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Evaluation of "critical view of safety" in laparoscopic cholecystectomy

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Abstract
Background: Laparoscopic cholecystectomy, a gold standard in the treatment of cholelithiasis, is the most common procedure in general surgery. Laparoscopic cholecystectomy is associated with an increased rate of Bile duct injuries. Bile duct injury carries a lot of morbidities, occasional mortality, and low quality of life. Bile duct injuries are due to inflammatory adhesions in Calot's triangle, anatomical variations, and the surgeon's faulty perception. Misidentification of the biliary ductal system is the leading cause of bile duct injuries. To avoid this misidentification Strasberg introduced a safety protocol named "Critical View of Safety". Following the Critical view of safety, the rate of bile duct injuries has been reduced.
Aims and Objectives: To study the efficacy and utility of the Critical View of safety in Laparoscopic Cholecystectomy in avoiding bile duct injuries. To compare the efficacy of the Critical view of safety with the infundibular technique.
Materials and Methods: A prospective study of the efficacy of the Critical View of safety in Laparoscopic Cholecystectomy was done in 50 cases. The results were compared with the procedure by conventional Infundibular technique.
Results: Critical View of safety was achieved in 47 (94%) of cases without BDI.
Conclusion: implementation Critical View of Safety is useful in avoiding Bile duct injuries.

Keywords: Critical View of Safety (CVS), Laparoscopic Cholecystectomy (LC), Open Cholecystectomy (OC), Bile Duct Injury (BDI), Common Bile duct (CBD), Cystic duct (CD), Infundibular method (IN)

Introduction

Laparoscopic cholecystectomy (LC) is considered a gold standard surgery for benign diseases of the gallbladder. It is one of the common surgical procedures taught to surgical residents. It has advantages of improved quality of life with lesser pain, reduced hospital stay, faster recovery, and early return to work. But LC is also associated with increased incidence of major Bile duct injuries (BDI) compared to Open Cholecystectomy (OC) at 0.3% vs 0.1% [1]. There was an increase of 0.74 - 2.8% BDI in the initial phases of LC due to the learning curve [2]. Even in present times, it is still high at 0.3-0.4%. Major bile duct injuries are associated with increased morbidity and mortality. They need complex surgical interventions with more complications and a decreased quality of life [3]. They are the major source of medico-legal litigation. The degree of severity of the BDI ranges from simple obstruction to excision of large parts of the extrahepatic biliary tree. BDI may need a very complex biliary reconstruction or even liver resection or transplantation [4]. The major cause of the BDI is intra-operative misidentification of biliary ductal anatomy (71-97%) [3]. The most common error is misidentification of Common Bile Duct (CBD) as the Cystic duct (CD) and hence cut. This is called the "classic laparoscopic injury". Injuries to the Common Hepatic duct (CHD) and Rt Hepatic artery are also common due to misidentification. Sometimes both duct and vascular injuries occur together leading to Vasculo-biliary injuries which are associated with major bleeding, BDI, and even liver failure. BDI occurs as a result of 1) Inflammatory adhesions in the Calots triangle secondary to acute or chronic cholecystitis 2) Aberrant anatomy of extra hepatic biliary apparatus and 3) surgeon's factors - knowledge of anatomy, faulty technique and, improper use of instruments.

Mechanism of BDI: LC is primarily a virtual surgery based on the surgeon's visual perception, which can be susceptible to errors or misinterpretations. Misidentification of the biliary ductal system is the major cause of BDI (up to 70-97%).

