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**A PROSPECTIVE COMPARATIVE STUDY BETWEEN EARLY AND  
INTERVAL LAPAROSCOPIC/OPEN CHOLECYSTECTOMY IN  
PATIENTS OF ACUTE CHOLECYSTITIS**

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**ABSTRACT**

**OBJECTIVE:** The present study is designed to compare early and interval laparoscopic/open cholecystectomy in patients of acute cholecystitis. The comparison was done on the basis of parameters such as intraoperative difficulty, perioperative bile duct injury and bile leak, time taken for operation, postoperative atelectasis, postoperative wound infection, duration of hospital stay and postoperative pain.

**METHODOLOGY:** This is a prospective study conducted in Department of General surgery, GCS MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE from AUGUST 2018 to DECEMBER 2019. 56 patients were enrolled in the study from which 26 patients were randomly assigned to early lap/open cholecystectomy and 30 were assigned to interval lap/open cholecystectomy group.

**RESULT:** There was no significant difference observed between the two groups. However, the duration of hospital stay was less in early laparoscopic/open cholecystectomy.

**CONCLUSION:** Both the methods, early and interval have no significant benefit over each other but through review of all literature, early lap/open cholecystectomy is found to be beneficial overall with less hospital stay.

**KEYWORDS:** Early cholecystectomy, Interval cholecystectomy, open/laparos

## **INTRODUCTION**

Biliary tract diseases are the commonest abdominal conditions, probably next to appendicitis, that the surgeons, gastroenterologist and radiologist encounter in daily life and gallbladder diseases are the most frequently encountered biliary tract disease. Acute cholecystitis is a pathology of inflammatory origin, usually associated with cholelithiasis. Other risk factors for acute cholecystitis include diabetes, sepsis, immunocompromised states and prolonged total parenteral nutrition. Complications of acute inflammation of gallbladder include chronic inflammation, obstructive jaundice, empyema, mucocele and perforation of gallbladder. The anatomy of Calot's triangle in acute cholecystitis is distorted due to adhesions which makes interval cholecystectomy somewhat difficult. It is now established that the standard treatment for acute cholecystitis is surgery. However, the question of timing cholecystectomy remains controversial. Currently, there are three attitudes towards this disease. The first, which is the oldest, is an elective surgery after an initial medical treatment allowing the cooling down of the inflammatory phenomenon, during a second hospitalization. The second is an interval cholecystectomy, scheduled during the same hospitalization but after a period of 6 to 8 weeks. The third is an early cholecystectomy, as soon as possible after admission. [8,9] More studies are focusing on the timing of cholecystectomy during the same hospitalization, should it be performed in an acute phase or scheduled after a few days of medical treatment. Laparoscopic cholecystectomy is widely established as the standard operation in acute cholecystitis. There are concerns about the potential hazards/complications, especially common bile duct injury and a high conversion rate to open cholecystectomy. The conversion rates for elective laparoscopic cholecystectomy range from 3-7%. However, in presence of acute inflammation, higher conversion rates of up to 30 % have been reported. Several studies have reported favorable outcomes with a low conversion rate if patients are operated within 96 hours of admission. [4,6-12] Since the last 20 years, an increasing number of surgeons have favored a policy of early surgery. Several randomized studies in the early 1980s have shown that performing early cholecystectomy for acute cholecystitis was better than interval cholecystectomy in terms of operative feasibility, postoperative complications and shorter hospital stay.[1-3]

The present study was undertaken to compare the safety, intra operative difficulty, postoperative morbidity, duration of stay in hospital and effectiveness of early lap/open versus interval lap/open cholecystectomy in Acute Cholecystitis.

## **MATERIALS AND METHODS**

This is a prospective study conducted in the Department of General surgery, GCS MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE from AUGUST 2018 to DECEMBER 2019. The study was done in cases attending our institute for treatment of acute cholecystitis. The diagnosis of acute cholecystitis was based on a combination of clinical criteria [acute right upper quadrant tenderness, temperature exceeding 98.6-degree Fahrenheit and total leukocytes count more than 11000 / cu mm] and ultrasonographic criteria [thickened edematous distended gallbladder, positive sonographic Murphy's sign, presence of gallstones and fluid collection]. Adult patients aged 18 to 75 years admitted with acute cholecystitis were included in the study. Those with age below 18 years or more than 75 years, any obvious septicemia, patients treated with steroids, immunosuppressive drugs or chemotherapy, those with other serious preexisting cardiovascular, pulmonary, immunological diseases and patients with choledocholithiasis were excluded from the study. A total of 56 patients were enrolled in the study. The study subjects were distributed in the

early (26 patients) and interval group (30 patients). The two groups were well matched in terms of age, sex, as well as clinical and laboratory parameters. Patients were made to understand and sign the informed consent form. After admission in the hospital, necessary particulars regarding the age, sex, religion and address of the patients were recorded. The patients were then studied clinically and investigations were done and operation was performed after proper preoperative preparation.

