SURGERY INSIGHTS

MIDITERRANEAN JOURNALS

Case Series

DOI: 10.55085/si.2022.620

Importance of Critical View of Safety, Rouviere's Sulcus, and Minimal Energy Device Usage in Reducing Biliary Injury in Laparoscopic Cholecystectomy

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ABSTRACT

Introduction: Major bile duct injury in laparoscopic cholecystectomy results in morbidity and needs further management, which adds to the increased cost of treatment. However, some studies have shown that by defining critical view of safety and seeing the relationship of Rouviere's sulcus with other structures, and minimal use of diathermy in Calot's triangle, we can bring down complications further close to zero percent. We wanted to see that such a low bile duct injury rate is achievable at every center by routinely following these steps. We retrospectively reviewed the database of patients who had undergone elective laparoscopic cholecystectomy (LC) in three years and evaluated the rate of bile duct injury and other complications.

Methods: We reviewed our database for patients and did a retrospective analysis on patients who were diagnosed with symptomatic cholelithiasis or chronic cholecystitis, and have undergone LC in our centre from January 2017 to December 2019. Patients less than 15 years of age, acute cholecystitis, and laparoscopic cholecystectomy combined with common bile duct exploration were excluded. We calculated the incidence of biliary injury. The secondary outcomes looked at were Veress needle or pneumoperitoneum-related complications, port site bleeding, intra-abdominal bleeding, bowel injury, liver injury, wound infection, and early port site hernia.

Results: LC was performed in 642 patients. In this study, there was no bile duct injury. Two patients (0.31%) had minor bile leak which resolved without any intervention within a week. Three (0.46%) patients developed port site infection, which responded to regular dressing and oral antibiotic therapy.

Conclusion: The effectiveness of these steps should make their use mandatory in every center to reduce bile duct injury.

Keywords: Laparoscopic Cholecystectomy, Cholelithiasis, Bile Duct Injury, Critical View of Safety, Rouviere's Sulcus.

Received: 11 Jan 2022
Revised: 20 Feb 2022
Accepted: 24 Feb 2022
Published: 11 Apr 2022

Academic Editor: Luigi Conti

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Cite this article as: Afaque MY, Rehman N, Alam J, Varshney H, Ali Rizvi SA, Aslam M. Importance of Critical View of Safety, Rouviere's Sulcus, and Minimal Energy Device Usage in Reducing Biliary Injury in Laparoscopic Cholecystectomy. Surg Insights. 2022;1:626. [https://doi.org/10.55085/si.2022.620]

Authors' contributions
The participation of each author corresponds to the criteria of authorship and contributorship emphasized in the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals of the International Committee of Medical Journal Editors. Indeed, all the authors have actively participated in the redaction, the revision of the manuscript, and provided approval for this final revised version.

Acknowledgments
None.

Funding
No funding was received from any organization to conduct the present study.

Conflict of interest
The authors declare that there is no conflict of interest regarding the publication of this article.

1. INTRODUCTION

Laparoscopic cholecystectomy (LC) is the standard technique for symptomatic cholelithiasis [1], as it provides several advantages over open cholecystectomy, which includes less pain, shorter hospital stay, and faster recovery [1]. However, bile duct injuries (BDI) encountered in LC (0.4%) are higher than open surgery (0.1-0.2%) [2–4]. A recent systemic review analysed 151 studies, and 65 of them, representing 170,059 patients described BDI as major bile duct injuries and bile leaks. It showed a prevalence of major injury as 0.28% and bile leak 0.46% [5].

The common cause of most major bile duct injury is the misidentification of biliary anatomy. The common bile duct (classical injury) or aberrant hepatic ducts may be misidentified as cystic duct (CD) and divided. There can also be a division of the hepatic ducts or the right hepatic artery. The misidentification can be because of incomplete dissection, as all these structures are tubular and look similar. These tubular structures in LC are identified by the direction they are arising and draining, their diameter, their number, and their relationship with the fixed anatomical landmarks like Rouviere's sulcus. For achieving safe dissection,

the experts have stressed the importance of critical view of safety, Rouviere's sulcus, and minimum diathermy in the Calot's triangle. The critical view of safety [CVS] is a method of goal identification, the goal being the cystic duct and cystic artery [6]. It involves the separation of the lower one-third of the gall bladder from the cystic plate, removal of fat and fibrous tissue off the hepatocystic triangle. And then identifying only two tubular structures attached to the gall bladder. Only after the CVS is achieved the cystic duct and artery should be divided. The SAGES safe cholecystectomy program also advocated the use and understanding of CVS for preventing bile duct injuries [7].

