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RESEARCH

Utility of near infrared fluorescent cholangiography in detecting biliary structures during challenging minimally invasive cholecystectomy

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Abstract

Background Surgeons can minimize the risk of bile duct injury (BDI) during challenging mini-invasive cholecystectomy through technical standardization by means of a precise anatomical landmark identification (Critical View of Safety) and advanced technology for biliary visualization. Among these systems, the adoption of magnified stereoscopic 3-dimensional view provided by robotic platforms and near infrared fluorescent cholangiography (NIRF-C) is the most promising.

Methods In this prospective cohort study, we evaluated all consecutive minimally invasive cholecystectomies (laparoscopic and robotic) performed with NIRF-C between May 2022 and January 2023 at General Surgery Unit, Department of Health Sciences, University of Milan, San Paolo Hospital (Milan, Italy). Inclusions criteria were as follows: (1) acute cholecystitis (emergency group), (2) history of chronic cholecystitis or complicated cholelithiasis (deferred urgent group), (3) difficult cases (patients affected by cirrhosis, with scleroatrophic gallbladder or BMI > 35 kg/m^2). For each group, the detection rate and visualization order of the main biliary structures were reported (cystic duct, CD; common hepatic duct, CHD; common bile duct, CBD; and CD-CHD junction).

Results A total of 101 consecutive patients were enrolled, including 83 laparoscopic and 18 robotic cholecystectomies. All patients were stratified into three subgroups: (a) emergency group ($n = 33$, 32.7%), (b) deferred urgent group ($n = 46$, 45.5%), (c) difficult group ($n = 22$, 21.8%). Visualization of at least one biliary structure was possible in 94.1% of cases (95/101). Interestingly, all four main structures were detected in 43.6% of cases (44/101). The CD was the structure identified most frequently, being recognized in 91/101 patients (90.1%), followed by CBD (83.2%), CHD (62.4%), and CD-CHD junction (52.5%). In the subset of patients that underwent emergency surgery for AC, the CD-CHD confluence was identified in only 45.5% of cases. However, early and precise identification of CBD (75.8%) and CD (87.9%) allowed safe isolation, clipping, and transection of the cystic duct. In the deferred urgent group, the CBD and the CD were easily identified as first structure in a high percentage of cases (65.2% and 41.3% respectively), whereas the CD-CHD junction was the third structure to be identified in 67.4% of cases, the highest value among the three subgroups. In the difficult group, NIRF-C did not prove to be a useful tool for biliary visualization. The rates of failure of visualization were elevated: CBD (27.3%), CD (18.2%), CHD (54.5%), and CD-CHD (68.2%).

Conclusions NIRF-C is a powerful real-time diagnostic tool to detect CBD and CD during minimally invasive cholecystectomy, especially when inflammation due to acute or chronic cholecystitis subverted the anatomy of the hepatoduodenal ligament.

Keywords Near-infrared fluorescent cholangiography · Minimally invasive cholecystectomy · Acute cholecystitis · Chronic cholecystitis · Complicated cholelithiasis

Introduction

Minimally invasive cholecystectomy provides a clear advantage over open approach in terms of decreased postoperative wound pain, shorter hospital stay, and faster recovery.

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However, surgical technique improvement did not demonstrate a reduction in serious complications such as bile duct injury (BDI), which is reported to occur in 0.7–1.5% of laparoscopic cholecystectomies (LC) [1, 2].

The high incidence of BDI was firstly considered to be consequent to the learning curve of the young surgeon who usually performs LCs; however, further studies displayed that BDI correlates more with the precision of surgical dissection rather than the number of LCs performed [3–5].

The incidence of BDI is increased in peculiar conditions such as in the presence of unexpected biliary anomalies or in challenging surgical cases, such as patients affected by acute cholecystitis, patients with high body mass index (BMI) or with cirrhosis [6, 7].

During LC, the surgeon must correctly identify both the structures to resect (cystic duct and artery) and those to preserve (common hepatic and bile duct). The choice is based only on two-dimensional (2D) view, in the absence of tactile feedback.

Standardization of the technique with the introduction of a precise anatomical landmark identification, i.e., the Critical View of Safety, along with advancement of surgical technology for biliary visualization, have proved to be of great value to minimize errors during laparoscopic cholecystectomy [8–13].

Among these systems, the adoption of magnified stereoscopic 3-dimensional view provided by robotic platforms and near-infrared fluorescent cholangiography (NIRF-C) is the most promising.

