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Article

The Integration of Critical View of Safety and Indocyanine Green Fluorescent Cholangiography to Enhance Patient Safety During Laparoscopic Cholecystectomy

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Abstract: Backgrounds: Laparoscopic cholecystectomy (LC) is the standard treatment for gallstone-related diseases, but bile duct injury remains a significant complication. This study investigates the efficacy of integrating the Critical View of Safety (CVS) and Indocyanine Green (ICG) fluorescent cholangiography to prevent bile duct injury**. Methods:** A retrospective study was conducted on 50 patients with cholelithiasis and gallstone-related complications who underwent LC at Srinakharinwirot University from April 2022 to April 2024. ICG (2.5 mg) was administered intravenously 60 minutes before surgery. LC was performed using a near-infrared light source. Statistical analysis included Chi-squared, unpaired t-tests, and logistic regression, with a significance level at $p < 0.05$. **Results:** The study included 25 males and 25 females, with an average age of 55.6 years. CVS was established in 78% of cases. Most cholecystectomies were complete (88%); no major bile duct injuries were reported. One patient (2%) experienced minor postoperative bile leakage, which resolved spontaneously. Visualization rates for the common bile duct (100%). Patients with gallbladder inflammation or previous ERCP had lower visualization rates, but these differences were not statistically significant. The non-CVS group had significantly longer operative times (75.9 vs. 60.5 minutes; $p<0.001$) and higher rates of incomplete cholecystectomy (54.5% vs. 0%; $p<0.001$) than the CVS established group. **Conclusion:** Integrating CVS and ICG fluorescent cholangiography enhances the patient safety of LC by improving bile duct visualization and reducing the risk of injury. This combined approach should be considered as standard practice in surgical training and healthcare.

Keywords: Cholelithiasis; Indocyanine green; Laparoscopic cholecystectomy; Patient safety

1. Introduction

Laparoscopic cholecystectomy (LC) has become the standard treatment for patients with cholelithiasis and gallstone-related diseases, including acute cholecystitis and acute pancreatitis. This surgical procedure offers advantages such as reduced postoperative pain, shorter hospitalization, faster resumption of full activity, and lower mortality compared to open cholecystectomy [1,2]. However, bile duct injury remains a severe complication, occurring in 0.3–1.8% of cases, leading to diminished quality of life and increased mortality rates of up to 20.8% [3].

Various techniques are employed to prevent bile duct injury during LC, including intraoperative cholangiography (IOC) [4]., bailout surgery in challenging cases [5], and the establishment of the Critical View of Safety (CVS) [6]. The CVS technique involves dissecting the triangle of Calot to remove fibrous and fatty tissue until the cystic artery and cystic duct are clearly identified before clipping and transection. Despite its benefits, the CVS technique has limitations, such as limited

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experience among general surgeons, challenges in visualizing the ventral view of Calot's triangle in inflamed gallbladders, and occasional inability to establish CVS in such cases [7,8].

Indocyanine green (ICG) is a water-soluble tricarbocyanine molecule approved by the US Food and Drug Administration (FDA) since the 1960s for safe administration without significant adverse effects. When exposed to near-infrared (NIR) light at 820 nanometers, ICG fluoresces, making it useful in gastrointestinal surgeries to minimize postoperative complications. After administration, ICG is rapidly metabolized and excreted into the bile, allowing for the visualization of biliary anatomy during LC [9,10].

This study aims to investigate the efficacy and safety of integrating CVS and ICG in preventing bile duct injury during LC in patients with cholelithiasis and gallstone-related complications. Additionally, it evaluates the visualization rate of ICG fluorescence cholangiography and factors affecting the visualization rate and establishment of CVS.

2. Materials and Methods

2.1. Patient Characteristics

A retrospective single-center, cross-sectional study was conducted on patients who underwent LC at the Department of Surgery, Faculty of Medicine, Srinakharinwirot University, Thailand, from April 1, 2022, to April 30, 2024. The study included patients aged 18 to 80 years diagnosed with cholelithiasis and gallstone-related complications, excluding those with iodine allergies or gallbladder cancer. The sample size was determined by a power calculation, requiring 45 patients for analysis, with a total of 50 cases included to enhance accuracy.

2.2. Ethics Approval and Informed Consent

The study received approval from the institutional ethics council of Srinakharinwirot University (Ethics code: SWUEC-673036). Informed consent was obtained from each participant, and patient information was collected in compliance with the Standards for the Protection of Personally Identifiable Health Information.

