Prospective Cohort Study

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The role of fluorescent cholangiography to improve operative safety in different severity degrees of acute cholecystitis during emergency laparoscopic cholecystectomy: a prospective cohort study

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Background: Currently, there is limited scientific evidence regarding the effectiveness of fluorescent cholangiography in emergency cholecystectomy for acute cholecystitis. The primary aim of this study was to assess the efficacy of near-infrared fluorescent cholangiography (NIRF-C) in different severity degrees of acute cholecystitis.

Materials and methods: Inclusion criteria were patients with a clinical and radiological (abdominal ultrasound and/or computed tomography) diagnosis of acute cholecystitis based on the revised 2018 Tokyo guidelines who underwent laparoscopic cholecystectomy within 24–72 h from the onset of symptoms and patients with ASA score of 0–3. NIRF-C was performed at three-time points during laparoscopic cholecystectomy: (i) following exposure of Calot's triangle, prior to any dissection; (ii) after partial dissection of Calot's triangle; and (iii) after complete dissection of Calot's triangle. The intraoperative severity degree of acute cholecystitis was assessed according to the American Association of Surgery for Trauma (AAST) classification.

Results: NIRF-C was successfully performed in all 81 consecutive patients who underwent emergency laparoscopic cholecystectomy. The cystic duct was identified by NIRF-C in 46 (56.8%) and 77 (95.1%) of the 81 patients before and after Calot's dissection, respectively. The common hepatic duct and common bile duct were successfully identified in 11 (13.6%) and 32 patients (39.5%) before Calot's dissection, respectively, and in 45 (55.6%) and 76 patients (93.8%) after complete Calot's dissection, respectively. When comparing the visualization rate of biliary structures before and after Calot dissection in different severity degrees of cholecystitis, the authors found a statistically significant difference in nongangrenous (AAST I) versus gangrenous and complicated forms (AAST II–V) for all biliary structures, both before and after Calot's dissection.

Conclusions: The study indicates that the use of fluorescence cholangiography during emergency laparoscopic cholecystectomy for acute cholecystitis may represent a valuable and useful tool for intraoperative visualization of the extrahepatic biliary tract.

Keywords: acute cholecystitis, fluorescent cholangiography, gangrenous cholecystitis, indocyanine green, laparoscopic cholecystectomy, operative safety

Introduction

Laparoscopic cholecystectomy (LC) is one of the most frequently performed general surgical procedures worldwide. Iatrogenic injuries of the biliary tract represent a serious and fearsome complication, leading to a significant increase in morbidity and mortality, healthcare costs, and medical-legal consequences[1–3].

HIGHLIGHTS

- The use of fluorescence cholangiography during emergency laparoscopic cholecystectomy for acute cholecystitis may represent a valuable tool for intraoperative visualization of the extrahepatic biliary tract and to enhance the operative safety during dissection.
- Preliminary dissection of the hepatocystic triangle is often necessary for the correct identification of the extrahepatic biliary anatomy, especially in cases of acute gangrenous cholecystitis.
- The visualization rate of the biliary tree was higher in nongangrenous cholecystitis (AAST I) than in gangrenous and complicated cholecystitis (AAST II–V).

In the majority of cases, iatrogenic injuries of the biliary tract are linked to a distorted perception of extrahepatic biliary anatomy, regardless of the surgeon's experience or age[4]. Since laparoscopic cholecystectomy became the 'gold standard' for treating symptomatic gallstone disease and acute cholecystitis, the incidence of iatrogenic biliary tract injuries has increased exponentially. The incidence rate of major biliary injuries ranges between 0.25 and 1%, according to the latest literature data[4]. Early

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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laparoscopic cholecystectomy represents the gold standard for patients with mild (grade I) and moderate (grade II) acute cholecystitis who do not respond to initial conservative treatment, if performed within 24–72 h of symptom onset according to the 2018 Tokyo Guidelines (TG18)[5]. One of the latest innovations in minimally invasive technology is fluorescence image guided-surgery. The effectiveness of near-infrared fluorescent cholangiography (NIRF-C) has been confirmed in several studies in elective surgery[6,7]. Fluorescent cholangiography can be quite challenging in an emergency setting, as inflammation and adhesions around the hepatoduodenal ligament can hinder the identification of biliary elements during dissection. Achieving the so-called 'critical view of safety' (CVS) can be particularly difficult in such situations. Currently, there is limited scientific evidence regarding the effectiveness of fluorescent cholangiography in emergency cholecystectomy for acute cholecystitis[7]. The TG18 represents a validated method to assess cholecystitis severity, but the variables are multifactorial. The American Association for the Surgery of Trauma (AAST) developed an anatomically based severity grading system for surgical diseases, including cholecystitis[8,9].

