

Comparative Study of Laparoscopic Cholecystectomy Versus Open Cholecystectomy in Elderly Patients: An Observational Comparative Study

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Abstract

Background: Surgery for cholelithiasis is more common in elderly patients as the incidence of gallstones increases with age. Age is one of the critical factors affecting the mortality and morbidity rates after open cholecystectomy (OC). The aim of this report was to evaluate and comparing the outcome of laparoscopic cholecystectomy (LC) in elderly patients (≥ 65 years old) with that of OC.

Methods: A prospective observational comparative study was conducted in the Department of General Surgery at R.G. Kar Medical College and Hospital, India, from January 2012 to June 2013. 50 patients were involved. Group 1 had patients planned for conventional LC, i.e., LC group and Group 2 with OC, i.e., OC group. Patients included were the cases who aged 65 years and above, with symptomatic gallstone disease, with asymptomatic gallstone with associated illnesses or with anticipated complications. Various variables were compared intraoperatively and postoperatively.

Results: Significant differences were seen in LC group with more duration of surgery than OC group. The pain score was significantly low in LC group after 6 and 24 hours. The duration of hospital stay was also significantly less in LC group. Pulmonary function tests were done on 1st and 6th post-operative days showed a significant difference of peak expiratory flow rate, forced expiratory volume₁, and forced vital capacity between LC and OC on 1st post-operative day.

Conclusions: LC should be advised for elderly patients as an elective procedure safely as post-operative morbidity is much less in LC compared to the OC.

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Introduction

Gallstone disease is one of the most common surgical encounters. According to world literature, it occurs among 3-20% of the world population (1). A gallstones survey suggested that the incidence of gallbladder (GB) stones is 7 times more common in Northern Indian than in Southern Indian population. Laparoscopic cholecystectomy (LC) is accepted as the gold standard treatment for this disorder (1). Surgery for cholelithiasis is more common in elderly patients as the incidence of gallstones increases with age. The use of a laparoscopic approach in aging patients may pose problems because the comorbid conditions that are concomitant with advanced age thereby increasing the post-operative LC complications and the frequency of conversion to open surgery (2). Cholecystectomy is the most frequent abdominal operation, and its employment in the elderly varies between 8.3% and

24% among all the operations (2-4). Although aging seems to have a negative influence on surgical outcome. In reality, the decline of functional reserves, the more frequent presence of comorbidities, chronic and complicated biliary disease, such as acute and chronic cholecystitis and biliary pancreatitis commonly associated with calculi of the common bile duct- are the greatest responsible for causing potential increase in perioperative morbidity, mortality, and need for conversion to open technique (5-7). Therefore, elective surgical treatment is recommended for the clinically symptomatic elderly, as long as they are compensated (2). Even with the clearer understanding of physiology, improved anesthesia, availability of efficient antibiotics, and increasing refinements in surgical techniques and technologies, the overall mortality rate from surgery in this age group is estimated to be twice that of the general population (3,8-10). As there are various researches done in many

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advanced centers across the developed world with their facilities and equipment, but there is insufficient data available in our part of the country. The aim of this report was to evaluate the outcome of LC in elderly patients (≥ 65 years old) and comparing with the outcome of open cholecystectomy (OC) in the short-term post-operative period.

Materials and Methods

This prospective observational comparative study was conducted in the Department of General Surgery at R.G. Kar Medical College and Hospital, India. All the relevant data were collected from January 2012 to June 2013. First, 50 patients were included in the study. Complete clinical history was recorded including all the relevant points, detailed physical examination was done, and the radiological and pathological investigation reports were recorded and analyzed. Written informed consent was taken from all patients. The study was approved by the Institutional Ethics Committee. 50 patients equally divided into two groups were taken up for the study. Then, patients were randomly divided into two groups: 25 cases (patients planned for conventional LC), i.e., LC group and 25 controls (patients planned for OC), i.e., OC group. In our study, patients were kept nil per orally (NPO) in the post-operative period till the bowel sounds appeared or flatus is passed whichever came first. Inclusion criteria were as follow: Patients aged 65 years and above, patients diagnosed as cases of symptomatic gallstone disease, patients with asymptomatic gallstones where cholecystectomy is indicated due to associated illnesses, and patients with asymptomatic gallstones with anticipated complications. Exclusion criteria were as follow: Patients with suspected GB carcinoma, gallstones associated with CBD stones (USG/MRCP proven or history of jaundice), patients with pancreatitis (serum amylase ≥ 3 times normal), and acute cholecystitis.

Techniques of cholecystectomy

OC was performed through standard right subcostal incision whereas LC was performed through standard four ports. The choice for the method of creating the first port was either open Hasson technique or closed Veress technique. A meticulous dissection of Calot's triangle was the key to success and safety. Usually, the integrate method was followed because of the safety. Sometimes for technical difficulties retrograde "fundus first" method was followed.