When the era of laparoscopic cholecystectomy began, the injury rates to the bile duct were exceptionally high [8]. As the techniques evolved over the first few decades, the bile duct injury rate fell significantly and plateaued at around 0.4%. And now the perception is that this is the lowest incidence we can achieve. However, some studies challenged this perception and showed that the bile duct injury rate could be further decreased to close to zero. Avgerinos et al. performed LC with CVS technique in 998 patients with a conversion rate of 2.6% and reported no bile duct injuries. [9]. Sanjay et al. carried out the same admission LC in 447 patients with acute biliary pathology with a policy of routine CVS and no bile duct injuries occurred in the series [10]. Similarly, Kaya et al. demonstrated the importance of CVS in their study by performing LC in 120 patients using CVS delineation and reported no intra-operative or post-operative biliary complications [11].

These studies have set a benchmark for others. Is the low complication rate due to exceptional surgical skills that others cannot replicate? We perform LC by following all the essential surgical principles: defining CVS, identifying Rouviere's sulcus' relationship with other structures, and minimal use of diathermy in Calot's triangle. We wanted to see that by following meticulously these surgical steps the bile duct injury rate will be very low (even less than 0.4%) in every hand. We retrospectively reviewed the database of patients who had undergone elective LC in the last three years. We evaluated the rate of bile duct injury along with other intra-operative and postoperative complications. We also described in detail the intraoperative maneuvers required for emulating these steps.

2. METHODS

In this retrospective study patients diagnosed with symptomatic cholelithiasis or chronic cholecystitis that underwent LC from January 2017 to December 2019 in two surgery units of the department were included. The operative surgeons were teaching faculties, who were proficient in laparoscopic procedures. The trainees also performed surgeries under the direct supervision of these faculty. The operative notes, post-operative progress notes and follow up notes (weekly for two weeks then after two weeks) were analyzed. Patients less than 15 years of age, acute cholecystitis, or LC combined with CBD exploration were not included in the study. The primary outcome noted was the incidence of biliary injury and was classified according to intra-operatively or postoperatively. Disruption including ligation, avulsion, or resection of the extra-hepatic biliary system was defined as major bile duct injury and small biliary leaks not requiring surgery was considered minor injury (12). The secondary outcomes were Veress needle or pneumoperitoneum-related complications, port site bleeding, gallbladder perforation or stone spillage, intra-abdominal bleeding, bowel injury, liver injury, wound infection, or early port site hernia.

Preoperative, intra-operative, postoperative, and follow-up details were entered in a Microsoft Excel worksheet. Data analysis of categorical variables was expressed as the number of patients and the percentage of patients. Continuous variables were expressed as mean and range. Institutional ethical clearance was taken for this study.

3. OPERATIVE TECHNIQUE

The LC was performed by the standard four ports technique in reverse Trendelenberg position under general anaesthesia. Single dose of cefazolin (2 gram) was given intravenously as prophylaxis in these patients. The camera and monitors had a high-definition (HD) resolution. After the creation of pneumoperitoneum using Veress needle through the umbilicus, the first trocar (10 mm) was placed through the umbilicus, and a 30º laparoscope was introduced. Rest all ports were introduced under direct vision. Lateral and inferior retraction of the infundibulum of gall bladder was done. Rouviere's sulcus was looked for, and dissection was avoided inferior to it (Pic 1).

In Calot's triangle, we started with the posterior dissection by removing the layer of fibro-fatty tissues. If the posterior dissection is incomplete, it is difficult to make the window from the anterior side. The anterior dissection in the Calot's triangle is started very close to the gallbladder (Pic 2). The reason is in case the cystic duct is short (Mirizzi's syndrome), the CBD will be close to the gallbladder. The Calot's triangle was dissected free of all fibro-fatty tissue and only two tubular structures joining the gallbladder were identified: the cystic duct and artery. In case of difficulty in anterior dissection we also tried to see from the posterior

side for identifying the structures. The most of length of the cystic duct was skeletonized and visualized but we did not try to go very close to the CBD. A wide window was created from the cystic duct to the liver margin with only the cystic artery lying in this window (Pic 3). The CVS was confirmed in both the anterior and posterior views (Pic 4). Any other tubular structure seen in this window was not divided. It could be the right hepatic artery (Pic 5), accessory bile duct, or even bile duct. Some degree of obsession in achieving CVS is worth it.

