

# Complications After Laparoscopic Cholecystectomy: A Video Evaluation Study of Whether the Critical View of Safety was Reached

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## Abstract

**Background** Achieving the critical view of safety (CVS) before transection of the cystic artery and duct is important to reduce biliary duct injury in laparoscopic cholecystectomy. To gain more insight into complications after laparoscopic cholecystectomy, we investigated whether the criteria for CVS were met during surgery by analyzing videos of operations performed at our institution.

**Methods** All consecutive patients who underwent a completed laparoscopic cholecystectomy between 2009 and 2011 were included. The videos of the operations of patients with complications were independently reviewed and rated by two investigators with a third consulted in the event of a disagreement. The reviewers answered consecutive questions about whether the CVS criteria were met. Patients who underwent an elective laparoscopic cholecystectomy and had no complications were used as a control group for comparison.

**Results** Of the 1108 consecutive patients who had undergone a laparoscopic cholecystectomy during the study period, 8.8 % developed complications (average age 51 years) and 1.7 % had bile duct injuries [six patients (0.6 %) had a major bile duct injury, type B, D, or E injury]. In the 65 surgical videos available for analysis, CVS was reached in 80 % of cases according to the operative notes. However, the reviewers found that CVS was reached in only 10.8 % of the cases. Only in 18.7 % of the cases the operative notes and video agreed about CVS being reached. CVS was not reached in any of the patients who had biliary injuries. In the control group, CVS was reached significantly more often in 72 %.

**Conclusions** In our institutional series of laparoscopic cholecystectomies with postoperative complications, CVS was reached in only a few cases. Evaluating surgical videos of laparoscopic cholecystectomy cases are important and we recommend its use to improve surgical technique and decrease the number of biliary injuries.

## Introduction

Many studies have confirmed that laparoscopic cholecystectomy is a safe procedure and that patients recover more rapidly after laparoscopic than after open cholecystectomy [1]. However, the procedure is not without risk.

Complications such as bowel perforations and bile duct injuries (BDIs) increase the morbidity and mortality risks of the procedure [2]. To prevent complications, especially BDIs, safety protocols have been developed over the past several years.

An important method to prevent BDIs was published in 1995 by Strasberg et al., who described how a “critical view of safety” (CVS) should be achieved in each laparoscopic cholecystectomy [3]. For CVS to be achieved, three criteria must be fulfilled. First, the triangle of Calot [4] must be cleared of fat and fibrous tissue and a 360°

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view of the cystic duct must be attained. Second, the lowest third of the gallbladder must be dissected from the liver bed. Third, two and only two structures, should be seen entering the gallbladder: the cystic duct and cystic artery [3, 5]. Once these three criteria have been fulfilled, CVS has been attained (Fig. 1). Attaining CVS would prevent accidental biliary and vascular injuries due to uncommon variations of anatomy, bleeding, and unclear anatomy.

Since the publication of several reports on serious biliary injuries, CVS has gained in popularity as a safety method [6, 7]. CVS is not a dissection technique, but rather a technique of identification [3]. Several methods besides CVS exist to prevent biliary injuries, including nine techniques for intraoperative assessment of bile duct anatomy [8], the use of vascular and biliary fluorescence imaging to visualize the anatomy [9], and intraoperative cholangiography, which has been shown to reduce the risk of BDIs and to decrease the mortality rate of cholecystectomy [10]. Another method is the use of a 30° laparoscope [11–13], and extra biliary reference points can play a role in avoiding BDIs [12, 13]. Finally, Hunter popularized maneuvers during laparoscopic cholecystectomy to aid in the safe dissection of the gallbladder hilum: firm cephalic traction on the fundus of the gallbladder to reduce redundancy in the infundibulum of the gallbladder, lateral traction on the infundibulum of the gallbladder to place the cystic duct perpendicular to the common bile duct, and dissection of the cystic duct at the infundibulum of the gallbladder' [3, 11]. However, the Dutch guidelines recommend to use CVS as the standard safety method in the Netherlands.

The Dutch guidelines [4, 14] also state that the operative note should contain a statement about whether CVS has been reached during laparoscopic cholecystectomy, and that a picture of CVS should be included. Because of



**Fig. 1** Critical view of safety

advances in visual technologies, it is now possible to record a video of the procedure and studies have shown that a video is better than a picture to evaluate CVS properly [15].

