

Critical View of Safety in Laparoscopic Cholecystectomy: Can it prevent bile duct injuries. An Institutional Prospective Observational Study

Tejinder Paul Singh,¹ Ashwani Kumar,¹ Simrandeep Singh,² Jaswinder Singh,¹ Dinesh Kumar Pasi,¹
Parth Dhamija,¹ Anshu Saini,¹ Ojassvi Rishi¹

¹ Department of Surgery GMC Rajindra Hospital, Patiala

² Department of Radiotherapy, GGSMC, Faridkot

Corresponding Author : Dr. Jaswinder Singh

Assistant Professor, Dept. of Surgery, Govt. Medical College, Patiala.,

E-mail: drjaswinderrahi@yahoo.co.in

ABSTRACT

BACKGROUND Laparoscopic Cholecystectomy is the most commonly performed procedure and is the 'gold standard' for the treatment of cholelithiasis, however, it is associated with a preventable complication that is bile duct injury. Strasberg, in 1995 suggested a technique called "Critical View of Safety" (CVS) to avoid this complication. The effectiveness of CVS in preventing bile duct injuries is still debatable.

METHODS This prospective trial was conducted on 100 patients posted for Laparoscopic cholecystectomy in the Department of General Surgery, Government Medical College and Rajindra Hospital, Patiala during the study period of May 2019 to December 2020. An attempt was made to achieve critical view of safety in each case. All the patients were assessed for various patient related and surgery related parameters which might affect the outcome and the results were evaluated.

RESULTS Critical view of safety could not be achieved in 14% of patients, all these patients were overweight (BMI = 25 to 29.9) and had longer hospital stay. 12 % of the patients were converted to open cholecystectomy and 2% had bile duct injuries.

CONCLUSION Critical view of safety is an effective method of preventing bile duct injuries and thereby minimizing complications while performing laparoscopic cholecystectomy. However further studies to strengthen these results may be warranted.

KEYWORDS Laparoscopic Cholecystectomy, Body Mass Index (BMI), Critical View of Safety (CVS), Calot's triangle, Bile duct injury.

Introduction

Gall bladder pathologies include symptomatic cholelithiasis, cholecystitis (acute and chronic), biliary dyskinesia, acalculous cholecystitis, gall stone induced pancreatitis and gall bladder masses/polyps. Among these cholelithiasis is the commonest pathology encountered. The prevalence of symptomatic cholelithiasis in the West is around 5.9-21.9% and 3.1-10.7% in Asia.¹

The National Institute of Health consensus declared Laparoscopic cholecystectomy as the "gold standard" for cholelithiasis in 1992.² Laparoscopic cholecystectomy provides the benefit of decreased post-operative pain, cosmetically better scar,

reduced duration of hospital stay and a faster recovery period in comparison to open cholecystectomy technique. However, Laparoscopic cholecystectomy is associated with an increase in incidence of bile duct injuries from 0.2% vs 0.4% as compared to open cholecystectomy.^{3,4}

Strasberg et al classified common bile duct injuries into five types ranging from bile leak from a minor duct (Type A) to complete occlusion, resection or division of major bile ducts (Type E).⁵ Lacerations under 25% of CBD diameter were classified as minor injury whereas transaction or lacerations more than 25% of CBD diameter and post-operative bile duct stricture were classified as major injury as per McMahon et al classification.⁶

The management of such injuries to bile duct may vary from Endoscopic Retrograde Cholangio Pancreatography (ERCP) to biliary anastomosis and more complex restorative procedures like Hepatico-Jejunostomy and hepatic transplantation in rare cases which leads to an increased post-operative morbidity.⁷ Despite of the time of three decades have elapsed since the first Laparoscopic cholecystectomy was performed, the prevention of such iatrogenic injuries is still a matter of significant concern.

Factors contributing to bile duct injuries can be patient-related like age, gender, BMI or surgery-related like anatomical anomalies, surgical technique, surgeon's experience or improperly functioning equipment. The correct approach to the gall bladder's pedicle and the accurate identification of cystic structures within Calot's triangle are the keys to reduction in biliary injuries. Strasberg⁵ observed that in cases of severe inflammation, one might injure common hepatic duct as it may be adhered to gall bladder wall which leads to increased complication rate. Three main techniques of Calot's triangle dissection have been standardized.

