

Role of Critical View of Safety in Laparoscopic Cholecystectomy during Training of Residents

SABIH NOFAL¹, AHSAN KHAN², ABDUL WAHEED KHAN³, MUHAMMAD ARIF⁴, SYED HAIDER ISHAQ⁵

^{1,2,4,5}Medical Officer, Lahore General Hospital Lahore.

³Assistant Professor, Services Hospital Lahore.

Medical Officer, Lahore General Hospital Lahore.

Correspondence to Dr. Sabih Nofal, Email: drsabih@gmail.com cell: 0331-4116277

ABSTRACT

Background: Laparoscopic cholecystectomy has become the preferred choice of management for gallstone disease. In spite of various theories explored trying to assess different aspects of management and outcome to reach the acceptable safest technique in laparoscopic operation and to compare it with its counterpart. Many surgical methods have been attempted to clarify their value in counteracting a serious complication of laparoscopic cholecystectomy, mainly is the bile duct injury.

Aim: To compare the mean operative time and frequency of bile duct injuries in patients undergoing Laparoscopic Cholecystectomy for Cholelithiasis by General Surgery Residents with the help of Critical View of Safety Technique versus Infundibular Technique

Methods: This Randomized Control Trial was conducted in Department of Surgery, Lahore General Hospital, Lahore. February 21, 2018 to August 21, 2018.

A total of 268 patients were enrolled for this study. Patients were divided into two groups by Computer Generated Lottery Method, Group A (Critical View of Safety Technique) and Group B (Infundibular Technique).

Data were entered and analyzed on SPSS v23.0. Data were stratified for age, gender of patient and the year of the training of the resident. Mean operative time was compared between groups by using t-test and frequency of BDI was compared by using chi-square test. For post-stratification, Chi-square and t-test were used. A p-value ≤ 0.05 was considered significant.

Results: A total of 268 patients were enrolled for this study. Patients were divided into two groups i.e. Group-A (Critical View of Safety Technique) and Group-B (Infundibular Technique). In group-A, mean duration of surgery was 60.0 ± 3.0 minutes, while 62.9 ± 3.4 minutes in group-B, which is statistically significant with a p-value of 0.000. In group-A, bile duct injury was in 2(1.5%) patients, while 6(4.5%) patients of group-B, which is statistically insignificant with a p-value of 0.151.

Conclusion: Critical view of safety technique in laparoscopic cholecystectomy has a significant effect in preventing bile duct injury as compared to infundibular technique with comparable time of surgery and it is best to be the preferred technique in laparoscopic cholecystectomy.

Keywords: Laparoscopic cholecystectomy; Biliary duct injury; Critical view of safety.

INTRODUCTION

Symptomatic Gallstone disease is a significant burden on modern healthcare and considerable resources are utilized for the management of this disease. The prevalence is around 5.9-21.9 % in the West and 3.1 – 10.7 % in Asia.¹ Dr. Eric Muhe (Germany in 1985) and Dr. Phillipe Mouret (France in 1987) introduced Laparoscopic Surgery by performing the first Laparoscopic Cholecystectomies.² In 1992, National Institutes of Health consensus nominated Laparoscopic Cholecystectomy as the 'Gold Standard' for the treatment of symptomatic gallstones.³ Laparoscopic Cholecystectomy was related to a reduced amount of pain,⁴ reduced hospital stay and less cost,⁵ however, an increase in iatrogenic biliary tree injuries was observed in comparison with Open Cholecystectomy

A 21 year prospective study of bile duct injuries during laparoscopic cholecystectomy was published in 2015,⁶ an incidence of Bile Duct Injuries of 0.4% was reported.⁶ It has been found that the rate of Bile Duct Injuries is higher during a surgeons first 12 Laparoscopic Cholecystectomies⁷. Today, Laparoscopic procedures are

being introduced early into the General Surgery curricula and Surgical Residents are being taught the procedure in most Tertiary Care Centers. There are multiple techniques for identification of Anatomy of Calot's triangle during Laparoscopic Cholecystectomy.⁸ One of these is the "Critical View of Safety (CVS) Technique", in which gallbladder is taken off the cystic plate so that the gallbladder is attached only by the 2 cystic structures.⁹ Textbooks of surgery may¹⁰ or may not¹¹ recommend CVS as the method of identification of anatomy of the Calot's triangle.

