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ORIGINAL ARTICLE

The critical view of safety and bile duct injuries in laparoscopic cholecystectomy: a photo evaluation study on 1532 patients

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Abstract

Background: Laparoscopic cholecystectomy (LCC) carries a 0.3–1.8% risk of bile duct injury (BDI). This study investigated if intraoperative photo documentation of the critical view of safety (CVS) is related to lower rates of BDIs and postoperative complications in LCC.

Methods: Surgeons were instructed to take photos of the view before clipping the cystic duct and artery. Two independent raters scored the photos 0–6 using predefined criteria for CVS. Mean scores of ≥ 4.5 were satisfactory.

Results: The study consisted of 1532 patients undergoing LCC between April 2018 and October 2019. CVS was satisfactory in 354 (23.1%), unsatisfactory in 823 (53.7%), and photos were missing in 355 (23.2%) patients. Patients with satisfactory CVS had the lowest BDI rate compared with unsatisfactory CVS or missing photos (0.3% vs. 1.0% vs. 2.3%, $p = 0.012$). Four major BDIs (Strasberg D-E) occurred, but none in patients with satisfactory CVS. Patients with satisfactory CVS had the lowest postoperative complication rate compared with patients with unsatisfactory CVS or without photos (4.8% vs. 7.9 vs. 9.9%, $p = 0.011$). Of patients with acute cholecystitis, 15.7% had satisfactory CVS, whereas 26.8% without cholecystitis had satisfactory CVS ($p < 0.001$).

Conclusion: Intraoperative photo documentation of satisfactory CVS is associated with lower rates of BDIs and complications.

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Introduction

Laparoscopic cholecystectomy (LCC) is one of the most common abdominal operations, with around 9000, 66 000 and 450 000 procedures a year in Finland, the UK and the USA, respectively.^{1–3} Among the most feared complications of LCC, are bile duct injuries (BDIs). At minimum, they result in prolonged recovery, but usually in reinterventions, and need for long term follow-up as well.^{4–7} The most severe BDIs usually arise from mistaking the common bile duct (CBD) for the cystic duct leading to complete transection of the CBD. LCC carries an overall 0.3–1.8% risk of BDI and 0.1–0.5% risk of severe BDI (Strasberg type D-E).^{8–12}

Several surgical techniques have been proposed to minimize the risk of BDIs. An identification method - the Critical View of

Safety (CVS) - coined by Strasberg *et al.*, in 1995,¹³ is considered one of the most successful. In CVS, the surgeon obtains a view where first, excess fat is cleared off Calot's triangle, second, only two structures enter the gallbladder and third, the gallbladder's lower third is lifted off the cystic plate. Only then, is transecting the cystic duct and artery safe. The safety and feasibility of CVS have been demonstrated by many studies that reported not a single BDI resulting from misidentified anatomy in surgeries, where CVS was used according to the operative note.^{14–16} However, as CVS cannot accurately be deduced from the operative note, studies have suggested intraoperative photos and videos as means to document satisfactory CVS.^{17–20} Conversely, previous studies on photo documentation have been rather small (less than 230 patients), and to our knowledge, no previous

studies have aimed at evaluating the association of photos of satisfactory CVS with the prevalence of BDIs.

The primary aim of this study was to investigate if satisfactory intraoperative photo documentation of CVS is associated with BDIs. Postoperative complications in regard to satisfactory CVS were a secondary outcome.

Methods

The study was carried out from April 2018 to October 2019 in Meilahti hospital and from October 2018 to October 2019 in Jorvi hospital. Meilahti hospital hosted mainly emergency LCCs, whilst Jorvi hosted both emergency and elective LCCs. Both hospitals are part of Helsinki University Hospital, which serves as a secondary referral center for 1.1 million and tertiary referral center for 1.6 million inhabitants. The hospital review board approved the study. Permission from the ethical review board was not needed since no patients were contacted. All surgeons performing LCC were instructed – without mention of CVS – to take one anterior and one posterior photo of the intraoperative view prior to clipping the alleged cystic duct and artery. Surgeons were allowed to omit photos if they converted to open cholecystectomy before clipping the structures. The staff in the operating room departments received an instruction sheet complete with model photos of the anterior and posterior views (Fig. 1).

