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General Surgery

CRITICAL VIEW OF SAFETY IN PREVENTING BILE DUCT INJURIES IN LAPAROSCOPIC CHOLECYSTECTOMY - A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT **Introduction:** Laparoscopic cholecystectomy (LC) is now considered the gold standard for the treatment of gallbladder lithiasis. Since it has been introduced , in the early 1990s, this technique has gained a remarkable consensus until and is now a routine surgical procedure. LC is characterized by reduced postoperative pain, hospital stay, faster recovery and reduced cost. Despite this, it comes with a cost of increased bile duct injuries (BDI), compared to open cholecystectomy (OC): 0.3% and 0.8% vs 0.2%. [1,2] **Aims:** To determine the importance of achieving Critical View of Safety in Laparoscopic Cholecystectomy in terms of incidence of Bile Duct Injuries.

Methodology:

a) Design of study: Prospective Observational study
b) Place of Study: JSS Medical College and Hospital, Mysuru
c) Study Duration: 1.5 years
d) Sample size: sample size estimated as 68 by simple random sampling.

Results: Most common indication of surgery was cholelithiasis 75%, 25% had cholecystitis and among 25% 14.7% had calculous cholecystitis and 10.3% had acalculous cholecystitis. Only 19.1% cases had previous history of surgery. 36.8% cases had co morbid conditions prior to surgery. Majority of cases (51.5%) had duration of surgery more than 60 min and only 48.5% had less than 60 min. There were no postoperative complications and no case had bile duct injury. Majority 70.6% required more than 10 min to dissect Calot's triangle and 29.4% needed less than 10 min. Satisfactory outcome of CVS was seen among all 68 cases. **Conclusion:** Study concludes that satisfactory outcomes are noted with CVS techniques. Additional training of the same is a must for the operating surgeons. This will help surgeons to correctly apply the technique in clinical practice and help to standardize the laparoscopic gall bladder surgeries and minimize bile duct injuries.

KEYWORDS : Laparoscopic Cholecystectomy , Bile Duct Injuries, Critical View Of Safety, Gall Bladder.

AIMS AND OBJECTIVES:

To determine the importance of achieving Critical View of Safety in Laparoscopic Cholecystectomy in terms of incidence of Bile Duct Injuries.

METHODOLOGY:

a) Study Design: Present study was a Prospective Observational Study.
b) Study Duration: DECEMBER 2020 TO OCTOBER 2022.
c) Sampling technique : Simple Random Sampling SAMPLE SIZE – 68

Sample size was calculated using the following – P=1.6% = 0.016 , where P = PREVALENCE

Z a/2 = 1.96 = conventional multiplier for alpha 0.05 “e”= allowable error at 3% Minimum sample size 'N' with 80% power = *P(1-P)/e2 =3.84*[0.016(1-0.016)]/(0.03)2=68

On solving
N=minimum 68 Critical view of safety cases (no controls)

d) Study setting and Method of collection of data:
This is a single centre, prospective , observational study of 68 patients admitted under various surgical units in JSS HOSPITAL from December 2020 to October 2022 who after undergoing confirmatory test i.e. USG and several other test for fitness for surgical procedure , the ones fit for laparoscopic cholecystectomy were taken for the study.

The operating surgeons were instructed to employ the critical view of safety technique during laparoscopic cholecystectomy and the patients were monitored for the development of potential complications notably bile duct injuries.

Study Population And Source Of Data:

- Study population consists of patients admitted to JSS Hospital for laparoscopic cholecystectomy under the department of General surgery.

Subject Eligibility: -

a. Inclusion Criteria: Patients with clinically and radiologically proven calculous and acalculous cholecystitis and cholelithiasis.

b. Exclusion Criteria: Patients unfit for cholecystectomy .
Patients with –

- Uncontrolled coagulopathy
- Suspected gallbladder carcinoma
- Generalized abdominal infection
- Known invasive gallbladder carcinoma
- Morbid obesity
- Intra-abdominal tumours
- Inability to tolerate General anaesthesia

Study Assessments of end points
Assessing the association of critical view of safety and incidence of bile duct injuries.