In a study, it was concluded that, 1.6% were found to have Bile duct injury in Infundibular Technique group while in Critical View of Safety group 0% had developed BDI. The mean duration of surgery in CVS group was 50.3 ± 17.7 minutes, while in IT group 49.8 ± 18.5 .¹³ In another study, it was reported that, 4.5% were found to have Bile duct injury in Infundibular Technique group while in Critical View of Safety group 1.2% had developed BDI. The mean duration of surgery in CVS group was 61.5 ± 13.4 minutes, while in IT group 69.7 ± 16.3 .¹⁴

The objective of this study was to compare the mean operative time and frequency of bile duct injuries in patients undergoing Laparoscopic Cholecystectomy for

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Cholelithiasis by General Surgery Residents with the help of Critical View of Safety Technique versus Infundibular Technique.

Hypothesis: Attaining Critical View of Safety leads to less mean operative time and lesser bile duct injuries as compared to Infundibular Technique.

MATERIALS & METHODS

This Randomized Control Trial was conducted at Department of Surgery, Lahore General Hospital, Lahore from February 21, 2018 to August 21, 2018. The sample size of 268 (134 in each group) cases is estimated by using 95% confidence level with 80% power of test and with an expected percentage of BDI as 0% in CVS group¹³ and 4.5% in IT group.¹⁴ Sampling was done via Non-Probability Consecutive Sampling. The following patients were included in the study 1. Symptomatic Cholelithiasis (Presence of gallstones in the gall bladder which are demonstrated by ultrasonographic examination. Patient can present with pain RHC or Epigastrium radiating to back associated with dyspepsia and abdominal bloating.) 2. Both genders 3. Age range from 18-60 years. The following were excluded from the study 1. Acute cholecystitis 2. Choledocholithiasis 3. Acute pancreatitis 4. Previous upper abdominal surgery 5. Immunocompromised and patients with bleeding diathesis

After approval of Hospital Ethics Committee, a total of 268 patients were enrolled for this study. Patients who fulfilled the Inclusion Criteria were admitted through Outpatient department for Laparoscopic Cholecystectomy. Informed Written Consent was taken. After pre-operative workup and pre anaesthesia fitness, patients were divided into two groups by Computer Generated Lottery Method, Group A (Critical View of Safety Technique) and Group B (Infundibular Technique).

A standardized 4 port approach was used for both Groups. In Group A (Critical View of Safety), the Calot's triangle was dissected with the aim to remove inferior one third of the gall bladder of the cystic plate and dissection of the fat to ensure that two and only two structures are seen entering the gall bladder. This was ensured prior to clipping the cystic duct and artery.

In Group B (Infundibular Technique), cephalad traction of the fundus was obtained by the surgeon assistant and the lateral traction of the infundibulum by the surgeon left hand. The peritoneum was incised parallel to the cystic duct and artery, just caudally to the infundibular edge, thus dissecting the duct and artery to open Calot's

triangle. After the identification of these two structures, passing through a fatty-free triangle, they were divided between clips, and retrograde cholecystectomy is completed.

Operative time and bile duct injuries were noted during surgery in Operating Room. All surgeries were performed by a General Surgery Resident under supervision of Head of Department to reduce bias. A comprehensive data collection form was used to record the data (attached).

Data were entered and analyzed on SPSS v23.0. Quantitative variables like age and duration of surgery were expressed as Mean±S.D (Standard Deviation), while qualitative variable like gender and Bile duct injuries were expressed as frequencies and percentages. Data were stratified for age, gender of patient and the year of the training of the resident. Mean operative time was compared between groups by using t-test and frequency of BDI was compared by using chi-square test. For post-stratification, Chi-square and t-test were used. A p-value ≤ 0.05 was considered significant.

