



A Comparative Study of Effectiveness of Mini Laparotomy Versus Lap Cholecystectomy in Tertiary Care Hospital of Western UP

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ABSTRACT

Introduction: The situation regarding the surgical care of cholelithiasis has significantly changed with the introduction of laparoscopic cholecystectomy. It has been discovered that laparoscopic cholecystectomy (LC) requires more time to complete and results in less discomfort after surgery than small-incision surgical procedures, or Mini laparotomy cholecystectomy (MC). However, outcomes regarding hospital stay and recovery have been inconsistent.

Aims/ objective: To compare efficacy and safety with respect to duration of surgery, post-operative hospital stay, and incidence of complications between laparoscopic cholecystectomy and mini-laparotomy cholecystectomy.

Materials and Method: 100 patients with cholelithiasis were operated via either laparoscopic cholecystectomy and mini-laparotomy cholecystectomy with 50 patients in each group. Their groups were labelled as group LC and group MC respectively. Effectiveness of the two technique of surgery was compared with respect to additional procedure required, duration of surgery, post-operative hospital stay, and incidence of complications.

Results: There were comparatively more cases of CBD exploration and intra-operative sphincterotomy in group MC as compared to group LC. Mean duration of surgery was 104.10 ± 71.22 minutes in LC group as compared to 7.95 ± 6.08 minutes in MC group with statistically significant difference ($p < 0.05$). Mean post-operative stay was 3.56 ± 0.59 minutes in LC group as compared to 5.72 ± 0.68 minutes in MC group with statistically significant difference ($p < 0.05$). There were more cases of wound infection, post-operative ileus and severe pain in MC group whereas cases of intra-operative bleeding and bile duct injury were more in LC group.

Conclusion: Laparoscopic cholecystectomy required more time to complete but resulted in a marginally shorter hospital stay following surgery and a more seamless recovery than cholecystectomy via mini laparotomy.

Keywords: Cholelithiasis, Laparoscopic Cholecystectomy, Mini-Laparotomy Cholecystectomy, Duration of Surgery, Post-Operative Complications.

INTRODUCTION

In India, cholelithiasis are a prevalent occurrence. Gallstones were present in as many as 15% and 29% of women over the ages of 40–49 and 50–59, respectively.¹ There are numerous patients with subclinical gallstones for each individual with symptomatic cholelithiasis. According to a number of studies done on dead people, the majority of gallstones are asymptomatic. Merely 14% of individuals with cholelithiasis had gone through cholecystectomy in the research of 9,332 post-mortem assessments conducted over a ten-year period, suggesting that as many as 86% were undiagnosed.

"The gallbladder needs to be evacuated, not since it harbors stones, rather because it forms them," stated Karl Langenbuch in 1882.^{2,3} Although numerous alternative treatments for gallstones have been developed, they have not proven to be effective. Cholecystectomy has long been the preferred surgical procedure for treating cholelithiasis. The situation regarding the surgical care of cholelithiasis has significantly changed with the introduction of laparoscopic cholecystectomy. It has created new opportunities for gallstone management.

Theoretically, a laparoscopic procedure can save hospital stays and associated costs, minimize pain, prevent huge

incisions for better cosmetic result, and shorten recovery times after surgery so that patients can return to work sooner. Recent trials indicate a rise in the prevalence of operational complications, particularly common bile duct damage, despite early positive outcomes.⁴ Laparoscopy utilization is further restricted by costly equipment, specialized training requirements, and a protracted learning curve. This has caused many people to reflect deeply and make multiple attempts to weigh the benefits and drawbacks of laparoscopic vis-a-vis small laparotomy cholecystectomy.

A new era of surgical therapy has begun with the recent spike in the use of laparoscopic and other limited access surgeries, which is having a significant impact on surgical management. Surgical specialties across the board have been impacted by minimal access surgery.⁵ ESWL (Extracorporeal Shock Wave Lithotripsy) and oral bile acid supplements (Chenodexychoic acid as well as Ursodexychoic acid) are two non-operative treatments for cholelithiasis that have not demonstrated encouraging outcomes.^{6,7}

It has been discovered that laparoscopic cholecystectomy (LC) requires more time to complete and results in less discomfort after surgery than small-incision surgical



procedures, or Mini laparotomy cholecystectomy (MC). However, outcomes regarding hospital stay and recovery have been inconsistent.⁶⁻¹² Assessing the external validity or generalizability of aforementioned trials is challenging since, except in one instance,¹¹ surgeries were carried out by specialty surgeons without the involvement of trainees. Furthermore, it's possible that the surgeons' familiarity with the two approaches under study differed, and it has been shown that this might have an impact on a randomized trial's outcome.¹³ Therefore, it was thought to be interesting to compare both of these approaches in a typical medical setting.

