Optimizing the Fluorescent Visualization with Indocyanine Green During Laparoscopic Cholecystectomy

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ABSTRACT

BACKGROUND: *The prevention of damaging the bile ducts during surgical interventions in patients with calculous cholecystitis remains a topical problem in modern abdominal surgery. The incidence of damaging the bile ducts reaches 0.4–2%, while in cases of complicated forms — up to 5.2%.* ***AIM:*** *determining the optimal dosage and timing of administering the Indocyanine green (ICG) for increasing the efficiency of fluorescent cholangiography during the course of laparoscopic cholecystectomy in cases of calculous cholecystitis. The top-priority task of the research is minimizing the risks of injuring the bile ducts by means of clear intraoperative visualization of the extrahepatic bile ducts.* ***METHODS:*** *Prospective non-randomized research was conducted within the premises of the University Clinical Center named after V.V. Vinogradov (affiliated branch) of the RUDN University during the period from March 2024 until April 2025. The research included 276 patients undergoing the laparoscopic cholecystectomy with using the ICG-cholangiography. The dosages of Indocyanine green used (1.25 mg; 2.5 mg; 5 mg; 10 mg) were administered in various time periods before starting the surgery (from 40 minutes up to 6 hours), as well as intraoperatively. The evaluation included the degree of fluorescence, the time from the moment of administering the Indocyanine green until the optimal fluorescence of the bile ducts and of the liver required for the safe conduction of laparoscopic cholecystectomy, as well as the possibility to correct the hyper- and hypofluorescence by changing the equipment settings.* ***RESULTS:*** *Optimal visualization of the extrahepatic bile ducts was observed at a dosage of 5 mg of ICG 3–5 hours after the administration, for the 2.5 mg dosage — 2–3 hours, while for the 1.25 mg dosage, the time was 40–120 minutes. Intraoperative administration of 1.25 mg provided a rapid visualization, but caused hyperfluorescence, complicating the determination of the topography of bile ducts, which was corrected by equipment settings.* ***CONCLUSION:*** *Fluorescent cholangiography with using the Indocyanine green is a safe and effective method of visualizing the extrahepatic bile ducts during laparoscopic cholecystectomy. The most optimal dosages of Indocyanine green are the following: 1.25 mg — 40–120 minutes, 2.5 mg — 2–3 hours and 5 mg — 3–5 hours before the intervention. The 1.25 mg dosage can be administered intraoperatively with further correction of equipment settings at the menu of the video-system (by lowering the enhancement and the intensity parameters) for decreasing the hyperfluorescence effect.*

Keywords: *calculous cholecystitis; indocyanine green; fluorescence visualization; laparoscopic cholecystectomy; dose optimization.*

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BACKGROUND

The prevention of damaging the bile ducts during surgical interventions in patients with calculous cholecystitis remains a topical problem in modern abdominal surgery. [1, 2]. According to worldwide statistics, each year more than a million of laparoscopic cholecystectomies are carried out for calculous cholecystitis [3, 4], with the rates of damaging the bile ducts reaching 0.4–2% and up to 5.2% for complicated forms, according to the data from foreign registries [5, 6]. The main reason of damaging the bile ducts is the inadequate intraoperative identification of the anatomic structures, especially in the settings of inflammatory changes and infiltration of tissues [7].

The method of fluorescent laparoscopy and fluorescent cholangiography with using the Indocyanine green (ICG), implemented at the real time mode, opens new possibilities in increasing the safety

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Оптимизация флюоресцентной визуализации с индоцианином зелёным при лапароскопической холецистэктомии

