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Laparoscopic cholecystectomy - A safe and feasible procedure in patients with mild-moderate acute cholecystitis: A single center, prospective, observational study

Saurabh Ranjan, Alish R. Mehta, Siddharth Tamaskar, Sandeep Dave, Jawwad Naqvi, Vikram Sharma

Department of General Surgery, Ramakrishna Care Hospital, Pachpedi Naka, Raipur, Chhattisgarh – 492001, India

ORCID ID of the author(s)

SR: 0000-0003-1594-7718
ARM: 0000-0003-2814-8886
ST: 0000-0002-7031-0659
SD: 0000-0003-0120-7815
JN: 0000-0001-5022-4211
VS: 0000-0002-2198-4964

Corresponding Author
Saurabh Ranjan
Department of General Surgery, Ramakrishna Care Hospital, Pachpedi Naka, Raipur, Chhattisgarh – 492001, India
E-mail: ranjandrsaurabh@gmail.com

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This study was approved by IEC-CS Apollo Hospitals Bilaspur (No. AHB/IEC-CS/28, 02.05.2019).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Laparoscopic cholecystectomy (LC) is the gold standard modality for treating the gallstone disease. However, it is associated with perioperative complications. Moreover, some of the patients with acute cholecystitis (AC) require conversion to open cholecystectomy (OC). Thus, the aim of this study is to assess the safety and feasibility of LC in patients with AC.

Methods: This was a single center, prospective, observational study performed, over a period of 18 months (March 2019 to August 2020), in Department of General Surgery of a tertiary care center located in Central India. 96 patients fulfilling Tokyo guidelines (2018 diagnostic criteria for AC) were included. The feasibility was assessed in terms of conversion to OC, while safety was assessed in terms of postoperative complications in the first 30 days.

Results: During LC, none of the patients required conversion to OC due to difficulty in dissection or anatomy. On postoperative day 1, the mean VAS score for pain was 2.1 (0.56), meaning of low pain. Mean length of hospital stay was 2.34 (0.61) days, thereby inferring shorter hospital stay. Mortality was not observed. During the follow-up period, 2 patients developed epigastric port-site infection, while other 2 reported port-site bleeding. Moreover, 2 patients had intra-abdominal collection. All the complications were managed conservatively.

Conclusion: The study confirms that LC is feasible and safe in patients with AC, among the age group studied. LC can be a method of choice for AC due to decreased conversion rate, short hospital stays, reduced morbidity, and swift transition to routine.

Keywords: Acute cholecystitis, Cholelithiasis, Feasibility, Laparoscopic cholecystectomy, Safety

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Introduction

Gallstones (GS) are one of the most common gastroenterological conditions with a prevalence of 10-15% in adults. Obstruction of the cystic duct due to GS can lead to distension of gallbladder (GB) and biliary colic. Prolonged obstruction results in acute cholecystitis (AC), a condition characterized by infection, inflammation, and ischemia, in severe cases [1]. AC accounts for one of the most frequent causes of emergency hospitalization in surgical care [2]. Etiologically, 90-95% cases of AC are due to GS, while remaining 5-10% are due to acalculous cholecystitis [3]. Following the trend in western countries, prevalence of GS is on rise in India and is estimated to be between 3%-6% [4]. While the majority of the patients with GS remains asymptomatic, about 1-2% of patients turn symptomatic annually. Among them, 10% progress to AC. Recurrent attacks of AC can lead to chronic cholecystitis with several changes in GB including atrophy of mucosa, wall thickening, and scarring [1].

For the past several decades, open cholecystectomy (OC) has been the standard treatment for symptomatic GS disease [5]. Subsequently, less invasive, but expensive methods including contact dissolution agents, oral desaturation agents, and extracorporeal shock wave lithotripsy were introduced. However, they were limited by size, number, and composition of GS [6]. Moreover, these non-surgical methods could not guarantee a permanent cure. In the last decade, introduction of laparoscopic cholecystectomy (LC) has revolutionized the treatment of GS disease. Compared to OC, LC is associated with several advantages including less postoperative pain, short recovery time, short duration of hospitalization, decreased expenditure, improved cosmetic results and patient satisfaction, and quick resumption of daily routine without added morbidity [7].