We divide the cystic artery first as a conventional and believe there are reasons for it. If we first divide the duct the traction on the gallbladder may avulse the artery (happened in our initial cases). After dividing the artery, the duct becomes better identifiable, especially in difficult cases, and also gives extra length to the cystic duct. In case the cystic duct had a large impacted stone the cystic duct was opened for removal of stone and then ligated with intra-corporeal suturing. No to minimum diathermy was used in Calot's triangle. Two clips were placed towards the CBD side on the cystic artery and cystic duct and one towards the gallbladder side. Care was taken not to place clips close to the CBD to avoid clipping the CBD wall and causing tenting injury. The cystic artery followed by the cystic duct was clipped and divided. In dilated cystic ducts we did intra-corporeal suturing for ligating it.

Finally, the gall bladder was dissected off the liver using a monopolar diathermy hook and removed via the epigastric port. In case the gallbladder was perforated it was put in a plastic bag and then delivered out to prevent port site contamination. Once the gallbladder was partially out its exteriorized part was opened and the bile was sucked and stones extracted with Desjardin forceps or Ovum forceps. Care was taken to prevent spillage of bile into the port site, and if it occurred, the port site was irrigated with saline. If there was a struggle in taking out the bulky gallbladder or large unbreakable stone, then the port site was dilated with the straight Mayo scissor or Kocher forceps. If struck at the level of skin then the skin incision was incised few more millimeters (like in episiotomy). Curved instruments here may make a false passage. The 10 mm port site was closed in two layers. A suction drain was placed in sub-hepatic space selectively, and the abdomen desufflated. We placed a drain when there was more than usual bleeding from the liver bed or dissection was difficult due to adhesions. Intra operative cholangiography was not done in any case.

4. RESULTS

A total of 642 LC were included, which had 502 women (78.19%) and 140 men (21.81%). Out of 642 patients, 52 were known hypertensive, 41 were diabetic, 9 had coronary artery disease, and 6 had hypothyroidism. The patients had a mean BMI of 24 kg/mt2 (range 15-48). Trainees (under supervision) performed 58 LC with no biliary injury, and the rest were done by four consultants. The surgeries given to the residents were those in which there was no adhesion so that they could complete it safely. A history of previous abdominal surgeries was present in 40 patients. In thirteen patients, Palmer's point was used for Veress needle insertion because of the midline surgical scar.

We converted seven patients to open cholecystectomy because of difficult bleeding (five patients) and dense adhesions (two patients). Bleeding was from the liver bed (two patients) and in the Calot’s triangle (three patients) which could not be managed by laparoscopic measures. On conversion, the cause of liver bed bleeding was superficial laceration which required suturing. The patients with bleeding from the Calot’s triangle had bleeding from multiple raw surfaces making visibility difficult. Problematic bleeding from the liver bed seen in five other patients was managed by compression, diathermy, and absorbable hemostat placement and did not require conversion. Bleeding from an avulsed cystic artery was seen in four patients. When the avulsed cystic artery was long enough and away from the vital structures then a short burst of energy was used. In case it was close to the CBD region clipping was preferred, and care was taken to not include any other structure in the clip. There were no major intra-abdominal bleeds requiring blood transfusion and no bowel injury during the surgery.

CVS identification was achieved in all except eight patients who had frozen Calot's triangle. These cases were approached by the fundus first technique, and subtotal cholecystectomy was done with the suturing of the remnant stump. The duct of Luschka was identified in the liver bed in one patient and was secured with sutures. Intra-operative gallbladder perforation occurred in 40 patients and it was during dissection in 35 patients and during extraction in five patients. There was stone spillage in ten of these patients. The perforated gallbladders were removed in a plastic bag. The mean operative time was 35 minutes (range 15-120 min). We did not encounter any Veress needle-related injury.

