

# Critical View of Safety: A Pathway for Safe Execution of Laparoscopic Cholecystectomy

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## ABSTRACT

The best method for treating gall bladder lithiasis is laparoscopic cholecystectomy. This original study objective was to assess the safety pathway's critical viewpoint from a standpoint of laparoscopic cholecystectomy implementation safety.

**Material:** Data was collected from patients who underwent laparoscopic cholecystectomy in the surgical divisions of Karachi. To gather information on the preoperative evaluation, surgical maintenance, and postoperative care of patients, as well as to determine whether the elements were isolated following the CVS after the process, a questionnaire was forwarded to the Digestive Pathologist Community. Records about icons were acquired and eventually examined by an auditor.

**Results:** Information from 300 patients was analyzed. The selection of participants was separated into 2 groups based on the proof (A; n = 5) or lack (B; n = 295) of bile duct injury and intraoperative hemorrhage. The non-use of CVS was detected in 56.6% of operations in group A, and 26.8% in group B, and analyzing the operator-related factors the implementation of CVS was linked with a considerably reduced occurrence of bile duct injury and perioperative hemorrhage.

**Conclusion:** The CVS has been proven that it is the safest method for identifying the Calot triangle's components, and when used appropriately, it has a considerable effect on reducing intraoperative problems. To prevent extreme circumstances that might necessitate extra treatments, it would be beneficial to offer more instructional sessions on how to correctly apply CVS in medical care.

**Keywords:** Cholecystectomy, laparoscopic, bile duct injury, surgery, bleeding, safety, gallbladder

## INTRODUCTION

Decreased postoperative suffering, hospital stays, and rehabilitation durations to regular everyday routines are characteristics of LC, that correlate to lower costs for the global medical systems [1]. In contrast, to open cholecystectomy (OC), this operation had a higher rate of bile duct injury (BDI): 0.4% and 0.9% versus 0.4% [2-7].

According to Strasberg et al classification of LC-related BDIs, which range in severity from minor wounds to complicated hilar wounds, the least serious forms correlate to type E wounds, which include persistent stricture, total blockage, resection, or splitting of the common bile duct [8, 9]. There are two categories of factors associated with BDI: patient- and surgery-related [10, 11].

Whereas biliary consequences of LC have received the majority of attention in the recent literature, intraoperative bleeds have additionally been described with varying frequency in various groups and incident cases [12, 13]. Intra- or postoperative hemorrhage, from small hematomas to major bleeding that require blood transfusions, is a common but underreported LC side effect. It causes most LC procedure-related deaths, according to reports. [13, 14].

The invention of laparoscopy, the "infundibular" approach, and intraoperative identification of the cystic duct and gallbladder connection have emerged as the two methods most frequently employed for gallbladder hilar dissection. In place of IT, Strasberg developed the "Critical View of Safety" (CVS) in 1996 to encourage the identification of key components, lower the danger of BDI, and prevent errors brought on by anatomical changes and modified visual interpretation [8].

The Society (SAGES), which pushed the implementation of this technology in the "Safe Cholecystectomy Plan" to reduce the risk of bile duct injury and encouraged the establishment of a global environment of safety in cholecystectomy, has acknowledged the significance of the CVS. Regardless of the extensive usage of CVS, a large drop in BDI has still not been noted. Furthermore, there is conflicting scientific research backing up this method of BDI prevention [15-18].

In comparison, some research [10, 19-23] reveals that CVS is not connected to a beneficial and accurate implementation in medical practice, contradicting the method's extensive acceptance in the scholarly field. By analyzing the effect of the proper

implementation of CVS concepts throughout LC on the occurrence of postoperative problems, also including BDI and hemorrhage, this research sought to evaluate the pathway for the safe implementation of laparoscopic cholecystectomy.

## MATERIAL AND METHODS

Well throughout a year-long study duration, the research involved gathering and analyzing clinical evidence related to patients treated in 30 surgical units in Karachi.

Everyone in the division has received an email inviting them to take part in the research by answering an online survey. The survey, which consisted of 23 questions broken up into 6 sections, reviewed the preoperative evaluation, the initial doctor's laparoscopic education, the participant's intraoperative treatment, and the postoperative period concerning any bile duct injury and perioperative hemorrhage. A significant volume of >50 laparoscopic cholecystectomies were conducted annually in each of the involved centers.