Study Conduct :

- This study was conducted in the various surgical units of JSS Hospital on patients undergoing laparoscopic cholecystectomy.
- All these patients were invited to participate in the study and an informed written consent was taken .
- The operating surgeons were instructed to achieve the critical view of safety and patient were followed up for any CBD injuries.

Data Analysis:

Statistical analysis was performed by the SPSS Program for windows , version 20.0. Continuous variables were presented as mean +/- Standard deviation, and categorical variable were presented as absolute numbers and percentage. Data was checked for normality before statistical analysis .Normally distributed continuous variables were compared using unpaired T test , whereas the Mann Whitney U test was used for those variables that were normally distributed. Categorical variables were analysed using either the chi square test or Fischer's exact test. For all statistical tests statistical significance was decided as given below

$P>0.05$ is not significant $P<0.05$ is significant

$P<0.01$ is highly significant

RESULTS

Table 1: Post-operative Complications

Post operative Complication	Frequency	Percentage
Bile duct injury	0	0

Absent	68	100
Total	68	100

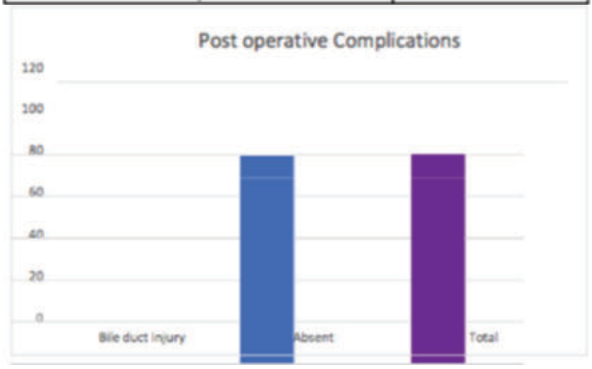

Figure 1: Post-operative Complications

None of the cases had any post-operative complication.

Table 2: Duration Of Calot's Triangle Dissection

Duration of Calot's triangle removal	Frequency	Percentage
≤10 min	20	29.4
>10 min	48	70.6
Total	68	100

Majority 70.6% required more than 10 min to dissect Calot's triangle and 29.4% needed less than 10 min.

Table 3: Bile Duct Injury During Operation

Bile duct injury	Frequency	Percentage
Yes	0	0
No	68	100
Total	68	100

Intraoperatively, none of the cases had bile duct injuries.

Figure 2: Outcome Of CVS

Satisfactory outcome of CVS was seen among 100 % of cases.

DISCUSSION

As Laparoscopic cholecystectomy is now "the" surgery for gall stone disease , the primary goal of this should be "safety, first" and cholecystectomy later. We should always keep safety at the fore front and remain vigilant about the various difficult intraoperative scenarios that we might encounter and achieving the triangle of safety definitely provides a road map for the same.

In this study , we have tried to bring out the actual association between bile duct injuries after attaining the safety triangle which means all three elements that it requires.

Age And Gender Distribution

Gall bladder lithiasis has always shown to have female proponderane over male .Similar was the case in this study. 55.9% were females and 44.1% were males with majority of cases (79.4%) in the age group of 25 to 50 years.

Clinical Presentation

Gall stones can have a variant presentation clinically. Some may present with only pain abdomen while some might be incidentally detected. Most common complaint was pain in abdomen (44.12%), followed by dyspepsia (22.05%), then came nausea and vomiting (14.7 %) and lastly, fever (7.35 %).

Indication Of Surgery

Gall stone disease if not surgically intervened can lead to a lot of complications in the long term. There are certain conditions which definitely need surgically intervention. Most common indication of we encountered was cholelithiasis 75%, cholecystitis 25 % and among 25% 14.7% had calculous cholecystitis and 10.3% had acalculous cholecystitis.

Previous History And Co Morbid Conditions

Any abdominal surgeries in the past can definitely be a factor for what is called a difficult cholecystectomy not due to any other reason but simply because of adhesions . in this study , only 19.1% cases had previous history of abdominal surgery and 36.8% cases had co morbid conditions prior to surgery.

Duration Of Surgery

The time duration required for surgery depends on a lot of factors right from adhesions due to previous surgeries to various anatomical variations encountered during calot's dissection . Majority of cases (51.5%) had duration of surgery more than 60 min and only 48.5% had less than 60 min.