The patients who presented with acute symptoms were treated as follows;

- 1.] Nasogastric tube aspiration as and when required.
- 2.] Intravenous fluid.
- 3.] Broad spectrum antibiotics.
- 4.] Analgesics.
- 5.] Vitamin B complex, Vitamin C, Vitamin K.
- 6.] Antispasmodics
- 7.] Proton pump inhibitors drugs.

Those in the early group were subjected to laparoscopic/open cholecystectomy within 7 days of onset of symptom. Whereas in the interval group, conservative treatment with intravenous fluids and antibiotics including third generation cephalosporins, aminoglycosides, piperacillin-tazobactam and metronidazole were given. The patients who responded to conservative treatment underwent an interval cholecystectomy 6 weeks after the acute episode had subsided. Primarily all patients were posted for laparoscopic cholecystectomy except severely obese, those with cardiac morbidities and those not fit for laparoscopy or general anesthesia. For these patients' elective open cholecystectomy was planned. Few patients had laparoscopic to open cholecystectomy conversion due to bile duct injury, difficult anatomy etc. These patients were included in the open group.

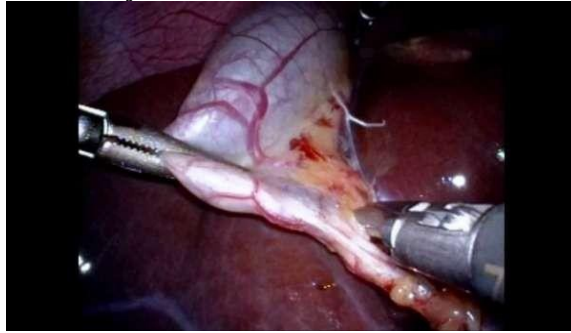
#### **SURGICAL PROCEDURE:**

The operation was performed by senior consultant surgeons and the surgery was done with the patient under general anesthesia and with endotracheal intubation. Pneumoperitoneum was created using Veress needle through a supra-umbilical incision. Four laparoscopic ports were used; two 10 mm ports [one umbilical 10 mm port for the optical system and one epigastric port for the dissector/suction device] and two 5 mm [one at the midclavicular line along the right subcostal margin and one in the right flank]. If necessary, a fifth port was added to improve exposure. First the adhesions were released and Calot's triangle was exposed. If necessary, the gallbladder was emptied through a laterally inserted needle to allow better grasping. The cystic pedicle was dissected to isolate the cystic duct and artery separately. Both were then clipped and divided. The gallbladder was dissected off its bed with a monopolar cautery hook. At completion of surgery, the gallbladder was placed in a retrieval bag and extracted through the epigastric incision, which was enlarged if necessary. Homeostasis was achieved in gallbladder bed and after a thorough saline lavage a suction drain was placed if clinically indicated and the incision was closed. When required, open procedure was performed through a right subcostal incision.

#### **INTRAOPERATIVE ASSESSMENT:**

Intraoperatively patients were assessed for complications like difficulty in identifying calot's

triangle, adhesions, bile duct injury and bile leaks and results were tabulated for both early and interval groups for statistical analysis.



### **POST OPERATIVE ASSESSMENT:**

On the day of surgery immediate postoperative vital parameters and urine output were checked closely in detail. A broad-spectrum antibiotic [usually cephalosporin + metronidazole] were routinely used in all cases. Removal of Nasogastric tube was done on the next day when condition permitted. Post operatively, the patients were allowed oral intake 18-24 hours after surgery provided, they had no nausea and vomiting. Removal of abdominal drain was done after 48 hours of operation, when condition permitted. Complications like lung atelectasis, wound infection, duration of stay in hospital with number of work days lost were analyzed and results tabulated for both early and interval groups for statistical analysis. Sutures were removed after 8 to 10 days. Some stable patients were discharged early without removing sutures.

### **FOLLOW UP:**

At the time of discharge from hospital all the patients were advised to revisit for checkup. First checkup was done after 3 days, then after one week and then monthly for three months and then six monthly and then as and when required. When the patients visited for checkup, they were enquired regarding persistence of previous symptoms, general improvement of health condition and for appearance of newer symptoms and then a thorough examination of the patient was done and investigations were done whenever necessary. Postoperative pain was assessed using visual analogue scale method.