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АННОТАЦИЯ

Обоснование. *Профилактика повреждений желчевыводящих путей при оперативных вмешательствах у больных с калькулёзным холециститом остаётся актуальной проблемой в современной абдоминальной хирургии. Частота повреждений желчных протоков достигает 0,4–2%, а при осложнённых формах — до 5,2%.* ***Цель исследования*** *— определить оптимальную дозировку и время введения индоцианина зелёного (ICG) для повышения эффективности флюоресцентной холангиографии во время лапароскопической холецистэктомии при калькулёзном холецистите. Приоритетной задачей исследования является минимизация риска травм желчных путей посредством чёткой интраоперационной визуализации внепечёночных желчных протоков.* ***Методы.*** *Проспективное нерандомизированное исследование проведено на базе Университетского клинического центра имени В.В. Виноградова (филиал) РУДН в период с марта 2024 по апрель 2025 года. В исследование включены 276 пациентов, которым выполнена лапароскопическая холецистэктомия с применением ICG-холангиографии. Использованы дозы индоцианина зелёного (1,25 мг; 2,5 мг; 5 мг; 10 мг), вводимые в разные временные промежутки до начала операции (от 40 минут до 6 часов), а также интраоперационно. Оценивались интенсивность флюоресценции, время от момента введения индоцианина зелёного до оптимального свечения желчных протоков и печени для безопасного выполнения лапароскопической холецистэктомии, а также возможность нивелировать гипер- и гипофлюоресценцию изменением настроек оборудования.* ***Результаты.*** *Оптимальная визуализация внепечёночных желчных протоков отмечена при дозе 5 мг ICG через 3–5 часов после введения, при дозе 2,5 мг — через 2–3 часа, при дозе 1,25 мг — через 40–120 минут. Интраоперационное введение 1,25 мг обеспечивало быструю визуализацию, но вызывало гиперфлюоресценцию, затрудняющую определение топографии желчных путей, которая нивелировалась настройками оборудования.* ***Заключение.*** *Флюоресцентная холангиография с использованием индоцианина зелёного является безопасным и эффективным методом визуализации внепечёночных желчных протоков при лапароскопической холецистэктомии. Наиболее оптимальные дозировки индоцианина зелёного: 1,25 мг за 40–120 минут, 2,5 мг за 2–3 часа и 5 мг за 3–5 часов до вмешательства. Доза 1,25 мг может быть введена интраоперационно с последующей коррекцией настроек оборудования в меню видеосистемы (снизить показатели усиления и насыщенности) для уменьшения эффекта гиперфлюоресценции.*

Ключевые слова: *калькулёзный холецистит; индоцианин зелёный; флюоресцентная визуализация; лапароскопическая холецистэктомия; оптимизация дозы.*

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of laparoscopic interventions. Especially important is the high accuracy of visualization in case of significant inflammation, which limits the possibilities of standard anatomical orientation.

Research aim — determining the optimal dosage and timing of administering the Indocyanine green (ICG) for increasing the efficiency of fluorescent cholangiography during the course of laparoscopic cholecystectomy in cases of calculous cholecystitis. The top-priority task of the research is minimizing the risks of injuring the bile ducts by means of clear intraoperative visualization of the extrahepatic bile ducts.

METHODS

Research design

Prospective non-randomized.

Conformity criteria

Inclusion criteria: patients aged over 18 years; confirmed (by the data from instrumental examinations) diagnosis of calculous cholecystitis; signed informed consent.

Non-inclusion criteria: patients aged under 18 years; pregnancy

Exclusion criteria: patient not presenting for hospitalization, refusal to undergo treatment.

Research facilities

The examination was carried out within the premises of the Department of Intermediate Level Surgery under the Medical Institute of the Federal State Autonomous Educational Institution of Higher Education "Patrice Lumumba Peoples' Friendship University of Russia" at the University Clinical Hospital named after V.V. Vinogradov.

Research duration

The research activities lasted from March 2024 until April 2025.

Medical procedure description

On admission, all the patients were examined in accordance with the current clinical recommendations from the Ministry of Health of the Russian Federation. The diagnosis of calculous cholecystitis was the indication for conducting the laparoscopic cholecystectomy with intraoperative fluorescent cholangiography.

For the fluorescent cholangiography, an intravenous administration of domestically manufactured Indocyanine green («Life Sciences — Obninsk Chemical-Pharmaceutical Company" LLC) was conducted at dosages ranging from 1.25 to 10 mg. The standard packaging of the product is 25 mg of lyophilized product per vial, intended for dissolving in 10 ml of water for injections before use.