Patients were retrospectively identified from the operating room database using procedure codes (JKA21 and JKA20) and International Classification of Diseases codes for benign gallbladder disease (K80.0-K85.9). Patient data were extracted from medical records. The authors (JH, LK, HL, PM), all consultant gastrointestinal (GI) surgeons, rated the intraoperative photos. The photos were randomly assigned, and the raters were blinded to all patient data. Two raters independently scored both the anterior and posterior photos of each patient. Each three criteria (excess fat cleared off Calot's triangle, only two structures enter the gallbladder, gallbladder lifted of the lower third of the cystic plate) of CVS received scores of 0–2 according to specifications by Sanford *et al.*²¹ The doublet score from 0 to 6 was the sum of

the better scored criteria for CVS. For example, if the anterior photo scored 2 points on only 1/3 criteria of CVS, but the posterior photo received 2 points on each remaining 2/3 criteria, the doublet score would be 6 points. The final CVS score was the mean of the doublet scores of the two raters. A final score of 4.5 or higher was deemed satisfactory for CVS, since other studies had used scores of over 4 to 5 as limits for satisfactory CVS.^{18,21}

The Strasberg classification was used for BDIs¹³ as following; (A) Cystic duct or liver bed leaks (B) Partial occlusion the biliary tree (C) Bile leak from duct that is non-communicating with the CBD (D) Lateral injury of the biliary system, without loss of continuity (E) Circumferential injury of biliary tree with loss of continuity. Postoperative complications were assessed with the Clavien-Dindo classification.²² The Comprehensive Complication Index (CCI) was calculated for each patient.²³

Statistical analyses were performed with SPSS Statistics v. 26.0 and STATA v. 16. The Pearson Chi-Square test was used for categorical variables and Kruskal-Wallis H test for continuous variables. The association of photo documentation (satisfactory, unsatisfactory, missing photo) with BDIs and postoperative complications was evaluated with the Linear-by-Linear Chi-Square test. The association between photo documentation and CCI was evaluated with the Jonckheere–Terpstra test. Inter-rater agreement was reported using the weighted kappa statistic, which accounts for the possibility of agreement by chance (values ≤ 0 as indicating no agreement, 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement.). A p value of <0.05 was considered significant. All tests were carried out two-sided.

Results

The electronic records of 1683 patients were extracted. Forty-six primarily open cholecystectomy patients were excluded. Furthermore, 99 patients, whose surgeries were converted prior to dissection of the cystic duct and artery, were excluded. Moreover, five patients had cholecystectomy in addition to another surgery and were excluded. One patient lacked the

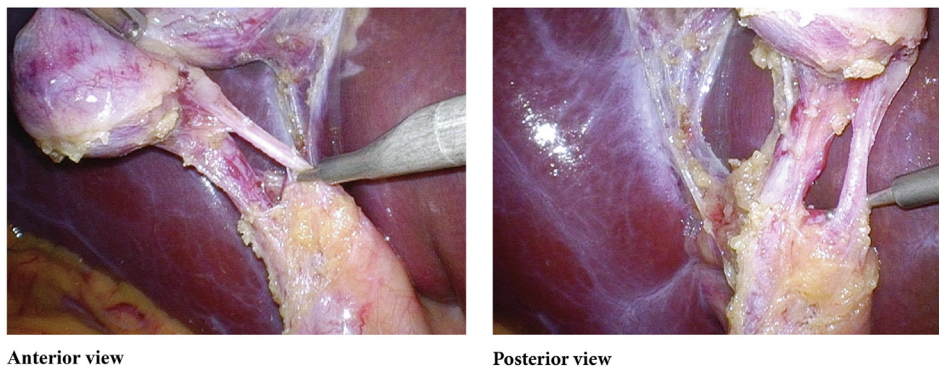


Figure 1 Intraoperative photos of the anterior and posterior view. Both photos received 6 points each by both raters

