Original Article

The Result of the Critical View of Safety Timeout Technique in Prevention of Bile Duct Injury in Laparoscopic Cholecystectomy: A Retrospective Study at a Large Community Teaching Hospital

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Background: Laparoscopic cholecystectomy (LC) is the standard treatment for cholelithiasis. However, despite improvements in technology and implementation of a safer approach, such as the critical view of safety (CVS) technique, the risk of bile duct injury (BDI) remains an issue.

Objective: To review LC cases at a large community hospital for BDIs and compare BDI rates between conventional technique and CVS timeout approaches. The authors hypothesized that there would be lower BDI rates in the CVS timeout group.

Materials and Methods: The authors conducted a retrospective study of 1,033 consecutive patients that underwent LC at the authors' institution between November 2015 and November 2018. Based on the timeout document and operative reports, the authors classified patients into CVS timeout and no CVS (noCVS) timeout groups and compared the BDI rates and other relevant clinical outcomes.

Results: Among the 1,033 patients, 635 and 398 patients were in the noCVS timeout and CVS timeout groups, respectively. There was no significant difference in the incidence of BDI between the two groups at 1.1% versus 1.8%, respectively (p=0.375). The CVS group exhibited less preemptive conversion to open cholecystectomy, lower incidence of uncontrolled intraoperative bleeding, shorter operative time, and shorter length of hospital stay than the noCVS group. In multivariate regression analysis, operative time of more than 90 minutes was the significant independent risk factor associated with BDI, while previous biliary inflammation was marginally associated with BDI.

Conclusion: The present study failed to demonstrate the beneficial effect of CVS timeout in preventing the development of BDI. The reasons could be attributed to surgeons' competency with their varying skills and experience, the occurrence of injury before timeout, the case selection biases, or the wrong CVS identification. Further review of the actual surgical videos may offer more clarity into the unexpected outcome.

Keywords: Bile duct injuries; Critical view of safety; Infundibular techniques; Laparoscopic cholecystectomy

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Laparoscopic cholecystectomy (LC) was first performed by Mühe in 1985[1]. LC has been widely applied since its introduction and provides advantages for patients[2]. In 1992, the National Institutes of Health (U.S.) and other institutes established LC as the gold standard for gallbladder lithiasis[3,4]. Despite its clear benefits, including decreased postoperative pain, faster recovery, and superior cosmetic results, the laparoscopic approach has been associated with increased bile duct injury (BDI)[4,5]. Compared to the 0.1% to 0.2% BDI incidence reported during the open cholecystectomy (OC) era, the incidence of BDI post-LC was reported as 0.2% to 1.5%[5-9].

The most classic BDI results from misperception of the common bile duct (CBD) as the cystic duct (CD)[10], particularly in severe acute and chronic inflammatory situations that cause fusion of the gallbladder to the lateral sidewall of the common hepatic duct[11]. In this setting, using the infundibular (IF) technique, a traditional technique that identifies the CD when the conventional "flare" or "tunnel" shape is demonstrated at the infundibulum-CD

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junction, can lead to misidentification of the CBD as the CD, thereby resulting in BDI.

The critical view of safety (CVS) technique was subsequently introduced to mitigate this misperception. It is currently considered a safe method that aims to achieve target identification of cystic structures by replicating the technique performed in the open approach. Large-scale epidemiological studies demonstrated a low incidence of BDI after implementing CVS during LC (0% to 0.03%)[12-14]. Recently, the Society of American Gastrointestinal and Endoscopic Surgeons incorporated this technique in the "Safe Cholecystectomy Program" to reduce the risk of BDI. The present study aimed to review the incidence of BDI following the introduction of the CVS in a large community teaching hospital and compare it to that of the conventional approach.

Materials and Methods

The present study was a retrospective comparative cohort study that included all consecutive patients who underwent LC at Hatyai Hospital, a university-affiliated tertiary care center in southern Thailand, between November 2015 and November 2018. The study was reviewed and approved by the Ethics Committee on Human Subjects of Hatyai Hospital (protocol number 26/2563) and performed in accordance with the Helsinki Declaration. The need for informed consent was waived because identifying patient information was anonymized before the analysis. The present study was registered in the Thai Clinical Trials Registry, TCTR20210705004.