The primary aim of this study was to evaluate the efficacy of NIRF-C for real-time visualization of the biliary tree in emergency laparoscopic cholecystectomy before and after hepatocystic triangle dissection and in different degrees of severity of acute cholecystitis according to the AAST classification, specifically distinguishing between nongangrenous (grade I) and gangrenous or complicated (grades II–V) forms. The secondary outcomes were: conversion rate, bail-out procedures (such as subtotal cholecystectomy and antegrade cholecystectomy), iatrogenic bile duct lesions, duration of surgery, postoperative complications within 30 days; length of hospital stay; and mortality at 30 days.

Materials and methods

From January 2023 to May 2024 81 consecutive emergency laparoscopic cholecystectomies were performed by using fluorescent cholangiography. All data regarding patients who underwent LC with fluorescence imaging were collected and entered into a specific database. Data included patients' characteristics, intraoperative findings, and postoperative outcomes. All patients included in the study signed a written informed consent before surgery. Inclusion criteria were patients aged > 18 years old with a clinical and radiological (abdominal ultrasound and/or computed tomography) diagnosis of acute cholecystitis based on the revised TG18 who underwent laparoscopic cholecystectomy within 24–72 hours from the onset of symptoms and patients fit for surgery (American Society of Anesthesiologists: ASA score 0–3). The main exclusion criteria were as follows: a) patients with a known allergy to indocyanine green, b) ASA score 4–5, c) patients deemed nonoperable via laparoscopic approach due to high cardio-respiratory risk, d) previous surgical interventions on the biliary tract, e) history of liver cirrhosis or severe liver disease, and f) ongoing pregnancy or breastfeeding. All the operations were performed by the same team of surgeons. Patients with a diagnosis of associated choledocolithiasis underwent endoscopic retrograde cholangio-pancreatography (ERCP) before sequential laparoscopic cholecystectomy within 48–72 h. Laparoscopic cholecystectomy was performed by using a four-ports French approach. For intraoperative fluorescent cholangiography, 2.5 mg indocyanine green (ICG, Pulsion Medical Inc.) was administered intravenously 45–60 min prior to surgery, according to the recent guidelines from the International Society for Fluorescence Guided Surgery (ISFGS) and the latest consensus conference published in 2021[10]. Near-infrared fluorescent cholangiography was performed by using Stryker's fluorescence imaging system (Stryker, Portage): the systems has a 10 mm laparoscope, a camera head, a xenon light guide cable, a video processor/illuminator, and a high-definition monitor. The charge-coupled device camera and the xenon light source could filter out light with wavelengths below 810 nm and above 800 mm. The laparoscope was able to transmit near-infrared

Table 1

Preoperative characteristics.

Total number of enrolled patients	81
Mean age ± SD (years old)	66.2 ± 17.5 years (range 27–93)
Male sex	49.4% (M/F: 40/41)
BMI (kg/m^2) *n* (%)	26.3 ± 3.5 (range 16.2–40.1)
< 25	25 (30.9)
≥ 25	56 (69.1)
ASA score *n* (%)	
I	10 (12.3)
II	34 (41.9)
III	35 (43.2)
IV	2 (2.5)
Previous MRI-cholangio *n* (%)	19 (23.5)
Preoperative ERCP n (%)	9 (11.1)
Previous acute cholecystitis *n* (%)	28 (34.6)
With associate acute lithiasic pancreatitis	10 (12.3)
Grade of severity – Tokyo guidelines *n* (%)	
I	38 (46.9)
II	38 (46.9)
III	5 (6.1)
First surgeon *n* (%)	
Young	25 (30.9)
Senior	56 (69.1)

ASA, American Society of Anesthesiologists; ERCP, endoscopic retrograde cholangio-pancreatography.