2.3. Laparoscopic Cholecystectomy and ICG Fluorescent Cholangiography

LC was performed by a single surgeon (TT) with over 300 operative cases of expertise. A dosage of 2.5 mg of ICG (Diagnogreen, Taiyo Pharma Tech, Osaka, Japan) was administered intravenously 60 minutes before the operation **[**11, 12**].** A conventional four-port LC was conducted under general anesthesia, with a 10-mm transumbilical port, a 5-mm subxiphoid port, and two 5-mm subcostal ports, establishing a pneumoperitoneum of 10-12 mmHg with carbon dioxide.

During Calot's triangle dissection, a 30-degree laparoscope with a near-infrared light source (Karl Storz Endoskope, Heusenstamm, Germany) was used to visualize bile duct anatomy and create CVS. The surgical technique has been previously described **[**13**].** After identifying the cystic artery and cystic duct, they were sealed with 5 mm non-absorbable polymer clips (Hem-o-lock®, Teleflex Medical, Durham, NC, USA) and divided using laparoscopic scissors, followed by retrograde cholecystectomy with a monopolar L-hook.

In cases where CVS was not established, the fundus-down method for subtotal or complete cholecystectomy was employed, securing the cystic duct stump with a pre-tied endoscopic ligation loop. During the dissection of Calot’s triangle, we utilized ICG cholangiography to evaluate the anatomical identification of the biliary tract in real-time, including the cystic duct, common bile duct (CBD), common hepatic duct (CHD), and the junction of the cystic duct and CBD

2.4. Clinical Variables

Data collected included patient characteristics, comorbidities, operative duration, visualization of bile duct anatomy, ability to achieve CVS, completion of cholecystectomy, intraoperative blood loss, and postoperative complications such as bile leakage, intra-abdominal collection, and bile duct injury.

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2.5. Statistical Analysis

Statistical analysis was performed using SPSS version 27.0 (SPSS Inc., Chicago, IL, USA). Descriptive analysis using mean, percentage, and standard deviation assessed clinical and demographic factors. Differences between groups were analyzed using Chi-squared and Fisher's exact tests for categorical variables and unpaired t-tests for continuous variables. Logistic regression analysis evaluated factors associated with the visualization rate of ICG cholangiography and the establishment of CVS during LC. A p-value below 0.05 was considered statistically significant.

3. Results

3.1. Patient Characteristics

The study included 25 males and 25 females, with an average age of 55.6 years (range 21 to 80) and an average BMI of 24.6 kg/m². ASA classifications were I (28%), II (58%), and III (14%). Cholelithiasis was the principal diagnosis in 62% of cases. Among those with gallstone-related complications, 30% had acute cholecystitis, 8% had acute pancreatitis, and 22% had CBD stones. Additionally, 36% had multiple diagnoses, and 24% had a history of ERCP (Table S1).

3.2. Surgical Intervention and Outcomes

The average operative time was 64.07 minutes, with a mean blood loss of 15.31 mL. Most cholecystectomies were complete (88%), while 12% were subtotal. CVS was established in 78% of cases. No intraoperative complications were recorded, and the conversion rate to open cholecystectomy was 6%. Minor postoperative bile leakage occurred in one patient (2%), resolving spontaneously by the third postoperative day, with no major bile duct injuries reported on postoperative ERCP. Pathologic diagnoses revealed chronic cholecystitis in 70% and acute cholecystitis in 30%, with 4% having concomitant gallbladder polyps (Table S2).

3.3. Comparison of CVS Established vs. Non-CVS Established Groups

There were no significant differences in patient characteristics between the CVS-established and non-CVS-established groups, including age ($p = 0.452$), male sex ($p = 0.545$), BMI ($p = 0.907$), and ASA classification ($p = 0.341$). Preoperative diagnostics revealed no significant differences, including cholelithiasis ($p = 0.237$). However, the non-CVS established group had greater gallbladder and biliary tract inflammation (72.7%, $p = 0.125$), previous ERCP (45.5%, $p = 0.154$), and multiple diagnoses (63.6%, $p = 0.236$), although these differences were not statistically significant.

Operative time (75.9 vs. 60.5 minutes; $p<0.001$) and the rate of incomplete cholecystectomy (54.5% vs. 0%; $p<0.001$) were significantly higher in the non-CVS established group. The rate of total cholecystectomy was significantly greater in the CVS established group (100% vs. 45.5%; $p = 0.038$). However, there were no statistically significant differences in blood loss ($p = 0.073$) and the conversion rate to open surgery ($p = 0.167$) (Table S3).