In this prospective cohort study, we evaluated the efficacy of NIRF-C during laparoscopic and robotic cholecystectomy in challenging surgical cases with impaired visualization of the biliary anatomy.

Material and methods

This study is reported following the STROBE statement for cohort studies [14].

Study population

In this prospective cohort study, we evaluated all challenging minimally invasive cholecystectomies (laparoscopic and robotic) performed with NIRF-C between May 2022 and January 2023 at the General Surgery Unit, Department of Health Sciences, University of Milan, San Paolo Hospital (Milan, Italy). Inclusion criteria were as follows: (1) acute cholecystitis; (2) history of chronic cholecystitis or complicated cholelithiasis (mild acute biliary pancreatitis or gallstones in the common bile duct with successful endoscopic retrograde cholangiopancreatography, ERCP); (3) difficult cases (patients affected by cirrhosis or with BMI > 35 kg/m^2). Exclusion criteria were as follows: (1) preoperative suspect of gallbladder cancer; (2) history of previous abdominal surgery (i.e. presence of adhesions). Data were prospectively collected in a surgical database.

The primary aim of the study was to report the efficacy of NIRF-C in detecting the following bile duct structures: cystic duct (CD), common hepatic duct (CHD), common bile duct (CBD), and CD-CHD junction. All patients were stratified into three subsets according to the setting of surgery: (A) emergency surgery; (B) deferred urgent surgery; (C) difficult cholecystectomy.

For each group, the detection rate and visualization order of the biliary structures was reported. The secondary aim was to report the surgical outcomes.

Preoperative management

The diagnosis of acute cholecystitis (AC) was based on the evidence of clinical, laboratory, and radiological findings. An abdominal ultrasound was performed in all patients. The severity of AC was graded according to the revised 2018 Tokyo Guidelines (TG-18) [15].

Patients with mild (grade I) and moderate (grade II) acute cholecystitis, within 96 hours from the onset of symptoms, were subjected to urgent laparoscopic cholecystectomy. Patients with suspected common bile duct stones underwent magnetic resonance cholangiopancreatography (MRCP) and, in case of positivity, subsequent ERCP. If no complications ensued after the procedure, minimally invasive cholecystectomy was planned. Patients with mild acute biliary pancreatitis and concomitant microlithiasis of gallbladder underwent cholecystectomy during the same hospital admission.

Ethics

This study was conducted in accordance with the Declaration of Helsinki (6th revision, 2008) of the World Medical Association. The study was approved by our Institutional Research Board and informed consent for all surgical procedures was obtained from each patient.

Surgical technique

All surgeries, laparoscopic and robotic, were performed by two surgeons with expertise in hepatobiliary surgery (GP and PPB). The approach was decided based on medical indication, patient opinion, and surgical cost evaluation. All patients received extensive explanation of the advantages and disadvantages of both approaches. Cholecystectomies were performed according to the principle of the Critical View of Safety [8]. All LCs were performed with a 4 K magnified ultra-high-definition video system capable

of near infrared (NIR) vision (IMAGE1 S™ RUBINA™, Karl Storz, Tuttlingen, Germany). All robotic cholecystectomies (RC) were performed with the Da Vinci Xi Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA).

Near infrared fluorescent cholangiography technique

An intravenous bolus of indocyanine green (ICG) dye at a dose of 0.5 mg/kg of body weight was administered 24 hours before surgery in non-urgent cases. In emergency setting, a reduced bolus of ICG dye (0.2 mg/kg) was injected 2 hours before surgery.

NIRF-C was evaluated through the 4 K cameras for LCs and the Firefly™ (Fluorescence Imaging Scope; Intuitive Surgical, Inc., Sunnyvale, CA, USA) integrated mode for RCs. The biliary structures were identified before and during dissection of Calot's triangle.

When it was impossible to obtain the Critical View of Safety because the biliary structures were not visualized or not fully visualized during NIRF-C, we adopted a bail out strategy such as partial cholecystectomy, fundus-first approach, or open conversion.

Postoperative outcomes

Postoperative complications, defined as adverse events occurring within 30 days from surgery, were assessed through the Clavien-Dindo classification [16].