In severe inflammatory conditions the cystic duct and the gallbladder fuse to the side of the common hepatic duct creating a deception that the CBD or CHD is the cystic duct resulting in bile duct injury. Misidentification of the CBD as cystic duct may also occur because of too much antero-lateral traction of the gallbladder infundibulum, which results in tenting of CBD, so-called lateral T [1]. Improper usage diathermy can lead to a ductal injury, sometimes delayed BDI due to sloughing of the duct. Many classifications of BDI are described in the literature. They include Bismuth-carlotte, Stewart-way classification, Strasberg classification, and Hannover classification. The Stewart-Way classification is a method of classifying the type of Bile Duct injury based on the specific mechanism and anatomy of injury [5]. The most common BDI is a class 3 Stewart-Way injury (61%) [3, 5]. It represents the complete section of the common hepatic duct and CBD. An injury of the Right hepatic artery (class 4) is seen in 27% of cases [5]. Mirizzi syndrome needs sharp dissection in Calot's Triangle, resulting in partial lesions of the CBD or Right Hepatic Duct. Bile leaks might occur due to clip displacement, necrosis of the cystic duct due to the clip, or damage to aberrant ducts. Excessive use of electrocautery, as well as a traumatic dissection along the CBD, are reasons for late BDI. The "infundibular" technique, (IN) is commonly used since the beginning of LC uses the intra operative recognition of cystic duct and gallbladder junction for gallbladder hilar dissection was primarily used. The "*infundibular method"* where dissection is done very close to gallbladder infundibulum, to avoid the risk of biliary injuries. But the "hidden cystic duct" syndrome gives a deceptive appearance of a false infundibulum that misleads the surgeon into identifying the CBD as the cystic duct leading to the BDI [4]. The "antegrade dissection or fundus first technique" is another way of dissection starting from the gallbladder fundus up to the infundibulum away from Calot's triangle. In this way, the gallbladder is left pedunculated by the cystic artery and cystic duct, which can be clipped and divided in turn, reducing the risk of BDI. Fundus first technique is cumbersome with loss liver retraction. In severely inflamed conditions it can cause visual misinterpretation of CBD as the Cystic duct. Strasberg [6] reported that extreme vasculo-biliary injuries tend to occur when fundus-down cholecystectomy is performed in the presence of severe inflammation. Inflammation thickens and shortens the cystic plate, making the separation of the gallbladder from the liver hazardous.

To avoid these problems Strasberg and colleagues suggested a three-pronged strategy called the "critical view of safety" (CVS) to minimize the risk of bile duct injuries in LC [1]. It follows three principles: (1) dissection of the Calot's/ Hepatocystic triangle from all fatty and fibrous tissue, (2) mobilization of the lower 1/3rd part of the gallbladder from liver bed (cystic plate), and (3) the clear identification of two and exclusively two structures of the cystic duct and the cystic artery entering the gallbladder. Not until all three elements of CVS are attained may the cystic structures be clipped and divided. This concept was introduced in 1992 by Strasberg and named it CVS in 1995 [1]. During the past 25 years, this method has been increasingly adopted by surgeons all over the world for laparoscopic cholecystectomy. CVS is not a way to do cholecystectomy, but it is a way to avoid BDI by clear identification of the ductal system. The CVS is an adaptation of the method used for ductal identification that was practiced in open cholecystectomy [7]. In Strasberg's opinion, CVS would prevent accidental biliary and vascular injuries due to uncommon variations, or unclear anatomy. These principles have been ignored until recent years, which may be due to the reluctance of surgeons to learn a new technique. But with supporting data that are appearing in the literature, it is evident that this CVS way of dissecting the gallbladder pedicle has a protective role against bile duct injuries. This is an important aspect in teaching the younger generation of surgeons for the approach to the gallbladder hilus.