In the intraoperative period, the following parameters were evaluated:

1- Grading of adhesion (5): Grade I: No adhesions, Grade II: Flimsy adhesions that permit easy dissection, Grade III: Chronic pericholecystitis and pericholecystic fibrosis, making dissection difficult but, permitting visualization of the anatomy, Grade IV: Thickened GB

wall and anatomical distortion due to dense adhesions around the GB, which do not permit safe dissection.

2- Duration of surgery: Starting from incision for the port to closure of port sites.

3- Intraoperative complications (any).

4- Requirement of drains.

The following parameters were noted in the post-operative period:

1- Post-operative complications were classified into four grades as follows (6)

- Grade 1: Minor complications treated with bedside therapy, e.g.: Low urinary tract infection, umbilical wound infection, hematoma, and post-operative delirium.

- Grade 2: Complications that require potentially morbid interventions such as treatment of arrhythmias, surgery, or other invasive procedure: Hemorrhage (cystic artery), small bowel laceration, laparotomy infection, bile leak, pulmonary embolism, umbilical hernia, common bile duct injury, peritonitis (T-tube removal), and retained stones.

- Grade 3: Complications that result in residual disability: Myocardial infarction and CVA.

- Grade 4: Death.

2. Evaluation of pain at 6, 24, and 48 hours by VAS score (7).

3. VAS consisted of a 100-mm horizontal line anchored at one end with the words "no pain" and at the other end with the words "worst pain imaginable."

4. Analgesic required (diclofenac sodium aqueous IV) number of IV dose (7).

5. Duration of hospital stay.

6. Duration of mandatory intravenous fluids was noted in hours.

7. Pulmonary function tests at the 1st and 6th post-operative day (8).

- Forced vital capacity (FVC) - in liters.

- Forced expiratory volume at 1 second (FEV₁) in liters.

- Peak expiratory flow rate (PEFR) in l/min.

- FEV₁/PEFR.

8. Chest X-ray - on 1st and 6th post-operative day (8).

9. ABG analysis immediately at the end of surgery (9).

The following parameters were recorded: pH, pCO₂, and HCO₃. Regarding criteria of acid-base changes:

A blood PH of range 7.35-7.45 was considered normal; higher or lower values were considered alkalotic or acidotic, respectively.

Results

The mean age of our subjects was 70.32 ± 5.65 years for the patients in the LC arm group and 70.96 ± 5.54 years for those in the OC arm for which the statistical difference was insignificant ($P = 0.98$). In our study male: female ratio in LC group was 20:5 and in OC group was 16:9, showing a homogeneous distribution.

Table 1. GB adhesions between two groups

Grading of adhesions	Experimental group LC group (n = 25)	Control group LC group (n = 25)	Chi-square	P-value*
Grade 1	0	0	0.44	0.800 ^{NS}
Grade 2	9	10		
Grade 3	9	10		
Grade 4	7	5		

*Significant at the rate ≤ 0.050 , NS: Non-significant; LC: Laparoscopic cholecystectomy; GB: Gallbladder

In our study, there were no complications of Grade 2, 3, or 4. There were 2 cases of urinary retention needing catheter, and 1 case of umbilical port infection managed conservatively in our LC group, in the OC group, there were 3 cases of urinary retention. The difference was insignificant in both the groups (12% Grade 1 morbidity).

Perioperative parameters

GB adhesions: Using grading system, preoperative adhesions were classified, and they were statistically similar in both the groups thus enabling us to compare other preoperative and post-operative complications in the two groups without bias. The mean duration of LC was 97.84 ± 37.20 , and for OC was 68.00 ± 16.39 minutes, difference was statistically significant ($P < 0.001$). There were 3 cases of GB perforation in LC group and only one such case in OC group, whereas 2 cases of cystic artery are bleeding in LC group 1 case of GB perforation in OC group. There were no cases of intraoperative CBD injury in both the groups (Table 1). Evaluation of pain at 6, 24, and 48 hours by VAS score provided in table 2. In our study in LC group, the mean period of NPO was 34.8 hours and in OC group it was 44.16, and the difference was statistically significant with $P < 0.050$ (Table 3).

Acid-base imbalance: In our study PH was in normal range immediate postoperatively in both the groups (7.39 in experimental group and 7.40 in control group) with statistically no difference, PCO_2 was also within normal range in both the groups (38.57 in experimental group and 39.32 in control group) difference been insignificant, thus showing no persisting effect of CO_2 pneumoperitoneum till the end of surgery. HCO_3 was also similar in experimental group and B (25.27 vs. 27.12) and was very close to the normal values thus showing no metabolic component involved to imbalance the equation.

Pulmonary function tests

The observations of our study are as follows:

- PEFR (l/min) on the preoperative day was on an average 311.92 in LC group, and 340.36 in OC group.

This difference was statistically insignificant at $P < 0.050$.