Two independent reviewers (AC and TJ) manually reviewed each patient's medical records with particular attention to the operative notes. Disagreements between reviewers were resolved by a third reviewer (AK). Based on the timeout document, the authors classified patients into two groups as the CVS and the no CVS (noCVS) groups. Charts were additionally reviewed for patient demographic and relevant clinical data, including gender, age, body mass index (BMI), comorbidities, surgical indication, history of previous upper abdominal surgery and endoscopic retrograde cholangiopancreatography (ERCP), American Society of Anesthesiologists (ASA) classification[15], and laboratory results on the day of admission. Detailed procedural data included technique, achievement of CVS, conversion to OC, use of intraoperative cholangiography (IOC) and bailout techniques, operative time, perioperative complications, and length of stay (LOS). The achievement of CVS was determined if all three elements of CVS were present in the operative note and confirmed by the surgeon. Additionally, the authors distinguished between preemptive conversion or before a complication occurred, and reactive conversion or after a complication occurred. The authors characterized preemptive conversion as a bailout technique.

The type of BDI was classified as minor (type A) or major (types B, C, D, and E)[13], according to the Strasberg Classification. Intraoperative, uncontrolled bleeding was defined as ongoing bleeding requiring conversion to an open approach.

Statistical analysis

Categorical variables were determined using frequency statistics and tested for significant differences using the Pearson chi-square test or Fisher's exact test as appropriated. Student's t-test and Wilcoxon rank-sum test were used to assess significant differences among continuous variables. The authors calculated the relationship between BDI and each variable separately using a logistic regression model or backward stepwise selection method. After univariate analysis, gender, age, variables with probabilities (p-value less than 0.1), and established risk factors for BDI and other perioperative complications based on the previous literatures, including comorbidities, pathological obesity with a BMI greater than 30 kg/m^2, ASA classification greater than 2, previous upper abdominal surgery, emergency intervention, operative time of more than 60 minutes, presence of acute inflammation, previous biliary inflammation including cholecystitis, cholangitis, and pancreatitis, and use of CVS technique, were included in the multivariate analyses[16-22]. Analyses were performed using Stata Statistical Software, version 15.1 (StataCorp LLC, College Station, TX, USA), and statistical significance was set at a p-value of less than 0.05.

Results

Patients and surgical characteristics

One thousand thirty-three patients with a mean age of 50.4±15.7 years, of which 26.7% were men, were included in this study. Fifty-seven-point-seven percent had biliary pain, 26.1% had subsided complicated biliary disease, 13.4% had acute cholecystitis, and 2.8% had gallbladder polyps. Most patients (98.4%) underwent elective surgery. Patients were classified into the noCVS (n=635), and the CVS (n=398) groups. In the CVS group, CVS could not be achieved in 32 patients (8.0%). Comparisons of demographic and clinical data between the groups

Table 1. Baseline characteristics and surgical information of participants

Variables	No CVS timeout (n=635)	CVS timeout (n=398)	p-value
Sex: male; n (%)	170 (26.8)	106 (26.6)	0.961
Age (years): mean±SD	49.2±15.9	52.4±15.3	0.001
BMI (kg/m^2): mean±SD	25.9±4.8	25.3±4.7	0.040
Comorbidities; n (%)	210 (33.1)	165 (41.5)	0.006
Previous upper abdominal surgery; n (%)	89 (14.0)	49 (12.3)	0.433
Previous ERCP; n (%)	53 (8.3)	12 (3.0)	0.001
Indication for surgery; n (%)			
Biliary pain	345 (54.4)	252 (63.3)	0.005
Subsided complicated biliary disease	186 (29.4)	84 (21.2)	0.003
Acute cholecystitis	88 (13.9)	50 (12.6)	0.545
Gallbladder polyp	16 (2.5)	13 (3.3)	0.482
ASA classification >2; n (%)	149 (23.5)	88 (22.1)	0.614
Preoperative laboratory			
WBC (cell/mm^3); median (IQR)	7 540 (6,200 to 9,370)	7 330 (6,170 to 9,010)	0.264
Creatine (mg/dL); median (IQR)	0.73 (0.60 to 0.88)	0.76 (0.63 to 0.93)	0.005
Total bilirubin (mg/dL); median (IQR)	0.50 (0.30 to 0.80)	0.50 (0.40 to 0.80)	0.360
Albumin (mg/dL); mean±SD	3.5±1.5	3.7±1.3	0.016
Emergency intervention; n (%)	10 (1.6)	7 (1.8)	0.821
Operation port; n (%)			<0.001
Single port	44 (6.9)	128 (32.2)	
Multiport	591 (93.1)	270 (31.4)	

CVS=critical view of safety; BMI=body mass index; SD=standard deviation; ERCP=endoscopic retrograde cholangiopancreatography; IQR=interquartile range; ASA=American Society of Anesthesiologists; WBC=white blood cell; N/A=not applicable

are shown in Table 1. The mean age, presence of comorbidities, indication of biliary pain, serum creatinine level, serum albumin level, and use of a single port were greater in the CVS group than in the noCVS group. Conversely, patients in the noCVS group were more likely to have higher BMI, previous ERCP, and the indication of subsided complicated biliary disease than patients in the CVS group.