Materials and Methods

A prospective study of the efficacy of CVS was done in our institute in 50 cases of LC. Evaluation of patient is taken routinely with clinical examination, ultrasonography, liver function tests and, other necessary tests. To achieve standardisation of cases, those with previous surgical intervention in the upper abdomen, liver parenchymal disease like cirrhosis were excluded in this study. A standard 4 port LC was done under general anaesthesia. The cephalad traction of the fundus is obtained by the grasper from the anterior axillary line and together with lateral traction of the infundibulum by the grasper in mid clavicular line. Difficulty of GB condition made according to Nasser classification. The Rouviere's sulcus is noted and dissection is done above or ventral to it. Where Rouviere's sulcus is absent an imaginary line "R4U line" is drawn from the umbilical fissure across the base of segment 4 of the Liver, extended on to the extra biliary tree helps in dissection. Dissection is done with either monopolar hook or curved bipolar cautery with low power settings of < 30 watts. Dissection in Hepatocystic triangle is done by removing all fibro fatty tissue from both posterior and anterior aspects of the cystic pedicle. The Gallbladder is dissected of the liver in the lower part (cystic plate). This leaves only two structures, cystic duct and cystic artery seen entering the gallbladder. Bare surface of the liver surface seen from both anterior and posterior sides of Calots triangle (double calots view). Only after fulfilling all these 3 principles of CVS, the cystic duct and artery are clipped and cut. GB is dissected of liver and removed. Time in achieving in CVS is noted from the start of the dissection of Calot's triangle. Not being able to achieve CVS even after 30 minutes of dissection of Calot's is considered as a difficult gall bladder surgery. A second opinion of a different surgeon is taken. With the failure to achieve CVS, a decision for a bail-out is taken. All cases were drained with a sub hepatic drain which was removed after 24 hrs in no bleed or bile leak cases. Post-operative incidence of bile leak and bleeding is noted. Results were compared cases previously done by the Infundibular technique.

Results

50 cases of LC were studied. 12cases were chronic cholecystitis, 34 cases were cholelithiasis, 4 were acute cholecystitis. The study included 13 males and 37 females. The age of the youngest patient in the study was 26 years and that of the oldest patient was 64 years. The majority of patients 19 cases (38%) were in the age group of 41-50 years. Intra operative assessment of difficulty was done by Nasser score. 13 cases were grade 1, 28 cases were in grade 2, 7 cases were grade 3, and 2 cases were grade 4. CVS was achieved in 47 cases and not in 3 cases. 2 were in grade 3 and 1 was in grade 4. These 3 cases belong to Nasser grades 3 & 4 with dense inflammatory adhesions. In these cases, CVS could not be achieved after a trial dissection of 30 minutes. They were considered a failure of the ductal identification and later bail-out procedures were taken up. Subtotal reconstituting cholecystectomy was done in all cases. Post-operative complications of bleeding, bile leak noted. Post-operative bleeding was present in 2 cases but controlled spontaneously in 3 days. In a case with Naser 4 class adhesions, active post operative bleeding but controlled with blood

transfusion. No mortality and major bile leak or BDI were noticed.

A retrospective study of 80 cases of LC in 1 year by Infundibular technique (IN) is taken for comparison. Age, sex, and disease distribution are similar in both groups. The incidence of complications is compared. In IN group there was no mortality but 2 cases of Bile leak. One case needed a major repair and other was minor controlled spontaneously. Bleeding was seen in 2 cases with 1 case needing a blood transfusion.

Table 1: Age & Sex distribution

Age in years	Male	Female	Total	Percentage
21-30	00	4	4	08
31-40	04	08	12	24
41-50	03	16	19	38
51-60	04	08	12	24
60 +	02	01	03	06
TOTAL	13	37	50	100

Table 2: Difficulty and CVS achieved

Nasser grade	No. of cases	CVS achieved	Not achieved
Grade 1	13	13	0
Grade 2	28	28	0
Grade 3	07	05	2
Grade 4	02	01	1

Table 3: Complications

Complications	CVS (50 cases)	Infundibular technique (80 cases)
Mortality	0	0
Bile leak	0	2 (1 major) (2.5%)
Bleeding	2 (minor) (4%)	2 (1 major) (2.5%)

