Intraoperative Near-Infrared Fluorescence Imaging Using Indocyanine Green for Visualization of the Hepatobiliary System

BRIAN R. SMITH, M.D., FACS, FASMBS

Associate Professor of Surgery &
General Surgery Residency Program Director
Co-Director, Minimally Invasive Surgery Fellowship
University of California, Irvine School of Medicine
Chief of Surgery
VA Long Beach Healthcare System

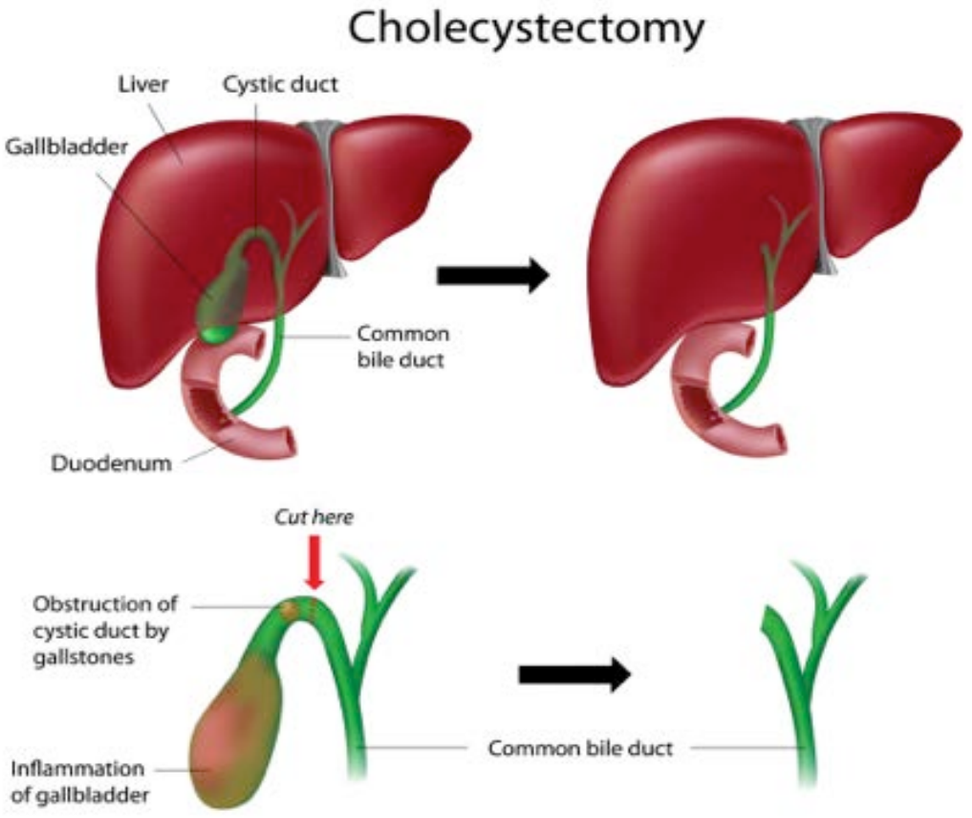
September 10, 2019
ICD-10 Coordination and Maintenance Committee

Disclosures: Consulting (Novadaq/Stryker)

UCI

Surgical Management of Gallstones: Cholecystectomy

- Surgical removal of the gallbladder
- Most frequently performed gastrointestinal surgery
- >1.2 million laparoscopic cholecystectomies performed annually in the US for gallbladder disease[1]



[1]McClusky D. Laparoscopic Cholecystectomy. SAGES. Accessed on May 10, 2019 at https://www.sages.org/wiki/laparoscopic-cholecystectomy/

The Problem Before Us

- Major morbidity 5% of cases
- Duct anatomy mis-identification during surgery
- Bile Duct Injury 3/1000
- Average duct injury cost >$587K (nearly $670K if it requires surgery)
- Average hospital stay 11.5 days
- Unusual anatomy in up to 23% of cases

Keleman et al. *Am Surg.* 2011

The Problem Before Us

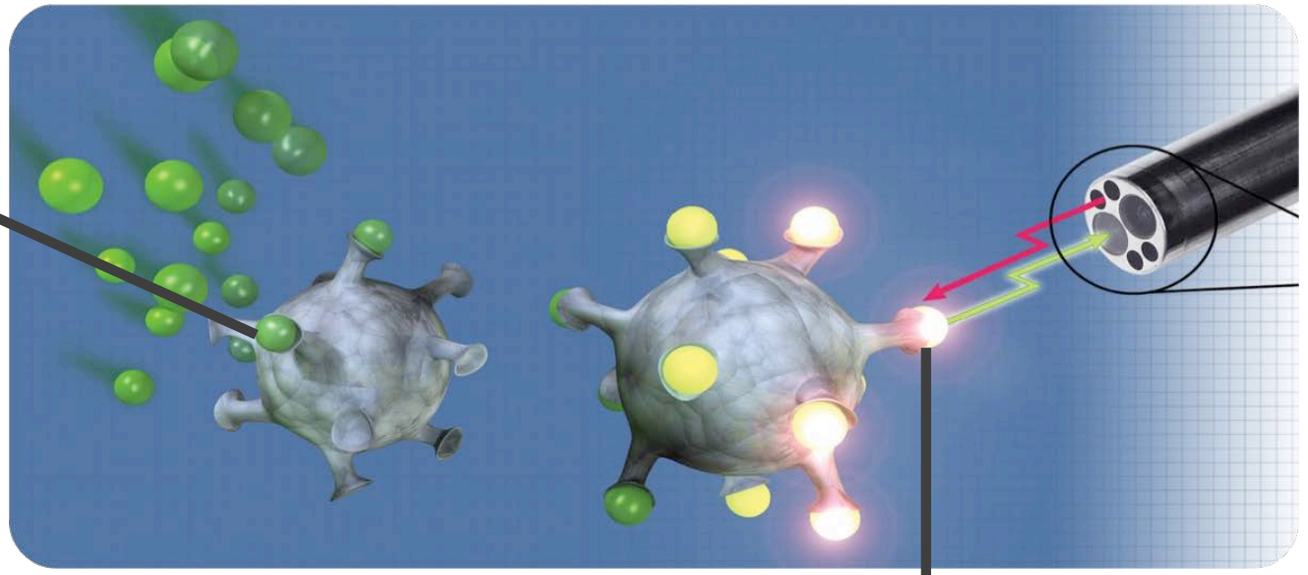
- Bile duct injury (BDI) results in long-term disability and reduced survival
- High medical/malpractice claims associated with cholecystectomy-related injuries
  - BDI = 53% of all claims
- BDI-related claims stable over last 30 years
- Every $1 for payout, add $.54 on admin costs + legal fees
- Surgeon involvement in claims related to
  - Burnout
  - Depression
  - Suicidal Ideation
- Perceived threat of malpractice claims highest among surgeons