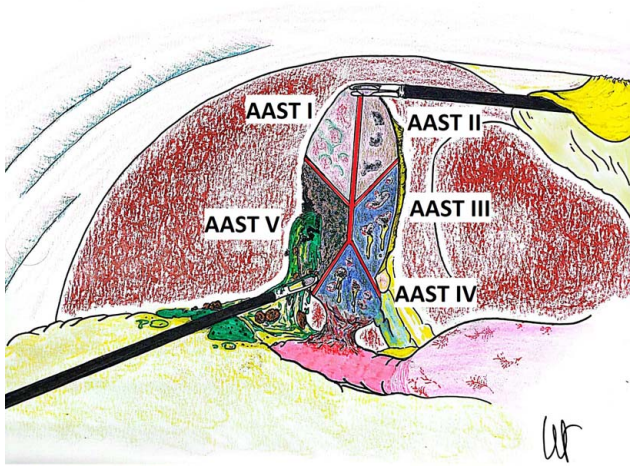

Figure 1. Graphical representation of different severity degrees of acute cholecystitis according to AAST classification. AAST I, localized inflammatory changes; AAST II, distended gallbladder with pus, nonperforated wall necrosis areas; AAST III, gallbladder wall microperforation with bile limited to a right upper quadrant; AAST IV, pericolecystic abscess, bilio-enteric fistula; AAST V, diffuse biliary peritonitis.

light, allowing images to be switched from full color to fluorescence images. NIRF-C was performed at three defined time points 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[11,12]. When possible, a critical view of safety was reached correctly, by also reviewing surgical records. Each surgeon, at the end of the procedure, completed a form where all patients' data and intraoperative features have been carefully reported. To evaluate postoperative complications, the Clavien–Dindo classification has been used as a combined measure of morbidity and mortality[13]. Additionally, a survey assessing the usefulness of fluorescent cholangiography in emergency laparoscopic cholecystectomy was conducted using a Likert scale. After each procedure, surgeons were asked four specific questions regarding how the technique influenced their visualization of anatomical structures and their perception of the benefits of the device. The study protocol was approved by the local Ethical Committee and was performed in accordance with the Declaration of Helsinki guidelines. This study is reported following the Strengthening The Reporting Of Cohort Studies in Surgery (STROCSS) guidelines[14].

Table 2

Intraoperative variables.

AAST score (range I–IV) *n* (%)	
I	54 (66.6)
II	8 (9.9)
III	12 (14.8)
IV	6 (7.4)
V	1 (1.2)
Identification of biliary stuctures before Calot's dissection *n* (%)	
CD	46 (56.8)
CHD	11 (13.6)
CBD	45 (55.6)
Identification of biliary structures after Calot's dissection *n* (%)	
CD	77 (95.1)
CHD	32 (39.5)
CBD	76 (93.8)
Conversion rate *n* (%)	0 (0)
Intraoperative complications *n* (%)	6 (7.4)
Gallbladder bed bleeding	4 (4.9)
Infundibulum-cystic duct junction perforation	2 (2.4)
Biliary anomalies *n* (%)	8 (9.9)
Short cystic duct	3 (3.7)
Parallel course of the cystic duct with low insertion	2 (2.5)
Spiraliform course of the cystic duct	2 (2.5)
Hepatocystic duct (right postero-lateral hepatic duct joining cystic duct)	1 (1.2)
Vascular anomalies *n* (%)	
Caterpillar hump right hepatic artery	1 (1.2)
Bail-out surgery *n* (%)	4 (4.9)
Antegrade cholecystectomy	3 (3.7)
Subtotal cholecystectomy reconstituting technique	1 (1.2)
Bile duct injuries *n* (%)	4 (4.9)
Minor lesions (three Luschka leaks, one cystic duct leak)	4 (4.9)
Major lesions	0 (0)
Abdominal drain *n* (%)	51 (62.9)
Mean operative time ± SD (minutes)	104.7 ± 44.2 min (range 45–310 min)

AAST, American Association of Surgery for Trauma; CBD, common bile duct; CD, cystic duct; CHD, common hepatic duct.