Discussion

BDI is a major complication of LC with increased morbidity, mortality, and decreased quality of life. BDI is a complex problem affecting healthy young people. The major cause of BDI is the misidentification of the biliary ductal system. The problem of misidentification of the common bile duct as the cystic duct during LC is well recognised and documented [4]. The approach to the gallbladder's pedicle is of utmost importance for the prevention of injuries. The commonly performed "infundibular technique" is based on recognition of cystic duct widens to become the gallbladder infundibulum [8]. This is referred to as a funnel shape or elephant trunk sign. Due to inflammation, the cystic duct may be adherent to CHD. It creates a visual deception of CHD as the cystic duct. This is described as "Hidden duct syndrome" by Strasberg [4]. BDI is more likely when cystic duct identification is made by relying solely on the appearance of the junction of the cystic duct with the infundibulum of the gallbladder [9]. Strasberg *et al*. [9] strongly suggest that the infundibular technique for identification of the cystic duct is unreliable, especially in presence of acute inflammation. With serious consequences of a biliary injury and the fact that other more secure methods for the identification of ductal system exist, it would be logical to abandon the infundibular technique [9]. The fundus first or fundus down technique involves dissection of gallbladder starting from fundus and keeping close to gallbladder in front of the cystic plate down to cystic pedicle and clipping and cutting cystic artery and artery. This leads to problems of loss of the liver retraction and the gallbladder tends to twist on the cystic pedicle once it is separated from the cystic plate. The lower end of the cystic plate inserted in front of the right portal pedicle. In case of severe inflammation, the cystic plate is contracted and shortened and it pulls the right portal pedicle or structures close to the right portal pedicle, the main portal vein, or hepatic artery into the area behind and below the cystic plate.[9] Due to dense adhesions the dissection becomes difficult and when it enters the wrong plane behind the cystic plate, injury to the right portal vein and duct can occur.[9] This can cause severe and fatal bleeding. Strasberg reported a series of severe vasculo-biliary injuries in fundus first cholecystectomy with severely inflamed gallbladders [7].

CVS: Misidentification is due to failure to achieve identification of the ductal structures. The cystic duct and the cystic artery are the only structures that require division during cholecystectomy. The objective of dissection is to identify these structures. "Conclusive identification" is the key [9]. In 1995, Strasberg introduced CVS technique for conclusive identification of the cystic structures in LC [9]. CVS is conceived on the basis of anatomic identification of ductal system in open cholecystectomy [1]. CVS is not a way of doing LC but a systemic way to identify the ductal system to avoid BDI. The CVS is not a dissection technique, but a technique of anatomical identification of the ductal system. The CVS has 3 requirements**.** Once these 3 criteria have been fulfilled, CVS is achieved. It is not necessary to see CBD but a 360-degree view around the cystic duct and artery should be obtained. The CVS should be apparent from both the anterior and posterior (reverse Calot) viewpoints. The dissection of the cystic plate depends on the degree of inflammation. Dissection of the lower third is enough in cases with minimal inflammation. In case of severe inflammation, it is more with half of the gallbladder is dissected off the cystic plate. Simply making 2 windows does not meet the criteria of CVS. Enough of Gallbladder should be dissected off the cystic plate so that only next step left is the removal of GB after the division of cystic pedicle. It is crucial for safety that no tubular structure may be severed until the cystic duct and the cystic artery are identified without any doubt. The importance of the CVS was also recognized by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). They encouraged the use of the CVS technique in the "Safe Cholecystectomy Program" to minimize BDI risk and promoted the adoption of CVS as a universal culture of safety in cholecystectomy. In the Tokyo 18 guidelines for AC, the CVS proposed by Strasberg is strongly recommended to prevent BDI [10]. In Delphi consensus, on BDI during laparoscopic cholecystectomy, more than 600 expert international LC surgeons opined that always obtaining CVS (as long as it is safe and secure to do so) must be done [11]. Morgenstern *et al*. in 1992 reported on 1200 consecutive open cholecystectomies with a BDI incidence rate of < 0.2% and it is considered this value the standard on which LC should be compared [12]. But even the introduction of CVS could not help in achieving the original 0.2% rate of BDI, with the present BDI rate is still higher at 0.3 - 0.4%. Avgerinos C reported 998 cases in which CVS was used for target identification without a biliary injury due to misidentification [13]. The conversion rate was 2.7%. There were no major bile duct injuries. In a study by Yegiyants *et al*. 3042 patients had laparoscopic cholecystectomy from 2002-2006 using CVS for ductal identification. One of these patients had ductal injury [14]. By the standard rate of BDI around 15-20 cases of BDI were expected in these series. Heistermann *et al*. [15] in their study of 100 patients using CVS, completed 97 cases laparoscopically, despite of high incidence of cute cholecystitis and prior abdominal surgery. These studies are highly supportive of the efficacy of CVS. Though multiple studies favour use of