To gain more insight in laparoscopic cholecystectomies resulting in complications, we conducted a retrospective study to determine whether the requirements of CVS were met. We also sought to determine whether the operative note concurs with the video in patients who developed complications after undergoing a laparoscopic cholecystectomy.

## Patients and methods

The study population consisted of all consecutive patients who underwent a laparoscopic completed cholecystectomy for symptomatic gallstone disease at the Amphia Hospital in Breda, a major teaching hospital in the Netherlands, between 2009 and 2011. Acute and elective cases were included and no distinction was made between cholelithiasis or cholecystitis. The routine use of a 30° scope and a cholangiography are not standard in our practice. The study was approved by our IRB and the need for informed consent was waived due to the retrospective study design and the fact that no interventions were carried out.

Medical records, videos if available, and the operative notes were reviewed retrospectively. Standard demographic information, including imaging, surgery information, and complications (BDIs and non-bile duct injuries) were recorded. Videos of laparoscopic cholecystectomies were routinely saved on DVD, which were stored in the medical archive. We also noted complications in patients who underwent conversion from laparoscopic to open cholecystectomy, and the reason for conversion.

Complications were defined as all adverse events within 30 days after surgery. In case of a BDI, the type of injury was recorded according to the Strassberg classification: minor BDI (type A: leakage into the gallbladder bed) or major BDI (type B, C, D, and E) [3]. Non-bile duct injuries were recorded retrospectively from electronic patient records. Wound infections were defined by the following criteria. Infection must occur within 30 days of the operation and at least one of the following is present: purulent discharge from the surgical site, purulent discharge from wound or drain placed in wound, and organisms isolated from aseptically obtained wound culture. In addition, there must be at least one of the signs and symptoms of infection—pain or tenderness, localized swelling, or redness/heat. ‘Abdominal pain’ was defined as tenderness or abdominal discomfort which led to extra consultation at the outpatient clinic, emergency department or hospital admission, without any specific diagnosis post-operatively. To ensure that we did not exclude late BDIs such as

**Table 1** Patient and surgical characteristics

	Complication group ( <i>N</i> = 98)	Control group ( <i>N</i> = 75)	<i>p</i> value <sup>a</sup>
Female <i>n</i> (%)	70 (71.4 %)	50 (66.7 %)	n.s.
Average age in years (range)	51 (20–84)	50.4 (19–81)	n.s.
Indications for surgery			n.s.
Symptomatic cholecystitis	81 (82.7 %)	55 (73.3 %)	
Acute cholecystitis	16 (16.3 %)	10 (13.3 %)	
Elective: after cholecystitis	1 (1 %)	3 (4 %)	
Elective: gallbladder polyps	0	1 (1.3 %)	
Elective: after biliary pancreatitis	0	4 (5.3 %)	
Elective: A typical abdominal pain	0	1 (1.3 %)	
Elective: after cholangitis	0	1 (1.3 %)	
Missing video	29 (28 %)	n.a.	n.a.
Resident performing the surgery	28 (28.6 %)	24 (32 %)	n.s.
CVS reached in the operative notes in reviewed cases	52 (80 %)	73 (97.3 %)	0.003
CVS reached in reviewed cases	7 (10.8 %)	54 (72 %)	<0.001

*n.a.* not applicable, *n.s.* not significant

<sup>a</sup>  $\chi^2$  test and *t* test

obstruction due to injuries that were missed during the operation, we reviewed all medical records for data from gastroenterology and surgery departments for BDIs that were diagnosed more than 30 days after laparoscopic cholecystectomy in patients who had complications.

As a control group, we included a random group of 75 consecutive patients in whom the DVD with video was available who underwent an elective laparoscopic cholecystectomy for symptomatic gallstone disease without complications. All cases with conversion to open cholecystectomy or missing videos were excluded.

Available videos of the surgery of all patients with complications were reviewed and rated by two researchers (surgical intern and senior resident in gastro-intestinal (GI) surgery) and one GI surgeon independently. The reviewers answered consecutive questions about the three CVS criteria. If all three criteria were reached, CVS was considered to have been obtained. When the observers disagreed about whether CVS was obtained, the outcome was discussed and a third GI surgeon was consulted. All reviewers were blinded for clinical and surgical data and patient outcome. A discrepancy between what the operative note said about CVS and what the video analysis showed was recorded.