The research was carried out prospectively. Following patient discharge, the national registry was updated with the patients' information. Patients did receive the best surgical care possible depending on their medical settings, the results of the preoperative research, and the results of the surgery itself. The descriptions of pathophysiological obesity (BMI 30 kg/m<sup>2</sup>), biliary spillages (existence of bile in retroperitoneal drainages just under 300-500 daily or intra-abdominal compilations) [24, 25], bleeding (characterized as internal bleeding between minor hematomas to considerable bleeds that necessitate to blood transfusions) [13], and iatrogenic abnormalities thus agreeing to CVS were given to the ability to enroll centers.

The CVS was successful while these 3 main requirements were met: (1) the Calot triangle, which is surrounded by the cystic duct, common hepatic duct, and inferior hepatic edge; (2) the lower 3rd of the gallbladder is detached from the liver to the visual representation of the exterior of the liver with proof of the Rouviere sulcus thru the plucked region; and (3) the certain identification of 2 different structures that enclose the cystic duct and common hepatic.

After the process, the surgeon had been requested to evaluate the results for himself. As he filled out the survey, he simultaneously

presented information on the pre-, intra-, and postoperative doctor instructions and attached a video feature if the Calot triangle had been revealed to have been severed with the proper CVS implementation. Complete preoperative assessment was carried out by the surgical team, patients committed to emergent LC, for acute cholecystitis, chronic diseases, other significant laparoscopic procedures, were suitable for participation. Individuals who had surgery and had cancerous gallbladder diseases were not included.

The iconographic recording was sent to a specific secured email account during compiling, together with information on the surgical date, the participant's initials, their birthdate, and the recruitment center. SIPAD was used to properly document the data gathering, which made sure the main operative was blind. Furthermore, as an auditor, a highly skilled specialist in hepatobiliary and laparoscopic operations analyzed all the iconographic data to confirm that the stated maneuver strictly adhered to the three criteria of the CVS. Thus according to CVS guidelines and after being examined by an auditor.

With SPSS, the statistical analysis was completed. Statistical power was defined as a p-value less than 0.05. The chi-square and Fisher's exact tests were used as necessary in the univariate test. Following the most recent research [17, 26–28], we included factors in the analysis that were known to affect the likelihood of developing BDI. In particular, we took into account both the abdomen circumference and pathogenic obesity (BMI > 30 kg/m<sup>2</sup>) because research has shown that obese persons are three times more likely than non-obese patients to experience CBD damage [27]. According to historical data, preceding upper abdominal operates may be a potential danger for complicated LC because of the existence of scar tissue [28]. We also examined the effect of prior abdominal operations on BDI and the median operating time as potential indicators of surgical difficulty when operating times exceed 60 minutes [29].

Finally, we talked about how acute cholecystitis affects BDI incidence while discussing acute cholecystitis recommendations [17]. A model of logistic regression was employed for the multivariate evaluation, which produced odds ratios (OR) and confidence interval (CI) of 95% to assess the effect of the Critical View of Safety on bile duct injury and bleeding while accounting for the pertinent parameters identified by the univariate analysis.

**RESULTS**

Data from 500 patients who had submitted forms to LC between August 2021 and August 2022 were gathered in a hospital in Karachi. 300 of them were examined, with 172 women (57.3%) and 128 men (42.6%).

Gallbladder lithiasis was the reason for operation in 80% (n = 240) of the cases, while AC was the reason for operation in 20% (n = 60) of the patient population. The operation was completed in 8.3% (n = 25) of the cases under 24 hours, while 91.6% (n = 25) of the patients received postponed urgent care. In contrast to the 28 patients who reported preoperative pathogenic obesity (9.3%), 81 patients (27.1%) exhibited substantial abdominal adipose at the moment of surgery, with an abdomen circumference of > 89 cm for females and > 103 cm for males. Only 0.3% of patients (n = 1) had undergone both upper and lower abdominal operations in the past. 2.6% of participants (n = 8) had undergone an upper abdominal operation in the past. 8% (n = 24) of the patients with preoperative measures examined at admittance had major comorbidity.

