

White Paper

GE HealthCare - Surgical Visualization and Guidance.

The Value of Intraoperative Imaging in Laparoscopic Cholecystectomy

Can the latest real-time imaging technologies offer safer, faster and smarter procedures?

Introduction

Surgical innovation and patient care remain at the core of the ever-evolving landscape of healthcare. But at the heart of these core tenets are a myriad of conditions and their existing procedures, which taken at face value may appear banal or almost commonplace in certain regions of the world when they are, in fact, becoming an increasing burden to healthcare systems.

Gallstones, as Cholelithiasis is more commonly referred to, is a common condition in many parts of the world, and has seen a marked increase in recent years, especially in the west.

When looking at subpopulations as they relate to affected ethnic groups and contributing factors, we see gallstones tending to occur more frequently among certain ethnic groups than others, with a prevalence ranging from around 10% to 20%¹ in western Caucasian adults, to over 50%² in people of Native American origin.

In Africa, we see rates of approximately 3%, while In Asian countries, the prevalence of cholelithiasis ranges from 3% to 10%; specifically, according to recent studies, 3.2% in Japan³, 10.7% in China⁴, 7.1% in North India⁵, and 5.0% in Taiwan⁶.

Even across gender we see a large disparity in incidence - women are diagnosed with gallstones almost three times more often than men, with estrogen levels and birth control pills being probable factors.⁷

Other factors include age, obesity, genetics, cardiovascular disease (CVD), sugar metabolism and the individual microbiome.⁸

While most people with gallstones are asymptomatic (circa 80%)¹, for those requiring treatment, performing a Cholecystectomy – the removal of the gallbladder, is the most common treatment option. And as innovative technologies continue to evolve, we begin to expect new standards of care.

A laparoscopic approach

Cholecystectomies are now one of the most frequently performed procedures worldwide. With an indication for symptomatic or asymptomatic Cholelithiasis, Cholecystitis (Inflammation of the gallbladder) and Gallbladder polyps over 0.5cm. Most Cholecystectomy procedures today are carried out laparoscopically, with far fewer open surgeries.

“Between 750,000 - 1,000,000 Laparoscopic Cholecystectomy procedures are performed annually in the United States⁹”

The Laparoscopic cholecystectomy (LC) was introduced into clinical practice around 30 years ago and it has helped to usher in a new era of minimally invasive surgery and has become the established gold standard for patients with symptomatic gallstones.¹⁰

The laparoscopic approach has laid claim to such a title in part due to several advantages over open surgery, including decreased postoperative pain, reduced need for postoperative analgesia, shortened hospital stays (1 week vs < 24 hours), and faster return to full activity (1 week vs 1 month after open cholecystectomy).^{11,12} LC is a case study in the evolution of healthcare as a practice and a continual drive to provide a solution that is, by all accounts, better than what came before it.

The value of intraoperative imaging

Factors such as anatomical variations, inadequate visualization of extrahepatic structures, and surgeon inexperience can all increase the risk of potentially serious bile duct injuries (BDIs). In the US, common bile duct injury (BDI) is approx. 0.4% of all LCs, which represents more than 3000 injuries annually¹³⁻¹⁶, and over \$1 billion in associated costs¹⁷.

Real-time intraoperative imaging which, since its inception, has helped surgeons in many specialties providing valuable insights into critical anatomy such as individual biliary tract anatomy, identification of anomalies, and assistance in the creation of surgical plans and assessing outcomes.

Currently there are 3 primary intraoperative imaging modalities used in LC:

- **Intraoperative Cholangiography (IOC)** – fluoroscopic live imaging using a C-arm and a contrast agent.
- **Intraoperative ultrasound (iUS)** – real-time imaging using specially designed intraoperative transducers, controlled by the surgeon.
- **Intraoperative Fluorescent Cholangiography (ICG FC)** – live imaging using near-infrared (NIR) fluorescent light and Indocyanine Green (ICG) dye.

Imaging Modalities Compared

	Intraoperative Cholangiography (IOC)	Intraoperative Ultrasound (iUS/LUS)	ICG Fluorescent Cholangiography (ICG FC)
Invasive/Non-invasive	Invasive	Non-invasive	Non-invasive
Identify biliary anatomy and CBD stone	Yes, both	Yes, both	No, only biliary anatomy, not CBD stones
Real-time	No, static images	Yes	Yes
Radiation risk	Yes	No	No
Repeatable	No	Yes	Yes
Cost	Capital & Disposable	Capital	Capital & Disposable
Patient selection	Selective	All	Most
Preop prep	No	No	Yes

When compared we can see how each of these modalities stack up against each other. Intraoperative Cholangiography (IOC) is currently considered the standard of care (see below), with varying levels of adoption.

