Original Article

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Clinical Evaluation of Intraoperative Indocyanine Green (ICG) Fluorescent Cholangiography During Laparoscopic Cholecystectomy: A Comparative Study

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ABSTRACT

Background: Laparoscopic cholecystectomy (LC) is one of the most common surgical procedures performed globally. While it is generally considered safe, there remains a risk of serious biliary injuries occurring during the procedure. Indocyanine green (ICG) is a water-soluble, non-toxic dye that allows real-time intraoperative visualization of the extrahepatic biliary tree. **Aim**: This study aims to compare the bile duct injury rate, duration of surgery, conversion rate, length of hospitalization, and overall outcomes between laparoscopic cholecystectomy with and without indocyanine green (ICG). **Methods**: Ninety-two patients who underwent LC from October 2023 to October 2024 were included in the study; 42 of them underwent LC with ICG (group 1), and 50 did not receive it (group 2). Both groups were compared regarding intraoperative complications, duration of surgery, conversion rates, length of hospitalization, and overall outcomes. **Results**: The mean total operative time in minutes for group 1 was 44.6 minutes, compared to 51.1 minutes for group 2 (p-value = 0.001). No CBD or cystic duct injuries occurred in any patient in either group. Two patients were converted to open cholecystectomy in group 2, while none were converted in group 1; however, there was no statistically significant difference between the two groups (p-value = 0.174). There was no significant statistical difference in the length of hospital stay between both groups (p-value = 0.08). **Conclusions**: Indocyanine green (ICG) in LC allows for better visualization of the extrahepatic biliary system, leading to a significant reduction in operative time, gallbladder perforation, and bile spillage; however, there is no significant difference in bile duct injury rates, conversion rates to open surgery, or length of hospitalization in the ICG group.

Keywords: Cholecystectomy, ICG, cholangiography.

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INTRODUCTION

Since the German surgeon Erich Muhe performed the first laparoscopic cholecystectomy (LC) in 1985, tremendous progress has been achieved in the following decades in laparoscopic surgery, making laparoscopic cholecystectomy the standard of care in the management of cholelithiasis, biliary dyskinesia, acalculus cholecystitis, and gallbladder neoplasms. More than 750,000 surgeries are performed annually in the

U.S. alone, and laparoscopic cholecystectomy has largely replaced open cholecystectomy due to less postoperative pain, shorter hospital stays, earlier return to normal activities, and better cosmetic results.[1] Although the overall complication rates have declined since then, complications can still occasionally occur, with iatrogenic gallbladder perforation being the most common (5.3%), followed by intra-abdominal bleeding (3.6%), bile duct leaks (1.9%), and surgical wound infections (0.9%). The most serious complication, associated with high mortality rates, is injury to the common bile duct (0.5%) and major vascular injury (0.04%-1%).[2] Bile duct injury is the most dreaded complication following LC, related to mortality rates of up to 3.5%.[2] Considerable morbidity can occur even in minor bile duct injuries due to persistent bile leakage and biliary sepsis, leading to significant impairment in quality of life even after clinically successful treatment, along with a high economic impact of biliary reconstructive surgeries, which can cost 4.5 to 26.0 times more than the uncomplicated procedure.[3]

Risk factors for CBD injury include:

1. Anatomical variations: accessory cystic duct, presence of the duct of Luschka.
2. Patient condition: obesity, previous history of hepatobiliary surgery, chronic liver disease.
3. Gallbladder pathology: acute cholecystitis, Mirizzi syndrome.
4. Surgeon-related factors: surgeon experience.