Perioperative outcomes

Table 2 summarizes the perioperative outcomes between the two groups. There were no significant between-group differences regarding the incidence of BDI and other complications. Patients in the noCVS group were more likely to require preemptive conversion to OC, exhibited a greater incidence of uncontrolled bleeding, with significantly longer operative time and LOS than those in the CVS group.

Details of the patients who developed BDI and their treatment are summarized in Table 3. There was no 30-day mortality observed in the present study.

Comparison of baseline characteristics and clinical outcomes among patients with and without BDI

Table 4 compares the baseline characteristics and clinical outcomes between the patients with and without BDI.

There were no significant differences in baseline characteristics or surgical techniques between the two groups, except for the surgical indications. Patients who did not develop BDI exhibited a significantly higher incidence of biliary pain at 58.2% versus 30.8% (p=0.047) and reduced gallstone complications at 25.8% versus 3.9% (p=0.013) than those who developed BDI. The duration of surgery and LOS were significantly longer in patients who developed BDI than those who did not.

Risk factors for the development of BDI

To identify factors associated with BDI, logistic regression analysis was performed. In multivariate analysis, operative time longer than 90 minutes was the independent factor significantly associated with BDI (OR 6.665, 95% CI 2.034 to 21.845, p=0.002), while previous biliary inflammation was marginally associated with BDI (OR 2.717, 95% CI 0.912 to 8.096, p=0.073) (Table 5).

Discussion

Although BDI during LC can be caused by

Table 2. Comparison of perioperative outcomes between the two groups

Variables	No CVS timeout (n=635)	CVS timeout (n=398)	p-value
Achievement of CVS; n (%)	N/A	366 (92.0)	N/A
Bile spillage; n (%)	106 (16.8)	55 (14.0)	0.233
Reactive conversion; n (%)	8 (1.3)	1 (0.3)	0.165
Bailout technique; n (%)	75 (11.8)	38 (9.5)	0.257
Fundus first	57 (9.0)	29 (7.3)	0.339
Subtotal cholecystectomy	23 (3.6)	15 (3.8)	0.903
Preemptive conversion	8 (1.3)	0 (0.0)	0.027
BDI (primary endpoint); n (%)	7 (1.1)	7 (1.8)	0.375
Major BDI	3 (0.5)	2 (0.5)	1.000
Minor BDI	4 (0.6)	5 (1.3)	0.292
Non-BDI complication; n (%)			
Intraoperative uncontrolled bleeding	7 (1.1)	0 (0.0)	0.048
Surgical site infection	28 (4.4)	11 (2.8)	0.177
Incisional hernia	2 (0.3)	1 (0.3)	1.000
Operative time (minutes); median (IQR)	70 (55 to 100)	60 (45 to 80)	<0.001
Length of stay (days); median (IQR)	3 (2 to 4)	3 (2 to 4)	0.001

CVS=critical view of safety; BMI=body mass index; SD=standard deviation; ERCP=endoscopic retrograde cholangiopancreatograpy; IQR=interquartile range; ASA=American Society of Anesthesiologists; WBC=white blood cell

Table 3. Clinical data of patients who developed bile duct injuries

No.	Sex	Age (years)	Indication	BDI Strasburg classification	Time of detection	Treatment
No CVS timeout group						
1	M	52	Acute gangrenous cholecystitis	D	Intraoperation	Primary laparoscopic repairment with suture
2	M	57	Subsided cholecystitis	A	Intraoperation	Control stump of cystic duct with surgical clip
3	F	31	Acute cholecystitis	A	Intraoperation	Control stump of cystic duct with surgical clip
4	F	52	Subsided cholecystitis	E	2 weeks after operation	Percutaneous transhepatic biliary drainage with interval laparotomy with Roux-en-Y hepaticojejunostomy
5	F	40	Subsided cholecystitis	A	Intraoperation	Control stump of cystic duct with endoloop and suture
6	F	48	Acute cholecystitis	A	Intraoperation	Control stump of cystic duct with endoloop
7	M	79	Acute cholelithiasis	E	Intraoperation	Convert to open cholecystectomy with Roux-en-Y hepaticojejunostomy
CVS timeout group						
1	F	57	Subsided cholecystitis	A	Intraoperation	Control stump of cystic duct with surgical clip
2	F	54	Acute gangrenous cholecystitis	A	Intraoperation	Control stump of cystic duct with surgical clip
3	F	27	Acute cholecystitis	D	Intraoperation	Primary laparoscopic repairment with suture
4	F	31	Subsided cholecystitis and cholangitis	E	Intraoperation	Convert to open cholecystectomy with Roux-en-Y hepaticojejunostomy
5	F	64	Subsided cholecystitis	A	Intraoperation	Control stump of cystic duct with surgical clip
6	F	46	Subsided cholecystitis	A	Intraoperation	Control stump of cystic duct with endoloop
7	F	80	Gallbladder polyp	A	Intraoperation	Control stump of cystic duct with endoloop

