

## EVALUATION OF FEASIBILITY AND EFFICACY BETWEEN THE CRITICAL VIEW OF SAFETY AND INFUNDIBULAR TECHNIQUE IN LAPAROSCOPIC CHOLECYSTECTOMY: A SINGLE-CENTRE EXPERIENCE.

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### ABSTRACT

**BACKGROUND:** Laparoscopic cholecystectomy (LC) is one of the most commonly performed procedures worldwide. The critical view of safety (CVS) technique is a method to standardize the procedure and prevent bile duct injuries. We compared this technique with the widely used infundibular technique to assess its feasibility and efficacy in patients undergoing LC.

**METHOD:** A cohort of 224 consecutive patients undergoing LC were randomly divided into two groups: Group A with CVS technique and Group B with infundibular technique, having 112 patients each. Preoperative, intraoperative, and postoperative parameters were compared for both groups.

**RESULTS:** Both groups had a comparable population in terms of age, gender, and preoperative parameters. CVS group had lesser operative time (p-value: 0.045) and blood loss (p-value: 0.019) compared to the infundibular group. The postoperative complications were similar in both groups. We did not find any bile duct injury in the cohort. The rate of attainability of CVS was 92.8%.

**CONCLUSION:** In our observation, CVS is a feasible and more effective method compared to infundibular technique in LC. Apart from being known for its safety, this study expounds the advantages of implementing the CVS method in LC.

**Keywords:** Biliary tract, intraoperative complications, common bile duct, cholelithiasis, cholecystitis

### INTRODUCTION

Laparoscopic cholecystectomy (LC) is a minimally invasive technique where the pathologic gallbladder is excised. The routine use of this procedure started in the early 1990s, and now it has become the gold standard procedure for benign indications of the gallbladder.<sup>1</sup> Initially the indication of the procedure was limited to simple elective cases only but eventually, more challenging acute case scenarios are now being managed laparoscopically. It is a safe procedure that can easily be performed as daycare surgery.

The most dreaded complication of cholecystectomy is common bile duct injury (CBDI) with an incidence of 0.4- 1.5% with LC and 0.2%-0.3% with open cholecystectomy.<sup>2,3</sup> The recent trend of CBDI is decreasing, but the injuries tend to be more severe and difficult to manage.<sup>4</sup> Since the introduction of LC, Calot's triangle has been dissected by the infundibular technique, where the dissection is commenced

from the Calot's triangle and progressed towards the gall bladder. The cystic duct is delineated by dissecting away the fibrous tissue all around the duct. Manifestation of a funnel-shaped appearance is considered conclusive of cystic duct entering the Hartmann's pouch. This is a commonly applied technique as it is too facile to secure with minimal dissection before clipping the structures at Calot's. However, inadequate dissection occasionally causes misinterpretation of common bile duct as cystic duct. This ensued exploration into techniques that can assist to perform LC more objectively. Strasburg et al., introduced the concept of critical view of safety (CVS) to prevent misidentification of CBD or accessory bile duct as the cystic duct.<sup>5</sup> Attaining a good CVS subjugates the probability of misidentification, therefore many surgeons accepted this technique as a key to perform a safe cholecystectomy.<sup>6</sup> Achieving CVS require three criteria to be fulfilled i.e. Clear all fat and fibrous tissue around the Calot's triangle, dissect away the gallbladder from the lower third of the cystic plate, and, display only two structures entering the gallbladder.

Presently, 77.1% of cholecystectomies are being performed laparoscopically in urban and rural referral hospitals.<sup>7</sup> This figure will only increase with time, therefore it is necessary to compare its feasibility and efficacy with the most commonly performed infundibular technique. This study hypothesized that the CVS is a more feasible and effective method compared to the infundibular technique.