Statistical analysis

All collected data were included in a study-specific database and analyzed using MedCalc 20.011 (Ostend, Belgium). Descriptive statistics were used to characterize the population, including proportions, medians, means ± SDs, and ranges. The two-tailed χ^2 test was used for the statistical comparison of proportions. The χ^2 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 common bile duct (CBD)] before and after Calot's dissection in all patients. Comparisons of the proportion of successful FC visualization of the biliary tree were performed by comparing the different degrees of acute cholecystitis according to the intraoperative AAST classification. A P-value < 0.05 was considered statistically significant.

Results

NIRF-C was successfully performed on all 81 consecutive patients undergoing emergency laparoscopic cholecystectomy. Baseline characteristics are reported in Table 1. The mean age of the patients was 66.2 years, with a male predominance of 49.4%. We did not encounter any specific allergic reactions to ICG dye in our study. However, it is known that mild to moderate-severe allergic reactions to ICG can occur, including flushing, itching, swelling, angioedema, and, in rare cases, anaphylactic shock[6]. After administering ICG, patients are typically monitored closely for any signs of allergic reactions or other potential side effects, particularly in the first few minutes when such reactions are most likely to occur. The cystic duct (CD) was identified by NIRF-C in 46 (56.8%) and 77 (95.1%) of the 81 patients before and after

Table 3

Postoperative outcomes.

Mean hospital stay ± SD (days)	7.3 ± 5.5 (range 1–22)
Clavien–Dindo complications (30-days) *n* (%)	26 (32.0)
Grade I	5 (6.1)
Grade II	12 (14.8)
Grade IIIa	5 (6.1)
Grade IIIb	2 (2.5)
Grade IVa	1 (1.2)
Grade IVb	0 (0)
Grade V	1 (1.2)
Reoperation *n* (%)	3 (3.7)
Surgical revision for subhepatic collections	2 (2.5)
Surgery for complicated incisional hernia	1 (1.2)
Percutaneous drainage *n* (%)	3 (3.7)
Mortality (30-days) *n* (%)	1 (1.2)
Pathological report *n* (%)	
Acute necrotic cholecystitis	24 (22.7)
Acute purulent cholecystitis	4 (4.9)
Acute and chronic cholecystitis	8 (11.4)
Chronic cholecystitis	35 (40.9)
Chronic cholecystitis with riacutization	5 (6.1)
Chronic sclero-atrofic cholecystitis	1 (1.2)
Erosive cholecystitis	3 (3.7)
Follicolar gallbladder lymphoma	1 (1.2)

Calot's dissection, respectively. The common hepatic duct (CHD) and the common bile duct (CBD) were successfully identified in 11 (13.6%) and 32 (39.5%) patients before Calot's dissection, respectively, and in 45 (55.6%) and 76 (93.8%) patients after complete Calot's dissection, respectively.

Regarding the intraoperative grading of acute cholecystitis severity, AAST grade I was found in 54 patients (66.6%), followed by AAST II, III, IV, and V in 9.9%, 14.8%, 7.4%, and 1.2% of patients, respectively. Figure 1 presents a graphical representation of the different severity degrees of acute cholecystitis based on the AAST classification. The intraoperative variables and postoperative outcomes are summarized in Tables 2 and 3, respectively. Some examples of intraoperative real-time NIRF-C images during emergency laparoscopic cholecystectomy are displayed in Figures 2–4.

The preliminary dissection of Calot's triangle increased the visualization rate of all extrahepatic biliary structures, as shown in Table 4. When comparing the visualization rate of biliary structures

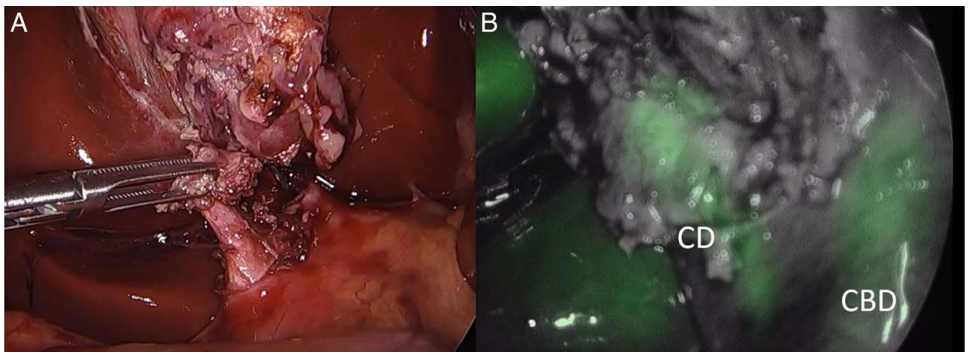

Figure 2. Intraoperative visualization of a malacic and inflamed cystic duct (CD), inadvertently sectioned during dissection (A) and visualized by fluorescence (B).