RESULTS

A total of 268 patients were enrolled for this study. Patients were divided into two groups i.e. Group-A (Critical View of Safety Technique) and Group-B (Infundibular Technique). In group-A, there were 78(58.2%) males and 56(41.8%) females, while in group-B, there were 63(47.0%) males and 71(53.0%) females. Mean age of group-A patients was 38.4±13.0 years and 37.5±12.1 years in group-B. In group-A, 48(35.8%) patients were in 18-30 years age group, while 37(27.6%) and 49(36.6%) were in 31-45 years and >45 years age groups respectively. In group-B, 41(30.6%) patients were in 18-30 years age group, while 55(41.0%) and 38(28.4%) were in 31-45 years and >45 years age groups respectively. In group-A, 46(34.3%) residents were in 3rd year of training, while 37(27.6%) and 51(38.1%) were in 4th year and 5th year of training respectively. In group-B, 53(39.6%) residents were in 3rd year of training, while 42(31.3%) and 39(29.1%) were in 4th year and 5th year of training respectively. In group-A, mean duration of surgery was 60.0±3.0 minutes, while 62.9±3.4 minutes in group-B, which is statistically significant with a p-value of 0.000. In group-A, bile duct injury was in 2(1.5%) patients, while 6(4.5%) patients of group-B, which is statistically significant with a p-value of 0.151.

Table-1: Stratification with respect to age for comparison of bile duct injuries in both groups

Age group	Bile duct injuries	Critical View of Safety Group	Infundibular Technique Group	Total	p-value
18-30 years	Yes	1(2.1%)	2(4.9%)	3(3.4%)	*0.593
	No	47(97.9%)	39(95.1%)	86(96.6%)	
	Total	48(100%)	41(100%)	89(100%)	
31-45 year	Yes	1(2.7%)	3(5.5%)	4(4.3%)	*0.646
	No	36(97.3%)	52(94.5%)	88(95.7%)	
	Total	37(100%)	55(100%)	92(100%)	
>45 years	Yes	0	1(2.6%)	1(1.1%)	*0.437
	No	49(100%)	37(94.7%)	86(98.9%)	
	Total	49(100%)	38(100%)	87(100%)	

Table-2: Stratification with respect to year of the training of the resident for comparison of bile duct injuries in both groups

Year of the training of the resident	Bile duct injuries	Critical View of Safety Group	Infundibular Technique Group	Total	p-value
3 rd year	Yes	1(16%)	4(5.6%)	5(3.7%)	0.223*
	No	62(98.4%)	68(94.5%)	130(96.3%)	
	Total	63(100%)	72(100%)	135(100%)	
4 th Year	Yes	1(1.4%)	2(3.2%)	3(2.3%)	*0.481
	No	70(98.6%)	60(96.8%)	130(97.7%)	
	Total	71(100%)	62(100%)	133(100%)	

Table-3: Stratification with respect to year of the training of the resident for comparison of duration of surgery in both groups

Year of the training of the resident	Groups	n	Mean	Std. Deviation	p-value
18-30 years	Critical View of Safety	48	60.31	3.07	0.000
	Infundibular Technique	41	62.83	3.38	
31-45 years	Critical View of Safety	37	59.54	3.18	0.000
	Infundibular Technique	55	63.20	3.75	

Table- 4: Stratification with respect to age for comparison of duration of surgery in both groups

Age groups	Groups	n	Mean	Std. Deviation	p-value
18-30 years	Critical View of Safety	48	60.31	3.07	0.000
	Infundibular Technique	41	62.83	3.38	
31-45 years	Critical View of Safety	37	59.54	3.18	0.000
	Infundibular Technique	55	63.20	3.75	
>45 years	Critical View of Safety	49	60.22	2.85	0.000
	Infundibular Technique	38	62.84	3.02	

DISCUSSION

After LC the injuries of bile duct are most important complications for mortality and morbidity. For these injuries the main risk factors are inflamed gallbladder, surgical team experience and nearby anatomical structures with anatomical biliary variations¹⁵.