Post-operative Complications

There can be a lot of complications post Laparoscopic cholecystectomy . In the current study , none of the patients had bile duct injuries , no other major complications , bile leak or cystic duct injuries.

Calot's Triangle Dissection

Dissection of the calots triangle is the most important step when it comes to performing laparoscopic cholecystectomy . Proper dissection of calots triangle and delineation of the cystic duct and cystic artery is an important approach towards safer cholecystectomy as it helps to achieve one of the elements of critical view of safety . 70.6% required more than 10 min to dissect Calot's triangle and 29.4% needed less than 10 min.

Bile Duct Injury

This study was performed to see the actual incidence of BDI's after attaining the safety triangle. In this study , 68 patients were evaluated out of which no cases showed bile duct injuries.

Study by Lucia Ilaria Sgaramella et al[3] showed that laparoscopic cholecystectomy is considered the gold standard for the treatment of gallbladder lithiasis; nevertheless, the incidence of bile duct injuries (BDI) is still high (0.3–0.8%) compared to open cholecystectomy (0.2%)

Outcome of CVS

The outcomes of CVS were evaluated in terms of any major postoperative complications such as bile leak , postoperative jaundice , bile stained discharge in the drain, smooth postoperative period and timely discharge.

Study by Mariano Eduardo. Et al [4]showed that a total of 446 surgeons responded the survey (21%). The percentage of surgeons that correctly identified the elements of CVS was 21.8% and 24.8% among surgeons claiming to know the CVS. The percentage of surgeons that reported

BDI was higher among those that incorrectly identified the elements of the CVS (p=0.03). In the multivariate analysis, career length was the most significant factor related to BDI (p=0.002). The percentage of surgeons that correctly identified the Critical View of Safety was low, even among those who claimed to know the CVS. The percentage of surgeons that reported BDI was higher among those that incorrectly identified the elements of the CVS. Satisfactory outcome of CVS was seen among all 68 cases.

CONCLUSION

The critical view of safety technique of surgery when applied correctly, proves to be the safest method for gall bladder surgeries. It helps to identify the Hepatocystic triangle and its elements correctly, which further helps operating surgeon to dissect properly, directly minimizing the injuries to internal organs mainly the bile duct and decreases the post operative complications.

Study concludes that satisfactory outcomes are noted with CVS techniques. Additional training should be given for CVS techniques to the operating surgeons. This will help surgeons to correctly apply the technique in clinical practice and help to standardize the laparoscopic gall bladder surgeries and minimize bile duct injuries.

SUMMARY

Amongst those who underwent the procedure(68 cases) , the results showed that none of them had any postoperative complications . No bile duct injuries were encountered . No postoperative bleeding from the site was noted. Outcome was satisfactory in all 68 cases in terms of - smooth postoperative period , no bile leak , no postoperative jaundice , timely discharge and no major complications at the first follow-up.

Hence, with gall bladder lithiasis being one of the most common pathology , proper employment o safer dissection techniques is necessary and especially the critical view of safety , as it is not only helpful to the skilled and experienced surgeons but also to the upcoming residents so that they can properly understand and apply the concept of safe surgery in their future endeavours.

REFERENCES

1) Russell JC, Walsh SJ, Mattie AS, Lynch JT. Bile duct injuries, 1989-1993: a statewide experience. Archives of surgery. 1996 Apr 1;131(4):382-8.
2) Caputo L, Aitken DR, Mackett MC, Robles AE. Iatrogenic bile duct injuries. The real incidence and contributing factors--implications for laparoscopic cholecystectomy. The American surgeon. 1992 Dec 1;58(12):766-71.
3) Sgaramella LI, Gurrado A, Pasculli A, de Angelis N, Memeo R, Prete FP, Berti S, Ceccarelli G, Rigamonti M, Badessi FG, Solari N. The critical view of safety during laparoscopic cholecystectomy: Strasberg Yes or No? An Italian Multicentre study. Surgical endoscopy. 2021 Jul;35(7):3698-708.
4) Giménez ME, Houghton EJ, Zeledón ME, Palermo M, Acquafresca P, Finger C, Serra E. The critical view of safety prevents the appearance of biliary injuries? Analysis of a survey. ABCD. Arquivos Brasileiros de Cirurgia Digestiva (São Paulo). 2018 Jul 2;31