gallbladder is an organ located in the human abdomen, positioned just underneath the liver. Its purpose is to store bile produced by the liver for the digestion of fatty food. The bile flows inside the liver bile ducts which start as tiny pipes that gradually join to form wider branches, ending up in the main duct that brings the bile into the small bowel for the digestion of food. This main duct is called the common bile duct (CBD) and is joined by the cystic duct, the branch coming from the gallbladder. The bile moves from the CBD where it is stored between meals, ready to be released after a heavy meal.

The Western diet, in combination with genetic factors, has led to the high incidence of gallstones in the gallbladder. Although most of the time gallstones are asymptomatic, for some patients they can lead to pain, inflammation (cholecystitis), and sepsis. Sometimes the gallstones escape the gallbladder and cause further problems such as inflammation of the pancreas (pancreatitis) and obstruction of the CBD, leading to localized infection (cholangitis), sepsis, and multiple organ failure.

The treatment of choice for symptomatic gallstones is to surgically remove the gallbladder, an operation known as a cholecystectomy. During the operation, an x-ray technique called intraoperative cholangiography (IOC) informs the surgeon whether gallstones are present outside the gallbladder. However, some surgeons doubt the value of IOC for every cholecystectomy. Since the natural course of gallstones that have migrated from the gallbladder is not known, it is impossible to predict what will happen with the stones outside the gallbladder. The benefit of removing them may therefore be questioned. The research of Dr Gabriel Sandblom and colleagues at the Karolinska Institute, Sweden, aims to investigate this further.

What is laparoscopic cholecystectomy?

Laparoscopic cholecystectomy is the removal of the gallbladder using keyhole surgery. It has become the standard procedure of care for patients with gallstone disease, and one of the most common operations performed by abdominal surgeons worldwide.

To remove the gallbladder, the surgeon makes small incisions on the abdomen, allowing the camera and very small instruments to be inserted. The gallbladder must be identified, as well as the bile duct anatomy in relation to the surrounding structures, so that the cystic duct and the cystic artery can then be clipped and divided. Once detached from the liver, the gallbladder is finally removed from the abdomen through one of the incisions.

This method of identifying target structures is known as the critical view of safety. It is a clear, multi-angle view of the anatomy of the ducts of the cystic duct and artery, as well as the lower edge of the liver, and the main bile duct.

What is intraoperative cholangiography?

Intraoperative cholangiography (IOC) is a radiological procedure that can be performed during a laparoscopic cholecystectomy. Sandblom explains, ‘IOC ensures that the anatomical structures are what they are assumed to be by the surgeon and that no vital bile duct is misinterpreted and accidentally injured’. During IOC, the surgeon injects contrast into the bile ducts through the cystic duct and then takes x-ray images. These give the surgeon further information on the anatomy of the gallbladder and the bile ducts, helping to achieve the critical view of safety. The images can also show potentially dangerous gallstones inside the CBD that can often be removed during the same procedure, as well as other missed bile duct lesions, including cancer. It has the added benefit of providing a map of the biliary system that can be filed as part of the medical records.

IOC can also help the surgeon detect accidental injury to the CBD early on in the operation. This important information prevents surgeons from proceeding and turning a potentially small cut into a more severe injury, such as the complete division of the CBD, a complication that then requires a large, much riskier operation.

Routine versus selective IOC

In Sweden, IOC is routinely performed during cholecystectomy. In contrast, in most other Western countries, IOC is done selectively – only when considered necessary; for example, when there is uncertainty regarding the anatomy or suspicion of bile duct stones. Indeed, some surgeons question the benefit of performing IOC for every procedure. Opponents argue that IOC makes the procedure longer, has an extra financial cost, and poses potential complications for the patients such as a possible allergic reaction to the dye and exposure during the operation rather than afterwards, indirectly suggesting an improvement to the patient’s safety. The study also found that the costs involved in performing IOC in every cholecystectomy are lower in the long run, compared to the total cost of further procedures to treat complications and retained stones that weren’t dealt with during the initial procedure. However, this study should be interpreted with caution since it was carried out without randomisation and there are numerous factors that may have affected the outcome.