The "infundibular" technique which entails dissecting the gallbladder from its neck upwards, after dissecting the cystic artery and the cystic duct using electrocautery. This classical dissection of Calot's triangle may result in misidentification of vascular or biliary anatomical variants, which are frequently located in the medial part of this region.⁸ The "dome down" or "fundus first" technique is another way of preventing bile duct injuries even though it concerns the possible injury to the right hepatic artery as it may get retracted downwards along with the gallbladder.^{9,10}

The effort to standardize an approach to the cystic artery and duct that could effectively avoid the area where ductal and vascular anomalies are likely to be encountered brought Strasberg et al to outline the Critical View of Safety (CVS) in 1995.¹¹ Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in its "Safe Cholecystectomy Program" has advocated the use of CVS technique to minimize the risk of bile duct injuries¹². Currently, the CVS technique is accepted as a Gold Standard for reducing morbidity associated with Laparoscopic cholecystectomy by the European Association of Endoscopic Surgery (EAES)¹³

The criteria of a Critical View of Safety included¹¹:

1. Calot's triangle to be completely free of fat and fibrous tissue, it does not require that the common bile duct be exposed.
2. The lower one-third part of the gallbladder be separated from the cystic plate. The cystic plate referred to as the liver bed of the gallbladder is part of the plate/sheath system of the liver.
3. The two and only two structures should be seen entering the gallbladder i.e., cystic duct and cystic artery.

However the incidence of bile duct injuries have not decreased even after use of CVS technique¹⁴ and there are very few studies published up-to-date to give us level-1 evidence that achievement of critical view of safety prevents such injuries. Factors influencing the attainment of CVS and its role in preventing bile duct injuries need to be studied in detail. The current study focused on the attainment of the principles of CVS and its role in preventing bile duct injuries.

MATERIALS AND METHODS

The present study was conducted on 100 patients enrolled for Laparoscopic cholecystectomy in the Department of General Surgery, Government Medical College and Rajindra Hospital, Patiala in a span of May 2019 to December 2020 after approval of the Ethics Committee of the institute.

The subjects in the age group 18-70 years presenting with symptoms of gall stone disease and enrolled for Laparoscopic cholecystectomy were included in this study. Patients converted to open cholecystectomy due to difficult Laparoscopic cholecystectomy were also included. Pregnant females, patients with coagulopathy disorder, cirrhosis and associated portal hypertension, diagnosed case of carcinoma gallbladder or patients with any relative contraindications to laparoscopic procedure were excluded from this study.

After getting approval of institutional ethics committee, patients coming to outpatient department of General Surgery, Rajindra Hospital, Patiala were selected on the basis of inclusion and exclusion criteria adopted for the study. After a complete pre-operative workup, pre-anesthetic checkup and a written informed consent, patients were posted for Laparoscopic cholecystectomy. A standard 4-port technique was used and patient put

in Reverse Trendelenburg position with slight rotation of the patient to the left for proper visualization of the gall bladder region.

The fundus of the gallbladder was grasped with a forceps through the lateral port and cephalad traction was given in the direction of the right shoulder of the patient. Then the infundibulum of the gallbladder was grasped and infero-lateral traction was given to open the Calot's triangle. The dissection was then performed along the infundibulum on the anterior and posterior surfaces to expose the base of gallbladder and the Calot's triangle was cleared off all fibrofatty tissue. With continued dissection, cystic duct and artery were exposed circumferentially. Critical View of Safety was attempted to achieve in each case.

After confirmation of anatomy, cystic artery and cystic duct were clipped and divided. The gallbladder was then separated from liver bed maintaining hemostasis and extracted out. Closure of all the port incisions was done after putting the subhepatic drain.

Intra-operative findings were observed and recorded in view of presence of aberrant anatomy, delineation of anatomy of Calot's triangle, presence of adhesions, achievement of Critical View of Safety and conversion from laparoscopic to open cholecystectomy. Post-operatively, patients were observed and monitored regarding drain output, abdominal adhesions, jaundice, pain, drain removal and duration of hospital stay. They were then followed up post-operatively at 1 month, 3 months and 6 months period and were checked for any signs and symptoms of bile duct injury like fever, pain and jaundice.