Acute cholecystitis, an general clinical condition, has more chance as three times causing biliary injury than standard procedure of laparoscopic.¹⁶ In a study (retrospective) of 4445 cholecystectomies laparoscopic an very important risk factor was found at inflammation Calot's triangle¹⁷. Most of the biliary injuries occur by surgeons in first 100 cholecystectomies laparoscopic. Injuries occur by also experienced hands.

Strasberg et al¹⁸ recommended a surgical strategy that called CVS, to reduce the bile injury in LC. This technique that called CVS have three parts: (1) Calot's triangle dissection that include ligament hepatoduodenal, (2) mobilization in the gallbladder lowest part and (3) identification and isolation of the main two structures (cystic artery and cystic duct)

The CVS technique is very simple and easy procedure, which also used easily and applied by all cholecystectomy surgeons. This procedure implemented and used as follows by us. First dissected the hepatoduodenal ligament by cother hook. Then oped the gallbladder serosal leaf after that medial dissection carried out.

Vettoretto et al.¹⁹ done with CVS procedure 90 cholecystectomies. Then compared with 84 patients that operated by infundibular classical technique.

They find that only one cystic duct leak in CVS group as compared two intraoperative hemorrhages reported in patients that operated by infundibular classical technique. They conclude CVS technique have similar rate of

hemorrhagic and biliary complications, it is consider as gold standard due to shorter time of operations in LC.¹⁹

Honda et al.²⁰ also used and applied the CVS technique with little changes. They firstly dissect the gallbladder subserosal layer above rouviere sulcus levels in gallbladder right hepatic lobe.

This little changed technique very useful in patients of severe inflammation in Calot's triangle. Presently the CVS technique is consider to be safe and effective in reducing or minimize the risks of mortality and morbidity that connect with cholecystectomy laparoscopic. The European Association of Endoscopic Surgery (EAES) recommends the CVS as the most effective approach to prevent bile duct injury²¹.

Therefore the CVS technique used and applied also integrated through national guidelines and declare mandatory for surgeons during training. O Kelly done a research in Ireland nationwide in surgeons that performed cholecystectomy laparoscopic. The CVS used by 27(31%) of surgeons and 13% surgeons not using CVS technique also not the infundibular approach²²

There is another procedure and technique called fundus down that used in patients where dissection is difficult of Calot's triangle. This procedure starts with the gallbladder dissection from liver bed. This is also a safe procedure injuries of vessels may be occur near pouch of Hartman in severe inflammation cases with veins and artery right hepatic injury¹⁶.

The role and function of intraoperative cholangiography still unsolvable in LC. Some believe that intraoperative cholangiography minimize the injuries of biliary duct and some believes that the use and application of this technique is time consuming and unnecessary. The introduction and use of CVS procedure is an best and proper alternate of intraoperative cholangiography.¹⁵

In this study, in group-A, bile duct injury was in 2(1.5%) patients, while 6(4.5%) patients of group-B, which is statistically in-significant with a p-value of 0.151.

In a study, it was concluded that, 1.6% were found to have Bile duct injury in Infundibular Technique group while in Critical View of Safety group 0% had developed BDI. The mean duration of surgery in CVS group was 50.3±17.7 minutes, while in IT group 49.8±18.5.¹³

In another study, it was reported that, 4.5% were found to have Bile duct injury in Infundibular Technique group while in Critical View of Safety group 1.2% had developed BDI. The mean duration of surgery in CVS group was 61.5±13.4 minutes, while in IT group 69.7±16.3.¹⁴

CONCLUSION

Critical view of safety technique in laparoscopic cholecystectomy has a significant effect in preventing bile duct injury as compared to infundibular technique with comparable time of surgery and it is best to be the preferred technique in laparoscopic cholecystectomy.

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