CVS in LC, for evaluation by the evidence based practice, they are at a low level of evidence. There is no level 1 evidence that CVS reduces BDI. Evidence will be difficult to attain as the incidence of BDI is so low that it would be difficult to adequately power a prospective randomized trial [1]. Then the question is how CVS is an effective means of preventing BDI? There are numerous case series that show a reduction in the incidence of BDI when the CVS is attained. They indicate CVS is the "safest" technique for performing laparoscopic cholecystectomy. Secondly in studies that investigated the mechanisms of major biliary injury, it is observed that CVS was not the method of target identification [1]. Even after 25 years of the introduction of CVS, many surgeons have a poor concept of it as they were not taught the concept of CVS in their training. The reluctance of the surgeons to learn a new technique is another cause. The infundibular technique, taught in standard textbooks is much easier and needs less dissection than CVS. International societies such as the European Association of Endoscopic Surgery (EAES) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) have provided the guidelines for laparoscopic cholecystectomy. Their guidelines describe dissection in Calot's triangle using the ''critical view of safety'' technique. The Dutch Society of Surgery established a commission to study the problem of biliary injury in Netherlands. They have adopted CVS as the standard method of performing ductal identification [16]. An Italian multicentric study (2017-2019) by 30 different hospitals on 604 patients suggest that the CVS is the safest technique to recognize the elements of the Calot triangle and, if correctly performed, it significantly impacted on preventing intraoperative complications [17]. CVS is a part of a broad concept of "Culture of safety in Cholecystectomy" (COSIC) which is taken up by SAGES in their new program "Safe cholecystectomy [19]." This SAGES program aims at the prevention of BDI with a better understanding and use of CVS with other strategies and bailout techniques. CVS is not a method of LC but a strategic approach to the ductal system. It helps the surgeon in avoiding misidentification of ductal anatomy. One must understand CVS is not always attainable and alternate ways to complete cholecystectomy must be considered. Awareness of the CVS through mandatory documentation may improve both trainee and surgeon technique in laparoscopic cholecystectomy [18].

In our small series, CVS was helpful in avoiding bile duct injuries. CVS reduced BDI as it eliminates misinterpretation of ductal anatomy. Following CVS either ductal identification is achieved or failing of which a bailout procedure is taken up as a policy in our study. Bail-out procedures are more in cases with severe inflammation as in acute cholecystitis or a dense fibrosed calot's triangle. The small number of our study is not sufficient to analyse the outcome of the "bile duct injury rate," as larger data is required to analyse the outcome. It is important to know that CVS is not the ultimate in LC and it shall not be taught as a rigid principle. Instead, we recommend and teach residents to use CVS as a way for ductal identification and to avoid/minimize BDI. The application of the "critical view of safety" is made a compulsory criterion for minimising the risk of iatrogenic injuries of the bile duct and decision on bailout procedure.

Conclusions

The CVS is the safest technique to recognize the anatomy of the calot's triangle and it significantly helped in preventing ductal injury by misinterpretation. Application of CVS in clinical practice is essential to avoid major bile duct injuries and complications. CVS is less susceptible to visual deception because more exposure of ductal structures is needed to achieve CVS.

Declarations

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee.

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