## **MATERIALS AND METHODS**

A prospective study was conducted between November 2019 to January 2021, in a rural tertiary centre. Institutional ethical committee approval was procured (Reg no: IEC/377). A total of 224 consecutive patients who underwent laparoscopic cholecystectomy for cholelithiasis were included in the study after taking consent from all the participants. These patients were randomly divided into two groups of 112 subjects each: Group A where CVS performed and Group B where infundibular technique was used. Patients with a diagnosis of cholelithiasis on ultrasonography were included and patients with choledocholithiasis, gall bladder carcinoma, ASA  $\geq$  4 and patients with contraindications for laparoscopy were excluded from the study. Demographic details, body mass index, previous history of cholecystitis attack or jaundice, or previous abdominal surgery of all patients were documented, followed by an abdominal ultrasound to confirm the diagnosis. Pre-operatively, all the patients had a nil-per-oral status for eight hours before surgery and received injection ceftriaxone 1g (after antibiotic sensitivity testing dose) half an hour before incision, as the standard protocol. The surgeon who performed the four-port laparoscopic cholecystectomy had experience in laparoscopy for more than five years. Pneumoperitoneum was created using a Veress needle and blind trocar entry for the camera port. The duration of surgery was noted from the time of incision for the umbilical port to skin closure of all ports. Blood loss in each surgery was documented in milliliters by noting the weight of gauze and blood collected in the suction machine (deducting the saline used). Bile duct injury was considered if the common bile duct gets injured. Stone spillage was defined as if the gall bladder got perforated and stones fell out into the Morrison pouch. Apart from these, the achievability of CVS and conversion to open were also documented in all cases. Ryle's tube 16F was used as a drain from the lateral most port if required. Postoperatively, patients were monitored

in SICU for twelve hours for vitals, urine output, pain abdomen, and respiratory evaluation. Clear liquids started eight hours after surgery and solids were given twelve hours after surgery, considering the status of the patient. Local examination of the port site with band-aid application was done on day one of surgery. The surgical site infection was defined as purulent discharge from port sites.

Statistical analysis of the data was performed using the IBM® SPSS® Statistics 21.0 program. The mean value, standard deviation (SD), and maximum and minimum values were determined using descriptive statistics. Parametric data were evaluated with the chi-square test and nonparametric data with the Mann–Whitney U test. A p-value of less than 0.05 was considered statistically significant.

## RESULTS

One hundred sixty-six (74.1%) patients were females and 58 (25.9%) were male. Descriptive data of all patients (n=224) are presented in Table 1. All patients were symptomatic and a history of previous cholecystitis was the most common (76.7%) symptom. There were 112 patients in the CVS group and 112 patients in the infundibular technique group. Preoperative, intraoperative, and postoperative descriptive data for both groups are presented in Table 2, Table 3, and Table 4, respectively. In the CVS group, there was significantly lower operative time and blood loss (p-value: 0.045; 0.019 respectively). Twenty-two patients had stone spillage with thirteen during gallbladder dissection from the liver bed and nine during cystic duct dissection. CVS was achieved in 104 (92.8 %) and eighteen patients had dense adhesions due to which case had to be completed by the open method. Bile duct injury was not detected in either group. The mean period of hospitalization and surgical site infections was comparable between both groups. Follow-up of all patients was done for six months, telephonically.

## DISCUSSION

LC by CVS technique is being performed in our institute since 2018, with an average of 200 - 250 LC procedures being performed annually. CVS application standardizes the procedure making it easier and safer to be performed by surgeons with variable experience. In our study, female predominance (2.8:1) was observed; it is comparable with the literature too.<sup>2,8</sup> Similarly, the mean age of patients was also comparable with other studies conducted previously.<sup>2,4,8</sup>

Approximately two-thirds (71.1%) of patients presented with a history of the previous attack of cholecystitis in both groups. This was in contrast to the literature which reports that at the time of presentation 70%-80% patients are asymptomatic, diagnosed on ultrasound incidentally.<sup>9</sup> Our institute caters rural areas where connectivity is limited, so the patient present when symptoms get worse or when treatment from primary health care fails. The number of patients with a previous history of abdominal surgery was comparable between groups, but the conversion rate was higher in the infundibular group. However, the observation was not statistically significant.

Strasberg et al. postulated that more than three-fourths of bile duct injury occurs while isolating the cystic duct from Calot's triangle and misidentification of CBD as the cystic

duct. They also found that inflammatory adhesions due to cholecystitis attacks obscure the Calot's triangle leading to increased risk of bile duct injury while doing LC with infundibular technique.<sup>5</sup> In our study, two-third of patients had a previous history of cholecystitis and there was no difference between the two groups (p-value: 0.07).