operation note and was excluded. These exclusion criteria yielded 1532 patients, of which 851 (55.5%) had gallstone disease with biliary colic, 549 (35.8%) had acute cholecystitis, 71 (4.6%) had symptomatic bile duct stones, 47 (3.1%) had biliary pancreatitis, and 14 (0.9%) had other diagnoses. A total of 851 (55.5%) patients had elective surgery, and 681 (45.5%) patient's emergency surgery. The lead surgeon was a consultant GI surgeon in 769 (50.2%) of the surgeries.

Of the patients, 1177 (76.8%) had two photos of intraoperative CVS each. The median (IQR) CVS score was 3 (1.5–3.5), and 354 (23.1%) patients had a satisfactory CVS (score \geq 4.5). The weighted kappa statistic for inter-rater agreement was 0.36 for the anterior view, indicating fair agreement, 0.42 for the posterior view, indicating moderate agreement, and 0.33 for the doublet score, indicating fair agreement. The median (IQR) CVS scores given by the four raters were 2 (0–4.0), 2 (1.0–4.0), 4 (2.0–5.0) and 4 (2.0–6.0), ($p < 0.001$), and the rates of photos with scores of \geq 4.0 were 208/606 (34.3%), 144/567 (25.4%), 348/588 (59.2%), and 394/593 (66.4%), respectively.

Patients with satisfactory CVS (score \geq 4.5) were compared with patients with unsatisfactory CVS (score $<$ 4.5) and patients

without photos in Table 1. Patients with unsatisfactory CVS or missing photos were older, and had more comorbidities and emergency procedures than patients with satisfactory CVS. Of patients with acute cholecystitis, 86 (15.7%) of 549 patients had satisfactory CVS, whereas 263 (26.8%) of 983 without cholecystitis had satisfactory CVS, ($p = <0.001$). In emergency LCC, patients with unsatisfactory CVS had significantly higher C-reactive protein levels and higher white blood cell counts than patients with satisfactory CVS (Table 1). Intraoperative cholangiography (IOC) was performed in two patients; in one with a CVS score of 6 for suspected bile duct stones, and in another without photos to confirm a suspected choledochal injury (Strasberg E). The percentage of LCCs with photo documentation and satisfactory CVS are presented in Fig. 2. The percentage of photographed LCCs remained unchanged during the study.

BDIs are presented in Table 2. The overall BDI rate was 1.1% with 0.3% for severe BDIs (Strasberg D-E). Emergency and elective surgeries had 9 (1.3%) BDIs of which 2 (0.3%) were severe and 8 (0.8%) BDIs of which 2 (0.2%) were severe, respectively. Patients with satisfactory CVS had the lowest BDI rate compared with patients with unsatisfactory CVS or without photos (0.3% vs. 1.0% vs. 2.3%, $p = 0.012$). The only BDI among

Table 1 Comparison of patients ($n = 1532$) with satisfactory (score \geq 4.5), unsatisfactory CVS (score $<$ 4.5) or missing photos. OR expressed for satisfactory CVS compared with unsatisfactory CVS or missing photo