The recommended dosages mentioned in the package leaflet vary from 0.25 to 0.5 mg/kg, however, the literature data contain lower values — 0.1–0.2 mg/kg [8]. The practical experience shows that the fluorescence effect depends to a greater extent on the quantity of the product and on the timing of its administration rather than on the body weight-based calculations, which is related to the technical characteristics and the sensitivity of the equipment along with the sufficient level of the drug product accumulation in the hepatobiliary system.

Methods for registration of outcomes

During the course of the research, the employed equipment was from the leading manufacturers, having various characteristics of infrared radiation with a wavelength for the excitation of fluorescence ranging from 780 nm to 805 nm: Arthrex 4K (USA), ELEPS 4K (Russia), Rubina Carl Storz 4K (Germany), Olympus OTV-S200 (Japan), Stryker PINPOINT HD (Canada), Olympus OTV-S700 (Japan).

The evaluation of the efficiency of fluorescence was conducted visually using the monitor screen. The sufficient level was considered the one at which there was a clearly detectable topography of structures of the hepatoduodenal ligament and of the Calot's triangle.

The obligatory criterion for surgical safety was achieving the critical view of safety (CVS). The surgeries were carried out using the uninterrupted fluorescence mode at all the stages.

Statistical analysis

For representing the results and for the statistical processing of the data, the Microsoft Excel software was used. Data were presented as the mean values ± standard deviation.

RESULTS

Research sample (participants)

The research included 276 patients with clinically and instrumentally confirmed diagnosis of calculous cholecystitis, of which there were 78 (28.3%) men and 198 (71.7%) women, the mean age was 65.0±15.6 years and the mean body mass index was 32.2±5.78 kg/m^2.

Laparoscopic cholecystectomy with using the ICG-cholangiography was carried out for all the 276 patients with various dosages.

During the initial stage of the research, in 5 (1.8%) patients, the dosage used was 10 mg with the administration 6–8 hours before surgery, which was accompanied by significant intraoperative fluorescence of the liver, of the gall bladder and of the extrahepatic bile ducts, complicating the differentiation of anatomic structures and hindering the confident dissection at the Calot's triangle. Later on, during the time periods ranging from 1 to 5 hours from the moment of administering the drug product and before the initiation of surgery, the dosages of 5 mg (in 72 patients, 26.1%), 2.5 mg (in 116, 42.0%) and 1.25 mg (in 83, 30.1%) were tested.

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Main research outcomes

In a group of patients with a 5 mg dosage (*n*=72), the best conditions for the visualization were achieved in the interval of 3–4 hours from the moment of administering the ICG. In this time interval, clear fluorescence was observed for the extrahepatic bile ducts with minimal background fluorescence or its absence in the hepatic parenchyma. In the time interval from 1 to 3 hours, hyperfluorescence was reported, which was hindering the isolation of the cystic duct, the identification and the determination of the topography of the common bile duct. In the time interval of 3–4 hours from the moment of administering the ICG, hepatic fluorescence was not observed and clear differentiation was achieved for the cystic duct and for the common bile duct at the real time mode. As for the time interval of 4–5 hours, the visualization persisted, however, the intensity of fluorescence was slightly decreased, requiring the light source to be moved closer.

In the second group (*n*=116), the Indocyanine green dosage used was 2.5 mg. The drug was administered 1–4 hours and more before the initiation of the intervention.

In this group, at an interval of 2–3 hours, the best visualization was achieved: hypofluorescence of the hepatic parenchyma with optimal fluorescence of the extrahepatic bile ducts. When administering the ICG 1–2 hours before surgery, hyperfluorescence was observed, as a result of which, the tissues had an intensive generalized fluorescence, which hindered the differentiation of the structures in the Calot's triangle. After 3 hours, the intensity of fluorescence was decreasing, but the anatomical characteristics remained distinguishable. After the expiration of 4 hours, there was only a weak fluorescent effect observed, which required adjusting the equipment settings.