The data was collected and analyzed using SPSS (Statistical Package for the Social Science) version 21.0 for Microsoft Windows.

RESULTS

A total of 100 patients were admitted and enrolled for this study and posted for laparoscopic cholecystectomy. An attempt was made to achieve Critical View of Safety in each case and results were

Table 1- Patient Characteristics

Age	< 30 years	22%
	31 to 40 years	26%
	>40 years	52%
Gender	Males	18%
	Females	82%
Food habits	Vegetarians	76%
	Non vegetarians	24%
Oily food intake	Present	76%
	Absent	24%
BMI	Underweight	10%
	Normal	32%
	Overweight	40%
	Obese	18%
Co morbid states	Diabetes	18%
	Hypertension	22%
	No co morbidities	66%
Presenting complaints	Pain abdomen	80%
	Post meal fullness	50%
	Dyspepsia	52%
	Fever	0
	Asymptomatic	8%
Complaints duration	< 5 months	38%
	5 to 10 months	36%
	>10 months	26%

Majority (52%) of the patients in this study were above the age of 40 years and 82% patients were females. A large proportion of the patients were overweight (40%), had oily food intake (76%). Most common presenting symptoms were pain abdomen

(80%) followed by post meal fullness (50%) and dyspepsia (52%). As in our population, most of the patients tend to ignore early symptoms of gall bladder disease, so 62% patients in this study had symptoms for 5 to 10 months or more.

Table 2- Investigations

USG FINDINGS	Multiple gall stones	86%
	Single gall stone	14%
	Gall bladder sludge	14%
	Stone impacted in neck	4%
	Gall bladder wall thickness >4mm	4%

The investigation of choice in gall bladder pathologies is ultrasonography. Therefore, USG was performed in all patients. Most common finding was multiple gall stones (86%) followed by single gall

stone (14%), gall bladder sludge (14%), stone impacted in GB neck (4%) and GB wall thickness (4%).

Table 3- Per-operative Characteristics

Conversion to open cholecystectomy	Absent	88%
	Present	12%
Intra operative findings	Aberrant anomalies	4%
	Emphyema	4%
	Adhesions	28%
Contents of drain	Bilious	2%
	Serous	98%
Duration of surgery	< 60 minutes	58%
	>60 minutes	42%
Intra operative aim	CVS achieved	86%
	CVS not achieved	14%
Bile duct injury	Absent	98%
	Present	2%

All the patients were subjected to laparoscopic cholecystectomy, while in 12% of the patients, due to dense pericholecystic adhesions (frozen calot's triangle) or non-achievement of critical view of safety, procedure was converted to open

cholecystectomy. Intra operative findings suggested 28% of patients had adhesions followed by emphyema and aberrant anomalies in 4% of patients. Most of the patients (98%) had serous drain output whereas it was bilious in 2%. Bile duct injury was diagnosed in

Table 4- Association of CVS

		CVS Achieved	
		YES	NO
Age	<30	23.3%	14.3%
	31 to 40	27.9%	14.3%
	>40	48.8%	71.4%
Gender	Female	90.7%	28.6%
	Male	9.3%	71.4%
BMI	Underweight	11.6%	0%
	Normal	37.2%	0%
	Overweight	30.2%	100%
	Obese	20.9%	0%
Presenting complaints	Pain abdomen	79.1%	85.7%
	Post meal fullness	46.5%	71.4%
	Dyspepsia	46.5%	85.7%
	Asymptomatic	9.3%	0%
	Fever	0%	0%
Conversion to open cholecystectomy	Not done	100%	14.3%
	Done	0%	85.7%
Content of drain	Bilious	0%	100%
	Serous	87.8%	12.2%
Bile duct injury	Absent	100%	12.2%
	Present	0%	87.8%

DISCUSSION

Laparoscopic Cholecystectomy is considered as the gold standard for the treatment of symptomatic cholelithiasis. The incidence of bile duct injuries associated with Laparoscopic Cholecystectomy has been evaluated by many studies describing its causes and risk factors¹⁵. The present study was done to evaluate the role of critical view of safety in preventing the bile duct injuries during Laparoscopic Cholecystectomy.