However, LC is limited by higher rates of complications including injuries to bile duct, liver, and bowel that are significantly increased with less experience and training of the surgeon [8]. Moreover, around 1.8-27.7% of LCs are converted to OC and the increased conversion rate counters the advantages of LC. Converted cases have higher postoperative complications leading to longer post-operative hospitalization, and higher rates of morbidity and mortality [9]. With improved surgical skills and laparoscopic instruments, LC is now considered safe for AC [10]. In a developing world such as India, where absenteeism from work and high healthcare expenditure form the primary concern, we speculated that LC could be a safe and feasible alternative in patients with mild-moderate AC. Thus, in the present study, we aimed to assess the safety and feasibility of LC in patients with mild to moderate AC.

Materials and methods

Study design and setting

This was a single center, prospective, observational study performed over a period of 18 months (May 2019 to October 2020) in the Department of General Surgery of a tertiary care hospital located in Central India. The study was conducted after the approval of study protocol by the Institutional Ethics Committee, Ramkrishna Care Hospital, Raipur (AHB/IEC-CS/28, Dated May 2, 2019) and obtaining written informed consent of the patients.

Eligibility criteria

Patients of either sex, belonging to the age group of 18 to 70 years, undergoing LC, fulfilling the Tokyo Guidelines 2018 (TG18) diagnostic criteria for AC, and with mild-moderate AC were included in the study [11]. In contrast, patients with severe AC, acute hepatitis, obstructive jaundice, malignancy, patients planned for OC, pregnant patients and medically unfit patients for general anesthesia were excluded from the study.

Study procedure

A total of 110 patients presenting with upper abdominal pain, nausea, vomiting, or fever were screened for eligibility. Of these 110 patients, 7 did not give consent, 5 were planned for OC, and 2 were found to have obstructive jaundice. Thus, these 14 patients were excluded and 96 patients were enrolled in the study. Based on laboratory (complete blood count, C-reactive protein (CRP), and liver function test) and radiological (chest X-ray, abdominal ultrasonography) investigations, the diagnosis of AC was established as per the TG18 Criteria. All the patients were operated by a single experienced surgeon and the standard 4 ports technique was used for performing LC. Both the feasibility and safety outcome measures were noted. Post-operatively, pain was assessed on postoperative day 1 with the help of visual analogue scale (VAS) ranging from 0 to 10, where 0 and 10 suggested none and excruciating pain, respectively. Sutures were removed on postoperative eighth day. All 96 patients were followed-up at first month, for any complications and recurrent symptoms.

Outcome measures

Assessment of feasibility

The feasibility of performing LC was assessed, intra-operatively, in terms of conversion rate i.e., the number of patients requiring conversion of LC to OC.

Assessment of safety

The safety associated with LC was evaluated in the intra- and post-operative period. It was assessed in terms of intra-operative injury to organs including common bile duct, bowel, or liver; discontinuation of LC due to unclear or difficult anatomy; undue intra-operative bleeding leading to intra- or post-operative resuscitation and blood transfusion; post-operative complications including bleeding from port-site, port-site infection, jaundice, drain dislodgement, and readmission; post-operative intra-abdominal collection requiring drainage; and repeated laparoscopy following the primary LC.

Statistical analysis

Data was collected and collated with Microsoft Office Excel 2013. The data was analyzed with SPSS v23.0 (IBM, Armonk, NY, USA) for Windows. Continuous and categorical variables were represented as mean (standard deviation (SD)) and frequencies (percentages), respectively. Independent sample t-test was used to assess any association between continuous variables. A two-tailed probability value of <0.05 was considered as statistically significant.

Sample size calculation

Sample size was calculated on the basis of the proportion of patients with severe AC undergoing LC and requiring OC i.e., 6% [12].