Two patients developed bile leak on postoperative day one, which was initially less than 100 ml (minor leak described as Grade A Bile leakage requiring no or little change in patients’ clinical management, lasting less than one week [13]). It gradually decreased with no drain output on the fifth and seventh postoperative days respectively, without requiring any

intervention. Ultrasonography revealed no collection and MRCP showed no ductal injury after which the drain was removed, and the patients were discharged. These two bile leaks were Strasberg Type A, partial injury [14]. Three patients developed port site infection. The pus culture was sterile, and there was no intra-abdominal collection. These were suspected to be atypical mycobacterium infection, and patients responded to up to one month of oral clarithromycin therapy (500 mg twice daily) and antiseptic dressing. The patients were discharged on postoperative day one or day two, and those who developed bile leak were discharged at one week. There was no case of port site hernia in the minimum follow up of one month. On histopathological examination, four specimens revealed gall bladder malignancy, and these cases were referred to the gastrointestinal oncology unit. Intra-operative complications are shown in table 1 and postoperative complications are shown in table 2. The post-operative complications included wound infection and minor bile leak which were Clavien Dindo grade I complications.

Table 1: Intra operative complications.

Intra operative complications	**Number of patients**	**%**
Veress needle related complication	0	0.0
Pneumoperitoneum related complication	0	0.0
Port site bleeding	3	0.46
Perforation of gallbladder	40	6.23
Gall stone spillage	10	1.55
Intra-abdominal bleeding requiring conversion	5	0.78
Biliary injury	0	0.0
Bowel injury	0	0.0
Liver injury requiring conversion	2	0.31

Table 2: Post-operative complications.

Post-operative complications	**Total**	**%**	**Clavien Dindo classification**
Bile duct injury	0	0.0	
Minor bile leak	2	0.31	Grade I
Bleeding requiring intervention	0	0.0	
Wound infection	3	0.46	Grade I
Port site hernia in one month follow-up	0	0.0	

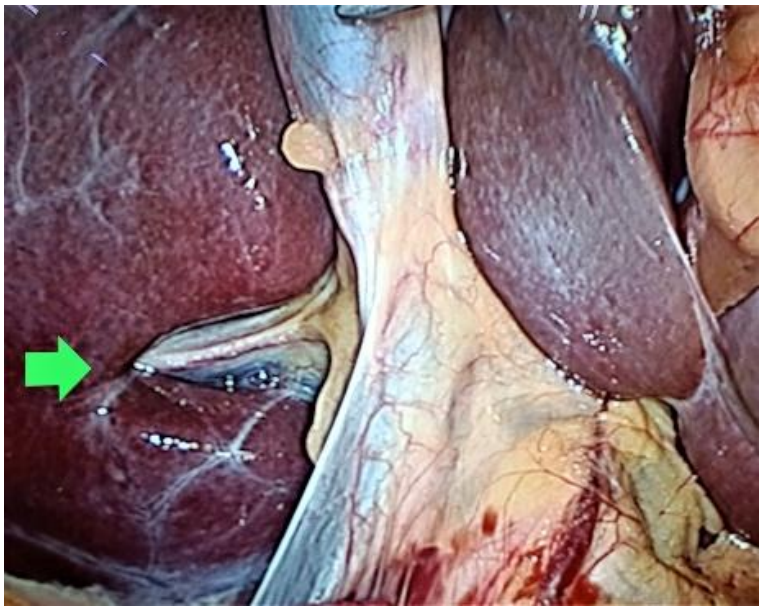

Figure 1: The Rouviere's sulcus (Green arrow).