The average age of the patients in our study was 41.14 years and most of the patients were of middle age which is similar to the results obtained in studies conducted by Shaheed M et al¹⁶ and Vishwanathan et al¹⁷. A majority of patients in our study were females (82%) which is attributed to higher prevalence of cholelithiasis in females and is in

concordance with the studies conducted by Bulent kaya et al¹⁸ and Zarin et al¹⁹. Out of 18 males enrolled, critical view of safety could not be achieved in 10 patients, which is statistically significant (p value 0.0001). This could be explained as per study conducted by Yol S et al²⁰ due to aberrant anatomy, late presentation and a more prevalence of pericholecystic adhesions and recurrent cholecystitis in male patients.

In the present study, 32 patients were having normal range BMI while 40 patients were overweight, while 18 patients were obese. Critical view of safety was not achieved in 14 out of 40 overweight patients. Obesity is a predisposing risk factor for cholelithiasis. Obese patients are three times more likely to have perioperative complications such as bile duct injuries as suggested

by Aziz et al²¹. Presence of other co-morbid conditions like diabetes, raised blood pressure, COPD, thyroid disorders were seen in 34 patients, while 66 patients were not having any co-morbid conditions. Volkan Genc et al²² in their study observed that patients with co-morbid conditions have a higher incidence of conversion to open cholecystectomy.

On searching the literature, we could not find much studies to show the association of achievement of critical view of safety with age, gender and body weight. Further studies with larger sample sizes need to be conducted to establish this association.

The most common presenting symptom of patients enrolled in this study was pain in the abdomen (80%) followed by dyspepsia (52%), fullness of abdomen (50%) and asymptomatic in 8% of patients. These findings were in concordance with the results of study done by Ajay Kumar²³ and Vishwanathan et al¹⁷ who have also reported pain abdomen as the main symptom. History of recurrent cholecystitis presenting as recurrent biliary colic was seen in 10 % of the patients which result in dense adhesions of omentum and gut with gall bladder making the dissection difficult during Laparoscopic Cholecystectomy. This prevents the achievement of critical view of safety and a more incidence of conversion of Laparoscopic procedure to Open one. Out of 20 patients presenting with recurrent attacks of biliary colic, critical view of safety could not be achieved in 12 patients which is statistically significant (p value = 0.001). Volkan Genc et al²² proved in a study conducted on 5382 patients that failure of achievement of critical view of safety due to severe inflammation and dense adhesions caused by recurrent attacks of acute cholecystitis leads to conversion to open cholecystectomy.

As per our study, Critical view of safety could not be achieved in 28.6 % of cases with pre-operative ultrasonographic finding of stone impacted in the neck of gall bladder making the dissection difficult during laparoscopic cholecystectomy, which was statistically significant with a p value 0.017. Jethwani et al²⁴ in their study concluded a similar finding

that male patient, impacted large stone, cholecystitis and history of previous abdominal surgery were the factors causing the dissection difficult during laparoscopic cholecystectomy.

Critical view of safety was achieved in 86 patients in our study which correlates with the findings of the study done by Sanjay et al²⁵ (87%) and Tsalis et al²⁶ (95.82%). The mean duration of the surgery in our study was 63.8 minutes. The operative time of undergoing a Laparoscopic Cholecystectomy with Critical view of safety technique was 50 minutes, 51.5 minutes and 55.7 minutes in the study done by Zarin et al¹⁹, Vettoretto et al²⁷ and Vishwanathan et al¹⁷ respectively.

In our study, all the 14 patients in whom critical view of safety could not be achieved were having gall bladder adhesions with omentum and gut thereby making the Callot's triangle dissection difficult. In 12 patients, procedure was changed from laparoscopic to open cholecystectomy. Ashfaq et al²⁸ reported a similar conversion rate of 19.9% due to severe pericholecystic adhesions. Volkan Genc et al²² concluded in their study that tissue inflammation and fibrosis of Calot's triangle were the main reasons of conversion from laparoscopic to open method.