The sample size was determined on the basis of the following formula:

$$\frac{Z^2_{1-\frac{\alpha}{2}}p(1-p)}{d^2} = \frac{(1.96)^2 \times 0.06(1-0.06)}{(0.05)^2} = \frac{3.84 \times 0.0564}{0.0025} = 86.63$$

Where,

p = prevalence of conversion of LC to open cholecystectomy = 6% = 0.06

d = Absolute precision required on either side of the proportion = 5 % = 0.05 (2-sided)

$Z_{0.025}$ = 1.96 for 95% confidence interval

Thus, sample size was calculated to be 87. Considering the drop-out of 10%, a total of 96 patients were included.

Results

The present study had female (61.46%) predominance with female to male ratio of 1.6:1. Majority of the patients belonged to the age group of 51-60 years (30.21%). The mean age of the study population was 48.47 (13.36) years and mean age of males was significantly greater than that of females (p=0.021). The majority of the patients (62.5%) had leukocytosis (WBC count >10000 /dl). The mean WBC count and CRP levels were 11527.11 (4149.1) /dl and 41.26 (34.02) mg/dl, respectively. In all patients, USG was suggestive of acute calculus cholecystitis. Moreover, majority of the patients had moderate AC (56.25%) (Table 1).

Table 1: Baseline demographic and clinical characteristics

Characteristics	n	%
Sex distribution		
Male	37	38.54
Female	59	61.46
Age group (years)		
21-30	12	12.5
31-40	18	18.75
41-50	19	19.79
51-60	29	30.21
61-70	18	18.75
Mean Age (years)		
Male	52.43 (12.47)	-
Female	45.98 (13.39)	-
Total	48.47 (13.36)	-
USG suggestive of acute calculus cholecystitis		
Yes	96	100
No	0	0
WBC count (/dl)		
< 10000	36	37.5
> 10000	60	62.5
Severity of AC		
Mild	42	43.75
Moderate	54	56.25
Mean WBC count (/dl)	11527.11 (4149.1)	-
Mean CRP mg(/dl)	41.26 (34.02)	-

WBC: White blood cells, CRP: C Reactive protein, USG: Ultrasonography

The majority of the patients had double presenting symptoms (54.17%). Pain (95.83%) followed by dyspepsia (40.63%) were the most common solitary presenting symptoms. Moreover, pain + dyspepsia (29.17%) and pain + vomiting + fever (15.62%) were the most frequently observed double and triple presenting symptoms, respectively (Table 2).

Assessment of VAS score demonstrated that majority of the patients had a VAS score of 2 (91.67%). Moreover, the mean VAS score was 2.17 (0.56), suggesting low postoperative pain (Table 3).

Table 2: Presenting symptoms

Presenting symptoms	n	%
Number of symptoms		
One	22	22.92
Two	52	54.17
Three	22	22.92
Presenting symptoms		
Pain	92	95.83
Dyspepsia	39	40.63
Vomiting	33	34.38
Fever	28	29.17
Combination of symptoms		
Pain + Dyspepsia	28	29.17
Pain	21	21.88
Pain + Vomiting + Fever	15	15.62
Pain + Vomiting	15	15.62
Dyspepsia + Pain + Fever	7	7.292
Pain + Fever	6	6.25
Vomiting + Dyspepsia	3	3.125
Dyspepsia	1	1.043

Table 3: Distribution of patients according to VAS score

VAS pain score	n	%
2	88	91.67
4	8	8.33
6	0	0
Mean VAS score	2.17 (0.56)	-

Assessment in terms of surgical difficulties demonstrated that none of the patients had difficult anatomical structures and none required conversion to OC. Thus, the conversion rate was 0%. The mean operative time was 57.39 (14.7) minutes (Table 4).

Mean length of hospital stay was 2.34 (0.61) days, suggesting shorter length of hospital stay. Assessment of postoperative complications revealed that 2 patients developed epigastric port-site infection, while other 2 reported port-site bleeding within the 30-days follow-up period. Port-site infection required oral antibiotics and drainage of abscess on an out-patient basis and thus, was managed conservatively. The port-site bleeding was reported on postoperative day 1 and was managed conservatively with suturing and required no further intervention. Two patients developed intra-abdominal collection which required USG-guided pigtail drainage of the collection. The drain output subsided gradually and drain was removed by postoperative day 18. No mortality was reported in post-operative period during the 30-day follow-up (Table 5).

