Safety of laparoscopic ChOlecystectomy performed by Trainee surgeons with different CHolangiographic techniques (SCOTCH)

Contents

1. Study summary

Study Title	**Safety of laparoscopic ChOlecystectomy performed by Trainee surgeons with different CHolangiographic techniques (SCOTCH)**
Internal ref. no. (or short title)	**SCOTCH study**
Study Design	Multiceter prospective interventional trial
Study Participants	Patients
Endpoints	**Primary endpoints** Time to reach CVS with the utilisation of three different intraoperative imaging modality during LC performed by ST
Summary of eligibility criteria	**Inclusion Criteria** – Patient scheduled for elective laparoscopic cholecystectomy – Patient age ≥ 18 years – Patient able to give consent to the procedure **Exclusion Criteria** – Open cholecystectomy – Emergency laparoscopic cholecystectomy – Allergy towards iodine, lohexol or indocyanine green – Liver or renal insufficiency – Thyrotoxicosis – Pregnancy or lactation – Legally incompetent for any reason – Withdrawal of inclusion consent at any time – Age outside inclusion range
Arms of the study	**Group CVS-WL (control group)**: the CVS is achieved in white light, without the utilization of an intraoperative imaging technique. CVS in white light was selected as the control group since it constitutes the actual recognized standard in clinical practice. **Group IOC**: the CVS is achieved with the help of intraoperative cholangiography **Group NIR-C**: the CVS is achieved with the help of near-infrared fluorescence cholangiography
Version and date of protocol amendments	Vers. n.1.1- 15/11/2020
Clinicalstrials.gov Registration number	NCT04863482

2. Key Study Contacts

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Key Protocol Contributors	Prof Mario Guerrieri Dr Monica Ortenzi

3. Glossary of Terms

LC= laparoscopic cholecystectomy
ST= surgical trainee
CVS= critical view of Strasberg
IOC= intraoperative cholangiography
NIR-C= Near-infrared fluorescence cholangiography
CBD= common bile duct
BDI= bile duct injury

4. Background

Laparoscopic cholecystectomy (LC) gained popularity among general surgeons in 1990s and rapidly become one of the most commonly performed procedures in digestive surgery [1, 2], with more than one million cholecystectomies being performed in the United States per year [3]. LC remains also one of the most commonly performed procedure by general surgeons during the training period [4, 5].
Even if previous report LC cases performed by surgical trainees (ST) are not associated with higher operative morbidity [6], the length of operative time is significantly increased when compared with that of LC cases performed by attending surgeons, due, most of all, to difficulties in identifying the anatomical structures [7, 8], and this sometimes leads to an attending surgeon taking away the case from the trainee.

Furthermore, despite the fact that LC has proven to be a safe procedure, the rate of common bile duct (BDI) injury still remains unacceptably high even in the hands of minimally invasive trained surgeons [9] ranging from 0.2 to 1.5% in individual reports [10, 11-14], much higher than initial reports [14, 15], associated with significant morbidity and mortality, lower quality of life and increased costs, related to additional health care measures, loss of work days, and insurance claims [2,10, 16, 17]. Way et al reported that, in 97 % of cases, non-technical errors, predominantly relating to perceptual errors, in which the operator was led to make false assumptions regarding the position of the bile duct in relation to the anatomy at hand, were at the root cause of the injury. [18] From these observation many of the existing recommendations to avoid BDI insist on the importance of the establishment of the critical view and and understanding the relevant anatomy, aided by adequate retraction and visualization. [19]

The correct identification of Calot's triangle, sometimes hard even in expert hand, may be particularly challenging for ST leading at those misidentification of the structures that are the most frequent causes of BDI during LC as previously stated. As a matter of fact, the most frequent site of CBD injury is below the bifurcation of the right and left hepatic ducts (65 %), and once anatomic confusion has led the surgeon astray, injury tends to occur in relatively predictable locations along the biliary tree [4]

With laparoscopic surgery, there is also loss of haptic input and stereoscopic depth perception, which predisposes to the misperception that leads to BDI [20] Various methods have been described to help the identification of the structures in Calot's triangle; these include intraoperative cholangiogram (IOC) [22], critical view of safety (CVS) [23] and the near-infrared fluorescent cholangiography (NIRF-C) [24].