The laparoscopic surgical learning was found to be relevant in the data analysis, and the findings demonstrate that young doctors with less than 35 LC of training underwent surgery in 4.3% (n = 13) of situations, while surgeons with 35 to 50 LC of training did surgery in 5.3% (n = 16) of situations. However, the vast large number of practices (89.6%) were managed to perform by surgeries with much more than 50 LC of learning. 51.5% of the time, the surgery took more than 60 minutes (range: 30- 240 min). The complete iconographic evidence was reviewed by the outside auditor. Among LC, CVS was correctly used in 73.6% (n = 221) of the cases but was not in 26.6% (n = 80) of the cases.

The selection of participants was subsequently divided into 2 groups according to whether there was evidence of BDI and post-LC perioperative hemorrhage (Group A; n = 5, 1.6%; Group B; n = 295, 98.3%).

Table 1:

Classify BDI	Bile duct injury (n=5)	CVS	NON-CVS
Class A	3	ERCP was used to treat one lesion appropriately.	ERCP was used to treat two lesions appropriately.
Class B	-	-	-
Class C	-	-	-
Class D	-	-	-
Class E	2	-	Two lesions greater than 2cm. Common bile duct biliary anastomosis.

The non-user of CVS was identified in 54.4% of operations in A, and 25.6% in B. Concerning a group of subjects with just bile duct injury symptoms (n = 5), 1 (20%) patient sustained bile duct injury under conditions of declared critical safety, whereas the remaining four (80%) patients still lacked critical safety. Patients who had CVS-related biliary injuries showed signs of lesion type A. Two full wounds of the primary biliary tract located more than 2 cm from the superior biliary (type E), one of which is associated with tissue damage, and two spillages from subsidiary ducts made up the second instance of bile duct injury not the use of critical safety (type A). Reoperation was used to treat these subjects with type E abnormalities. This final demonstration showed how BDI is related to vascular damage caused by the hepatic vein and collateral artery, which was supported by a CT scan and a liver lab test.

4 (1.3%) of the 300 participants in the sample under analysis had bleeding that was treated appropriately. In the 60 patients who underwent surgical emergent care for AC, there were no problems during or after the procedure. Proper CVS use was observed in most of these patients (67.6%; n = 203), and no patients were managed by a surgeon who had conducted fewer than 35 cholecystectomy procedures.

The mean conversion rate across all participating centers was 4.9%, while the most frequent causes were the necessity for common bile duct exploration because of the changed Calot's triangle anatomical, BDI, and intraoperative hemorrhage. In five patients (1.6% of converted patients), BDI and hemorrhage were the reasons to move toward open surgeries. Even during the time of the trial, no patient passed away.

After examining patient-related preoperative characteristics, abdomen circumference (> 86 cm in females and > 105 cm in males) was a protective predictor factor for bile duct or hemorrhage (p = 0.03). In the investigated cohort, preoperative AC assessment, prior operations, and pathologic obesity did not predict the surgical intervention's negative outcome (p = 0.21, 0.41, and 0.62). Contrarily, comorbidity was significantly related (p = 0.05) with intraoperative difficulties and suggested to indicate a weak group with a worse outcome. Critical safety was associated with a significantly reduced rate of bile duct injury and perioperative hemorrhage (p = 0.02) than laparoscopic learning (p = 0.70), which was unrelated to perioperative problems. The multivariate test showed that intraoperative hemorrhage and BDI are risk factors for preoperative comorbidities (p = 0.002), although CVS prevents intraoperative issues (p 0.04). Preoperative comorbidities remained significant (p = 0.002), although high abdominal circumference lost importance. Due to the short sample size, the same variables lost significance when evaluating the category with perioperative issues univariately.

Gallbladder lithiasis caused 80% (n = 240) of operations, while AC caused 20% (n = 60). 8.3% (n = 25) of the operations were completed within 24 hours, whereas 91.6% (n = 25) were postponed. Unlike the 28 patients (9.3%) who reported preoperative pathogenic obesity, 81 patients (27.1%) had significant abdominal adipose at surgery, with an abdomen circumference of > 89 cm for females and > 103 cm for males.

Only 0.3% (n = 1) underwent both upper and lower abdominal procedures. 2.6% (n = 8) had upper abdominal surgery. Major comorbidity was found in 8% (n = 24) of preoperative patients.