In a group of 83 patients, the drug was administered at a dosage of 1.25 mg intraoperatively 90 minutes before the surgical intervention.

Upon administering the Indocyanine green intraoperatively (40 minutes before surgery) the observed findings in the patients included significant fluorescence of the liver and of the gall bladder, as well as of the hepatoduodenal ligament area, which, at the beginning of surgery, hindered the accurate anatomical identification of extrahepatic bile ducts. With the time interval of administering the ICG ranging from 40 to 120 minutes, the intensity of fluorescence was decreasing to the comfortable level, which allowed for determining the topography of extrahepatic bile ducts and to safely conduct surgery with the fluorescence mode turned on. The summarized data on the dosages and the time intervals of administering the ICG are provided in table 1, with the data on the optimal fluorescence periods — in table 2.

The technical capabilities of the equipment allow for adjusting the visual intensity of fluorescence (hyper- and hypofluorescence): for this, in the settings menu of the video-system assembly, in the fluorescence mode section, it is necessary to adjust the enhancement and the intensity depending on the requirements. The brightness and the contrast ratio can be adjusted for the visual comfort of the surgeon.

Undesirable phenomena

Based on the results of the research, in a group of 276 patients undergoing the laparoscopic cholecystectomy with ICG-fluorescent visualization of the extrahepatic bile ducts, no complications were observed. In 23 (8.3%) patients, the complications were successfully avoided by clear following the technique of critical view safety (CVS) and by using the intraoperative fluorescent ICG-cholangiography (examples provided in Fig. 1, 2).

Table 1

Dosages and time intervals of administering the Indocyanine green (ICG)

Dosage, mg	Time interval, h	Number of patients, *n* (%)
5	1–3	15 (20.8)
	3–4	34 (47.3)
	4–5	23 (31,9)
2.5	1–2	19 (16.3)
	2–3	69 (59.5)
	3–4	25 (21.7)
	>4	3 (2.5)
1.25	≤40 min.	32 (38.5)
	40–120 min.	51 (61.5)

Table 2

Optimal fluorescence windows

Dosage, mg	Intraoperative administration	1–2 hours	2–3 hours	3–4 hours	4–5 hours
5					
2.5					
1.25					
Designation					
	Hyperfluorescence — difficult to differentiate the structures				
	The intensity of hepatic staining is decreased				
	Optimal fluorescence window				
	Hypofluorescence — weak fluorescence				

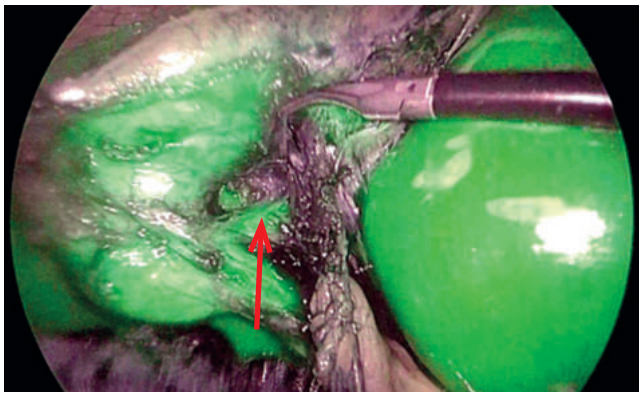

Fig. 1. Mirizzi syndrome: tight fusion of the Hartmann pouch with the hepatic duct (arrow) due to inflammation (incipience of Mirizzi syndrome formation).

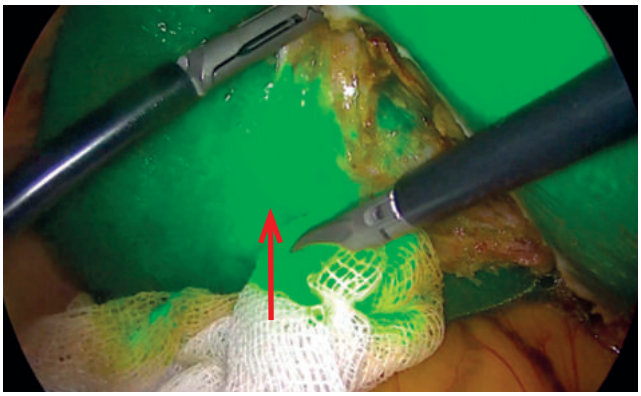

Fig. 2. Damage of the subsegmental duct: bile leakage after damage to the subsegmental duct (arrow).