	CVS satisfactory ($n = 354$) (%)	CVS unsatisfactory ($n = 823$) (%)	Photo missing ($n = 355$) (%)	OR (95% CI)	P
All LCCs					
Gender: male	105 (29.7)	323 (39.2)	144 (40.6)	0.6 (0.5–0.8)	0.003
Age, mean (IQR)	53 (39–67)	56 (42–69)	59 (46–72)		<0.001
Diabetes	20 (5.6)	84 (10.2)	39 (11.0)	0.5 (0.3–0.8)	0.023
ASA category $>$ 2	99 (28.0)	274 (33.3)	162 (45.6)	0.7 (0.5–0.9)	<0.001
Previous surgery on upper abdomen	17 (4.8)	21 (2.6)	23 (6.5)	1.3 (0.7–2.3)	0.004
Any previous abdominal surgery	108 (30.5)	215 (26.1)	117 (33.0)	1.1 (0.9–1.5)	0.041
Fundus first method used	7 (2.0)	25 (3.1)	12 (3.4)	0.6 (0.3–1.4)	0.488
Intraoperative cholangiography	1 (0.3)	–	1 (0.3)	3.3 (0.2–53.4)	0.313
Length of surgery, min (median, IQR)	63 (51–88)	82 (63–109)	82 (60–113)		<0.001
Emergency LCCs only					
CRP, median (IQR) ^a	109 (31–168)	143 (53–239)	126 (46–225)		0.004
WBCC, median (IQR) ^a	12.0 (8.8–15.0)	13.1 (9.9–16.9)	12.3 (9.8–16.7)		0.009
Surgical findings:					
Acute cholecystitis	85 (73.3)	325 (81.7)	138 (82.6)	0.6 (0.4–1.0)	0.097
Gangrene	14 (12.1)	109 (27.4)	48 (28.7)	0.4 (0.2–0.6)	0.002
Abscess	1 (0.9)	7 (1.8)	6 (3.6)	0.4 (0–2.9)	0.228
Perforation	2 (1.7)	14 (3.5)	8 (4.8)	0.4 (0.1–1.9)	0.388

ASA American Society of Anesthesiologists, BDI Bile Duct Injury, CI Confidence Interval, CRP C Reactive Protein CVS, Critical View of Safety, IQR Interquartile Range, LCC Laparoscopic cholecystectomy, OR Odds Ratio, WBCC White Blood Cell Count.

^a CRP and WBCC missing in 11 patients.

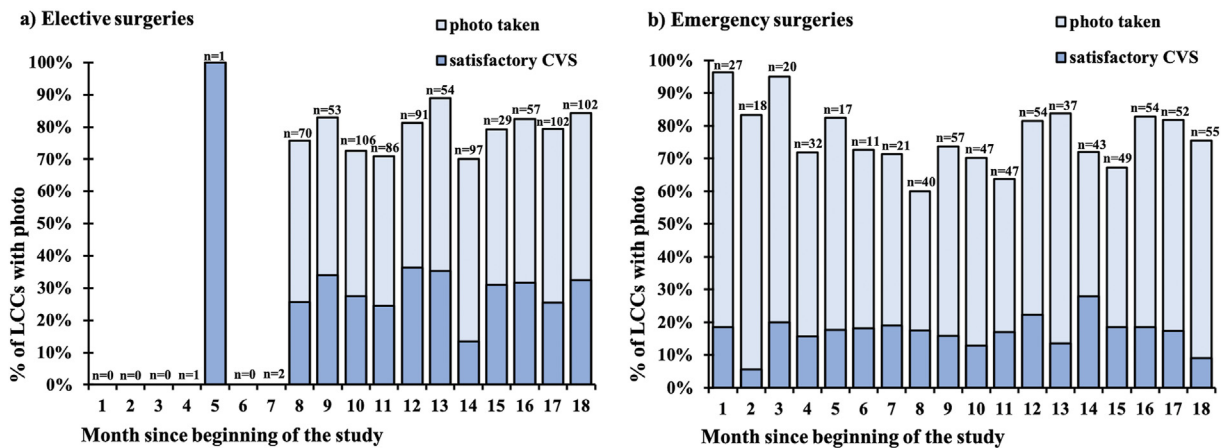


Figure 2 Intraoperative photos taken in elective (n = 851) and emergency (n = 681) laparoscopic cholecystectomies. The photographing of elective procedures in Jorvi hospital began in the 8th month of the study. Elective cholecystectomy was rarely performed in Meilahti hospital, which recruited from the beginning of the study. CVS Critical View of Safety, LCC Laparoscopic cholecystectomy

Table 2 Bile duct injuries that occurred during laparoscopic procedures only (n = 1532). Two of the procedures were converted upon the discovery of bile duct injury following division of the alleged cystic duct