Statistical analysis was performed with SPSS 20.0 for Windows. Means are shown with standard deviation if data were distributed normally and shown as medians and interquartile range if data were not normally distributed. The inter-observer agreement (Kappa score) was calculated for the video assessments. The  $\chi^2$  test was used to analyze the relationship between complications (including BDIs specifically) and whether CVS was obtained.

## Results

### Patient and surgical characteristics

During the study period, 1116 consecutive patients with symptomatic gallstone disease underwent a laparoscopic cholecystectomy. Of these patients, the medical records could not be retrieved for eight, yielding a total of 1108 patients available for analysis.

Most (83.7 %) of the 1108 patients underwent elective surgery, most often for symptomatic cholecystolithiasis, followed by recurrent biliary pancreatitis, and recent cholecystitis. The operations were performed by 16 surgeons. In 29 % of cases, the operation was carried out by a resident, with an attending surgeon supervising. In 31 %, the operation was carried out by a GI surgeon. The remaining operations were done by surgeons who are generalists in laparoscopic abdominal surgery.

The control group of patients who did not have complications (Table 1) consisted of 25 men and 50 women (mean age 50.4 years, range 19–81 years). Indications for surgery were symptomatic cholecystolithiasis (55 cases, 73.3 %) and acute cholecystitis (10 cases, 13.3 %). This group was comparable with the complication study group.

### Complications

A total of 98 (8.8 %) patients developed complications (Table 2), the most common of which were wound infections and non-specific abdominal pain, which was defined as abdominal pain for which there is no diagnosis after examination and baseline investigations. Nineteen patients

**Table 2** Complications in 98 patients after laparoscopic cholecystectomy

Type of complication	N (%)
Non-specific abdominal pain	34 (3.06)
Wound infection	22 (1.96)
Biliary injury	19 (1.71)
Trocar/wound bleeding	10 (0.90)
Recurrent symptomatic choledocholithiasis	9 (0.81)
Intra-abdominal bleeding	4 (0.36)
Bowel injury	3 (0.27)
Trocar hernia	1 (0.09)
Septic shock (resulting in death)	1 (0.09)
Other <sup>a</sup>	8 (0.36)

<sup>a</sup> Other complications: urinary tract infection, pneumonia, pancreatitis

(1.7 %) had BDIs, six of whom (0.6 %) had a major BDI, type B, D, or E (Table 3).

Thirty-two patients (2.8 %) were re-admitted to the hospital, and 33 (2.9 %) re-interventions were performed in 29 patients (2.6 %). Of these patients, 17 underwent an ERCP, eight underwent percutaneous drainage (six bilomas, two abscesses). Eight patients required another surgical procedure, six of whom underwent a re-laparoscopy for suspected bowel perforation, bile duct injury, or bleeding. Three of these eight patients underwent an additional laparotomy for persistent fistula, bowel perforation, or bleeding.

Three patients of the complication group (3 %) underwent an ERCP after more than one month after the cholecystectomy. In two cases, the ERCP was done to extract a common bile duct stone. In one of this cases also a bile duct stent was placed as the common bile duct was very narrow, which might have been a stricture. The third ERCP was performed cause of the suspicion of late bile leakage. No leakage was found but the ERCP was complicated by a perforation. All of these patients were diagnosed with minor complications in the first 30 days like as wound infections.

In 31 cases (2.8 %) of the overall group, the laparoscopic cholecystectomy was converted to an open procedure. Mostly this was done due to massive adhesions and infiltration (90 %) surrounding the gallbladder. In three cases a late conversion was performed, after CVS was already reached according to the operative notes. In these cases, the surgeon decided to convert due to a bleeding from the cystic artery after dissection. In one case (3 %), a minor bile duct injury occurred for which a re-laparotomy was performed. Three patients (10 %) developed a wound infection. In five cases (16 %), an ERCP or MRCP was performed because of persistent abdominal complaints, none of which revealed any abnormal findings.