The duration of surgery was shorter in CVS group as compared to the infundibular group (p-value: 0.045). As this finding was incredulous, on searching the literature it was found that various studies also observed CVS to be a quicker method out of the two.<sup>10,11</sup> It could be attributed to the time which is saved in dissecting the liver bed as lower one-third is already dissected during demonstration of CVS. Also, in the infundibular technique, there is uncertainty to identify the structures that are present below the cystic plate and therefore their dissection utilize majority of the time. Another reason could be

In the literature, it is noted that the amount of blood loss increases when the gall bladder bed is more than fifty percent of gallbladder surface area and/ or when the operative time is longer.<sup>12</sup> In our study, the infundibular group had significantly higher blood loss (p-value: 0.019) due to frequent minor vascular injuries and longer operative time in this group. Also, the conversion rate was higher in infundibular group which added to the amount of blood loss. However, blood transfusion was not required in any patient included in the study.

The incidence of stone spillage ranges between 0.1-20 %, according to published data.<sup>13</sup> Our findings also unveiled similar rates and the spillage happened predominantly during the liver bed dissection. However, no difference was observed between the two groups in the stone spillage (p-value: 0.31). Stone spillage increases the risk of surgical site infection, longer hospital stays and delayed complications like a subdiaphragmatic abscess, migration, or fistulization.<sup>14,15,16</sup> Meticulous clearance of stones and thorough wash with saline prevents such complications. We did not observe any such complication in the follow-up of six months.

In our observations, three (2.7%) patients had SSIs at the epigastric port, because of the gallbladder extraction from this site. In these patients, suture removal, wash with saline, and local antiseptic ointment application was done. The results were comparable between the two groups. In previous studies, SSIs were seen in 1.94%–7.43% patients who were operated for LC,<sup>13,17</sup> therefore, results are comparable.

In the literature, the mean period of hospitalization is 24.9 h after LC and therefore it is considered a daycare surgery.<sup>18</sup> In contrast, our results show that the mean length of stay was 3- 4 days, it is because, as a protocol of our institute, patients are admitted one day prior to surgery as COVID-PCR testing is done before every surgery. Secondly, as a rural setup follow-up for patients is difficult, therefore, it is difficult to adhere to the principles of daycare surgery here. Also, we have calculated the length of stay from the time of admission to discharge and most of the studies have removed the period of preoperative preparation while considering the period of hospitalization.

There is abundant data in the literature to show that applying CVS while performing LC prevents bile duct injuries due to misinterpretation.<sup>5,6,19</sup> Therefore, as anticipated, no bile duct injuries were observed in the cohort. Mascagni et al. observed that

intraoperative timeout for 5 seconds significantly increased achievement rates of CVS.<sup>20</sup> We also found that the intraoperative timeout taken while confirming CVS with fellow surgeons reinforce the certitude of correct identification of the structures. Additionally, CVS approach can descry an obscure aberrant anatomy of the bile ducts arduously.

Evaluating the observations, it can be clearly seen that the CVS approach is effective to dwindle intraoperative blood loss and operative time. Also, the results are aligned with our hypothesis, that the CVS is a more feasible and efficacious method, whenever applied correctly. To the best of our knowledge, it's the first study with a comprehensive analysis between the two techniques. Also, the study connotes its implementation as a standard of dissection in LC. A limitation of our study is that for evaluating bile duct injury larger cohort would be required as no bile duct injury was encountered in the study. Although operative time and blood loss were lower in the CVS group, more analysis in series may be required.

## CONCLUSION

The critical view of safety can be considered a feasible and more effective method compared to infundibular technique in laparoscopic cholecystectomy. CVS was achieved in more than 90 percent of the cohort. The operative time and blood loss was substantially lower in the CVS group, compared to the infundibular group, in patients undergoing LC. Apart from being known as a safe technique, this study expounds the advantages of implementing the CVS method in LC.

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**Dr. Kunal Sharma-** Data collection, Data analysis and interpretation

**Dr. Saurabh Sharma-** Conception or design of the work, Data collection, Data analysis and interpretation, Critical revision of the article.