Multiple approaches and techniques have been implemented to prevent these complications, including the critical view of safety, partial cholecystectomy, fundus-first approach, intraoperative radiological cholangiography, intraoperative ultrasonography, and intraoperative fluorescent study. The critical view of safety (CVS) has a median success rate of 95.8%, but it is not always achievable due to various pathological difficulties, such as adhesion to the gallbladder, empyema, and Mirizzi syndrome.[4] The fundus-first laparoscopic cholecystectomy (FFLC) has a median success rate of 89%.[4] and is indicated in cases of severe adhesions, short cystic duct, or impacted stones in Hartmann's pouch; however, it is noted that more complications occur in FFLC than in conventional laparoscopic cholecystectomy (20% vs. 1.4%, respectively).[5] Laparoscopic subtotal cholecystectomy (LSC) has a median success rate of 90.2%, but it is also associated with an Increased risk of biliary fistula, retained gallstones, and subhepatic or sub phrenic abscess collection.[6] Intraoperative radiological cholangiography has a median success rate of 89%,[4] yet it has not been adopted worldwide in routine LC due to being time-consuming, involving radiation exposure to patients and staff, and requiring additional equipment and maneuvers. One of the techniques developed to reduce the risk of bile duct injury is intraoperative biliary study using indocyanine green (ICG). ICG is a water-soluble fluorescent dye that is rapidly taken up by the liver and excreted into the biliary ducts within minutes of injection. It was first developed during World War II for color imaging and introduced into medicine in 1950. Since ICG levels in the blood are directly related to hepatic function,[7] it has been used as early as 1959 to assess liver function. Recently, with the rapid evolution of robotic technology; ICG has gained broad applications in tumors identification, lymphatic mapping, assessment of organ perfusion, evaluation of anastomosis, and retinal vascular assessment.[7] There are few contraindications for ICG, including known allergies to contrast material, iodine-containing dyes, and pregnancy. Recently, ICG has emerged as a novel technique for intraoperative mapping of the extrahepatic biliary system, likely due to its simplicity and well-known pharmacokinetic and safety profile. Other advantages of ICG include the absence of radiation exposure and the lack of need to create an entrance to the cystic duct or common bile duct (as required in intra operative radiological cholangiography), allowing for better real-time visualization of vital structures like the cystic duct and CBD.[7]

MATERIALS AND METHODS

This is a prospective comparative study conducted in one of the private hospitals in Basrah city during the period from October 1, 2023, to October 1, 2024. Ninety-two patients who underwent laparoscopic cholecystectomy during the study period were included and divided into two groups: group 1 include forty-two patients who received ICG during their laparoscopic cholecystectomy, and group 2 included 50 patients who did not receive ICG during their laparoscopic cholecystectomy. Patients in both groups were matched for age, gender, and BMI, and the surgeries in both groups were performed by the same surgeon. Exclusion criteria included pregnant patients and those allergic to iodide. The Study tools: A data collection form that captured the following aspects: Age, sex, smoking habits, past medical and surgical history, and a detailed drug history were recorded.

Patients' height and weight were measured. Preoperative workup included complete blood counts, liver function tests, and ultrasonography. Informed consent was obtained from all patients, and they were assured of the confidentiality of their information. All patients in both groups underwent classical LC with four-port insertion under general anesthesia. There are two ways to deliver ICG: either intra biliary injection or intravenous injection. In group 1 (patients who received ICG), a total dose of 2.5 mg of ICG was administered intravenously eight hours before surgery. Fluorescence imaging was obtained using the Storz/Rubina® imaging system; ICG emits fluorescence when illuminated with near-infrared light (800-820 nm), causing the extra hepatic biliary structures to glow green against a darker background. The ability to toggle between white light and fluorescence imaging without delay is controlled by a foot pedal. Cholangiography is performed before the cystic duct (CD) is exposed and after the CD is confirmed by dissecting the Calot triangle (Fig. 1-4). Details of the surgery were recorded, including the total operative time, which was recorded from the time of the first incision to the closure of the last incision (T1), the time of cystic duct isolation, clipping, and division (T2), and the time for gallbladder removal from the hepatic fossa (T3). Any intraoperative complications, such as bile duct injury and bile spillage, were recorded, along with the length of hospital stay. Patients were followed up after surgery for any postoperative complications for one month.

The Statistical Package for Social Sciences (SPSS) version 26 was used to enter and analyze the data, with the significance threshold (p-value) set at ≤ 0.05 for all statistical analyses.