Statistical analysis

Patient characteristics were summarized using basic descriptive statistics. Continuous variables were presented as median (min-max) or mean ± standard deviation (SD) accordingly, and compared using the Mann–Whitney *U* test. Categorical variables were expressed as proportions and analyzed using Chi-squared test. Statistical analysis was performed using IBM SPSS Statistics for Macintosh, version 26 (IBM Corp., Armonk, NY, USA). *P* values < 0.05 were considered statistically significant.

Results

Patient characteristics

A total of 101 consecutive patients were enrolled, including 83 LCs and 18 RCs. Female sex was predominant (57.4%). Mean age was 58 years (SD ± 14.4).

Patients were stratified into three groups: (A) *emergency group* ($n = 33$, 32.7%), affected by acute cholecystitis (within 96 hours from the onset of symptoms) treated with emergency cholecystectomy; (B) *deferred urgent group* ($n = 46$, 45.5%), including patients with chronic cholecystitis (long-standing gallbladder inflammation (more than 96 hours) or with more episodes of acute cholecystitis during the last year) or complicated cholelithiasis (common bile duct stones treated with ERCP or mild acute biliary pancreatitis); (C) *difficult group* ($n = 22$, 21.8%), with patients with concomitant cirrhosis, scleroatrophic gallbladder, or with BMI > 35 kg/m^2 (Table 1).

NIRF-C biliary structure identification

NIRF-C allowed identifying four distinct structures of the biliary tree: CD, CHD, CBD, and CD-CHD junction. Visualization of at least one biliary structure was possible in 94.1% of cases (95/101). All four main structures were detected in 43.6% of cases (44/101). CD was the structure identified most frequently, being recognized in 91/101 patients (90.1%), followed by CBD (83.2%), CHD (62.4%), and CD-CHD junction (52.5%). The visualization order of the single biliary structures was also reported. CBD was recognized as first structure in 50% of cases. CD was most commonly identified as first or second structure, in 32.5% and 58.8% of cases, respectively. CD-CHD junction and CHD were identified later (most commonly as third or fourth structure), after preliminary dissection of Calot's triangle (Table 2).

NIRF-C biliary structure identification: subgroup analysis

The influence of the different surgical setting on the frequency and order of visualization of biliary structures was also analyzed.

Table 1 Demographical features of patients subjected to cholecystectomy with NIRF-ICG

Variable	*n* (%)
Sex	
Male	43 (42.6%)
Female	58 (57.4%)
Age, years	
Mean (SD)	58.0 (14.4)
Median [min–max]	56.0 [21.0–83.0]
Surgery	
Laparoscopic cholecystectomy	83 (82.2%)
Robotic cholecystectomy	18 (17.8%)
Groups	
(A) Emergency group	33 (32.7%)
(B) Deferred urgent group	46 (45.5%)
(C) Difficult group	22 (21.8%)

SD standard deviation

Table 2 Order of visualization of the distinct structures of the biliary tree through ICG fluorescence

Variable	Order of visualization			
Visualized structure	1°	2°	3°	4°
Common bile duct (CBD)	60 (50.0%)	16 (20.0%)	2 (3.2%)	6 (20.7%)
Cystic duct (CD)	39 (32.5%)	47 (58.7%)	3 (4.8%)	2 (6.9%)
Common hepatic duct (CHD)	4 (4.2%)	4 (5.0%)	29 (46.8%)	15 (51.7%)
CD-CHD junction (CD-CHD)	16 (13.3%)	13 (16.3%)	28 (45.2%)	6 (20.7%)

Table 3 Order of visualization of the distinct structures of the biliary tree through ICG fluorescence

Structure visualized	Setting of surgery			
	Emergency group	Deferred urgent group	Difficult group	*P*-value
Common bile duct (CBD)	25 (75.8%)	43 (93.5%)	16 (72.7%)	0.037
Cystic duct (CD)	29 (87.9%)	44 (95.7%)	18 (81.8%)	0.194
Common hepatic duct (CHD)	20 (60.6%)	33 (71.7%)	10 (45.5%)	0.124
CD-CHD junction (CD-CHD)	15 (45.5%)	31 (67.4%)	7 (31.8%)	0.017

In all groups, the structure most frequently recognized with NIRF-C was the CD with a frequency of 87.9%, 95.7%, and 81.8%, in group A, group B, and group C, respectively; the difference between groups was not statistically significant. In emergency or deferred urgent groups, NIRF-C failed to identify CD only when the gallbladder was excluded, meaning there was a stone within the cystic duct. The CBD was visualized in 75.8%, 93.5%, and 72.7% of cases respectively in the above three groups, representing a landmark to guide surgeons through a safe dissection. A statistically significant increased visualization rate of CBD ($p = 0.037$) and CD-CHD junction ($p = 0.017$) was reported in the deferred urgent group (Group B, Table 3).