### **STATISTICAL ANALYSIS:**

The results were tabulated and scrutinized statistically based on safety, effectiveness, outcome, complications, quality of life and early resumption of activities. To find the significant difference between the bi variate samples in independent groups the unpaired sample t-test was used. To find the significance in categorical data Chi-square was used. In all the above statistical tools the probability value .05 was considered as statistically significant.

### **RESULTS**

In our study the average age of patients in the early group and interval group was  $40 \pm 13$  Years, and  $38 \pm 10$  Years respectively. Overall male: female ratio was 1.15:1 in the study subjects. Among the early group 14[54%] were females and 12[46%] were males, while in the interval group 12[40%] were females and 18[60%] were males. Distribution of patients in

both early and interval groups as per open or laparoscopic cholecystectomy is shown below. **(Table 1)** In the early group 4 [16%] patients and within the interval group 6 [20%] patients had undergone laparoscopic to open conversion.

**TABLE 1: TREATMENT GROUPS**

		Groups		
		Early	Interval	Total
LAPAROSCOPIC	LAPAROSCOPIC Count % within Groups	17 65.0%	22 73.0%	39 70.0%
	LAPAROSCOPIC converted to OPEN Count % within Groups	4 16.0%	6 20.0%	10 18.0%
OPEN	ELECTIVE OPEN % within groups	5 19.0%	2 7.0%	7 12.0%
	Total Count % within Groups	26 100.0%	30 100.0%	56 100.0%

In the early group there was difficulty in identifying Calot's triangle and separating peritoneal adhesions in 16 [62%] patients whereas in the interval group, difficulty was faced in 15 [50%] patients. The p value was 0.874. 2 patients [8%] in the early group and 4 patients [13%] in the interval group had bile duct injury (p value 0.5). 6 patients [23%] in the early group and 10 patients [33%] in the interval group had lung infections (p value 0.115). In the Early group, nearly one third of the patients had operative duration of <1 hr and the remaining patients had duration of >1 hr. of duration, whereas in the interval group half of the patients had duration more than 1 hour and half had duration less than 1 hour. P value was 0.874, which is not significant. **(Table 2)**

**TABLE 2: DURATION OF OPERATION**

		Groups		Total	P value
		Early	Interval		
DURATION	<1 HOUR	10 38.0%	15 50.0%	25 45%	
	>1HOUR	16 62.0%	15 50.0%	31 55%	
Total		26 100.0%	30 100.0%	56 100.0%	0.874

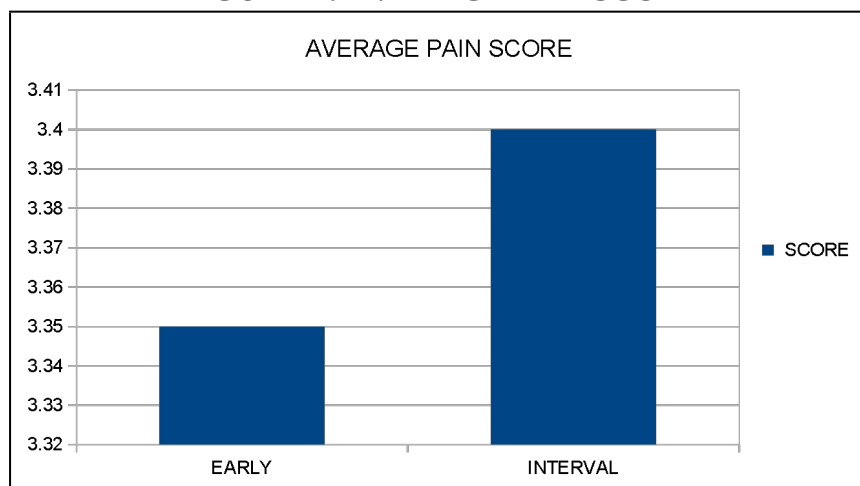
In the study subjects, postoperative wound infections were seen in 4 patients [15 %] in the early group and 7 patients [23%] in the interval group. Duration of stay in hospital for both groups was compared. Average duration of stay for patients in the early group was 8.6±4.58 days and in the Interval, group was 15.3±7.57 days. **(Table 3)**

**TABLE 3: COMPARATIVE RESULTS OF QUANTITATIVE DATA (T-Test)**

Groups		N	Mean	Std. Deviation	Std. Error Mean
AGE	Early	26	40	13	2.55
	Interval	30	38	10	1.82
DURATION OF SYMPTOMS	Early	26	3	1.1	0.216
	Interval	30	6	2	0.364
DURATION OF STAY IN HOSPITAL	Early	26	8.6	4.58	0.9
	Interval	30	15.3	7.57	1.38
POST OPERATIVE AVERAGE PAIN SCORE	Early	26	3.35	1.414	0.28
	Interval	30	3.4	1.25	0.23