Each of these technique have been proved to be useful and, at the same time, to have some intrinsic drawback that could be amplified when in unexperted hands.

The use of IOC during LC is well established [25] with the aim to detect of bile duct stones, defining biliary tree anatomy and the early recognition of iatrogenic common bile duct (CBD) injuries. [26-29]
Although regarded as a safe procedure with a low risk of complications, the merits of routine IOC usage remain an area of debate. Some studies suggest that it adds significant operating time and cost, without reducing the risk of detection of retained CBD stones or bile duct injury. [30-33] Others

demonstrated that the routine use of IOC for cholecystectomy plays a crucial role in the detection of intraoperative CBD stones and CBD injury.
It could be argued, however, that to perform IOC it is necessary to incise what is presumed to be the CD, which in itself may be the cause of a lateral injury of the CBD (or CHD) in case of mistaken anatomy [30] and, in a training setting, IOC can be difficult to teach and residents do not gain enough experience with it as not all surgeons perform it routinely and that [1]

The CVS, more than a technology the others, is a technique, introduced by Strasberg and Brunt in 1995, [23] and it is considered the gold standard to perform a safe cholecystectomy with identification of biliary structures (eg, cystic duct, common hepatic duct, and common bile duct) during dissection. Three criteria are required to achieve the CVS: (1) the hepatocystic triangle must be cleared of adipose and fibrotic tissues; the common bile duct and common hepatic duct must not be exposed; (2) the lower third of the gallbladder must be separated from the liver bed to expose the cystic plate; and (3) 2 and only 2 structures should be seen entering the gallbladder. In this case, the main drawback for ST is the necessity to dissect around the Calot's triangle to demonstrate the CVS. It can become challenging for an attending surgeon to supervise the resident to dissect and demonstrate CVS without any visual landmarks.

The most recently introduced intraoperative imaging technique is the near-infrared fluorescent cholangiography (NIRF-C), described by Ishizawa et al in 2009. [24] The NIRF-C allows a real-time enhanced visualization of the extrahepatic biliary tree by fluorescence. NIRF-C is based on the administration of a fluorophore, the indocyanine green, which is excreted in the biliary system, and on the use of a nearinfrared light source, exciting the fluorophore and enabling the visualization. NIRF-C offers some clear advantages when compared with the conventional cholangiography (real-time visualization of biliary tree, reduced costs, easy learning curve, lack of X-ray exposure, safer dissection of Calot's triangle, and possibility to associate fluorescent angiography to highlight vessels). [34, 35] Additionally, NIRF-C has shown a good potential as a teaching tool for trainees. [1, 36]

Previous report demonstrated the feasibility and safety of NIRFC [37]. Prospective study comparing IOC and NIRFC, that the latter is associated with a shorter duration of operation [38] and confirmed its non-inferiority to IOC to X-ray cholangiography in visualizing the critical junction during LC. [39]
Unfortunately, however, as confirmed the EURO-FIGS registry on fluorescence-guided surgery, there is a wide disparity in terms of protocols for NIRFC, across several European surgical centers, particularly in terms of ICG dose and timing of administration. [40]

The aim of this study is to address which of the techniques now available could be addressed as the best option in a training setting to enhance the learning curve, to ideally build a safe cholecystectomy training program and virtually eliminate the risk of BDI due to anatomic misinterpretation during the training period.

5. Patients and study design

5.1 Study design

The study will be a multicentre prospective observational study. Members of the Italian Society of Endoscopic Surgery [SICE] will be invited to participate. All participating centers will be required to register the study according to local regulations. Evidence of successful registration should be sent to your national network committee prior to beginning of data collection.

5.2 Study groups

The enrolled patients will be divided into three groups, 1 control group and 2 treatment groups, according to the selected technique to achieve the CVS during LC:

Group CVS-WL (control group): the CVS is achieved in white light, without the utilization of an intraoperative imaging technique. CVS in white light was selected as the control group since it constitutes the actual recognized standard in clinical practice.
Group IOC: the CVS is achieved with the help of intraoperative cholangiography
Group NIR-C: the CVS is achieved with the help of near-infrared fluorescence cholangiography

5.3 Rationale for Study Design

Since to date there is no consensus on which is the best technique to correctly identify the anatomy of the Calot's triangle during LC performed by ST, this trial would aim to propose a standard technique to be used in this peculiar setting.