CVS=Critical View of Safety; BDI=bile duct injury; F=female; M=male

errors related to technical failures such as clip failure, wrong dissection plane, and wrong decision-making, it majorly results from misidentification[10,23,24]. To prevent this, CVS was introduced as a technique to provide insight into biliary anatomy and has been established as a standard of care for target identification[25].

Presently, there is no level I evidence supporting CVS over other methods for reducing BDI risk. However, expert consensus and several population-

Table 4. Characteristics and clinical outcomes of patients with versus without bile duct injuries

Variables	No BDI (n=1,019)	BDI (n=14)	p-value
Male: sex; n (%)	273 (26.8)	3 (21.4)	0.771
Age (years); mean±SD	50.4±15.7	51.3±16.2	0.839
BMI (kg/m^2); mean±SD	25.7±4.8	26.3±4.8	0.616
Comorbidities; n (%)	369 (36.2)	6 (42.9)	0.608
Previous upper abdominal surgery; n (%)	138 (13.5)	0 (0.0)	0.237
Previous ERCP; n (%)	65 (6.4)	0 (0.0)	1.000
Indication for surgery; n (%)			
Biliary pain	593 (58.2)	4 (30.8)	0.047
Subsided complicated biliary disease	262 (25.8)	8 (3.9)	0.013
Acute cholecystitis	136 (13.3)	2 (15.4)	0.689
Gallbladder polyp	29 (2.8)	0 (0.0)	1.000
ASA classification >2; n (%)	233 (22.9)	4 (28.6)	0.538
Preoperative laboratory			
WBC median (cell/mm^3); median (IQR)	7,470 (6,190 to 9,170)	8,510 (6,740 to 11,920)	0.200
Creatine (mg/dL); median (IQR)	0.74 (0.61 to 0.90)	0.77 (0.59 to 1.02)	0.726
Total bilirubin (mg/dL); median (IQR)	0.50 (0.40 to 0.80)	0.45 (0.30 to 0.70)	0.641
Albumin (mg/dL); mean±SD	3.6±1.4	3.6±1.4	0.928
Setting of surgery; n (%)			0.208
Election	1003 (98.4)	13 (92.9)	
Emergency	16 (1.6)	1 (7.1)	
Experienced surgeon >50 cases; n (%)	423 (41.5)	5 (35.7)	0.662
Experience in laparoscopic surgery of >3 years; n (%)	408 (40.0)	4 (28.6)	0.384
Operation port; n (%)			1.000
Single port	849 (83.3)	12 (85.7)	
Multiport	170 (16.7)	2 (14.3)	
CVS timeout; n (%)	391 (38.4)	7 (50.0)	0.375
Achievement of CVS timeout	360/391 (92.1)	6/7 (85.7)	0.446
Intraoperative cholangiography; n (%)	42 (4.1)	1 (7.1)	1.000
Operative time (minutes); median (IQR)	65 (50 to 90)	122.5 (105 to 180)	<0.001
Length of stay (days); median (IQR)	3 (2 to 4)	5.5 (2 to 8)	0.019

BDI=bile duct injury; BMI=body mass index; SD=standard deviation; ERCP=endoscopic retrograde cholangiopancreatograpy; IQR=interquartile range; ASA=American Society of Anesthesiologists; CVS=critical view of safety; WBC=white blood cell

Table 5. Univariate and multivariate logistic regression analyses of predictive factors of development of bile duct injuries