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Another large 2021 study in Sweden which involved over 130,000 participants demonstrated benefits from performing IOCs routinely during cholecystectomy and sequentially removing even asymptomatic stones of a size that could cause obstruction of the bile ducts in the future. This reduced the need for further procedures to remove symptomatic bile duct stones and potentially the number of related serious complications, such as bile duct obstruction and sepsis. Nevertheless, in countries with routines other than those in Sweden, no excess risk of serious complications has been reported.
The Swedish studies indicate that routine IOC may be beneficial during cholecystectomy, potentially reducing CBD injuries. Unfortunately, there is a lack of worldwide consensus regarding the optimal way of managing stones outside the gallbladder and the value of IOC.

To end the doubt and controversy regarding the value of routine IOC for good, Sandblom and colleagues designed the COGNAC trial. Sandblom explains, ‘The diverging habits of IOC are, to a great extent, the result of local traditions. To evaluate the safety, potential advantages, and costs of these two strategies, we are conducting a randomised controlled trial, and we ask patients undergoing laparoscopic cholecystectomy to participate’.

THE COGNAC TRIAL

The Karolinska Institute researchers’ new study is known as the COGNAC trial, which stands for ChOlanGiography performed by abdominal surgeons. This randomised, multicentre register-based randomised Controlled trial, which stands for ChOlanGiography performed by abdominal surgeons, has been designed by the Karolinska Institute researchers. Sandblom explains, ‘The diverging habits of IOC are, to a great extent, the result of local traditions. To evaluate the safety, potential advantages, and costs of these two strategies, we are conducting a randomised controlled trial, and we ask patients undergoing laparoscopic cholecystectomy to participate’.

The patients will be followed up for at least one year after their cholecystectomy, at which point all data will be analysed. Relevant data captured will include re-admission of the patients to hospital and the need for any extra procedures including surgery, endoscopy, or imaging tests related to complications from their cholecystectomy or any retained stones.

The researchers will also gather information on the length of the operation, the hospital stay, costs, patient life quality, and 30-day and one-year mortality rates. Complications related to the IOC itself will also be recorded, such as allergy to the contrast, or risk of the contrast causing pancreatitis compared to the risk of pancreatitis from potentially leaving CBD stones behind in the field.

The COGNAC trial aims to end the debate as to whether IOC is safe, cost-effective, and essential for every cholecystectomy.

The cystic duct and the cystic artery need to be clipped and divided during surgery. The gallbladder is responsible for storing the bile produced by the liver to digest fatty food.

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Research Objectives

Dr Gabriel Sandblom investigates the varying local traditions for intraoperative cholangiography (IOC) during gallstone surgery.

Detail

Bio

Dr Gabriel Sandblom is a senior consultant at Stockholm South General Hospital and senior lecturer in the Department of Surgery at the Karolinska Institute in Sweden. Sandblom specialises in gallstone surgery and has conducted research focusing on biliary pancreatitis, intraoperative cholangiography, postoperative pain after gallstone surgery, and intraoperative antibiotic prophylaxis.

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Collaborators

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Competing interest statement

Dr Gabriel Sandblom is a member of the board of the Swedish national register for gallstone surgery and EIRCP (GaIRRs).

References


Personal Response

What created the need for such a trial in Sweden, especially since most surgeons in your country already routinely perform intraoperative cholangiography during cholecystectomy?

Striving for safety should always be the main goal of surgery. However, just by following local traditions and adapting routines set by role models with the own country does not necessarily mean that the ideal strategies have been identified. To improve safety, the experience acquired from different healthcare systems should be compared on equal terms and on the same ground. We believe that this study may provide results enabling guidance on safe conduct of gallstone surgery in Sweden as well as in the rest of the world.

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