Strasberg class	CVS score satisfactory (n = 354) (%)	CVS score unsatisfactory (n = 823) (%)	Photo missing (n = 355) (%)	Total (n = 1532)	P
A	1 (0.4)	6 (0.7)	6 (1.7)	13 (1.0)	
B					
C					
D		1 (0.1)		1 (0.1)	
E		1 (0.1)	2 (0.6)	3 (0.2)	
Total	1 (0.3)	8 (1.0)	8 (2.3)	17 (1.1)	0.012

CVS Critical View of Safety.

patients with satisfactory CVS, was Strasberg type A. Three BDIs were Strasberg type E, where the CBD was completely transected. Two of these had no photos of attempted CVS at all, and the third one had an unsatisfactory CVS score of 1.0. All three patients were treated with hepaticojejunostomy.

Postoperative complications are presented in Table 3. The most severe complication was reported for each patient. Patients with satisfactory CVS had the lowest postoperative complication rate compared with patients with unsatisfactory CVS or without photos (4.8% vs. 7.9 vs. 9.9%, $p = 0.011$). The CCI was the lowest in patients with satisfactory CVS as well ($p = 0.009$). Furthermore, patients with satisfactory CVS had no Clavien-Dindo class 4 or 5 complications.

Discussion

In this study, patients with satisfactory CVS had the lowest BDI rate and had no severe BDIs arising from misidentification of anatomy. Second, satisfactory CVS was associated with fewer

postoperative complications. These findings are supported by other studies, in which no severe BDIs have been reported to arise with the successful use of CVS,^{14–20} and where satisfactory CVS has been linked to a lower rate of postoperative complications.²⁰

The overall BDI rate of 1.1% is within limits of 0.3–1.8% reported by other studies.^{8–11} Many of these studies, however, seem to exclude minor postoperative bile leaks. The overall rate for severe BDIs (Strasberg D–E) of 0.3% is also in line with the 0.1–0.5% described by previous literature.^{8–12} In comparison, only 0.3% of patients with satisfactory CVS in this study had BDIs and 0% had severe BDIs, suggesting CVS as possible means to lower the BDI rate. The overall postoperative complication rate (7.6%) of this study also fell within limits (7.4–8.8%) reported by other studies.^{5,20,24}

Interestingly, patients with no photo documentation of CVS had the highest BDI and postoperative complication rates. Several reasons, such as technical issues, might account for missing photos. Furthermore, patients with missing photos were

Table 3 Postoperative complications based on the Clavien-Dindo Classification (n = 1532)

Clavien-Dindo Class	CVS score satisfactory (n = 354) (%)	CVS score unsatisfactory (n = 823) (%)	Photo missing (n = 355) (%)	Total (n = 1532)	P
1	2 (0.6)	5 (0.6)	3 (0.8)	10 (0.7)	
2	8 (2.3)	30 (3.6)	13 (3.7)	51 (3.3)	
3A	6 (1.7)	20 (2.4)	10 (2.8)	36 (2.3)	
3B	1 (0.3)	2 (0.3)	5 (1.4)	8 (0.5)	
4		4 (0.1)	2 (0.6)	6 (0.4)	
5		4 (0.1)	2 (0.6)	6 (0.4)	
Total	17 (4.8)	65 (7.9)	35 (9.9)	117 (7.6)	0.011
CCI, median (IQR)	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)	0.009
CCI, mean (SD) ^a	1.1 (4.9)	2.3 (9.5)	3.0 (11.1)	2.2 (9.1)	

CCI Comprehensive Complication Index, CVS Critical View of Safety, IQR Interquartile Range, SD Standard Deviation.