3.4. Clinical Parameters Affecting CVS Achievement

Multivariate logistic analysis identified no clinical parameters associated with the success or failure of CVS achievement. Factors analyzed included age ($p = 0.936, 0.846$), sex ($p = 0.669, 0.465$), BMI ($p = 0.539, 0.223$), diabetes mellitus ($p = 0.992, 0.652$), hypertension ($p = 0.579, 0.668$), cholelithiasis ($p = 0.06, 0.510$), inflammation of the gallbladder and biliary tract ($p = 0.06, 0.512$), previous ERCP ($p = 0.610, 0.270$), and multiple diagnoses ($p = 0.566, 0.231$) (Table S4).

3.5. Visualization of Bile Duct Anatomy with ICG Fluorescence Cholangiography

The common bile duct (CBD) was visualized in 100% of cases. The cystic duct visualization rate was 90% in cholelithiasis (OR=1.61, 95% CI=0.28-9.28; p=0.597), 73.7% in gallbladder inflammation (OR=1.28, 95% CI=0.22-7.588; p=0.783), and 66.7% in patients with ERCP history (OR=0.77, 95% CI=0.11-5.40; p=0.789). The CBD-cystic duct junction was visualized in 93.3% of cholelithiasis cases

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(OR=1.42, 95% CI=0.19-10.84; p=0.737), 78.9% in gallbladder inflammation (OR=1.33, 95% CI=0.17-10.27; p=0.787), and 66.7% in ERCP history cases (OR=1.31, 95% CI=0.11-15.01; p=0.828), with no statistical significance.

The common hepatic duct (CHD) visualization rate was 86.7% in cholelithiasis (OR=1.42, 95% CI=0.19-10.84; p=0.737), 84.2% in gallbladder inflammation (OR=1.33, 95% CI=0.17-10.27; p=0.787), and 75% in ERCP history cases (OR=1.31, 95% CI=0.11-11.31; p=0.828). No significant differences were found in the visualization rates of the cystic duct, cystic duct-CBD junction, and CHD between groups. (Table S5) ICG fluorescence cholangiography enhanced biliary tract visualization during laparoscopic cholecystectomy, as shown in Figure S1. ICG fluorescence cholangiography prevented misidentification of the CBD and cystic artery in one patient and over traction of the CBD in another.

4. Discussion

The Critical View of Safety (CVS) is a surgical method used to dissect Calot's triangle, facilitating the identification of the cystic duct and artery, potentially reducing the occurrence of bile duct injury to 0.09% **[**14**].** Due to a bile duct injury incidence of 6% in our institution in 2015, CVS was implemented as a standard practice to prevent such injuries, achieving a success rate of 75-80% **[**8**].**

In cases where CVS was not established, particularly in acute cholecystitis or prior inflammation, various techniques such as the fundus-first approach or subtotal cholecystectomy were used, which may increase the incidence of postoperative bile leakage to 21% **[**15**].** This can be attributed to anatomical variations in the insertion of the cystic duct and accessory cystic artery, occurring in 7.4% of cases within Calot's triangle, potentially leading to misidentification during surgery **[**16**].**

Although this study did not determine the factors associated with the achievement of CVS, this may be due to all cases being conducted by a single experienced surgeon. However, the results indicate that patients in the non-established CVS group experienced significantly longer operative times and required subtotal cholecystectomy more frequently than those who achieved CVS.

Previous studies on ICG fluorescent cholangiography reveal visualization rates for the extrahepatic bile duct ranging from 71.4-100% for the cystic duct, 33.3-100% for the common hepatic duct, 50-100% for the CBD, and 25-100% for the cystic duct-CBD junction **[**17**].** Correspondingly, this study found a 100% visualization rate of the common bile duct. Patients with gallbladder and biliary tract inflammation, along with those with previous ERCP, exhibited lower visualization rates of the cystic duct, common hepatic duct, and cystic duct-CBD junction compared to the cholelithiasis group; however, these differences were not statistically significant.

This study illustrates that ICG fluorescent cholangiography, when integrated with CVS, presents several benefits, including enhanced visualization of bile duct anatomy during the dissection of Calot's triangle, assisting in the precise identification of the CBD, improving surgical outcomes for both CVS and complete cholecystectomy, mitigating the risk of misidentifying the cystic duct and cystic artery, and alerting surgeons to avoid excessive traction on the CBD.