## Video analysis

The video of the operation was missing for 29 of the 98 patients who had complications. Four additional patients were excluded from video review for the following reasons: in two cases, the gallbladder was freed from the liver fundus first, in which case no CVS would be reached. For two patients, only a video of the re-intervention laparoscopy was available.

For the 65 available videos of laparoscopic cholecystectomies analyzed by the three reviewers (MN, JS, AR), inter-observer agreement for reaching CVS was very high, with a Kappa score of 0.96. The inter-observer agreement was 0.99 for 360° view, 0.97 for two-structure view, and 0.97 for 1/3 of the gallbladder freed. In two cases (1.4 %), observers disagreed initially about whether CVS was reached, but after discussion and consultation with a third GI surgeon, consensus was reached in both cases.

## Agreement between video analysis and operative note

According to the operative notes for the 65 patients who had videos, CVS was attained in 52 patients (80 %). However, video review indicated that in CVS was attained in only 10.8 % of cases, all of which occurred when a resident was performing the surgery. When CVS was not reached, a gastro-intestinal surgeon was performing the surgery in 22.4 % of the cases, a non-GI surgeon in 50 %, and a resident in 27.6 % of the cases. The operative note and video agreed in 18.7 % about CVS being reached. Eleven videos of patients with BDIs were available. In 73 % of the cases with biliary injuries, the operative report noted that CVS was attained. Importantly, according to the video analysis CVS was not attained in any of the patients with a BDI. In most of these patients none of the three criteria for CVS appeared to have been met, which is significantly different than in the other cases (non-bile duct complications and control group) ( $p = 0.008$ ) (Table 4).

In the control group of 75 patients, the operative notes indicated that CVS was attained in 73 cases (97.3 %). According to the video analysis, CVS was actually reached in 54 cases (72 %). There was no significant difference in reaching CVS between gastro-intestinal and general surgeons in the study and control group overall ( $p = 0.48$ ). CVS was reached in much more operative notes (97.3 vs. 80 %) and was reached significantly more often in the control group (72 vs. 10.8 %,  $p = 0.0001$ ).

## Discussion

Attaining CVS in laparoscopic cholecystectomy is critically important. This way of dissecting the gallbladder

**Table 3** Type of biliary injury after laparoscopic cholecystectomy in 1108 patients

Type of biliary injury	N (%)
Type A leakage into the gallbladder bed	13 (1.17)
Type B occlusion injuries of aberrant right hepatic ducts	2 (0.18)
Type C transection injuries of aberrant right hepatic ducts	0 (0)
Type D lateral damage to the common bile duct resulting in a biliary leak	3 (0.27)
Type E injuries to the main ducts	1 (0.09)
Total	19 (1.71)

Type B, C, D, E = major bile duct injury

pedicle is highly protective against bile duct injuries [6, 14–16]. Our study sought to examine if CVS was attained in patients who underwent a laparoscopic cholecystectomy that resulted in complications. Of 1108 patients studied, 8.8 % developed complications ranging from wound infection to biliary injuries. The percentage of BDIs was relatively high (1.7 %), and 0.6 % were major bile duct injuries. This percentage did not exceed the average of 0.26–0.6 % reported in other studies [17].

The incidence of biliary injuries has not decreased in the past decade [18]. One reason for this may be that although CVS is recommended, it is often not attained. In our study, the video reviewers found that CVS was not reached in any of the patients who had BDIs. Furthermore, one or two of the three CVS criteria were met only in a few cases. Consequently, there was a high risk of BDI. As far as we know, other studies have not reported yet whether CVS was actually reached in cases with complications.

Our analysis of 65 patients who had both an operative note and a video showed that a large discrepancy regarding whether CVS was attained. According to the operative notes, CVS was reached in 52 patients (80 %), whereas video review indicated that this was true in only 10.8 % of cases. The operative note and video agreed about CVS being reached in only 18.7 % of cases; a finding that agrees with those from another study that reported that operative notes do not always adequately represent the actual laparoscopy performed [19]. In our study, CVS was not reached in any of the patients who had biliary injuries, although CVS was reported to be reached in 73 % of operative notes. These findings suggest that although a surgeon may have stated or believed that CVS was reached, as documented in the operative note, this was not the case. Whether surgeons actually believed they had reached CVS or if they just routinely state that they have cannot be determined from our study. Since the video reviewers' task was only to ascertain whether the criteria of CVS were met, there is no way to tell whether surgeons could have

prevented BDIs if CVS was reached in the patients in our series.