^a The CCI was not normally distributed so no statistical tests were performed.

older with higher ASA scores, and underwent more emergency surgeries. These factors in themselves might increase the risk of BDIs and complications, in addition to preventing taking a satisfactory photo, which might cause the surgeon to exclude it altogether. A multivariate analysis on risk factors for BDIs was, however, deemed unreliable due to the low number of events (n = 17) and hence, was not performed. However, particularly in these more challenging cases, striving for taking photos and using CVS might increase the surgeon's focus and heighten awareness of the risk of BDI. The better results of surgeries with photo documentation might partially be explained by the "Hawthorne effect", which causes individuals to alter their behavior in response to observation, and in this case; performing more meticulous dissection before placing clips. Capturing a satisfactory CVS view with still photos might be technically impossible in some cases, even if the surgeon is certain of the view intraoperatively, where more than two points of view are available. Nevertheless, if CVS can be neither photographed nor visualized, one should consider bail-out techniques such as requesting assistance from a more experienced colleague, IOC, subtotal cholecystectomy or conversion.

CVS is seemingly not the most commonly used identification method, although many studies have recommended it as an effective way to lower BDIs. Indeed, CVS has not been routinely used at our institution, which might reflect in the high rate of unsatisfactory CVS photos. Previous studies have, as well, demonstrated poor knowledge of CVS among surgeons, as only 20–25% of surgeons in these studies were identifying CVS correctly.^{18,20} After all, since CVS was first described as late as in 1995, and widespread knowledge of it took time, a majority of surgeons might not yet have had the chance to be educated in it. Hence, further knowledge and education on CVS are needed.

As deduced, mandatory photo documentation of CVS might motivate better performance, and the rate of satisfactory photo documentation of CVS has been shown to rise with teaching interventions, such as lectures given by more experienced

surgeons.^{17–19} Furthermore, implementing CVS as the standard technique for training surgeons might be the most straightforward way of achieving widespread use of CVS. First however, senior surgeons would need to learn CVS. Encouragingly, a study found that consultant GI surgeons were more adept to learning a new technique, and achieved higher rates of satisfactory CVS following teaching interventions, compared with residents or general surgeons.¹⁹ In addition, in BDIs, intraoperative photos could aid in educating individual surgeons on safe LCC, as they provide concrete documentation on why it was unsafe to precede to clipping the seen structures. Some studies have recommended the use of videos,^{17,20} but these are usually more expensive and harder to store than photos.

The true rate of satisfactory CVS in this study might have been influenced by several confounders. First, some of the unphotographed procedures in 355 patients might actually have been satisfactory for CVS. Second, the inter-rater agreement for CVS scores was only fair. Furthermore, the raters differed significantly in their criticalness in the ratings but using two raters for each picture instead of one might have balanced out some of the differences in criticalness. Also, choosing a mean score of >4.5 as satisfactory meant that no pictures with scores under 3 could be rated satisfactory, and at least one of the raters must have given a score of 5 or higher. Third, poor technical qualities of some pictures might have earned them lower ratings compared with what technically precise pictures would have received. In the future, problems with subjective rating might be solved with Artificial Intelligence models that have been able to provide more objective, yet reliable ratings for CVS.²⁵ The study results might further have been affected by the retrospective nature of the data collection as it is prone to reporting and interpretation errors. Further, since this was not a randomized controlled trial, no causality of CVS and BDIs or complications can be assessed.

Intraoperative photos provide a safe and easy way to document CVS. Satisfactory CVS is associated with lower BDI and postoperative complication rates, and the photos might be used

to educate surgeons in safe LCC outside the operating room as well. We recommend that CVS with photographic documentation should be attempted in all LCCs as means to heighten awareness and minimize the risk of BDIs.

Conflict of interest

Dr. Terho reports grants from Finska Läkaresällskapet and Victor-iaistiftelsen, outside the submitted work. Dr. Koskenvuo reports grants from Mary et Georg Ehrnrooth's Foundation and grants from the Cancer Foundation Finland (Syöpäsäätiö), outside the submitted work. Dr. Sallinen reports grants from Helsinki University Hospital research grants, during the conduct of the study and grants from Vatsatautien tutkimussäätiö Foundation, grants from Mary et Georg Ehrnrooth's Foundation, grants from Academy of Finland, and grants from Cancer Foundation Finland (Syöpäsäätiö), outside the submitted work. Dr. Harju, Dr. Lampela and Dr. Mentula have nothing to disclose.

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