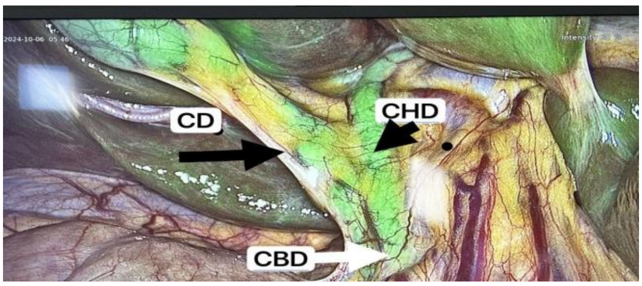

Figure 1: CD, CHD, CBD identified

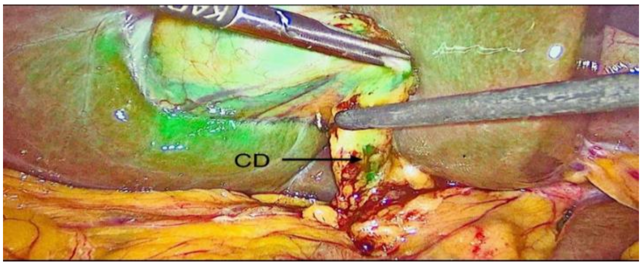

Figure 2: Posterior dissection of Calot's triangle

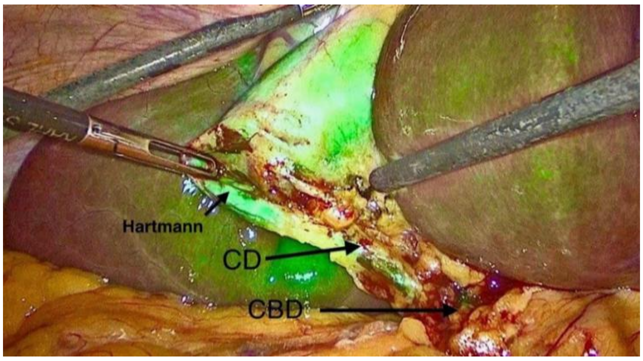

Figure 3: Anterior dissection of calot's triangle

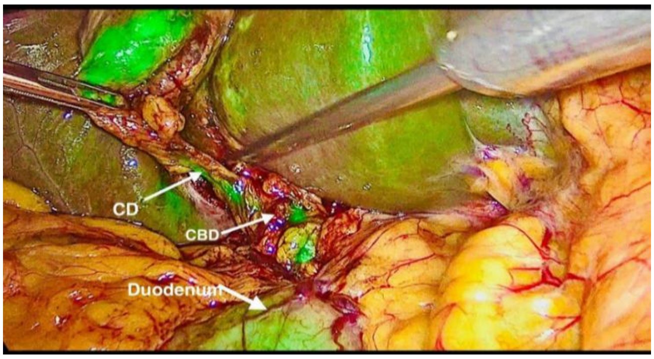

Figure 4: Critical view of safety achieved

RESULTS

The study included 92 patients who underwent LC: group 1 (42 patients) received ICG during their LC, while group 2 (50 patients) did not receive ICG during their operation. The mean age was 42.3 years for the first group and 40.7 years for the second group. Two-thirds of patients in both groups were female. A history of smoking was found in 23.8% and 22.0% of patients in the first and second groups, respectively. All these variables are presented in Table 1, and none showed a statistically significant difference between the two groups (p-value > 0.05).

Table 1: The demographic characteristics of both groups

Variables		Group 1 (N=42)	Group 2 (N=50)	p-value
Age (year)	Mean ± SD	42.3 ± 5.6	40.7 ± 4.9	0.916
	<20 (%)	5 (11.9%)	7 (14%)	
	20-39 (%)	16 (38.1%)	20 (40%)	
	40-60 (%)	21 (50%)	23 (46%)	
Gender	Male (%)	13 (30.9%)	18 (36%)	0.609
	Female (%)	29 (69.1%)	32 (64%)	
Smoking	Yes (%)	10 (23.8%)	11 (22%)	0.836
	No (%)	32 (76.2%)	39 (78%)	