Current use of IOC in LC procedures⁵

11% Routine IOC

71% Selective IOC

18% No IOC

Why is Intraoperative Cholangiography (IOC) the dominant modality?

Studies have shown IOC can enhance anatomical visualization during cholecystectomy. It can also help to reduce complications, with improved patient outcomes.¹⁶

IOC helps surgeons in identifying anatomical defects such as ductal branching patterns or auxiliary ducts, enabling them to avoid injuries to vital structures during surgery.

"...IOC safeguards against iatrogenic injury to the common bile duct, which might result in biloma, intraabdominal abscess and infection, and sepsis."¹⁸

It can also provide insights into the existence of stones or structures inside the biliary system, assisting in surgical decision-making.

What are the drawbacks of IOC?

Since intraoperative cholangiography involves x-ray exposure, it can only be performed once per procedure, and requires the presence of a radiography technician. It is considered costly, relatively slow¹⁹, and is invasive, requiring cannulation of the cystic duct.

"Historically, surgeons have striven to detect CBD stones and anatomical abnormalities during cholecystectomy by using intraoperative cholangiography (IOC) as part of a perceived better surgical practice. Its use is decreasing, performed in a variable fashion from routinely to never. The reason for this variance probably relates

to the time required; difficulty of the procedure, especially in acute cholecystitis; and having a clear algorithm for detected CBD stones.”²⁰

What about Intraoperative Fluorescent Cholangiography (ICG FC)?

Near-infrared fluorescent cholangiography has demonstrated superiority over white light for the visualization of biliary structures and reduction of LC risks. It is repeatable and offers non-invasive, real-time imaging. It also has other benefits, such as enhancing anatomic visualization in obese patients and those with moderate to severe inflammation.

Some disadvantages of this modality include the requirement for pre-operative administration of intravenous dye, and the fact that it is of limited value in identifying CBD stones.

“To date, there is no evidence that ICG FC can effectively identify CBD stones by replacing IOC”^{21,22}

What does iUS/LUS bring to the table?

In practice, intraoperative ultrasound (iUS) has been demonstrated to be a viable, safe and effective alternative to IOC. iUS does not require cannulation or contrast agents, needs no special pre-operative preparation, and avoids exposing patients and staff to radiation. It has also been demonstrated to be effective in the detection of CBD stones.^{23,24}

A literature review by Alexandra Dili and Claude Bertrand found iUS to be:

“...faster, less invasive, cheaper, with no adverse events, and can be repeatedly used during the operation...”²⁵

In addition, iUS can help to detect Choledocholithiasis – common bile duct stones, and differentiate between sludge, stones, polyps, cysts and tumors when determining the presence of gallstones in the CBD.^{26,27}

It can also offer biliary tract visualization, with color flow doppler to help differentiate between vessels and ducts and is overall effective at imaging difficult cases such as inflammation or fibrosis.²⁸⁻³¹

Conclusion

Modern intraoperative imaging techniques offer today’s surgeons valuable, real-time guidance, with the potential to shorten procedure times and improve outcomes. With the addition of a reduction in BDIs, one can see why surgeons have become enthusiastic advocates for adding them to their toolkit.

As to the most effective of these imaging modalities, iUS/LUS and ICG FC both offer advantages over IOC, in terms of safety, speed, cost and repeatability.

While IOC can help to improve surgical outcomes, especially in detecting bile leaks / bile duct injuries, it has some downsides in terms of cost, radiation exposure, and the need for additional radiography personnel in the OR.

iUS and ICG FC present surgeons with credible alternatives that avoid these limitations, and can offer clear benefits in terms of safety, reduced length of surgery and fewer BDIs. ICG FC

is, however, unable to detect the presence of CBD stones, which suggests iUS may be the better alternative as an additional imaging modality.

The principal hurdle for the adoption of routine iUS may be due to concerns about the learning curve, and a general lack of familiarity with the advantages of iUS systems.

“... as ultrasound and laparoscopy become standard techniques in modern surgery, most surgical trainees and junior surgeons will be exposed to them, and will be more inclined to include them in their skill set...”²⁵

With the improved quality and shorter learning curve offered by the latest iUS imaging technology, LC, in combination with effective real-time Intraoperative Imaging, seems likely to continue to evolve, to the benefit of patients and surgeons alike.

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