Thus, this study was conducted to compare efficacy and safety with respect to duration of surgery, post-operative hospital stay, and incidence of complications between laparoscopic cholecystectomy and mini-laparotomy cholecystectomy.

MATERIALS AND METHODS

This was a prospective randomized open label study with parallel 1:1 allocation conducted on patients with cholelithiasis in department of general surgery in a tertiary care hospital of western UP. Informed consent was taken from eligible patients with cholelithiasis after providing and explaining them written informed consent under the recommendations of good clinical practice and declaration of Helsinki.

Inclusion Criteria:

- Patients of either gender of age group 18-65 years
- Patients with ASA status 1 or 2
- Patients with cholelithiasis
- Patients planned for elective or emergency cholecystectomy

Exclusion Criteria:

- Patients with liver cirrhosis
- Patients with suspected or diagnosed malignancy
- Patients with previous upper gastro-intestinal surgery
- Patients with coagulopathy

Sampling Method: Consecutive sampling was done and 100 patients of cholelithiasis undergoing cholecystectomy were enrolled with 50 patients in each group.

Methodology: Preoperative evaluation, intraoperative practice, postoperative care, and a three-month follow-up were all included in this study. Every patient was examined in terms of the length of the procedure, the analgesic used after the procedure, the length of stay following the procedure, and any intra- and post-operative problems. In the event of an elective cholecystectomy, patients were admitted from the outpatient department at least one day before surgery, following the completion of all necessary investigations for general anaesthesia.

The patient received the first dosage of antibiotics just after intubation, right before the incision. No matter the kind of operation, a nasogastric tube was always inserted.

All of the patients received general anaesthesia. Then, cholecystectomy was done using either laparoscopic (Group LC) or mini-laparotomy technique (Group MC) with respect to web generated random numbers. Following surgery, there was no oral intake until bowel movements were audible. In situations of bile leak, injections of metronidazole and amikacin were given. Analgesics were administered when required. Pus from the wound was removed and submitted for microbiological culture and sensitivity tests if there were any indications of a wound infection.

Statistical Analysis: Data from patients with cholelithiasis were presented in tabular form using Microsoft Excel 365 and transferred to SPSS version 24 for further statistical analysis. Continuous data such as age, duration of surgery and post-operative hospital stay were expressed as mean \pm SD (standard deviation). Statistical significance of difference in continuous data between LC and MC group was evaluated by unpaired t-test. Categorical data, including complications, additional procedures and baseline demographic and clinical variable were reported as frequencies and then compared by chi-square or Fisher's exact test. A p-value of less than 0.05 was taken as cut-off for statistical significance.

RESULTS

50 patients each were operated via laparoscopic cholecystectomy and mini-laparotomy cholecystectomy. Their groups were labelled as group LC and group MC respectively.

Table 1: Comparison of Baseline Demographic and Clinical Characteristics between Laparoscopic Cholecystectomy (LC) and Mini-Laparotomy Cholecystectomy (MC) Group

Parameters	Group LC N = 50	Group MC N = 50	P-Value
Age in years (mean \pm SD)	52.38 \pm 5.17	53.46 \pm 5.84	0.33
Gender			
Male	15	18	0.67
Female	35	32	
Type of Surgery			
Emergency	6	9	0.58
Elective	44	41	
ASA Grade			
1	21	23	0.84
2	29	27	

Most of the patients were females and belonged to 40-60 years of age group. There were more patients of ASA grade 2 as compared to ASA grade 1. There was no significant



difference between group LC and MC with respect to age, gender, type of surgery and ASA grade ($p > 0.05$).