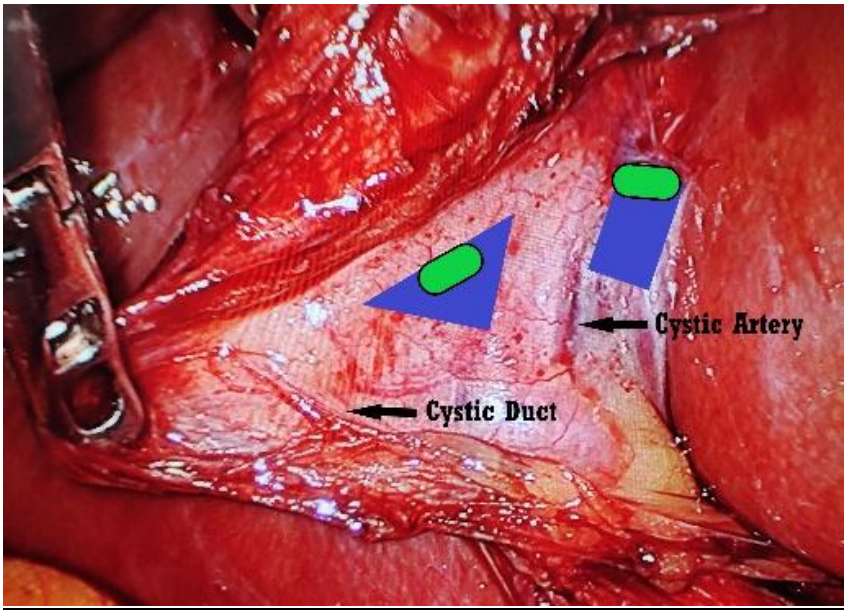

Figure 2: Green is the region of starting the dissection close to the gallbladder. Blue is the region of completed dissection.

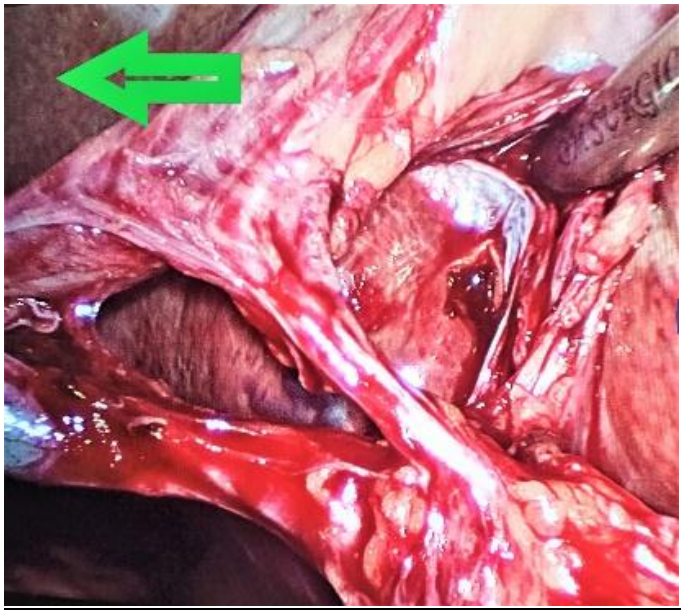

Figure 3: The critical view of safety. The green arrow shows the direction of the left-hand traction which is inferio-lateral.

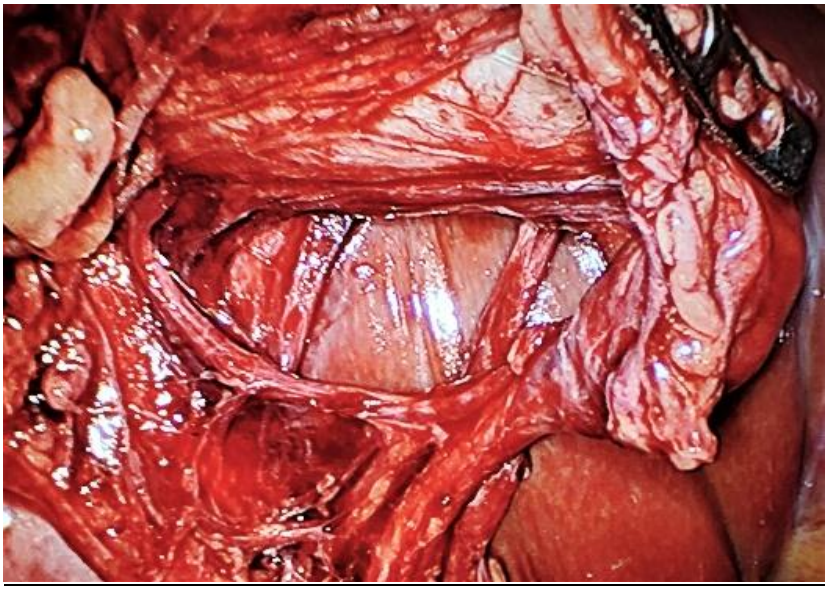

Figure 4: Critical view of safety is confirmed also from the posterior view.