5.4 Potential Benefit for Patients

In teaching hospitals and, more generally in a training setting, overcoming the problem of providing high surgical quality while educating ST can be challenging. This may change in the future if residents are able to better identify the anatomy with IOIFC, shortening the learning curve and improving the safety pofile of LC, that, in a clinical point of view, would translate into a shorter operative times and reduction of the potential risk of BDI.

5.5 Patient Risk

There are no additional risks on the participation of this study as no additional procedures are being performed to clinical guidance. In accordance with standard care, patients shall receive written information regarding the index procedure.

6. Study objectives

6.1 Primary Outcomes

The primary objective is to compare NIFC, IOC and CVS-WL for identification of the junction between the cystic duct, the common hepatic duct and the CBD during LC performed by general surgery trainee always supported by an expert surgeon. The technique will be considered successful when the CVS will be achieved. The time to achieve the CVS will be recorded by an independent surgeon who will be present in the operative room during the procedure.
The definition of trainee will be on the number of the procedures performed before the beginigging of the study. Surgeons who performed less than 30 procedures before the beginning of the study, since learning curve studies have determined the steep portion to consist of 10 to 30 operations [40–43]. The operating surgeon will complete a structured questionnaire focusing on anatomical identification of the bile ducts immediately after each operation (**Appendix A**) and a more generic

questionnaire on task load. (**Appendix B**) The surgeon's satisfaction score will be given on a subjective visual analogue scale ranging from 1 to 5 (1 = not satisfied, 5 = extremely satisfied). (**Appendix C**)

6.2 Secondary Outcomes

Secondary endpoints will be the ability to visualize the common hepatic duct (from the junction to the bifurcation), common bile duct (from the junction to the retroduodenal part) and the cystic duct (from the junction to the infundibulum of the gallbladder).

Other secondary outcomes will be short-term outcomes, procedural characteristics (operating time, intraoperative complications, need for conversion), rate and type of BDI, postoperative care characteristics (type of postoperative admission, length of postoperative stay, intensive care unit stay).
Intraoperative, unpredicted events will be recorded and classified according to a grade of unfavourable intraprocedural events. (**Appendix D**)
Short-term will be defined as within 30 days after surgery or until discharge, if the patient remained in hospital at that time. The size of the excised lesions and patients characteristics were assessed and compared as well.

6.3 Evaluated parameters

i) Age
ii) Sex
iii) ASA scores
iv) Preoperative work up
v) Type of procedure (CVS-WL, NIFC, IOC)
vi) Operative parameters (operative time, intraoperative complications)
vii) BDI (according to the ATOM , Stasberg's and LAU classification [44-46] **Appendix E**)
viii) How the BDI was diagnosed intraoperatively
ix) Duration of cholangiography
x) Time needed to obtain a CVS
xi) Post-operative outcomes (post-operative complications, late complications, need of readmission, length of hospital stay)
xii) Surgeons' ease at performing the procedure (questionnaire on identification of anatomical stuctures, NASA task load test)
xiii) Surgeons' satisfaction (visual analog scale)

7. Selection of Subjects

Consecutive eligible patients will be recruited at the outpatient clinic in the participating center by the involved physician (surgeon). All patients fulfilling the above-mentioned criteria will be informed about the study by the physician. After consent is given, central data acquisition will take place web-based and patients will treated according to the study protocol.

7.1 Consent

Potential participants will be counselled by a member of the research team directly involved with the study and who hold good clinical practice certification. Patients will be provided with written information and the consent form at the time of counselling with an opportunity to ask any questions. All patients participating in the study must hold capacity- this is an inclusion criteria and the absence of it an exclusion criteria.

7.2 Inclusion criteria

- Patient scheduled for elective laparoscopic cholecystectomy
- Patient age ≥ 18 years
- Patient able to give consent to the procedure

7.3 Exclusion criteria:

- Open cholecystectomy
- Emergency laparoscopic cholecystectomy
- Allergy towards iodine or indocyanine green
- Liver or renal insufficiency
- Thyrotoxicosis
- Pregnancy or lactation
- Legally incompetent for any reason
- Withdrawal of inclusion consent at any time
- Age outside inclusion range

8. Study procedures

Critical view of Safety(CVS)