Concerning the order of visualization of biliary structures, the CBD was identified as first in all groups, with no statistically significant difference ($p = 0.121$).

For patients who underwent *emergency surgery* for acute cholecystitis, CBD was visualized in 75.8% of cases, and as first structure in 54.5% of cases. CD was visualized as first or second structure in 87.9% of cases. On the other hand, the CD-CHD confluence was identified in only 45.5% of cases.

In the *deferred urgent group*, the CD-CHD was the third structure to be identified in 67.4% of cases, after CBD and CD, more commonly than in the other two subgroups.

In the *difficult group*, the rates of failure of structure visualization were elevated: CBD (27.3%), CD (18.2%), CHD (54.5%), and CD-CHD (68.2%). In this group, there were six cases in which no biliary structures were recognized: two patients were affected by grade III obesity, one patient had HCV-related cirrhosis, and one had a scleroatrophic gallbladder. In the other two cases, ICG failed to identify biliary structures due to technical issues, likely inadequate timing of injection before surgery.

Surgical outcomes

Intraoperative and postoperative data are summarized in Table 4. Mean operative time (OT) was 90.8 min (SD 39.8). Bile duct injury occurred intraoperatively in only one patient during LC for AC (type D, according the Strasberg classification), which required conversion to laparotomy and direct repair of the injury with interrupted sutures (absorbable poliglecaprone 25, 5/0 sutures) and placement of a Kehr's tube.

Table 4 Intraoperative and postoperative features of patients subjected to cholecystectomy with NIRF-ICG

Variable	*n* (%)
Operative time (min)	
Mean (SD)	90.8 (39.8)
Median [min–max]	85.0 [30.0–205.0]
Bile duct injury (BDI)	1/101 (1.0%)
Placement of abdominal drainage	17 (16.8%)
Postoperative length of stay (days)	
Mean (SD)	1.9 (1.9)
Median [min–max]	1.0 [1.0–13.0]
Clavien-Dindo grade	
Grade IIIa	1 (1.0%)
Grade IIIb	1 (1.0%)