Table 4: Intra-operative characteristics of patients

Characteristics	n	%
LC Abandoned due to difficult anatomy		
Yes	0	0
No	96	100
Patients converted to laparotomy due to difficult anatomy		
Yes	0	0
No	96	100
Mean Operating time (Mins)	57.39 (14.7)	-

Table 5: Post-operative findings of patients

Parameter	n	%
Post-op complications		
Port-site infection of epigastric port	2	2.08
Bleeding from port-site	2	2.08
None	92	95.84
Post-operative intra-abdominal collection requiring drainage		
Yes	02	2.08%
No	94	97.92%
Mortality		
Yes	0	0
No	96	100
Mean hospital stay (Days)	2.34 (0.61)	-

Discussion

The principal findings of the present study suggested that LC is feasible as well as safe in patients with mild-moderate AC among the age group studied. With regards to feasibility, successful completion of the laparoscopic procedure as planned at the outset without any intra-operative complications that might lead to conversion to OC was observed. LC resulted in reduced

intra-operative complications, abandoning of surgery due to unclear or difficult anatomy, and post-operative complications, thus increasing the safety of patients with mild-moderate AC.

In the present study, none of the patients were converted to OC. Moreover, difficult anatomy was not encountered in any of the patients and thus, all the patients underwent LC successfully. Available literature suggests that around 1.8-27.7% of LCs are converted to OC [9]. Sippey et al. [13] reported a conversion rate of 6%. Terho et al. [14] reported a conversion rate of 22.5%, and the most common reasons were severe inflammation and difficulty in identification of anatomy. Thus, the conversion rate observed in the present study is significantly lower than that documented in literature. We attribute the 0% conversion rate to the fact that we rigorously practiced the primary principles of laparoscopic surgery including employing Veress needle, having sufficient visual field, nominal use of electrocautery in the Calot's triangle, clipping preceded by exhibition of the structures in the Calot's triangle, sufficient traction in an appropriate direction, employing gauge dissection in cases with difficult anatomy, and repeated confirmation of the anatomy. We excluded patients with severe AC and LC was performed in a single center with the same laparoscopic surgeon, which was mainly responsible for attaining 0% conversion rate, as has been reported in other studies [15]. Moreover, critical view of safety was used for identification of all the structures in the hepatocystic triangle and thus, bile duct injury was avoided. Singh et al. documented a conversion rate of 0.42%. They observed that out of 22.66% difficult cases, conversion was required only in 1.86%. Thus, highlighting the fact that LC can be successfully performed even in difficult cases by following the basic principles of laparoscopic surgery [16].

In the present study, the overall complication rate of 4.2% was less than the complication rates of 9-20% reported by other studies [17, 18]. Within the 30 days follow-up period, 2 patients each reported epigastric port-site infection and bleeding from port-site. All the patients were managed conservatively. Similarly, Lohiya et al. [19] reported minimal post-operative complications with LC. They observed that 2 patients had prolonged bile leak, and 1 each had post-operative hemorrhage and surgical site infection, and all patients were treated conservatively. In another study, Singh et al. reported that only three patients had developed surgical site infection, and all were managed with daily dressings [16].

In the present study, 1 patients developed fever on post-operative Day 2, while another patient had right upper quadrant discomfort on post-operative Day 4. On USG, both were found to have intra-abdominal collection which required USG-guided pigtail drainage of the collection. The collection subsided and drain was removed between post-operative Day 14 and 18 in both the patients. Thus, intra-abdominal fluid collection was successfully managed with drain placement. Similarly, Alberto et al. reported a case of intra-abdominal fluid collection after LC which was successfully managed with drain placement [20]. Chau et al. reported two patients complicated by post-LC leakage of cystic stump. Both the patients were successfully treated by percutaneous drainage of the intra-abdominal collection under ultrasound guidance [21].

In the present study, mean hospital stay was 2.34 (0.61) days and no mortality was reported during the 30-day follow-up period. Singh et al. reported the mean hospital stay of 1.5 days following LC [16]. Another study by Karim et al. [22] observed a mean hospital stay of 3.7 days post-LC. Contrarily, Jeong et al. [23] observed significantly longer hospital stay of 10.3 days, however, it was shorter compared to patients that underwent OC (17.7 days).