The CVS has 3 requirements. First, the triangle of Calot must be cleared of fat and fibrous tissue. It does not require that the common bile duct be exposed. The second requirement is that the lowest part of the gallbladder be separated from the cystic plate, the flat fibrous surface to which the non peritonealized side of the gallbladder is attached. The cystic plate, which is sometimes referred to as the liver bed of the gallbladder, is part of the plate/sheath system of the liver. The third requirement is that 2 structures, and only 2, should be seen entering the gallbladder. Once these 3 criteria have been fulfilled, CVS has been attained). The rationale of CVS is based on a 2-step method for ductal identification that was and continues to be used in open cholecystectomy. First, by dissection in the triangle of Calot, the cystic duct and artery are putatively identified and looped with ligatures. Next, the gallbladder is completely dissected off the cystic plate, demonstrating that the 2 structures are the only structures still attached to the gallbladder. Time consumption and includes the period from the initial dissection and the obtaining of an acceptable view according to the previously described criteria in order to safely transect the cystic duct.

Intraoperative cholangiography (IOC)

IOC is performed after dissection of the cystic duct in a standardised manner, by cannulation of the cystic duct with a catheter using either a Kumar or Olsen grasper. Leakage is controlled by injecting saline prior to injection of iodine contrast means, according to the centre usual habits. A mobile X-ray C-arm system is used, and the monochrome X-ray image is shown on a separate screen. After satisfactory identification of the extra-hepatic biliary ducts, the intraoperative cholangiography is discontinued and the gallbladder is removed in a standardised manner. Time consumption includes

the period from application of the Kumar/Olsen grasper until it is removed again after obtaining a satisfactory cholangiogram and the cystic duct is transected.

Near infrared cholangiography (NIR-C)

NIFC is performed injecting intravenously, 2.5-7.5 mg of indocyanine green (0.2 mg/kg) at the admission of the patients into the hospital, in patients admitted he same day of surgery, and at least 45 mins before the acquisition of the images. Indocyanine green rapidly binds to plasma proteins and is exclusively and entirely excreted by the hepatic parenchymal cells into the bile, starting within a few minutes after injection. During dissection, the fluorescence imaging mode is used when needed until critical view of safety is obtained. Before division of any tubular structure, the fluorescence imaging mode is routinely used again, and fluorescent angiography is performed by re-injecting the same dose of indocyanine green as initially used. After division of the cystic duct and artery, the fluorescence imaging mode is applied again to check for bile leakage. Time consumption and includes the period from the initial dissection and the obtaining of an acceptable CVS and transect the cystic duct.

9. Statistical analysis

Descriptive statistics will be provided for all discrete variables in the form of rates and proportions with 95% confidence intervals. Continuous variables will be described by mean, standard deviation, median and range. Overall survival, disease free survival, local recurrence rate and metastasis rate will be estimated using the method of Kaplan Meier. Exploratory comparisons of discrete variables will be performed using a Chi-squared test, using continuity correction or Fisher's exact test. Continuous variables will be compared using a Student's t-test, or a non-parametric equivalent (Wilcoxon). All tests will be two sided with a p-value of less than 0.05 considered to indicate statistical significance. Data will be analysed according to intention-to treat principles.

9.1 Sample size

Sample size was estimated using simulations for a superiority design. Assuming a success rate of 80% for the conventional intraoperative cholangiography, 90 % for the intraoperative fluorescent cholangiography and . This was done for a range of sample sizes. We then analysed each dataset to test whether intraoperative fluorescent cholangiography was no more than 10% inferior to conventional intraoperative cholangiography in a one-sided test applying a 5% level of significance. In conclusion, 60 patients in each group would yield a power of 90%.

Prior to data collection, assuming a baseline structure detection rate of 20%, 300 subjects per group was the estimated sample size needed to detect a 10% absolute increase (from 20 to 30%) in extrahepatic biliary structure visualization rates, with 95% confidence and 80% power. In addition to comparing structure detection rates between the 2 study arms, exploratory analysis was performed to identify potential effect modifiers like age, sex, body mass index (BMI), liver

Based on power calculations to demonstrate superiority of NBI over WLE for the endoscopic diagnosis of coeliac disease, 328 patients would be required in total (44 in each group): calculated using a significance level (alpha) 5%, power 1 (beta) 95%, %success in control (WLE) group 60% [25] and % success in experimental group (NBI) 91% [24].