Keleman et al. *Am Surg.* 2011

PINPOINT Fluorescence Imaging System and Indocyanine Green (ICG) Imaging Agent

FLUORESCENCE: Light absorbed and remitted within nanoseconds (lower energy, higher wavelength)

SPY AGENT™ GREEN (Indocyanine Green for Injection USP),
binds to proteins



NIR
Near Infrared Light from iRGB Endoscope absorbed by ICG; re-emitted

Processor combines live HD and fluorescence images; monitor displays images in parallel and real time

PINPOINT FDA 510(k)-Cleared Indications for Use

- Minimally invasive surgery using standard endoscope visible light to assess vessels, blood flow and tissue perfusion

- Lymph nodes and lymphatic vessels in women with cervical and uterine tumors who are undergoing lymphatic mapping.

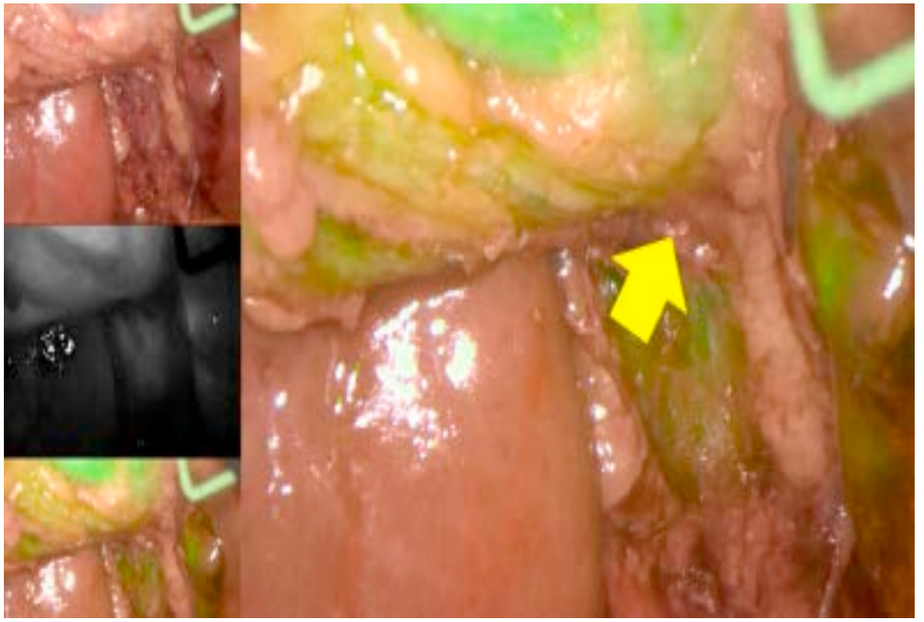
- **Extrahepatic biliary ducts and when indicated, intraoperative cholangiography***

**Multiple systems are approved for visualization of extrahepatic biliary ducts and intraoperative cholangiography.*

Intraoperative ICG Imaging

Above shows the gallbladder was adequately imaged with ICG fluorescence.[1]

Below shows the boundary between the gallbladder and liver was clearly visible (arrow), and the gallbladder could be detached easily.[1]



[1]Tsutsui N, Yoshida M, Kitajima M, Suzuki Y. Laparoscopic cholecystectomy using the PINPOINT endoscopic fluorescence imaging system with intraoperative fluorescent imaging: A case report. *Int J Surg Case Rep.* 2016;21:129–132.

How ICG Cholangiography May Increase Safety

- Helps define duct anatomy
- Can be accomplished in more patients compared with using intraoperative radiography (cholangiogram)
- Less expensive than cholangiogram
- Faster than cholangiogram
- Excellent teaching tool that can be utilized by learners at all levels
- Incisionless
- Exceptional safety record of ICG
- Minimal learning curve
- No X-rays/radiation exposure
- ICG presence in US market since 1959
- 31 studies (n=1,199) demonstrate ICG cholangiography safe, effective, and ***may*** reduce biliary tract injuries

The SAGES Safe Cholecystectomy Program[1]

“Make liberal use of cholangiography or other methods to image the biliary tree intraoperatively.

Cholangiography may be especially important in difficult cases or unclear anatomy. Several studies have found that cholangiography reduces the incidence and extent of bile duct injury but controversy remains on this subject.[2]”

[1]Society of American Gastrointestinal and Endoscopic Surgeons. The SAGES Safe Cholecystectomy Program. Accessed at https://www.sages.org/safe-cholecystectomy-program/ on 30-July-2019.

[2]Traverso LW. Intraoperative cholangiography reduces bile duct injury during cholecystectomy. *Surg Endosc.* 2006;20:1659-1661.

Thank You