In a recently published randomized trial, Kiviluoto et al. [24] found that LC does not result in increased mortality rates in patients with AC but that the morbidity rates are substantially lower than that observed following OC. Similar to the present study, Johansson et al. [25] reported no mortality during or after LC. Similarly, Pessaux et al. [26] reported no mortality in patients undergoing LC, but 4 patients died following OC.

In the present study, majority of the patients had WBC count >10000 /dl and all the patients had CRP levels of >3 mg/dl. Moreover, the mean WBC count and CRP levels of the study population were 11527.11 (4149.09) /dl and 41.26 (34.02) mg/dl, respectively. Similarly, Chau et al. reported leukocytosis in 61.3% of the patients [21]. In another study, Terho et al. [14] reported the mean WBC count of 13000/dl, ranging from 2500 to 32000/dl. Moreover, the median CRP levels reported by Johansson et al. were considerably greater than the present study. They reported the median CRP levels of 140 mg/l, ranging from 23 to 290 mg/l [25]. Similarly, Terho et al. [14] reported elevated median CRP levels of 123 mg/l, ranging from 3 to 524 mg/l. Thus, in the present study, median CRP levels were considerably less than those cited in literature, thereby suggesting lower levels of inflammation among the enrolled patients.

In the present study, USG of abdomen was suggestive of AC in all the patients and this was supported by the findings on LC. None of the patients had suspected complications of AC and thus, CT of abdomen was not performed. Similarly, Lohiya et al. [19] and Haziraka et al. [27] used USG of abdomen as the main investigation to diagnose GS disease and reported the presence of GS in all the patients. However, Terho et al. [14] reported that, even if USG is the main choice of imaging in patients with clinical suspicion of AC, they used CT in patients who presented with severe or diffuse symptoms, and magnetic resonance imaging in patients with suspicion of bile duct stones, in addition to AC. Thus, in the present study, USG abdomen was found to have a high diagnostic accuracy.

In the present study, 4-port technique was used and the operating time ranged from 35 to 96 minutes, with mean of 57.39 (14.7) minutes. Considerably greater median operating time was documented by Johansson et al. They used 4-port technique and reported the median operating time of 90 minutes, ranging from 30 to 155 minutes. While, significantly shorter time was observed in patients that underwent OC. This difference was attribute to the longer time taken for the converted procedures (median 125 min) [25]. In contrast, Chau et al. reported no significant difference between LC and OC in terms of the mean operation time (92.5 (25.5) vs 84.8 (41.0) minutes) [21]. Thus, the mean operating time in the present study was considerably less than that documented in the literature. The reason for reduced operating time was due to experience of the surgeon and

use of advanced laparoscopic technology (such as 3D laparoscopic cholecystectomy).

As the present study was not comparative in nature, randomization was not performed. Moreover, the patients underwent surgery, so blinding was not done. However, standard operative procedures were followed and LC was performed by single laparoscopic surgeon, thereby eliminating the chances of performance bias.

In the present study, majority of the patients had the post-operative VAS pain score of 2 and the mean score was 2.17 (0.56). Johansson et al. reported that the median pain score at discharge was not statistically different with OC and LC [25]. Similarly, Enes et al. [28] reported that post-operative VAS was lower in patients operated by LC than OC. This difference was pronounced throughout the entire postoperative period. In another study, Kum et al. reported that patients who underwent LC had significantly less pain on the day of operation (mean VAS score 3.8 vs 7.7) and on the first post-operative day (mean VAS score 2.8 vs 6.2) than those who underwent OC [29].

Conclusion

The findings of the present study support the safety and feasibility of LC in patients with mild-moderate AC among the age group accentuated. If possible, LC should be used to minimize the postoperative complications in terms of shorter length of hospital stay and lower morbidity rates. However, OC should not be avoided if necessary, to ensure patient safety in severe cases or those with difficult anatomy. Moreover, major focus should be on training the surgeons regarding the appropriate technique for performing LC.

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