**Dr. Samir Anand-** Drafting the article, Data analysis and interpretation

**Dr. K S Jaswal-** Conception or design of the work, Final approval of the version to be published

**Dr. Renuka Sharma-** Data collection, Critical revision of the article

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| <b>S no</b> | <b>Character</b>                 | <b>n (%)</b> | <b>Mean <math>\pm</math> SD</b> |
|-------------|----------------------------------|--------------|---------------------------------|
| 1.          | Age (years)                      | 224          | 44.5 $\pm$ 21.8                 |
| 2.          | Gender                           |              |                                 |
|             | M                                | 58 (25.9)    |                                 |
|             | F                                | 166 (74.1)   |                                 |
| 3.          | BMI (kg/m <sup>2</sup> )         | 224          | 28 $\pm$ 7.1                    |
| 4.          | Previous cholecystitis attack    | 172 (76.8)   |                                 |
| 5.          | History of pancreatitis          | 64 (28.6)    |                                 |
| 6.          | Previous abdominal surgery       | 34 (15.1)    |                                 |
| 7.          | Duration of surgery (min)        | 224          | 59 $\pm$ 37.4                   |
| 8.          | Blood loss (ml)                  | 224          | 50.1 $\pm$ 42.8                 |
| 9.          | Bile duct injury                 | 0            |                                 |
| 10.         | Stone spillage                   | 33 (14.7)    |                                 |
| 11.         | Conversion to open               | 38 (16.9)    |                                 |
| 12.         | Period of hospitalization (days) | 224          | 3.5 $\pm$ 1.4                   |
| 13.         | Surgical site infections         | 8 (3.6)      |                                 |

**Table 1. Descriptive analysis of all the patients.**

| <b>S no</b> | <b>Character</b>              | <b>Group A</b> | <b>Group B</b> | <b>p-value</b> |
|-------------|-------------------------------|----------------|----------------|----------------|
| 1.          | Age                           | 44 $\pm$ 18.34 | 45 $\pm$ 22.61 | 0.91           |
| 2.          | Gender                        |                |                |                |
|             | M                             | 26 (23.2)      | 32(28.6)       |                |
|             | F                             | 86 (76.7)      | 80 (71.4)      |                |
| 3.          | BMI                           | 27 $\pm$ 6.4   | 29 $\pm$ 8.2   | 0.88           |
| 4.          | Previous cholecystitis attack | 80 (71.4)      | 92 (82.1)      | 0.07           |
| 5.          | History of pancreatitis       | 28 (25.0)      | 36 (32.1)      | 0.24           |
| 6.          | Previous abdominal surgery    | 14 (12.5)      | 20 (17.9)      | 0.26           |

**Table 2. Comparison of preoperative descriptive data between groups A and B.**

| <b>S no</b> | <b>Character</b>          | <b>Group A</b> | <b>Group B</b> | <b>p-value</b> |
|-------------|---------------------------|----------------|----------------|----------------|
| 1.          | Duration of surgery (min) | 50 $\pm$ 19.3  | 68 $\pm$ 33.8  | <b>0.045</b>   |
| 2.          | Blood loss (ml)           | 34 $\pm$ 14.3  | 66 $\pm$ 34.9  | <b>0.019</b>   |
| 3.          | Bile duct injury          | 0              | 0              | -              |
| 4.          | Stone spillage            | 14 (12.5)      | 19 (16.9)      | 0.31           |
| 5.          | Achievability of CVS      | 104 (92.8)     | -              | -              |
| 6.          | Conversion to open        | 18 (16.1)      | 20 (17.8)      | 0.85           |

**Table 3. Comparison of intraoperative descriptive data between groups A and B.**

| <b>S no</b> | <b>Character</b>          | <b>Group A</b> | <b>Group B</b> | <b>p-value</b> |
|-------------|---------------------------|----------------|----------------|----------------|
| 1.          | Period of hospitalization | 3 $\pm$ 1.2    | 4 $\pm$ 1.6    | 0.59           |
| 2.          | Surgical site infections  | 3 (2.7)        | 5 (4.5)        | 0.72           |

**Table 4. Comparison of postoperative descriptive data between groups A and B.**