Table 2 shows the clinical characteristics of both groups. Hypertension was present in 30.9% and 24.0% of the patients in the two groups, respectively. Approximately 14% of patients had diabetes mellitus, and less than 10% had COPD and ischemic heart disease (IHD) (p-value > 0.05). About 12% of patients had a history of previous upper abdominal surgery in both groups, while 4.8% and 6% in the two groups, respectively, had a history of recent ERCP. Around 25% of both groups had a previous hospital admission for cholecystitis (p-value > 0.05). Patients' height and weight were measured, and their BMI was calculated. Most patients had a normal BMI, with a similar percentage of those who were overweight, and less than 20% were obese (p-value > 0.05). Regarding preoperative imaging, 90% of cases showed normal gallbladder wall thickness on ultrasound in both groups. Impaction of gallbladder stones was found in 21% and 24% of both groups respectively. About 2 % of both groups had CBD stone. Empyema and pericystic fluid were found in almost 2% of cases in both groups (p-value > 0.05)

The time of surgery was measured and is presented in Table 3. The mean total operation time (T1) was 44.6 minutes in group 1, while it was 53.9 minutes in group 2. This difference between the two groups is statistically significant, with a p-value of 0.001. Regarding the time of cystic duct isolation, clipping, and division (T2), the mean was 23.3 min in the first group, increasing to 29.3 minutes in the second group, with a p-value of 0.001, which is statistically significant. The time for gallbladder removal from the hepatic fossa (T3) showed a lower mean in the first group (21.2 minutes) compared to the second group (24.6 minutes), and this difference is statistically significant, with a p-value of 0.007.

Table 2: The clinical characteristics of both groups

Variables		Group 1 N (%)	Group 2 N (%)	p-value
Presence of comorbidities	Yes	20 (47.6%)	23 (46%)	0.877
	No	22 (52.4%)	27 (54%)	
Hypertension		13 (30.9%)	12 (24%)	0.557
Diabetes mellitus		6 (14.3%)	7 (14%)	0.968
COPD		3 (7.1%)	3 (6%)	0.824
Ischemic heart disease		3 (7.1%)	4 (8%)	0.877
History of previous upper abdominal surgery		5 (11.9%)	6 (12%)	0.988
History of recent ERCP		2 (4.8%)	3 (6%)3 (6%)	0.794
History of previous hospital admission for cholecystitis		10 (23.8%)	13 (26%)	0.809
BMI	Normal	18 (42.9%)	21 (42%)	0.879
	Overweight	17 (40.4%)	20 (40%)	
	Obese	7 (16.7%)	9 (18%)	
Preoperative image findings				
Gallbladder wall thickness	Normal	38 (90.5%)	45 (90%)	0.935
	Increased	4 (9.5%)	5 (10%)	
Impacted stone	9 (21.4%)	12 (24%)		0.769
CBD stone	2 (4.76%)	3(6%)		0.794
Empyema	1 (2.4%)1 (2.4%)	1 (2%)		0.901
Pericystic fluid	1(2.4%)	2 (4%)		0.663

Table 3: The time of surgery among both groups

Variables		Group 1 (N=42)	Group 2 (N=50)	p-value
Total operation time in minutes	Mean ± SD	44.6 ± 2.1	53.9 ± 8.01	0.001
Time of cystic duct isolation, clipping, and sectioning	Mean ± SD	23.3 ± 5.4	29.3 ± 10.9	0.001
Time of gallbladder removal from the hepatic fossa	Mean ± SD	21.2 ± 4.9	24.6 ± 7	0.007

Other surgery-related variables among both groups are presented in Table 4. Although two patients in the second group were converted to open surgery, while no conversions were needed in the first group, the difference is not statistically significant since the p-value is > 0.05. Gallbladder perforation and bile spillage were documented in 2 (4.7%) cases in the first group and 12 (24.0%) patients in the second group. This difference is statistically significant between the two groups, with a p-value < 0.05. No bile duct injuries were reported in either group, and there was no significant statistical difference in the duration of hospital stay postoperatively between both groups (p-value > 0.05