The sample size has been considered with reference to (1) recruitment (2) adequately powered calculations to be conducted to address the outcomes including inter-observer variation.

9.3 Expected Duration of Trial

The trial is expected to run for 6 months (time from first patient recruitment to last patient evaluation). Data analysis will take a maximum of 3 months after this time.

11. Ethics & Regulatory Approvals

The trial will be conducted in compliance with the principles of the Declaration of Helsinki (1996), the principles of GCP and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework and the Medicines for Human Use (Clinical Trial) Regulations 2004, as amended in 2006 and any subsequent amendments.

This study protocol will be submitted for local REC review in addition with patient information leaflet and consent form. The protocol/ any amendments will follow the local REC process. The chief investigator shall provide annual REC reports as required and will notify the REC at the end of the study.

If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

12. Data Handling

The Chief Investigator will act as custodian for the trial data. The following guidelines will be strictly adhered to:

All study data will be:

- Stored in line with the Medicines for Human Use (Clinical Trials) Amended Regulations 2006 and the Data Protection Act.
- archived in line with the Medicines for Human Use (Clinical Trials) Amended Regulations 2006 as defined in the Joint Clinical Trials Office Archiving SOP

13. Publication Policy

It is intended that the results of the study will be reported and disseminated at international conferences and in peer-reviewed scientific journals. Two investigators for each of the involved centres will be included in the authors' list.

14. Financial Aspects

The study does not require additional funding as all patients are not undergoing clinical procedures outside of their usual care. No other procedure is being performed that will require additionally funding than that to perform clinical investigation alone or histopathological analysis.

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16. Appendixes

16.1 APPENDIX A Questionnaire on anatomical identification of the bile ducts

Critical view of safety- WL (CVS)

1. What is the quality of visualization?

(Very poor) 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10 (Excellent)

2. Has the CVS been achieved?
   - Yes
   - Probably
   - Inconclusive

3. Would you transect the cystic duct based on this image?
   - Yes
   - No

Intraoperative cholangiography (IOC)

1. What is the quality of the IOC (grade best image)?

   (Very poor) 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10 (Excellent)

2. Is the duct that is cannulated the cystic duct?
   - Yes
   - Probably
   - Inconclusive

3. Would you transect the cystic duct based on this image?
   - Yes
   - No

Near infrared cholangiography (NIFC)

1. What is the quality of the NIFC (grade best image)?

   (Very poor) 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10 (Excellent)

2. Was the junction well visible?
   - Yes
   - Probably
   - Inconclusive

3. Would you transect the cystic duct based on this image?
   - Yes
   - No

Adapted from Buddingh KT, et al. Documenting correct assessment of biliary anatomy during laparoscopic cholecystectomy. Surgical endoscopy, 2012, 26.1: 79-85.

16.2 APPENDIX B NASA task load index

Name	Task	Date

Mental Demand — How mentally demanding was the task?

Very Low — Very High

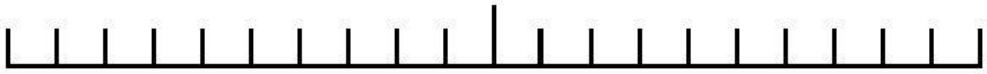
Physical Demand — How physically demanding was the task?

Very Low — Very High

Temporal Demand — How hurried or rushed was the pace of the task?

Very Low — Very High

Performance — How successful were you in accomplishing what you were asked to do?

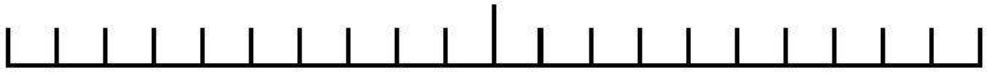


Perfect — Failure

Effort — How hard did you have to work to accomplish your level of performance?

