Gallbladder removal with or without bile duct imaging

A retrospective cohort study of US data raises caution about interpreting the benefits of using bile duct imaging during gallbladder removal.

**Overview:** Gallstones are small stones that develop in the gallbladder as a result of excess cholesterol or minerals. About 15% of the UK adult population is thought to have the condition, known as cholelithiasis, but most people with gallstones (80%) do not have symptoms. In some people gallstones can become trapped in ducts inside the gallbladder and cause sudden intense abdominal pain known as biliary colic. Gallstones can also cause inflammation of the gallbladder, known as cholecystitis.

Removal of the gallbladder using keyhole surgery (laparoscopic cholecystectomy) may be considered in patients who experience severe and frequent abdominal pain from gallstones. Cholecystectomy is one of the most common surgical procedures performed in the UK: around 50,000 cholecystectomies are performed each year, about one-third of which are for cholecystitis.

The common hepatic duct or common bile duct may be injured during cholecystectomy if the biliary anatomy is not identified correctly. Contrast-enhanced imaging during surgery – known as intraoperative cholangiography – may help prevent misidentification and injury of the common bile duct.

See the NICE Evidence Services topic page on gallstones for a general overview of this condition.

**Current advice:** NICE is currently developing guidance on gallstones that will advise on procedures for diagnosing acute cholecystitis and the relative effectiveness of different types of surgical and nonsurgical interventions for the management of symptomatic and asymptomatic cholelithiasis and acute cholecystitis.

NICE guidance on single-incision laparoscopic cholecystectomy advises that this form of surgery is technically challenging and should only be carried out by experienced laparoscopic surgeons who have received specific training in the procedure.

The NICE Pathway on gastrointestinal conditions brings together all related NICE guidance and associated products on gastrointestinal systems such as gallstones in a set of interactive topic-based diagrams.

**New evidence:** Sheffield et al. (2013) used Medicare files for Texas, USA, to retrospectively assess the effect of intraoperative cholangiography during cholecystectomy on the risk of injury to the common bile duct. Data were extracted for people aged 66 years or older who had undergone cholecystectomy with or without intraoperative cholangiography for biliary colic, biliary dyskinesia, acute cholecystitis or chronic cholecystitis. Common bile duct injury was defined as the patient having reconstructive surgery on the bile duct (choledochojejunostomy) or hepatic duct (hepaticojejunostomy) within 1 year of cholecystectomy. The effect of unmeasured confounding
factors was tested with instrumental variable analyses that used how frequently hospitals or individual surgeons used cholangiography as variables.

Between 2001 and 2009, cholecystectomy was performed on 92,932 Medicare patients at 307 hospitals in Texas. Injury to the common bile duct was reported in 201 of the 55,399 patients who did not have intraoperative cholangiography (0.36%) and 79 of the 37,533 people who had intraoperative cholangiography (0.21%). After controlling for the characteristics of patients, surgeons and hospitals, the risk of bile duct injury was higher when cholecystectomy was performed without imaging than when it was performed with imaging (odds ratio [OR]=1.76, 95% CI 1.34 to 2.32). However, the instrumental variable analyses found no association between intraoperative cholangiography and bile duct injury (OR=1.26, 95% CI 0.81 to 1.96 and OR=1.31, 95% CI 0.91 to 1.89, respectively).

The authors suggested that the association between intraoperative cholangiography and common duct injury shown in previous studies could be attributable to unmeasured confounding. Limitations of this study included that major bile duct injuries not managed with surgery could have been missed and that the small number of hospitals could have limited the statistical power of the instrumental variable analyses.

**Commentary:** “Ideally, a large randomised study would be done to prove that cholangiography decreases bile duct injury in cholecystectomy. But to show a 0.2% to 0.4% reduction in injury would need 15,700 participants for 90% power, meaning it is possible, but unlikely, that such a study will be done.

“Our next best evidence comes from the analysis of large population datasets. Most, but not all, studies of this type show a 30–50% reduction in bile duct injury with cholangiography. This current study also shows this magnitude of reduction, but on using instrumental variable analyses the association was attenuated to the point of not being statistically significant. The accompanying editorial (Bilimoria et al. 2013) points out that the use of hospital and surgeon cholangiography rates in these analyses assume those rates are independent of the outcome, and this is debatable. Sheffield et al. (2013) stated that this type of analysis evaluates the effect of cholangiography at the hospital level rather than the patient level. While this is correct, separating these factors in clinical practice is problematic.

“Conclusions about whether or not to advocate for an increase in cholangiography rates, or how to apply these study results to an individual patient, remain unclear. On balance, continuing with cholangiography seems the prudent course, but caution needs to be exercised in overstating the evidence for its utility.” – Mr Michael Rodgers, Chief of Surgery and Hepatobiliary Surgeon, Department of Surgery, North Shore Hospital New Zealand, University of Auckland

**Study sponsorship:** US National Institutes of Health.