SD standard deviation

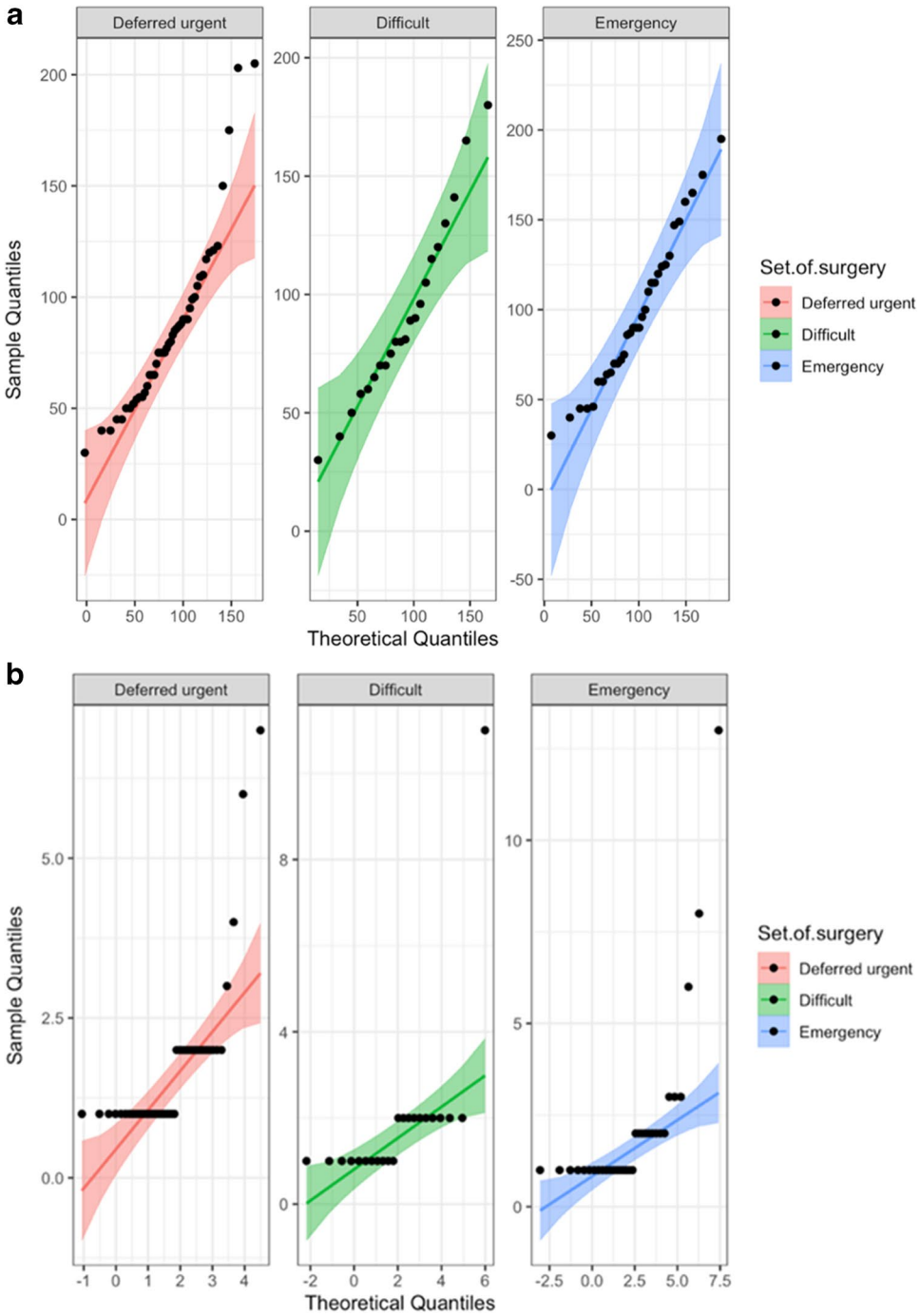

Fig. 1 **a** Q-Q plot for the graphic representation of the distribution quartiles of the duration of surgical intervention. **b** Q-Q plot for the graphic representation of the distribution quartiles of the postoperative hospitalization

An abdominal drain was placed in 17 patients (16.8%) at the end of surgery. Mean postoperative length of stay was 1.91 days (SD 1.89). Comparing the three groups using the Kruskal–Wallis test (Fig. 1a, b), there were no differences in terms of duration of surgery and postoperative hospitalization among the three groups.

Postoperative complications occurred in two cases (1.9%) in the difficult subgroup and were stratified according to the Clavien-Dindo classification, as shown in Table 4. In the first case, on postoperative day 1, a left lobe intrahepatic hematoma with active arterial bleeding was detected and treated with angiographic embolization (grade IIIa). In the second case, a major bleeding from the liver bed was identified and treated with surgical revision and hemostasis (grade IIIb). Post-operative mortality rate was 0%.

Discussion

According to current scientific literature, NIRF-C represents a powerful real-time diagnostic tool for the detection of biliary anatomy during LC. Many reports proved the importance of its routine use in elective LC to decrease BDI and conversion to open surgery [17, 18].

However, there are limited data about its feasibility and usefulness in challenging cases. NIRF-C may be very difficult to perform in an urgent setting, in obese patients (BMI $\geq$ 30 kg/m^2) or in patients affected by cirrhosis. The optimal time of injection and dosage of ICG is still under investigation, with strong variability in literature. Recently, the predominant trend is to adopt a lower and standardized dose of ICG dye. Zarrinpar et al. [19] used a single dose of 0.25 mg/kg administered at least 45 min prior to surgery. Boogerd et al. [20] proposed the injection of a standard dosage of 5 mg of ICG 3 hours before surgery for all patients.

In the present study, an intravenous bolus of ICG dye at a dose of 0.5 mg/kg of body weight was administered 24 hours before surgery in non-urgent cases. In emergency setting, a reduced bolus of ICG dye (0.2 mg/kg) was injected 2 hours before surgery.

Currently, there are few reports on the use of ICG in urgent cholecystectomy, mainly retrospective studies with only two randomized controlled trials [21–25].

Dip et al. [21] compared the efficacy of NIRF-C versus white light alone in patients who underwent LC for AC. The primary objective was the detection rate of biliary structures, both before and after dissection, in each study arm. The authors found that the degree of gallbladder inflammation was the most important variable, affecting detection of CD and CBD before and after dissection respectively, and of the CD-gallbladder junction only after dissection.