In our study, the operative note reported that CVS was reached much more often in patients who had no complications than in those who had them (97.3 vs. 80 %). The disparity was even greater for video review, which showed that CVS was attained much more often in the control group than in the complication group (72 vs. 10.8 %). This shows that CVS contributes to the safety of the operation and limits the complications.

The availability of surgical videos enabled us to analyze cases with complications in detail. Unfortunately, videos were missing for 28 % of patients with complications and 32 % of those without complications because not all videos were recorded or stored properly at the beginning of our study. Our Department's goal is to video record all minimally invasive procedures on DVD, but in many hospitals in the Netherlands, this is not yet a common practice, although there is clear evidence that a video analysis of CVS in laparoscopic cholecystectomy is better than a picture [15]. Since 2013, every laparoscopic procedure in our hospital has to be recorded on DVD. These DVDs are stored in the medical archive. However, we are aiming for digital video storage in the electronic patient system. Despite the absence of videos for many patients, our study still presents information about CVS for the majority of patients who had a complicated course. Another study limitation is that the video reviewers were not blinded for the purpose of the study. To limit the effects of this, they reviewed the videos independently.

The purpose of reaching CVS is specifically to prevent BDIs, not other complications. We nevertheless reported all complications rather than only BDIs, because we were interested in exploring a potential connection between CVS and other complications. For example, there might have been a relationship between not attaining CVS and less precise surgical dissection, or a technically challenging dissection due to inflammation. If we found that kind of relationship, there could also be a connection with the occurrence of other complications such as postoperative hemorrhage or infections because of bile leakage. We did not find any specific relationship, although our study design was not appropriate to investigate this and a sequel study is recommended. We consider follow-up rate and completeness of complication registration of postoperative patients as high, as all patients were seen for follow-up 2 weeks post-operatively and all patients lived in the area served by our hospital and emergency room.

Our findings lead us to recommend that surgeons and surgical residents continue to be trained on CVS. After we analyzed our findings, our Department implemented measures to educate surgeons and residents through lectures, an instructive email, and instructive videos on the topic of

**Table 4** Evaluation of critical view of safety (CVS) between patients who had complications and patients who did not have complications after laparoscopic cholecystectomy

CVS criteria		CVS not reached complications group overall <i>N</i> = 58 (89.2 %)	CVS not reached BDIs group <i>N</i> = 11 (100 %)	CVS not reached control group <i>N</i> = 21 (28 %)	<i>p</i> value
360° view of cystic duct	No <i>N</i> (%)	42 (64.6 %)	8 (72,7 %)	9 (12 %)	0.009
	Yes <i>N</i> (%)	23 (35.4 %)	3 (27.3 %)	66 (88 %)	
Two structures seen entering gall bladder	No <i>N</i> (%)	47 (72.3 %)	10 (91 %)	18 (24 %)	0.002
	Yes <i>N</i> (%)	18 (27.7 %)	1 (9 %)	57 (76 %)	
1/3 of gall bladder dissected from liver	No <i>N</i> (%)	44 (69.3 %)	11 (100 %)	15 (20 %)	0.000
	Yes <i>N</i> (%)	20 (30.7 %)	0 (0 %)	60 (80 %)	

CVS and the pitfalls of laparoscopic cholecystectomy. For the future, we aim to invest in 3D imaging in laparoscopy with angled scopes to improve safety.

In the Netherlands, all residents undergo intensive training in minimally invasive procedures and CVS related to laparoscopic cholecystectomy. Interestingly, the video review in our study showed CVS was attained in only 10.8 % of cases, all of which occurred when a resident was performing the surgery. Although we cannot generalize on the basis of a single institution, we hope this finding indicates that CVS will be attained more frequently in the future.

## Conclusions

Our study of laparoscopic cholecystectomy shows that CVS is frequently not attained in patients who have with biliary injuries, but is reached in most cases when there are no complications. Evaluating cases in which complications develop can help surgeons improve their technique and thereby prevent biliary injuries in the future.

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