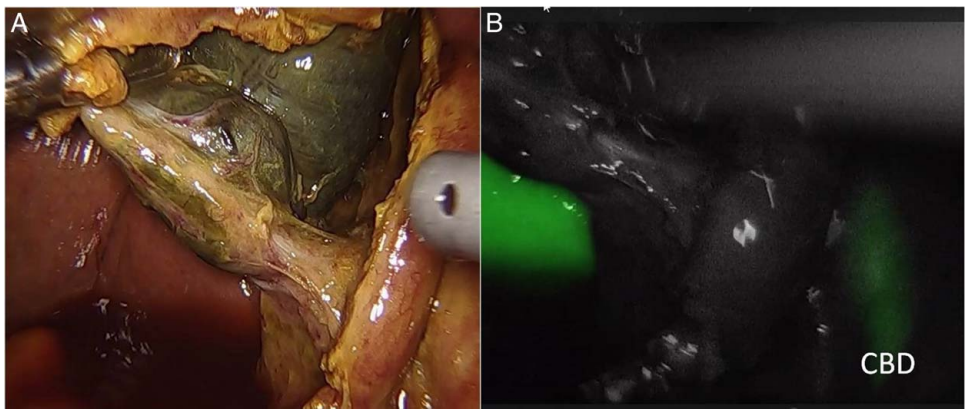

Figure 3. Acute necrotic cholecystitis (A) with an excluded cystic duct and intraoperative visualization of CBD by fluorescence (B).

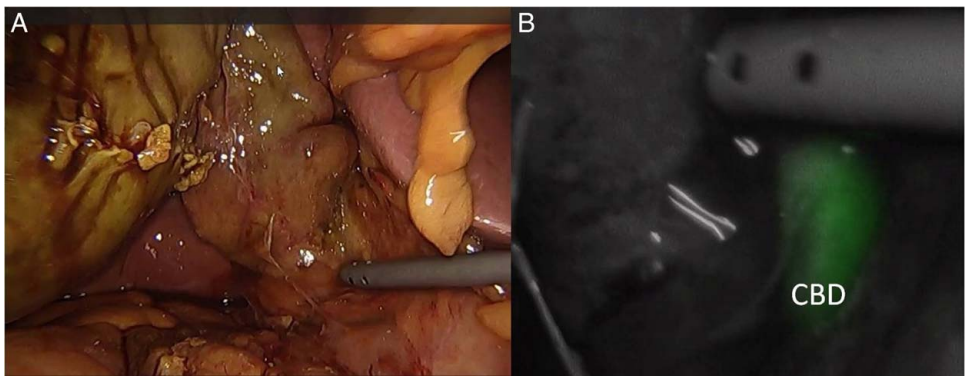

Figure 4. Acute necrotic cholecystitis (A) with intraoperative visualization of CBD by fluorescence before hepatocystic dissection (B).

Table 4

Biliary structures visualization before and after Calot's dissection.

	Before Calot's dissection	After Calot's dissection	*P*
CD	46 (56.8%)	77 (95.1%)	0.005
CHD	11 (13.6%)	32 (39.5%)	0.001
CBD	45 (55.6%)	76 (93.8%)	0.004

Table 5

Visualization of biliary structures before and after Calot dissection in different severity degrees of cholecystitis distinguishing nongangrenous (AAST I) from gangrenous and complicated forms (AAST II–V).