Aberrant anatomy of vascular system in the form of right hepatic artery abnormally in front of common hepatic duct was present in 2 cases in our study, which resulted in conversion from laparoscopic to open cholecystectomy. Regarding aberrant anatomy, our study is in concordance with study conducted by Ajay Kumar et al²³. They reported aberrant anatomy in 2.7% of the patients. Singh K et al²⁹ in their study on 740 patients undergoing laparoscopic cholecystectomy found 26.62% incidence of vascular anomalies and 12.16% ductal anomalies in the extrahepatic biliary system. Barot et al³⁰ stressed upon the achievement of critical view of safety as it increased the recognition of aberrant anatomy from 1.4% to 8.7%.

In this study, subhepatic drain was placed in all the cases. 2 cases had the biliary content of the drain suggestive of bile duct injury. In a study conducted by Bulent kaya et al there were no minor or major bile duct injuries. Shaheed M et al¹⁶ observed that the

incidence of bile duct injuries in infundibular technique was 1.6% while it was 0% in critical view of safety technique. Sgaramella et al⁷ concluded in their study that the achievement of critical view of safety resulted in significantly lower incidence of bile duct injuries.

CONCLUSION

The study concludes that if critical view of safety is achieved while performing laparoscopic cholecystectomy, it helps in preventing bile duct injuries especially in cases of technical difficulty and favours the positive outcomes. However, further studies may be required on a larger scale to further strengthen these results.

REFERENCES

1. Chuang SC, His E, Lee KT. Genetics of gallstone disease. *Adv Clin Chem.* 2013;60:143-85.
2. NIH Gallstones and laparoscopic cholecystectomy, NIH Consensus Statement 1992 Sep 14-16;10(3):1-20
3. Flum DR, Cheadle A, Prella C, et al. Bile duct injury during cholecystectomy and survival in Medicare beneficiaries. *JAMA* 2003; 290(16): 2168-73
4. Waage A, Nilsson M. Iatrogenic bile duct injury: a population-based study of 152276 cholecystectomies in the Swedish inpatient Registry. *Arch Surg* 2006;141(12):1207-13
5. Strasberg SM, Eagon CJ, Drebin JA. The "hidden cystic duct" syndrome and the infundibular technique of laparoscopic cholecystectomy- the danger of the false infundibulum. *J Am Coll Surg* 2000;191:661-7.
6. McMahon AJ, Fullarton G, Baxter JN, O'dwyer PJ. Bile duct injury and bile leakage in laparoscopic cholecystectomy. *British journal of Surgery.* 1995 Mar;82(3):307-13.
7. Sgaramella LI, Gurrado A, Pasculli A et al. The critical view of safety during laparoscopic cholecystectomy: Strasberg Yes or No? An Italian Multicentre study. *Surg Endosc* 35, 3698-3708 (2021).
8. J Reddick and D.O. Olsen. "Laparoscopic laser cholecystectomy". *Surg Endosc* 3, 131-33 (1989)
9. Almutairi AF, Hussain YAMS. Triangle of safety technique: a new approach to laparoscopic cholecystectomy. *HPB Surg.* 2009;ID476159:1-9.
10. Yegiyants S, Collins JC. Operative strategy can reduce the incidence of major bile duct injury in laparoscopic cholecystectomy. *Am Surg.* 2008;74(10):985-987.
11. Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. *J Am Coll Surg.* 1995;180(1):101-125
12. Pucher PH, Brunt LM, Fanelli RD, Asbun HJ, Aggarwal R. SAGES expert Delphi consensus: critical factors for safe surgical practice in laparoscopic cholecystectomy. *Surg Endosc.* 2015;29:3074-3085.
13. Eikermann M, Siegel R, Broeders I, Dziri C, Fingerhut A, Gutt C, et al. prevention and treatment of bile duct injuries during laparoscopic cholecystectomy: the clinical practice guidelines of the European Association of Endoscopic Surgery (EAES). *Surg Endosc.* 2012;26(11):3003-3039.
14. Strasberg SM, Brunt LM. The critical view of safety: why it is not the only method of ductal identification within the standard of care in laparoscopic cholecystectomy. *Ann Surg.* 2017;265(3):464-465.
15. Way LW, Stewart L, Gantert W, Liu K, Lee CM, Whang K et al. Causes and prevention of laparoscopic bile duct injuries: analysis of 252 cases from a human factors and cognitive psychology perspective. *Ann Surg.* 2003; 237(4):460-469.
16. Shaheed M, Mohammed MA, AlFaddagh ZA. Critical view of safety during laparoscopic cholecystectomy. *Bas J Surg.* 2016; 22:33-38
17. Vishwanathan V, Garg HP. Critical view of safety technique during laparoscopic cholecystectomy in prevention of biliary injuries. *Int J Int Med Res.* 2016; 3:35-40
18. Kaya B, Fersahoglu MM, Kilic F, Onur E, Memisoglu K. Importance of critical view of safety in laparoscopic cholecystectomy: a survey of 120 serial patients with no incidence of complications. *Annals of hepato-biliary-*