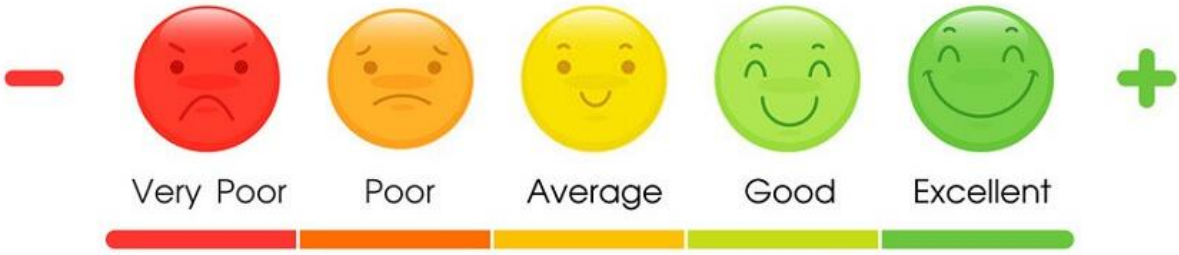
Very Low — Very High

Frustration — How insecure, discouraged, irritated, stressed, and annoyed wereyou?



Very Low — Very High

16.3 APPENDIX C Visual analog scale for surgeon's satisfaction



16.4 APPENDIX D Adverse events score

Table 1 The intraoperative adverse event classification

Grade	Intraoperative adverse event classification	Percentage of adverse events identified from laparoscopic TME case video review pilot (%)	Examples in laparoscopic colorectal surgery
1	Minor error, no damage or corrective action required	60.1	Peritoneal tear; tissue avulsion from excess traction
2	Minor consequential error requiring corrective action but no change in post-operative care	37.1	Bleeding requiring a corrective step (swab/diathermy), wrong plane dissection—identified and corrected, serosal injury
3	Consequential error requiring major corrective action and/or change in post-operative pathway	2.4	Splenic capsule tear; re-do anastomosis; enterotomy, unplanned stoma
4	Life-threatening complication that requires major or immediate corrective action which led to a significant alteration of the post-operative pathway which may include re-operation or intensive care admission	0.1	Visceral injury; major haemorrhage; any complication necessitating ITU admission
5	Major consequential error resulting in death	0	Major vessel injury, air embolus

The five categories cover all observed intraoperative events by basing the grouping of the therapeutic consequences of the event. Illustrative examples for each category are shown. The vast majority of observed adverse events were seen to be grades I and II with fewer serious events identified

Francis NK, Curtis NJ, Conti JA, Foster JD, Bonjer HJ, Hanna GB; EAES committees. EAES classification of intraoperative adverse events in laparoscopic surgery. Surg Endosc. 2018 Sep;32(9):3822-3829

16.5 APPENDIX E

Table 2 EAES classification matrix for bile duct injuries

Anatomical characteristics							***Time of detection***			***Mechanism***	
Anatomic level	Type and extent of injury					Vasculobiliary injury (yes=VBI+) and name of injured vessel (RHA, LHA, CHA, PV, MV); (no = VBI-)	Ei (de visu, bile leak, IOC)	Ep	L	Me	ED
	occlusion		division								
	C	P*	C	P*	LS**						
MBD											
1											
2											
3											
4											
5											
6											
NMBD											

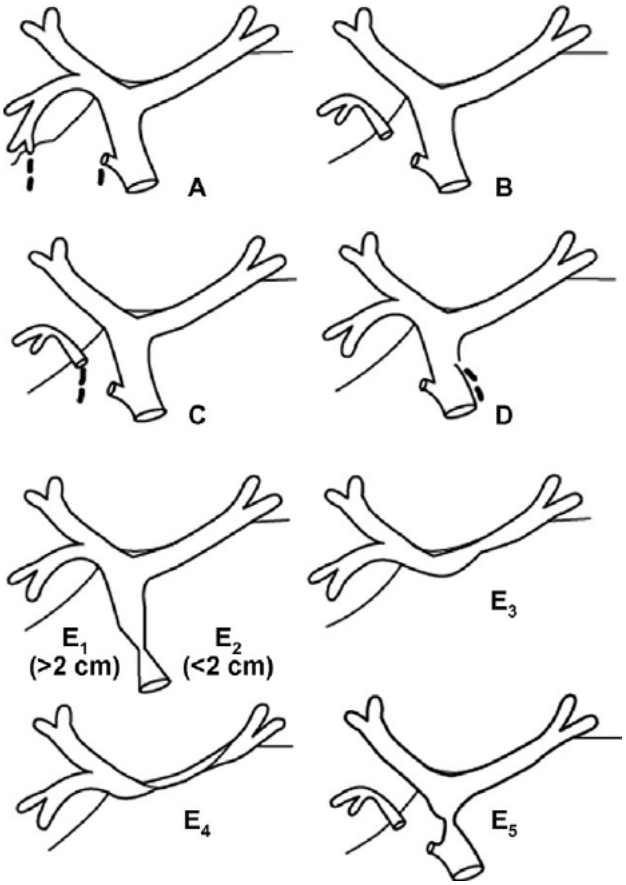
For each injury, the surgeon fills in the following matrix: (1) single injury (yes/no); (2) multiple injuries (yes/no). Then one matrix is filled in for each injury, as appropriate. For example, an injury made by an energy-driven (ultrasonic) dissector involving the superior biliary confluence with interruption of the right and left hepatic ducts, detected (intraoperatively) during the operation by the presence of bile would be classed as MBD 4 C VBI Ei, ED. The Connor Garden E6 injury is in fact a type 4 with LS: MBD 4 LS