Variables	Univariate analysis			Multivariate analysis		
	OR	95% CI	p-value	Adjusted OR	95% CI	p-value
Sex: male	1.342	0.372 to 4.846	0.654			
Age >70 years	1.391	0.307 to 6.299	0.668			
Pathologic obesity	0.798	0.177 to 3.598	0.769			
Previous upper abdominal surgery	0.000	0.000 to ∞	0.996			
Presence of comorbidities	1.321	0.455 to 3.837	0.609			
Biliary pain	0.319	0.098 to 1.044	0.059			
Subsided complicated biliary disease	3.832	1.317 to 11.147	0.014	2.717	0.912 to 8.096	0.073
Acute cholecystitis	1.180	0.259 to 5.383	0.830			
ASA classification >2	1.349	0.419 to 4.342	0.615			
Emergency setting	4.822	0.595 to 39.106	0.141			
Experienced surgeon >50 case	0.783	0.260 to 2.352	0.663			
Technique of targeted identification						
No CVS timeout	1	Reference				
CVS timeout	1.606	0.559 to 4.614	0.379			
Operative time >90 minutes	7.898	2.455 to 25.406	0.001	6.665	2.034 to 21.845	0.002*

ASA=American Society of Anesthesiologists; CVS=critical view of safety; OR=odds ratio; CI=confidence interval

* Statistically significant

based studies that used CVS for target identification support its efficacy in avoiding misidentification injuries[12-14,26]. Furthermore, a recent prospective, multicenter study involving 604 patients reported that CVS use was associated with decreased risk of intraoperative complications, including BDI and bleeding[21]. Although undoubtedly a significant step toward safer LC, it is unclear whether CVS can adequately reduce the risk of BDI in real-life practice because biliary injuries continue to occur in countries where CVS use is mandatory[27,28].

In the CVS timeout group, the implementation of CVS timeout was determined based on the accordance between the two surgeons, which were the surgeon who performed the operation and another surgeon. The authors hypothesized that using the CVS timeout method could diminish the risk of BDI down to zero. In the CVS timeout group, the rate of CVS achievement was 92%, which is comparable to that observed in a previous study[13]. However, the present study's results revealed no significant difference in terms of BDI between the groups, which is consistent with a previous study conducted by Vettoretto et al[29]. There are reasons for this finding. First, it has been hypothesized that CVS helps prevent major biliary injuries by avoidance of misperception but fails to avoid minor injuries, which mainly occur during dissection[21]. Second, it is important to indicate that CVS is a target identification technique, the conclusion of the dissection process. Few details describing how surgeons should obtain this endpoint or surgeons make the critical decision of finishing the surgery by alternative methods before BDI occurs. Third, wrong, or inadequate identification of CVS could occur during the procedure. Recently, Stefanidis et al revealed that the rate of inadequate CVS identification confirmed by video review was approximately 25%[30]. Therefore, the CVS identification technique, including timeout, or check before cut, alone in the present study, could not guarantee absolute protection against BDI.

Patient factors may also contribute to the increased risk of developing BDI. Multivariate analysis revealed that operative time longer than 90 minutes was the independent predictor for the development of BDI, while previous biliary inflammation was marginally associated with BDI. These results are consistent with the previous data indicating that this factor is associated with BDI[19,22,31]. Prolonged operative time is an indicator of surgical difficulty, which is associated with an increased chance of BDI development. Further, previous occurrence of local inflammation and subsequent adhesion lead to an increased risk of BDI.

The present study has limitations. First, this was a retrospective study, and data collection and clinical outcome assessments were based on existing medical records. There were several surgeons with various skill levels and experience involved. Additionally, there was possible selection bias. Although errors may have also resulted from the reviewer's bias, the authors believe that this would be minimized with the use of two independent reviewers and a third reviewer as the final arbiter when discrepancies were identified. Second, the main weakness may be the surgeons have no formal training for specific CVS identification in both groups. Therefore, the endpoint dissection may not represent the true CVS, as described by Strasberg. Hence, further study involving proper training of the surgeons in this regard could change the outcome.

In summary, although the present study failed to demonstrate the beneficial effect of implementing the CVS timeout in preventing the development of post-LC biliary injuries, the authors remain resolute on the benefits of CVS. In the future, the authors aim to carefully review and analyze recorded videos of cases with BDI in the CVS group to identify and elucidate the causes or the mechanism of injury.

What is already known on this topic?

LC is currently the standard treatment for cholelithiasis, and the CVS was introduced as a safe method that aims to secure the target identification of cystic structures by replicating the technique performed in the open approach.

What this study adds?

This study failed to demonstrate the beneficial effect of the implementation of the CVS timeout in preventing the development of post-LC biliary injuries. The reasons could be attributed to several factors including surgeons varying skill, knowledge, and experience in identifying CVS and case selection biases. Further review of the actual surgical videos may offer more clarity into the unexpected outcome.

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Conflicts of interest

The authors declare that they have no conflicts of interest or financial ties to disclose.

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