- pancreatic Surgery. 2017; 2:21(1):17-20
19. Zarin M, Khan MA, Shah SAM. Critical view of safety faster and safer technique during laparoscopic cholecystectomy? Pak J Med Sci. 2018;34(3):574-577
20. Yol S, Kartal A, Vatansev C, Aksoy F, Toy H. Sex as a factor in conversion from laparoscopic cholecystectomy to open surgery. JSLS: Journal of the Society of Laparoscopic Surgeons. 2006 Jul;-10(3):359
21. Aziz h, Pandit V, Joseph B, Jie T. Age and obesity are independent predictors of bile duct injuries in patients undergoing laparoscopic cholecystectomy. World J Surg. 2015; 39(7): 1804-1808
22. Genc V, Sulaimanov M, Cipe G, Basceken SI, Erverdi N, Gurel M, Aras N, Hazinedaroglu SM. What necessitates the conversion to open cholecystectomy? A retrospective analysis of 5164 consecutive laparoscopic operations. Clinics. 2011;66(3):417-420
23. Kumar A. Assessment of efficacy of critical view of safety (CVS) in laparoscopic cholecystectomy in avoiding the occurrence of bile duct injury. International Journal of Surgery. 2019;3(3):349-51
24. Jethwani U, Singh G, Mohil RS, Kandwal V, Razdan S, Chouhan J, Saroha R, Bansal N. Prediction of difficulty and conversion in laparoscopic cholecystectomy. OA Minimally Invasive Surgery. 2013 Aug 1;1(1):2
25. Sanjay P, Fulke JL, Exon DJ. 'Critical view of safety' as an alternative to routine intraoperative cholangiography during laparoscopic cholecystectomy for acute biliary pathology. Journal of Gastrointestinal Surgery. 2010 Aug 1; 14 (8): 1280-84
26. Tsalis K, Antoniou N, Koukouritaki Z, Patriddas D, Christoforidis E, Lazaridis C. Open access technique and "critical view of safety" as the safest way to perform laparoscopic cholecystectomy. Surg Laparosc Endosc Percutan Tech 2015;25:119-24
27. Vettoretto N, Saronni C, Harbi A, Balestra L, Taglietti L, Giovanetti M. Critical view of safety during laparoscopic cholecystectomy. J Soc Laparoendosc Surg. 2011;15(3):322
28. Ashfaq A, Ahmadi K, Shah AA, Chapital AB, Harold KL, Johnson DJ. The difficult gall bladder: outcomes following laparoscopic cholecystectomy and the need for open conversion. The American Journal of Surgery. 2016 Dec 1;212(6):1261-64
29. Singh K., Singh R, Kaur M. Clinical reappraisal of vasculobiliary anatomy relevant to laparoscopic cholecystectomy. Journal of Minimal Access Surgery. 2017 Oct;13(4):273
30. Barot TC, Canales A, Irving J, Unger SW. SAGES 6-step protocol for minimizing bile duct injuries: a single centre experience. SAGES 2016 [cited May 18]. Available at <https://www.sages.org/>