In our practice, a higher visualization rate of the CBD augments the efficacy of ICG fluorescent cholangiography in non-established CVS groups, consequently facilitating a safe cholecystectomy as follows: 1) Identifying the tubular structure connected with the CBD, which is amenable to clipping and division to facilitate a complete cholecystectomy in five cases; 2) regardless of conversion to open surgery, ICG can be utilized for assessing bile duct anatomy; and 3) in cases necessitating subtotal cholecystectomy, the Endo loop was applied for double ligation at a minimum distance of 1 cm from the CBD alignment to prevent bile duct injury.

A recent multicenter randomized controlled study reported that the use of ICG provided an early identification rate of bile duct anatomy, leading to faster achievement of CVS compared to conventional LC. However, there were no differences in the length of hospital stay or postoperative complications in elective circumstances **[**18**].** Losurdo et al. demonstrated that the use of ICG can decrease the incidence of intraoperative complications from 15.8% to 4.17%, indicating its protective role in preventing bile duct injury. These findings substantiate the conclusions drawn from our study **[**19**].**

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Our results support the routine use of CVS and ICG in LC to enhance surgical safety and prevent bile duct injury. ICG cholangiography was easily performed without special equipment, allowing surgeons real-time visualization of bile duct anatomy during the procedure. Moreover, the study's results are relevant for pre-operative planning in patients with gallbladder and biliary tract inflammation, previous ERCP, and multiple diagnoses, as these patients are at greater risk of failing to achieve CVS. This patient group may necessitate ICG fluorescence cholangiography to ensure safe operation.

This study's limitations include a small sample size, which may influence outcome evaluation. Nevertheless, comprehensive data were included, and appropriate statistical methods were employed for data analysis. The inability to demonstrate a factor associated with the visualization rate of bile duct anatomy may be due to the visualization of ICG being limited in patients with inflammation and a BMI exceeding 35 kg/m²; however, the average BMI in this study was 24.6 kg/m² [17, 20]. The dosage and administration time of ICG vary across studies; however, recent research recommends a dosage of 2.5 mg administered 30-60 minutes prior to surgery, which was applied in this study [12, 21].

Furthermore, future health care practice should integrate the emerging trend of ICG cholangiography, particularly for resident trainees and surgeons with limited experience in laparoscopic cholecystectomy. This technique enhances the surgeon's proficiency and confidence in dissecting critical structures within Calot's triangle, potentially improving outcomes, reducing bile duct injuries, and enhancing patient safety.

5. Conclusions

Indocyanine green (ICG) fluorescence cholangiography achieves a high visibility rate of the common bile duct, even in the presence of inflammation in the gallbladder and biliary tree. The findings indicate that combining CVS and ICG fluorescence cholangiography may enhance outcomes, especially in patients with inflammation, previous ERCP, and multiple diagnoses. These methods ought to be regarded as standard practice in surgical training and healthcare to improve patient safety.

Supplementary Materials: The following supporting information can be downloaded at: www.mdpi.com/xxx/s1. Figure S1: Illustration of biliary structure anatomy using Indocyanine Green Fluorescence Cholangiography during laparoscopic cholecystectomy. (Abbreviations: CBD = Common bule duct, CHD = Common hepatic duct, IHD = Intrahepatic bile duct). Table S1: Characteristics of patients. Table S2: Details of the surgical procedure, outcomes, and pathological findings. Table S3: Comparison of clinical parameters among patient groups based on their ability to achieve the Critical View of Safety. Table S4: Multivariate logistic regression analysis of clinical parameters influencing the success and failure in achieving the Critical View of Safety. Table S5: Anatomical visualization rate of the biliary tract demonstrated by Indocyanine Green Fluorescence Cholangiography.

Author Contributions: Thawatchai Tullavardhana was responsible for the study design, conceptualization, methodology, data acquisition, data analysis and interpretation, and manuscript writing, review and editing. Anuwat Chartkitchareon was responsible for study design, methodology, data collection and analysis, and preparation of the manuscript. All authors have read and agreed to the published version of the manuscript.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved institutional ethics committee of Srinakharinwirot University (Ethics code: SWUEC-673036) and Thai Clinical Trials Registry (Identification number: TCTR20241110010).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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Data Availability Statement: The data presented in this study are available on request from the corresponding author due to due to privacy or ethical restrictions. The patient's data was collected in compliance with the Standards for the Protection of Personally Identifiable Health Information.

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Conflicts of Interest: The authors declare no conflicts of interest.

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