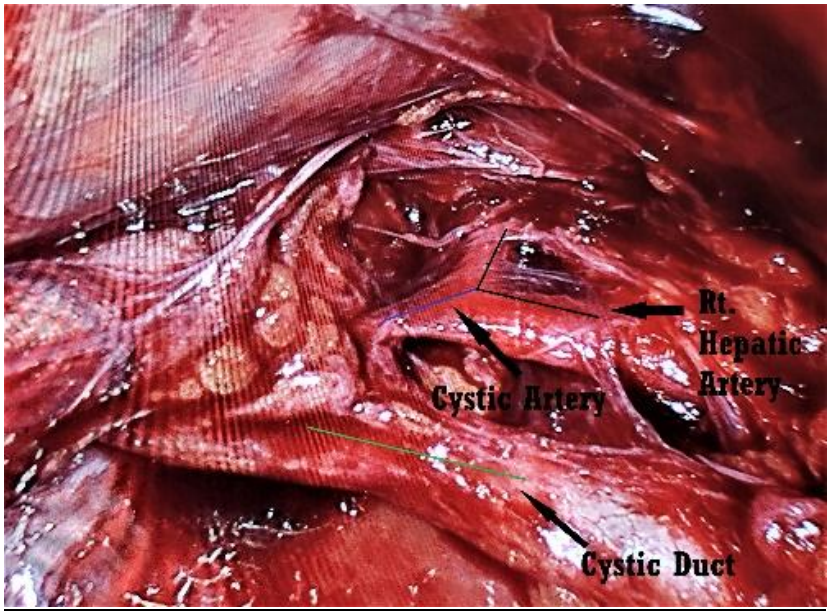

Figure 5: Right hepatic artery found close to the gallbladder.

6. DISCUSSION

For safe laparoscopic cholecystectomy, three things are to be avoided in dissection. First, the use of an energy device should be minimal in Calot's triangle as it is a potential source of biliary injury [14]. Energy device commonly used in LC is monopolar diathermy and sometimes harmonic scalpel in case of dense adhesion. Monopolar diathermy is used for coagulation or for cutting in pure and blend mode. An ex vivo study has shown that monopolar diathermy generates high temperature and results in a significant lateral thermal spread [15]. The damage from it is subtle to notice during surgery and appearing in the postoperative period when the burnt tissue undergoes necrosis. In places where the structure requiring division is close to structures that are vital then minimum or no energy device use is the safest.

Second, for making the window in the Calot's triangle the instruments should not be forced into the fibro-fatty tissue. Excessive force may penetrate any important unseen structure present there. Furthermore, the structures should be completely skeletonized as without it we may injure any hidden structure. The conventional teaching is 'see what you cut and cut what you see'. So, divide what you identify and don't divide what you cannot identify. When we divide a structure on assumptions, the chances are we may be wrong in some cases. The difference between correct division and injury is just that: was the structure identified or misidentified? Sometimes because of extensive adhesions complete skeletonization is not possible, but at least we should be sure that what we are dividing is not a critical structure.

Third, we should do the dissection above the Rouviere's sulcus (RS). By making a line from Rouviere's sulcus to the porta hepatis and then to the base of segment 4b of the liver, we can make out the area of dissection above this line [16]. The cystic duct and cystic artery lie above this plane, and the CBD lies below it. Dissection should be above the plane of the RS and is carried upward into the gallbladder fossa [17, 18]. Sometimes RS is absent and a meta-analysis with 23 studies consisting of 4,495 patients found the prevalence of RS to be 83% [19]. The gallbladder can be continuous with the bile duct (Mirizzi syndrome) or there can be dense adhesion making it difficult to assess the inferior limit of dissection. Rouviere's sulcus is of great help in such cases. RS is especially useful when there is difficulty in identifying the gallbladder surface due to severe inflammation, edema, or hemorrhage and this was highlighted in the recent Tokyo Guidelines 2018 for the surgical management of acute cholecystitis [20].