Table 2: Comparison of Additional Procedures between Laparoscopic Cholecystectomy (LC) and Mini-Laparotomy Cholecystectomy (MC) Group

Parameters	Group LC N = 50	Group MC N = 50	P-Value
Infiltration Anaesthesia			
Yes	39	43	0.44
No	11	7	
Intra-operative Cholangiography			
Yes	45	47	0.72
No	5	3	
Extended Incision			
Yes	9	14	0.34
No	41	36	
CBD Exploration			
Yes	2	3	>0.99
No	48	47	
Intra-operative Sphincterotomy			
Yes	1	2	>0.99
No	49	48	

There were comparatively more cases of CBD exploration and intra-operative sphincterotomy in group MC as compared to group LC but the difference was not significant ($p > 0.05$).

Table 3: Comparison of Intra-operative Time between Laparoscopic Cholecystectomy (LC) and Mini-Laparotomy Cholecystectomy (MC) Group

	Group LC	Group MC
Number of Patients (N)	50	50
Mean Intra-operative time in Minutes	104.10	71.22
Standard Deviation (SD)	7.95	6.08
Difference in Mean	32.88	
95% Confidence interval (Difference of Mean)	30.0712 to 35.6888	
P Value (Unpaired t-test)	<0.0001	

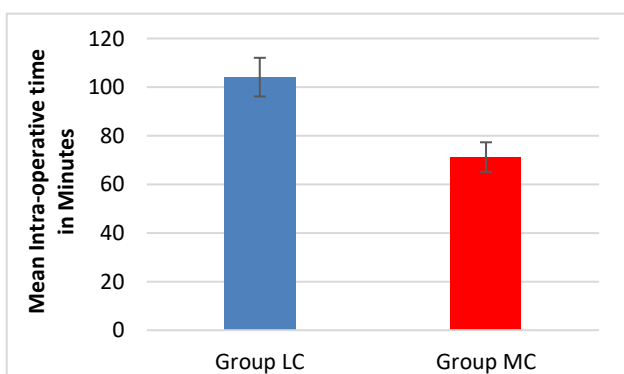


Figure 1: Intra-Operative Period in Two Groups

Mean duration of surgery was 104.10 ± 71.22 minutes in LC group as compared to 7.95 ± 6.08 minutes in MC group with statistically significant difference ($p < 0.05$).

Table 4: Comparison of Post-operative Hospital Stay between Laparoscopic Cholecystectomy (LC) and Mini-Laparotomy Cholecystectomy (MC) Group

	Group LC	Group MC
Number of Patients (N)	50	50
Mean Post-operative Stay in Days	3.56	5.72
Standard Deviation (SD)	0.59	0.68
Difference in Mean	-2.16	
95% Confidence interval (Difference of Mean)	-2.4127 to -1.9073	
P Value (Unpaired t-test)	<0.0001	

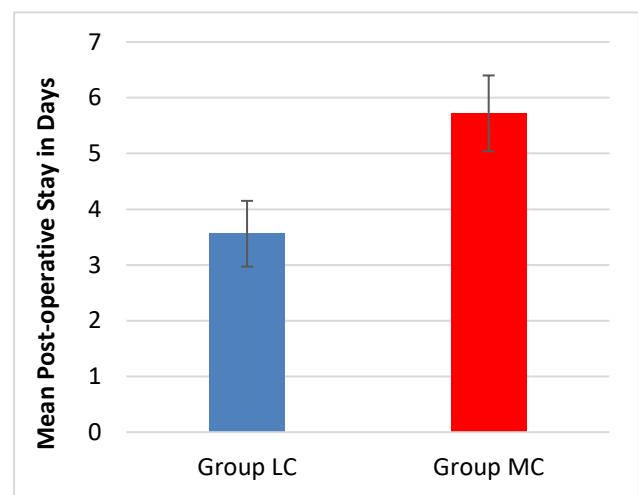


Figure 2: Post-operative Hospital Stay in Two Groups

Mean post-operative stay was 3.56 ± 0.59 minutes in LC group as compared to 5.72 ± 0.68 minutes in MC group with statistically significant difference ($p < 0.05$).

Table 5: Comparison of Baseline Demographic and Clinical Characteristics between Laparoscopic Cholecystectomy (LC) and Mini-Laparotomy Cholecystectomy (MC) Group

Complications	Number of Patients in Group LC N = 50	Number of Patients in Group MC N = 50
Wound infection	3	9
Intra operative bleeding	1	0
Bile duct injury	2	0
Postoperative ileus	3	5
Severe pain after 1 week	1	3

There were more cases of wound infection, post-operative ileus and severe pain in MC group whereas cases of intra-operative bleeding and bile duct injury were more in LC group.