	AAST I (tot 54)	AAST II–V (tot 27)	*P*
Before Calot's dissection			
CD	37 (68.5%)	9 (33.3%)	< 0.001
CHD	11 (20.4%)	0	0.004
CBD	38 (70.4%)	7 (25.9%)	< 0.001
After Calot's dissection			
CD	52 (96.3%)	25 (92.6%)	0.002
CHD	28 (51.9%)	4 (14.8%)	< 0.001
CBD	53 (98.1%)	24 (85.2%)	0.005

before and after Calot's dissection in different severity degrees of cholecystitis, we found a statistically significant difference in nongangrenous forms (AAST I) versus gangrenous and complicated forms (AAST II–V) for all biliary structures (CD, CHD, and CBD), both before and after Calot's dissection, as shown in Table 5. Figure 5 summarizes the feedback from the surgeons involved, showing a general consensus in favor of this method.

Discussion

This is the first study focusing on the utility of ICG in different severity degrees of acute cholecystitis. The correct identification and comprehension of extrahepatic biliary anatomy in difficult cholecystectomies represent a significant challenge for every surgeon in clinical practice. Laparoscopic cholecystectomy is often considered a straightforward surgical procedure in elective settings, but it should be emphasized that in emergency situations, it should be defined as an advanced laparoscopic procedure. Each cholecystectomy may present pitfalls, and any efforts toward reducing the risk profile of difficult cholecystectomies are highly appreciated. The usefulness of intraoperative fluorescent cholangiography has been confirmed in various studies on elective laparoscopic cholecystectomies, and its importance in the surgical training of young surgeons is well-documented[15–21]. However, there is little scientific evidence about its real efficacy in emergency settings, where some intraoperative scenarios could benefit from a useful tool during dissection.

In 2021, we performed an up-to-date overview regarding the application of NIRF-C in clinical practice, including acute cholecystitis[7]. We only found five studies providing data on the use of fluorescent cholangiography in patients who underwent laparoscopic cholecystectomy for acute cholecystitis. These included two cohort studies, one international European registry, and one randomized controlled trial (RCT) including elective and emergency cholecystectomies[7].

To date, there is only one single-center randomized controlled trial, published in 2022, focusing on the use of ICG in acute cholecystitis[22]. In this study, the authors did not find any statistically significant differences in terms of conversion and complication rates[22]. However, they concluded that ICG fluorescence imaging might be helpful in some difficult cholecystectomies and may be used as an adjunct. Recently, a Spanish group published a trial protocol called ENDURG, a multicenter randomized controlled study with the primary objective of determining whether the use of indocyanine green is associated with a reduction in operating time in emergency laparoscopic cholecystectomies[23]. In a recent web-based international survey (ARIES study) concerning the attitudes and practices of emergency surgeons regarding the use of indocyanine green (ICG) in emergency settings, 72.9% of emergency surgeons declared that difficult cholecystectomy could benefit from the use of ICG to support their intraoperative decision-making[24].

Losurdo *et al.*[25], in a propensity score-matched study, showed a shorter operative time in the NIRF-C group compared to the

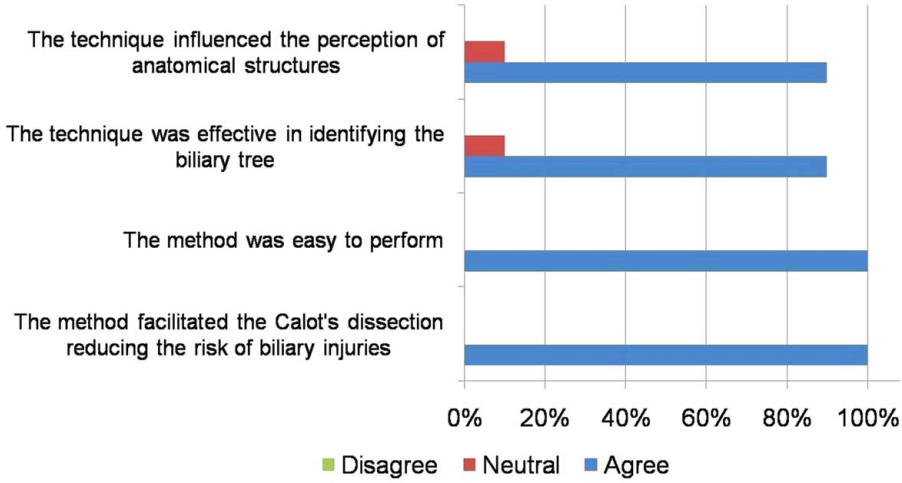

Figure 5. A survey assessing the usefulness of fluorescent cholangiography in emergency laparoscopic cholecystectomy was conducted using a Likert scale.

conventional group. Piccolo *et al*.[26] analyzed the efficacy of NIRF-C in specific settings of difficult cholecystectomies and the rates of correct identification of the cystic duct (CD) and common bile duct (CBD) in the subset of patients with acute cholecystitits were 87.9% and 75.8%, respectively.