EAES European Association for Endoscopic Surgery, *MBD* main biliary duct, *NMBD* nonmain biliary duct (Luschka duct, aberrant duct, accessory duct), *level 1* $\geq$ 2 cm from lower border of superior biliary confluent, *level 2* $<$ 2 cm from lower border of superior biliary confluent, *level 3* involves the superior biliary confluent but communication right left is preserved, *level 4* involves superior biliary confluent but communication right left is interrupted, *level 5a* right or left hepatic duct, *level 5b* right sectorial duct but bile duct still in continuity, *C* complete, *P* partial, *LS* loss of substance, *Me* mechanical, *ED* energy driven, *VBI* vasculobiliary involvement, *RHA* right hepatic artery, *LHA* left hepatic artery, *CHA* common hepatic artery, *PV* portal vein, *MV* marginal vessels, *Ei* early intraoperative, *Ep* early postoperative, *L* late, *OC* intra-operative cholangiogram

[a] Indicate percentage of circumference, if known

[b] Indicate length, if known

Fingerhut A, Dziri C, Garden OJ, et al . ATOM, the all-inclusive, nominal EAES classification of bile duct injuries during cholecystectomy. Surg Endosc. 2013 Dec;27(12):4608-19.



Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Coll Surg 1995;180:101-125.

Table 9. Our classification, mechanisms of injury, prevention and treatment

Type	Mechanism of injury	Preventive measures	Treatment for early detection	Treatment for late detection
1	Insecure closure of cystic duct Too deep dissection into gallbladder bed	Attention to operative details	Control bile leak with suturing Laparotomy if required Drain subhepatic space	Drain intraperitoneal collection Control sepsis Endoscopic stenting
2	Incision of CBD instead of cystic duct for operative cholangiogram Clipping of CBD but recognised Laceration of cystic duct/CBD junction Diathermy injury to CBD/CHD	Strasberg's critical view of safety Avoid too much traction on gallbladder Careful use of diathermy	Conversion to laparotomy Repair small laceration Place of T tube controversial Drain subhepatic space If tissue necrosis extensive due to diathermy, treat as Type 3	Early diagnosis without stricture Laparotomy, repair, and drainage Late diagnosis with stricture, treat as Type 3
3	CBD mistaken as cystic duct, with CBD/CHD transected or resected Diathermy injury	Strasberg's critical view of safety Avoid dissection too close to CBD	Conversion to laparotomy Trim divided ducts to healthy tissue Close distal stump HJ to proximal stump Drain subhepatic space	Control sepsis first by draining intraperitoneal collection and proximal bile duct Laparotomy and HJ when sepsis controlled
4	Right HD or sectorial duct mistaken for cystic duct	Recognition of biliary anomaly	Right/left hepatic duct biliary-enteric anastomosis	Asymptomatic: follow up Symptomatic: HJ, liver resection if HJ not possible
5	Right hepatic artery mistaken for cystic artery Diathermy or clip injuries to right hepatic artery during haemostasis	Recognition of vascular anomaly Avoid blind use of diathermy and clip	Reconstruction of vessels and bile ducts if technically possible If not technically possible, ligate duct and vessels and wait and treat as late detection	Asymptomatic with liver atrophy: follow up Symptomatic: HJ±liver resection/ liver transplant

CBD: common bile duct; CHD: common hepatic duct; HD: hepatic duct; HJ: hepaticojejunostomy.

Lau WY, Lai EC. Classification of iatrogenic bile duct injury. Hepatobiliary Pancreat Dis Int 007;6:459-463.