DISCUSSION

This study compared the use of LC and MC in standard medical care. Thus, the study included both senior surgeons and young surgeons working under supervision.

Acute cases were eligible for this trial since both LC and MC have been demonstrated to provide benefits over traditional large incision cholecystectomy for those with acute cholecystitis.^{7, 14} Laparoscopic cholecystectomy for acute cholecystitis had been linked, outside of specialized hospitals, to a greater rate of conversion and a higher incidence of significant bile duct damage.^{15–17} In contrast to elective procedures. Therefore, it is not unexpected that our randomized participants had a decreased incidence of acute instances. In order to prevent bias based on expectations from surgeons and numerous comparisons, preliminary analyses were not conducted.

There were more cases of wound infection, post-operative ileus and severe pain in MC group whereas cases of intra-operative bleeding and bile duct injury were more in LC group. In order to compare the small percentage of significant bile duct problems, the study's sample size was insufficient. Whether or not these incisions should be considered problems has been questioned by Strasberg et al.¹⁵ But as these experts have noted, it's possible that the common bile duct was dissected circumferentially and devascularized before to the incision, which could have resulted in the development of a stricture later on. Additionally, there is a progressive change in technique from a lateral incision to the full transection of a small duct. As a result, we believe that duct damage is the correct term for these lateral incisions.

Mean duration of surgery was 104.10 ± 71.22 minutes in LC group as compared to 7.95 ± 6.08 minutes in MC group with statistically significant difference ($p < 0.05$). With the exception of the Kunz et al. study, duration of surgery was greater in this study than in earlier research,^{9–12} Our lengthy operating times may have been caused by our wide inclusion criteria, which resulted in some conversion and further incision rates, and trainee participation. With one exception,⁸ the greater operating time for LC over MC is consistent with the results of other randomized studies; after adjusting for surgical expertise and manner of admission, the mean variation in operating time increased. According to Majeed et al., the laparoscopic surgery typically takes an additional 10 minutes to set up and test the equipment.¹²

Mean post-operative stay was 3.56 ± 0.59 minutes in LC group as compared to 5.72 ± 0.68 minutes in MC group with statistically significant difference ($p < 0.05$). When data were analyzed on an intent-to-treat basis, two of the three prior trials with 200 or more patients randomized showed no distinction in hospital stay across LC and MC,^{11, 12} whereas one trial showed that LC was linked to a briefer stay in the hospital.¹⁰

After LC, sick leave as well as the number of days needed to resume routine tasks at home and in leisure were much

less than they were after MC. Majeed et al. showed no distinction between LC and MC patients, however McMahon et al. reported significantly longer sick leave.^{10, 12} Only patients who have had their procedures "successfully completed" are included in the data by McGinn et al.'s study,¹¹ while no information regarding return to work is provided in the studies by Barkun et al. and Kunz et al.^{8, 9} Therefore, the variations in sick leave coming from the two surgical procedures pale in comparison to the differences deriving from patient counsel and societal situations.

It has also been demonstrated that one of the main factors influencing sick leave is differences in medical views on the surgical recovery period.¹⁸ Similar to previous controlled trials, throughout the first postoperative week, participants in the LC group experienced less pain for a shorter period of time than those in the MC group. Therefore, in terms of convalescence, the "no difference" theory is disproved. However, a month following surgery, there was no discernible difference in the two groups' perceptions of pain. Additionally, postoperative recovery was assessed using EuroQol quality of life metrics.

It is imperative that patients and surgeons understand that choosing to convert does not equate to failure, but rather to using a safe technique and good surgical discretion. Thus, it is imperative to inform patients about the possibility of switching to an open method when obtaining their consent for a laparoscopic cholecystectomy.^{19, 20}

CONCLUSION

In summary, under the study's circumstances, LC required more time to complete but resulted in a marginally shorter hospital stay following surgery and a more seamless recovery than MC. In terms of analgesic demand, early return to work, and post-operative pain, minimally invasive laparoscopic surgery is preferable to mini laparotomy cholecystectomy. For surgeons just starting out in their careers and in cases where cholecystectomy is problematic, the mini-laparotomy approach is the procedure of choice. Research on the health-care economy related to various techniques of cholecystectomy and evaluations of the frequency and results of cholecystectomy within certain groups are extremely pertinent.

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