Table 4: The surgery-related variables among both groups

Variables		Group 1 (N=42)	Group 2 (N=50)	p-value
Conversion to open (%)		0	2 (4)	0.174
Gallbladder perforation and bile spillage (%)		2 (4.7)	12 (24.0)	0.01
Bile duct injury rate (%)		0	0	1.00
Duration of hospital stay (day)	Mean ± SD	1.25 ± 0.3	1.39 ± 0.7	0.08

DISCUSSION

The key objective of using ICG during LC is to create a navigation plane to safely proceed with biliary dissection, recognize anatomical variations, and decrease the risk of biliary injury. This study adopts a comparative approach, distinguishing it from most existing literature in this field, where research predominantly focuses on descriptive analysis. By directly comparing specific variables, methods, or outcomes provides a more comprehensive understanding of specific aspects. While this, methodological difference broadens the scope of interpretation, it may also limit the direct comparability of our findings with prior studies, given their distinct focus on descriptive approaches. In this study, there was a significant reduction in total operative time for patients who underwent LC aided by ICG, as well as a significant reduction in the rate of gallbladder perforation and bile spillage. Iacuzzo et al. reported in a study published in 2021 that ICG was chosen more frequently by residents than by consultants, with a significant difference (p-value = 0.02). In the same study, they compare the results of LC with ICG performed by residents versus white light imaging LC performed by consultants, showing that the operative time significantly decreased in favor of the residents (p-value < 0.001), as did postoperative complications (p-value = 0.02) and length of hospital stay (p-value < 0.001).[8] Xu et al. demonstrated that ICG did not significantly improve surgical outcomes in simple cases (n = 208). However, in difficult cases (n = 228), ICG shortened operative time (P = 0.003) and length of hospital stay (P = 0.015), reduced blood loss (P = 0.028), and decreased the drain placement rate (P = 0.015).[9] Discordantly with most other studies, we found a significant reduction in operative time in the group of ICG patients. Similar results were observed in a recent study published by Van J et al., which found a significant reduction in operative time for patients undergoing ICG cholecystectomy.[10] In a recent study published by Losurdo et al., they investigated the use of ICG in urgent and emergency LC and compared the results with LC where only white light imaging was used. They found a significant reduction in operative time in LC aided by ICG (p-value = 0.002) and also noted a reduction in the postoperative biliary duct injury rate in the ICG group, although no significant statistical difference was observed.[11] Regarding the significance of gallbladder perforation, Evans et al. reported that iatrogenic gallbladder perforation during laparoscopic cholecystectomy may not increase the risk of surgical site infection (SSI) or intra-abdominal abscess collection, but it does increase the length of hospitalization and operative time, likely due to the increased time needed for stone retrieval, adequate intra-abdominal irrigation, or the intraoperative use of antibiotics.[12] In our study, we found, there is no significant difference between LC with and without ICG regarding bile duct injury, conversion rates, and length of hospital stay. Similar findings regarding bile duct injury rates, conversion rates, and length of hospitalization were reported in a study conducted by Ambe. et al.[13] In a study published by Gangemi et al., it was found that, ICG aided robotic cholecystectomy resulted in the lowest percentage of major biliary injury (0%) and the highest percentage of biliary anomalies identification (2.07%) compared to conventional LC.[14] however, this trend could not be applied in this study. The rate of injury to bile ducts was zero in both groups, attributed generally to the overall decline in complications in our centers related to:

1. Application of the critical view of safety.
2. The significant evolution in laparoscopic devices, which helped in improving the quality of digital imaging like high-resolution two-dimensional 4K monitors, significantly enhancing surgical outcomes by allowing better tissue definition and more accurate dissection.
3. Increased experience and training in laparoscopic surgery in recent years.

CONCLUSIONS

Indocyanine green has promising potential effects in future laparoscopic and minimally invasive surgery. It may reduce operative time, is easy to perform, safe, has no toxic side effects or radiation exposure, and allows surgeons to repeatedly visualize the extrahepatic biliary tree, facilitating the achievement of the critical view of safety.

Limitations:

The generalizability of this study is limited by the relatively small sample size.

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