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ORIGINAL ARTICLE

Near-infrared fluorescent cholangiography – real-time visualization of the biliary tree during elective laparoscopic cholecystectomy

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Abstract

Background: The purpose was to evaluate the efficacy of near-infrared fluorescent cholangiography (FC) in real-time visualization of the biliary tree during elective laparoscopic cholecystectomy.

Methods: Fifty consecutive elective laparoscopic cholecystectomies were performed with fluorescent cholangiography. FC was performed at three time points: following exposure of Calot's triangle, prior to any dissection; and after partial and complete dissection of Calot's triangle.

Results: The cystic duct (CD) was identified successfully by FC in 43 of 50 patients (86%) and in 45 of 50 patients (90%) before and after Calot's dissection respectively ($p > 0.05$). The common hepatic duct (CHD) and the common bile duct (CBD) were identified successfully in 12 of 50 patients (24%) and in 33 of 50 patients (66%) before Calot's dissection respectively and in 26 of 50 patients (52%) and in 47 of 50 patients (94%) after complete Calot's dissection ($p = 0.007$ and $p = 0.001$, respectively). Significant differences were observed for CBD visualization rate, in relation to BMI after Calot's dissection ($p < 0.05$) and history of cholecystitis, before Calot's dissection ($p = 0.017$). No bile duct injuries were reported.

Conclusion: Fluorescent cholangiography can be considered as a useful tool for intra-operative visualization of the biliary tree during laparoscopic cholecystectomies.

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Introduction

Laparoscopic cholecystectomy (LC) is one of the most frequently performed procedures worldwide in general surgery. Bile duct injury (BDI) is the most serious complication of LC, with an incidence of 0.3–0.7% resulting in a significant impact on quality of life and overall survival.[1–3] It has been demonstrated that the primary cause of BDI is the misinterpretation of biliary anatomy (71%–97% of all cases).[4,5] For many years intra-operative cholangiography (IOC) has been advised by many authors as the technique reduces the risk of BDI.[4] However, the procedure presents some limitations and is often reserved for selected cases.[5] One of the latest innovations in minimally invasive technology is fluorescence image guided-surgery. Fluorescent cholangiography (FC) is a novel approach, which offers real-time intra-operative visualization of the biliary anatomy. The first intra-operative use of FC in humans was described by Ishizawa *et al.* in 2009.[6] The method involves the intravenous injection of the dye indocyanine green (ICG) before surgery. ICG binds to plasma proteins, with albumin as the principle carrier (95%) and is eliminated exclusively by the liver. The excitation of protein-bound ICG by near-infrared light causes fluorescence, thereby delineating anatomy of the biliary system for the surgeon.

This study reports the results of 50 consecutive laparoscopic elective cholecystectomies with ICG fluorescence at a single institution. The primary aim was to evaluate the efficacy of near-infrared fluorescent cholangiography (FC) in real-time visualization of the biliary tree during elective laparoscopic cholecystectomy. The second aim was to analyze the possible factors that could influence the visualization rates of the biliary structures and to assess the perceived benefit of the novel technique for training surgeons.

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Methods

Fifty consecutive elective laparoscopic cholecystectomies were performed with FC. All data regarding patients who underwent LC with fluorescence imaging were collected and entered into a database. Data included patients' characteristics, intra-operative findings and post-operative outcomes. An Institutional Ethical Committee (ID protocol: 0009285) approved the study as part of standard care. Inclusion criteria were symptomatic cholelithiasis or chronic cholecystitis (as documented by abdominal sonography or computed tomography) without suspicion of bile duct stones, patients operable by laparoscopy and who agreed to study. The main exclusion criteria were the presence of hepatic failure, a history of bile duct surgery, ongoing pregnancy or breastfeeding and allergy to ICG. Patients with a history of cholecystitis and prior abdominal surgery were not excluded. All the operations were performed by the same team of surgeons, including training surgeons under direct supervision. During surgery, the resident was asked to decide whether it was believed that the "critical view of safety" was established and for the correct anatomical visualization of biliary structures. Laparoscopic cholecystectomy was performed by using both American and French approaches depending on surgeon' preferences. All patients included in the study signed a written informed consent before surgery.

For intra-operative fluorescent cholangiography, 5 mg ICG (ICG, Pulsion Medical Inc., Irving, Tx) was administered intravenously 20–30 min prior to surgery. An additional dose was administered if fluorescence degradation was noted intra-operatively. Near-infrared fluorescent cholangiography (NIRF-C) was performed by using a D-light P light-source unit (Karl Storz Endoskope, Tuttlingen, Germany) with the ability to switch between a xenon and infrared light with the aid of a foot pedal. NIRF-C was performed at three defined time point during laparoscopic cholecystectomy: (i) following exposure of Calot's triangle, prior to any dissection; (ii) after partial dissection of Calot's triangle; (iii) after complete dissection of Calot's triangle, according to the "Critical View of Safety" method. For fluorescent angiography, a second intra-operative bolus injection of ICG was required with identification of the cystic artery 20–30 s after the bolus.

A survey concerning the usefulness of the novel technique was analyzed, by using a Likert scale. At the end of each intervention, residents were asked five specific questions regarding the perceived benefit of the device. The survey data were collected anonymously.

Statistical analysis

All collected data were included in a study specific database and analyzed using the SPSS software (IBM SPSS Statistics for Windows, version 23.0). Descriptive statistics were used to characterize the population using proportion and median, means ± standard deviations (SDs) and range. The two-tailed Chi-square test was used for the statistical comparison of proportions. The Chi-square test was used to compare the proportion of successful FC visualization (i.e. visualization rates) of the biliary tree (cystic duct, CD; common hepatic duct, CHD and the

Table 1 Patients' characteristics, intra-operative data and post-operative outcomes

Total number of patients	50
Mean age	55.4 ± 15.3 years-old (range 24–80)
Male sex	26% (M/F: 13/37)
Mean ASA score	ASA II (range I–III)
Mean BMI (kg/m^2)	26.8 ± 5.8 (range 17.7–44.0)
- BMI <25	44% (22/50)
- BMI ≥25	56% (28/50)
Surgical indication	
- symptomatic biliary lithiasis	84% (42/50)
- chronic cholecystitis	16% (8/50)
Surgical technique	
- French technique	40% (20/50)
- American technique	60% (30/50)
First surgeon	
- Senior	50% (25/50)
- Resident	50% (25/50)
Previous MRI-cholangio	20% (10/50)
History of cholecystitis	54% (27/50)
Previous abdominal surgery	24% (12/50)
Mean operative time (minutes)	81 ± 8 min (range 45–150 min)
Successfully performed fluorescent cholangiography	100%
Identification of biliary structures before Calot's dissection	
CD	86% (43/50)
CHD	24% (12/50)
CBD	66% (33/50)
Identification of biliary structures after Calot's dissection	
CD	90% (45/50)
CHD	52% (26/50)
CBD	94% (47/50)
Identification biliary anomalies or anatomical variants	8% (4/50)
Associate fluorescent angiography	12% (6/50)
Conversion rate	8% (4/50)
Bile duct injuries	–
Peri-operative complications	8% (4/50)
Mean hospital stay (hours)	43.3 h

ASA, American Society of Anesthesiologists; BMI, body mass index; CD, cystic duct; CHD, common hepatic duct; CBD, common bile duct.

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