When these critical steps are followed, even a trainee surgeon does the surgery safely. A study compared 90 LC with CVS technique performed by a young surgeon to 84 LC using an infundibular approach performed by an experienced surgeon [21]. There was one bile leak in the CVS group and two intra-operative hemorrhagic complications in the infundibular approach group. This technique is ideal for residents teaching because of shorter operative time and a similar rate of biliary or hemorrhagic complications. In our series, 58 surgeries were performed by trainees under direct supervision and in that subset also there was no biliary injury. Nijssen et al [22] investigated whether the CVS was achieved during surgery by analyzing videos of operations. CVS was achieved in 80 % of cases according to

the operative notes but reviewers found that CVS was achieved in only 10.8 % of the cases. So there is marked discordance in the subjective feeling of achieving CVS and the actual scenario. Why we do not achieve this goal was evaluated by Nakazato et al [23]. They evaluated 12 surgeons performing LC by recording four of their LC cases: two videos were of LC done before and two after a training session focused on the CVS. After the training, surgeons achieved all CVS criteria in more cases (1/24 versus 10/24). Most of the surgeons, even though experienced, could not achieve CVS. However, they showed marked improvement after their training but still could achieve the target in less than half of their cases. So a continued effort and training are required in all phases of career for improving these skills.

In this series, CVS was not achieved in ten patients. In the eight of these, we performed the fundus first technique with subtotal cholecystectomy and the remaining two ended in open conversion. Not achieving it is also an indicator of going for an alternative procedure or bail out with an open conversion. The alternative procedure is the fundus first technique (retrograde cholecystectomy). We may also start separating the body of the gallbladder from the liver rather than fundus, and from there proceeding towards the Calot's triangle, as another type of retrograde cholecystectomy in LC.

Despite the introduction of CVS two decades ago, the rate of biliary injuries has remained somewhat constant over the years. But the studies which have particularly highlighted the importance of CVS have shown very promising results in decreasing the major bile duct injury (Table 3). The use of the critical view of safety (CVS) has been advocated based on indirect evidence from these studies. The second indirect evidence on CVS comes from case series of BDIs that have studied the cause of the injury. It showed that BDIs usually occurred in patients when the CVS was not visualized [24]. However, minor bile leaks are still there in the studies on CVS and it is considered from the duct of Lushka or slipped cystic duct clips. Such minor leaks stop within a week mostly without any intervention and do not add to long term morbidity [13]. In our series, we had atypical mycobacterium infection in three (0.46%) patients as we are still using 2 % Glutaraldehyde solution for sterilization of hand instruments. And all of them responded to oral Clarithromycin therapy and antiseptic dressing. These infections occurred in the same period suggesting some problem in a particular batch of Glutaraldehyde solution and never occurred again.

We think that biliary injury like any other complication can be minimized but not always eliminated. The complications occur due to factors that are: technical; patient-related; pathology-related; and procedure-related. Furthermore, everyone's anatomy is unique, so surprises are common due to these variations. Despite expertise and best techniques, mishaps may still occur, as even the gold standard techniques are not ideal and are revised from time to time. We aim for the best and still, everything is not in human control. The limitation of the study was that it was done in patients who did not have acute cholecystitis, which has more adhesions. Also, our patient's population is not much obese so is less difficult surgical candidates.

Table 3: Studies showing very low biliary complications with identification of critical view of safety.

Author	Year	No of patients	Biliary complications
Avgerinos C et al.[9]	2009	998	Minor (5) **Major (0)**
Sanjay P et al. [10]	2010	388	Minor (0) **Major (0)**
Kaya B et al. [11]	2017	120	Minor (0) **Major (0)**
Vettoretto N et al. [21]	2011	90	Minor (1) **Major (0)**
Hori T et al. [25]	2016	30	Minor (0) **Major (0)**
Heistermann H P et al. [26]	2006	97	Minor (1) **Major (0)**
Yegiyants S et al. [27]	2008	3042	Minor (0) **Major (1)**
Zarin et al. [28]	2018	218	Minor (1) **Major (1)**

7. CONCLUSION

Bile duct injury remained consistent throughout the three decades of laparoscopic cholecystectomy, but by strictly adhering to some key steps we can reduce biliary injuries further. The effectiveness of these steps should make their use mandatory in every center.

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