Table 2: Analysis Univariate

Risk factors of patient	Total (n=300)	Group A (n = 5)	Group B% (n = 295)	p <sup>2</sup>
Sex	128(42.6)	3(60)	134(44.6)	0.067
Male	172 (57.3)	2(20)	167(55.6)	
Female				
Acute cholecystitis	55(18.3)	0(0)	55(18.3)	0.227
Patient body weight >75	136(45.6)	110(36.6)	134(44.6)	0.553
Abdominal circumference(>89cm, >103cm)	82(27.3)	0(0)	82(27.3)	0.041
Previous operate	90(30)	0(0)	90(30)	0.412
Pathogenic obese	29(9.6)	0(0)	29(9.6)	0.613
Training of surgeon >35	14(4.6)	0(0)	14(4.6)	0.703
35-50	17(5.6)	0(0)	17(5.6)	
>35	265(88.6)	0(0)	265(88.6)	
Duration of operation>60 min	155(51.6)	18(71.2)	133(51.0)	0.154

Table 3: Multivariate Analysis

	OR(95% CI)	Pa
Circumference of abdominal	-	-
Comorbidity	9.01(2.12-37.28)	0.002
Critical view safety	0.27(0.07-0.97)	0.046

## DISCUSSION

Extensive research has questioned whether laparoscopic cholecystectomy may be performed safely. In 1992, Morgenstern et al. observed a BDI annual incidence of less than 0.2% in 1200 successive open cholecystectomies while at the same period regarded this figure as the benchmark against which LC must be measured [20]. The operation was linked to the prevalence of major problems within the first five years following the LC's implementation, a few of which are characteristic of the laparoscopic approach and uncommon in open surgery [23]. In fact, at first, it was reported that the frequency of bowel injuries, caused by trocar puncture or necrosis of the intestinal wall leading to delayed ranged from 0.67 to 0.8%.

It may be random or caused by enhanced attentiveness for logistically difficult surgeries. The considerable relationship between various illnesses and BDI is not confirmed in the literature and should be considered as a symptom of a sensitive population sample at high risk of a poor surgical prognosis. [24].

However, according to the most latest studies, the implementation of CVS may be difficult in cases of serious inflammation with the dissent of the Calot triangle anatomical structures, necessitating the consideration of substitute processes like fundus-first cholecystectomy, final value cholecystectomy, or converting to open operates [17].

The transition to open surgery is advised to avoid bile duct damage when the CVS can indeed be safely acquired as during dissecting of Calot's triangle [23]. The transition rate to open surgery, nevertheless, varies widely in the present literature and, according to this documented practice, ranges from 2 to 15% [54–56]. A study [26] states that severe adhesions, substantial inflammation, difficulties exploring the bile ducts during surgery, and obfuscating hemorrhage are all indicators for converting in the context of surgery.

According to the latest studies, CVS may be difficult in cases of serious inflammation with the dissent of the Calot triangle anatomical structures, necessitating the consideration of alternative processes like fundus-first cholecystectomy, final value, or open surgery. Some data suggests that the first LC procedures may cause iatrogenic harm. Moore et al. found that 90% of iatrogenic nodules developed within 30 cases in 8,838 cholecystectomies performed by 55 surgeons with varying laparoscopic training. The surgeon's trauma risk is 1.6% in the first laparoscopic cholecystectomy and 0.18% by the 50th. [25]. In their cohort of 49 individuals with iatrogenic lesions, 42 individuals had

injuries as a result of inaccurate anatomical feature recognition, and in 75% of cases, these injuries occurred during surgery.

In places where CVS is mandated, BDI has not decreased throughout LC, despite CVS's declared purpose. CVS may prevent significant lesions (Type E) but not type A injuries such biliary fistulas due to its inaccurate recognition of anatomical components. Some groups in this investigation have a full lesion of the major bile ducts more than 2 cm from the upper biliary confluent (type E). [2].

## CONCLUSION

When used properly, the Critical View of Safety is proven that it is the safest method for identifying the Calot triangle's components and has a considerable effect on reducing intraoperative problems. To normalize the laparoscopic treatment of gallstone illness, extra training in the successful implementation of the Critical View of Safety in medical care should be encouraged.

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