Postoperative pain score was compared using visual analogue scale method and calculated on postoperative day 1, 3, 7, 3 months, 6 months and then as and when required. Mean score in the early group was  $3.35 \pm 1.41$  while in the interval group it was  $3.4 \pm 1.25$ . (**Figure 1**)

**FIGURE 1: AVERAGE PAIN SCORE**



## DISCUSSION

In the early years of laparoscopic surgery, acute cholecystitis was considered a relative contraindication for laparoscopic cholecystectomy. Recently it has been shown that laparoscopic cholecystectomy is feasible and safe for acute cholecystitis. Adam et al [1947] was of the opinion that surgical treatment should be carried within 26 -72 hours of onset of

symptoms [14]. Zinninzer [1934], Mentzer [1936], Wright et al [1960], Ahmed [1992] all favored early cholecystectomy [15,18]. Various studies have reported higher conversion rates, ranging from 6% to 35% when early cholecystectomy is used to manage acute cholecystitis. The higher conversion rate obviates the advantages of early laparoscopic cholecystectomy. [19,20,21,22] Difficulty in identifying the calot's triangle was seen in both groups. The most serious complication of Laparoscopic cholecystectomy is bile duct injury, which is fatal and may necessitate reoperation. [5,13]. Mis-identification of common bile duct as the cystic duct is the most serious cause of bile duct injury. Two and four patients respectively in the early and interval group had bile duct injury. In the early group one case was converted to open due to a short cystic duct. Three patients in the interval group were converted to open due to major bile leak in two cases and injury to common bile duct in one case. One patient in the interval group had a rent in the cystic duct – common bile duct junction while applying traction was applied to the Hartmann's pouch. And thus, considering the friable nature of the tissues the procedure was converted to open surgery and the rent was closed with a single interrupted suture of 4-0 vicryl. This patient had features of cholangitis in the immediate postoperative period but became settled with higher antibiotics. Another patient in the early group with bile duct injury also experienced cholangitis postoperatively with increase in bile drainage through the drain. This was successfully managed by endoscopic retrograde cholangiopancreatography and stenting. Abdominal ultrasound done 6 months later was normal. In the interval cases, the increase in dense adhesions around the gallbladder after initial conservative treatment made laparoscopic dissection more difficult and constituted the main reason for intraoperative difficulty in identifying the calot's triangle and bile duct injury. Our study supports the belief that inflammation associated with acute cholecystitis creates an edematous plane around the gallbladder, thus facilitating its dissection from the surrounding structures. Waiting for the inflammation to settle down allows maturation of the surrounding inflammation and results in organization of the adhesions, leading to scarring and contraction, which makes the dissection more difficult. The inflammation in early stages may not necessarily involve the calot's triangle; chronic inflammation often scars and distorts the calot's triangle, making dissection in this area more difficult. We believe that increasing experience and skill of the surgeon can bring down the rate of complications. Postoperatively, pain scores and analgesia requirement were same in both groups. R.A. Pyne [1969] in his study found that the average duration of hospital stay was 16 days for the interval group and 8 days for the early group.[17] I. Ahmed [1992] in his study found that the average duration of hospital stay in early cholecystectomy group was ten days. [16]. Prolonged stay in hospital leads to some psychological stress in the patient. It also leads to increased cost. Similar to the above clinical studies, we found that hospitalization duration was significantly shorter and work lost days were lower with the early group as compared to the interval group. Therefore, we concluded that early cholecystectomy for acute cholecystitis is advantageous in terms of the length of hospital stay without increase in morbidity and mortality. The limitation of this study was that it was done at a single hospital and hence the sample size was small. Large scale multicentric large randomized control trials are needed for better outcome assessment and comparison. Also, all the patients enrolled were not operated by the same surgeon. Operative outcome varies depending on the skill and experience of the operating surgeon.

## **CONCLUSION**

As observed in this study, intraoperative and postoperative complications are almost similar in early and interval cholecystectomy. In today's time where hospitals are well equipped with trained medical personnel and robust infrastructure, we believe that immediate laparoscopic or open cholecystectomy should become treatment of choice for acute cholecystitis in



operable patients as it provides the advantage of reduced intra operative complications, decreased postoperative morbidity and shorter hospital stay.

**Declaration Of Patient Consent:**

The authors certify that they have obtained consent of all the patients. The patient was assured that his/her images or name would not be published in study and due efforts will be made to conceal their identity.

**CONFLICT OF INTEREST:** None

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