The current experience at a single institution confirmed the feasibility of this novel approach during emergency laparoscopic cholecystectomy. The results of this prospective study highlight that preliminary Calot's dissection is an important factor, resulting in an overall increase in the identification of the biliary system, particularly the common bile duct. Although the identification of the cystic duct is not always possible, especially in cases of cystic exclusion, NIRF-C allows visualization of the common bile duct and ensures that the dissection remains safely away from critical structures in the Mc Elmoyle danger zone. In this regard, the technology may enhance operative safety during dissection.

Another important result of the current series is that the visualization of the biliary tree was higher in nongangrenous cholecystitis (AAST I) than in gangrenous cholecystitis (AAST II–V). In necrotic cholecystitis, inflammation may extend to the gallbladder infundibulum-cystic duct junction, and the thickening and adhesions of the hepatoduodenal ligament could hinder the correct visualization of biliary structures by fluorescence, especially before dissection. Even though the preliminary dissection of the hepatocystic triangle increases the ability to visualize the biliary tract, the presence of gangrene, wall perforation with bile in the upper right quadrant, and pericholecystic abscess typical of AAST grades II–IV can make the identification of biliary structures more difficult.

However, NIRF-C may represent an important guide and useful tool in identifying biliary structures in a highly complex and inflamed environment, helping to avoid injury to critical structures. We hope that recent technological advances may overcome the obstacle of visualizing inflamed and thick tissues. However, we firmly believe that we are headed in the right direction. The method is here, and fluorescent cholangiography may become the gold standard for all cholecystectomies.

In this preliminary series, no conversion rates were encountered, and the need for bail-out procedures during surgery was limited to four patients (4.9%), confirming the usefulness of NIRF-C in improving operative safety. In 2021, Turcotte *et al*.[27] reported a need for bail-out surgery in 6.7% of the ICG group compared to 4.3% in the non-ICG group, with no statistically significant differences between the two groups. Regarding biliary injuries, no major biliary lesions were reported in the current series. The mean operative time was ~104 min, which aligns with other literature data ranging from 89 to 149.5 min[28,29].

The main limitations of this study are the single-center preliminary experience and the relatively small sample size. However, an important strength is that the same team of surgeons used the same equipment throughout the study, with the same dose and dosing time before surgery.

Conclusions

The study indicates that the use of fluorescence cholangiography during emergency laparoscopic cholecystectomy for acute cholecystitis may represent a valuable and useful tool for intraoperative visualization of the extrahepatic biliary tract. Preliminary dissection of the hepatocystic triangle is often necessary for the correct identification of the extrahepatic biliary anatomy, especially in cases of acute gangrenous cholecystitis. Further randomized controlled studies are needed to confirm the validity and effectiveness of this method in emergency settings.

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Ethical approval

The study protocol (ID:) was approved by the local Ethical Committee (*Comitato Etico Area Vasta Emilia Centro*– CE-AVEC) with ID 1032/2021/Oss/AUSLFe and was performed in accordance with the Declaration of Helsinki guidelines.

Consent

All patients included in the study signed a written informed consent before surgery.

Source of funding

Not applicable.

Author contribution

A.P., N.F., and C.F.: study concept and design, writing the paper, validation, and supervision; A.P., N.F., and L.B.: study concept, data collection and curation, data analysis, and interpretation; NF: drawing of AAST classification in acute cholecystitits; A.P. and C.F.: data analysis and interpretation.

Conflicts of interest disclosure

The authors declare no conflicts of interest.

Research registration unique identifying number (UIN)

1. Name of the registry: ClinicalTrials.gov.
2. Unique identifying number or registration ID: NCT06573021.
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://clinicaltrials.gov/study/NCT06573021

Guarantor

All authors.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

Provenance and peer review

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