DISCUSSION

The dissection of the area of the Calot's triangle during the laparoscopic cholecystectomy is an important surgical step, during which, serious iatrogenic complications can develop [8]. The accurate identification of the cystic duct and of the cystic artery can be quite difficult in cases of significant inflammatory changes or rare anatomic variations in this zone. In such situations, fluorescent visualization provides potentially great benefits, facilitates the course of the surgery and allows for avoiding the damage of the common bile duct [9]. However, as of today, there is no commonly accepted standard of conducting the fluorescent laparoscopy during cholecystectomy [10]. ICG is a widely used water-soluble staining agent, which is completely metabolized by the liver and excreted solely via the bile ducts [11]. The main mechanism of action is based on the fluorescence produced by the ICG staining agent upon the exposure of light in the near infrared range, which allows for visualizing the anatomical structures by means of a specialized visualization system [12]. The method allows for selectively highlighting various structures, including blood vessels, bile ducts and lymphatic vessels, however, the variation of dosage and time of administered ICG significantly affects the quality of fluorescent visualization [13]. In particular, lower dosages of ICG can increase the total visualization time, while higher dosages increase the intensity of the fluorescent signal [13].

Despite the great theoretical benefits of fluorescent laparoscopy with ICG during surgical interventions in the biliary excretion system, currently its clinical application is mainly experimental. In the systematic review by M. Manasseh et al. [10], the results of 14 research works were analyzed, which have demonstrated the safety of the method and its benefits in the complex cases, with this, only in single research works, the optimal dosage of the staining agent and the timing of its administration were determined. There are currently ongoing active discussions regarding the optimal ICG dosage [14].

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A foreign research arranged by the group headed by F. Pardo Aranda [13] has demonstrated the results similar to ours — the best visualization being achieved upon administering 2.5 mg of ICG to the patients 2–6 hours before surgery. Notably, this dosage was not adjusted depending on the weight of the patient or the body mass index, otherwise this variability could hinder the precise preparation of ICG solutions and could significantly increase the labour-intensity for the medical staff.

Thus, for achieving the optimal fluorescence window, the following dosages are recommended: 5 mg — when injecting 3–5 hours before surgery; 2.5 mg — when injecting 2–3 hours before surgery; 1.25 mg — when administering 40–120 minutes before surgery. Intraoperative administration of 1.25 mg ICG can be used, if necessary, but it requires changing the settings in the video-system.

CONCLUSION

In our research, we tried to investigate the effects of various dosages of domestically manufactured ICG on the intraoperative visualization and their effects on the surgical and post-operative results. This is the first ever research involving the usage of the domestically manufactured staining agent.

Intraoperative fluorescent cholangiography with using the Indocyanine green proves its safety and efficiency in the prevention of damaging the extrahepatic bile ducts during the course of laparoscopic cholecystectomy in patients with calculous cholecystitis, while the possibility of adjusting the fluorescence intensity by changing the equipment settings together with selecting the optimal dosages makes the fluorescent visualization technology controllable.

ADDITIONAL INFORMATION

Author contributions. *M.V. Kosachenko*: processing and discussion of research results, manuscript writing; *A.M. Leonovich, A.V. Burlakova*: search and analytical operations, discussion of research results, manuscript writing; *A.E. Klimov*: managing the treatment of patients and discussing the research results. Thereby, all authors provided approval of the version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethics approval. The research was approved by the local Ethics Committee of the RUDN University Medical Institute and of the University Clinical Hospital named after V.V. Vinogradov in February 2024, Protocol No. 2.

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