In our experience, patients who received *emergency surgery* for AC, CBD was visualized in 75.8% of cases, and as first structure in 54.5% of cases, representing a landmark to guide surgeons through a safe dissection even in emergency setting. CD was visualized as first or second structure in 87.9% of cases. On the other hand, the CD-CHD confluence was identified in only 45.5% of cases. However, this did not have an impact on the surgical outcome, as early and precise identification of CBD and CD allowed safe isolation, clipping, and transection of the CD without biliary injury.

Recently, She et al. [25] reported the results of a single-center radomized controlled trial of the University of Hong Kong. Patients enrolled in the trial were randomized to undergo either conventional LC (conventional arm) or LC with ICG-FC (ICG fluorescence cholangiography arm). The primary aim of the study was to compare the two groups in terms of conversion rate and incidence of BDI. Both groups had the same conversion rate (8.7%). The complication rate and the median hospital stay were also comparable between patients in the ICG group and in the conventional arm: 15.2% vs 10.9%, $p = 0.536$ and 3.5 days vs 4.0 days, $p = 0.380$, respectively. The authors concluded that the routine use of ICG in urgent LC is questionable and hypothesized that NIRF-C should be used as an adjuvant for difficult cholecystectomies to enhance operative safety.

In the present study, there was a single case of BDI during LC for AC which required a conversion to laparotomy and direct repair of the injury and placement of a Kehr's tube. Postoperative complications occurred in two cases (1.9%), and mean postoperative length of stay was 1.9 days (SD 1.9). These results are comparable with the data reported in the literature for conventional white light LC.

Only few authors analyzed the risk of BDI for patients that underwent deferred urgent LC for chronic cholecystitis or complicated cholelithias (acute gallstone pancreatitis, gallstones in the common bile duct previously treated with successful ERCP) [26, 27]. Chronic inflammation, due to an infundibular impacted stone, may lead to adhesions, fibrosis with consequent reduction of the inferior angle of Calot's triangle, shortening of the cystic duct, and finally biliary fusion between the gallbladder neck and the CHD. During LC for chronic cholecystitis, the tissues may become particularly hard to dissect, and the presence of an altered anatomy can lead the laparoscopic surgeon to mistake the CD with the CHD.

In our experience, in the *deferred urgent group*, the CBD and the CD were easily identified as first structure in a high percentage of cases (65.2% and 41.3%), whereas failure of CBD and CD visualization occurred only in 6.5% and 4.3% of cases, respectively. The CD-CHD junction was the third structure to be identified in 67.4% of cases, after CBD and CD, more commonly than in the other two subgroups. In this subgroup, after the preliminary visualization of CBD and CD, NIRF-C allowed to clearly identify all four biliary structures (including CHD and CD-CHD junction) at the end of the dissection of Calot's triangle. We hypothesize that these findings could lead surgeons to easily obtain the Critical View of Safety.

Lastly, in the *difficult subgroup*, there was a high percentage of failure of visualization of all structures. In six cases, no biliary structures were recognized, due to obesity, cirrhosis, or scleroatrophic gallbladder. Obesity represents a limitation for NIRF-C, because NIR light has a penetration capability of only 5 to 10 mm [21–28]. On the other hand, in patients affected by cirrhosis, ICG failed to identify biliary structures due to technical issues, likely inadequate timing of injection before surgery.

Conclusion

NIRF-C is a valid real-time method to detect extrahepatic biliary anatomy in difficult cholecystectomy. There is no considerable scientific evidence supporting the routine use of NIRF-C in emergency surgery. However, NIRF-C is a powerful real-time diagnostic tool to detect CBD and CD during minimally invasive dissection, especially when inflammation due to acute or chronic cholecystitis subverted the anatomy of the hepatoduodenal ligament.

Authors' contributions Conceptualization: GP; methodology: GP; formal analysis and investigation: GP; writing- original draft preparation: GP, GNP, FL; writing — review and editing: GP, GNP, PPB; and supervision: PPB. The authors read and approved the final manuscript.

Data availability All data and materials are contained within the paper.

Declarations

Ethical approval and consent to participate This prospective study was conducted in accordance with the Declaration of Helsinki (6th revision, 2008) of the World Medical Association. The study was approved by our Institutional Research Board, and informed consent for all surgical procedures was obtained from each patient.

Consent for publication This manuscript has been approved by all authors, and we are willing to meet the possible costs of article processing charge (APC) for publication.

Competing interests The authors declare no competing interests.

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