- The average PEFR on day 1 was 253.88 in LC group, and 175.12 in OC group. This difference was statistically highly significant at $P < 0.001$.
 - There was loss of PEFR of among LC and OC patients 18.13% versus 47.75% as compared to pre-operative PEFR values which were also highly significant at $P < 0.001$.
 - The average PEFR on day 6 was 293.88 in LC group and 284.64 in OC group which was statistically insignificant.
 - However, there was a statistically significant loss in the value of the percentage of loss, which was 5.48% on day 6 was in the experimental group, and 16.60% in control group.
 - FEV_1 (liters) on the pre-operative day was on an average 2.12 in LC group and 2.16 in OC group, the difference was not statistically significant.
 - FEV_1 on the 1st post-operative day was 1.76 for LC group and 1.13 for OC group, and the difference was statistically significant.
 - Furthermore, the percentage loss FEV 1 day 1 was also found to be significant (16.80% vs. 40.36%).
 - FEV_1 on the 6th post-operative day was 1.98 in LC group and 1.80 in OC group, and the difference was statistically insignificant. Percentages loss was also statistically insignificant (11.28 vs. 16.96) in this respect.
 - The average FVC (liters) on pre-operative day was 3.12 in LC group, and 3.00 in OC group and the difference in values was not statistically significant ($P < 0.050$).
 - FVC on day 1 was 2.36 in LC group and 1.56 in OC group, for which the difference was statistically significant. Here we observed that the difference loss of percentages was highly significant (23.04% vs. 44.12%).
- FVC on day 6 was 2.72 in LC group and 2.56 in OC group which was statistically insignificant. Moreover, we found that the percentages loss was also insignificant (8.99% vs. 13.21%) in this respect.

Table 2. Comparison of means of vas at 6, 24, and 48 hours (post-operative) in two groups

Times	Statistics	Experimental group (n = 25)	Control group (n = 25)	t	P-value
6 hours	Mean \pm SD	4.96 ± 1.20	6.76 ± 0.93	-5.92	$< 0.001^*$
24 hours	Mean \pm SD	2.28 ± 1.49	3.48 ± 1.36	-2.98	$< 0.001^*$
48 hours	Mean \pm SD	1.56 ± 1.16	2.20 ± 1.19	-1.93	0.060 ^{NS}

*Significant at the rate ≤ 0.050 ; NS: Non-significant; SD: Standard deviation

Table 3. Comparison of clinical outcomes in two groups

Variables	Statistics	Experimental Group (n =25)	Control Group (n = 25)	t	P-value
Dose	Means \pm SD	1.56 \pm 1.16	3.02 \pm 0.70	-5.61	0.001*
NPO (hours)	Mean \pm SD	34.80 \pm 16.25	44.16 \pm 6.68	-2.66	0.010*
Hospitalization (hours)	Mean \pm SD	79.52 \pm 15.42	92.16 \pm 19.20	-2.56	0.020*

*Significant level was considered less than 0.05; SD: Standard deviation; NPO: Nil per orally

Discussion

The aim of the present study was to determine the safety and efficacy of LC in the elderly patients comparing it is perioperative and post-operative parameters in a tertiary level of health care in this part of the world, along with the comparison of various physiologic changes occurring in pulmonary function parameters after laparoscopic and OC. Many articles in the western world have compared open and laparoscopic procedures in the geriatric population, but there is clearly a paucity of studies in the Indian subcontinent, especially when comparing PFT in older patients in the post-operative period. In our study, the age group was the central consideration in patient selection. We selected an age group of 65 years and above, considering the fact that life expectancy in India as per World Bank data which shows this to be 65.48 in year of 2011. The mean age of our subjects was 70.32 ± 5.65 years for the patients in the LC arm group and 70.96 ± 5.54 years for those in the OC arm for which the statistical difference was insignificant ($P = 0.980$). This was similar to other researchers for LC in the elderly. For example, Malik et al. (10) observed their results above 65 years of age, and Majeski (11) compared patients above 65 years, Pavlidis et al. (12) who also took 65 years cut off age. However, there were some other studies where the cutoff age was higher such as 70 years (13) and 80 years.

Using grading system, preoperative adhesions were classified, and they were statistically similar in both the groups thus enabling us to compare other preoperative and post-operative complications in the two groups without bias. No other research of LC in elderly incorporated this into account (5). The mean duration of LC was 97.84 ± 37.20 , and for OC was 68.00 ± 16.39 minutes. This difference is statistically significant at $P < 0.050$. The longer average operative time for LC in this study was attributable to the fact that LC in our setup is still in early phases of learning curve and is expected to improve in near future.

Ido et al. (14) observed an average operative time of 123 minutes in the elderly patients. Majeski (11) averaged at 75 minutes for LC in elderly patients. Over the years, the average duration of surgery is gradually getting shorter for LC as the learning curve is going up everywhere (13,15). There were 3 cases of GB perforation in LC group and only one such case in OC group, whereas 2 cases of cystic artery are bleeding in LC group 1 case of GB perforation in OC group. In the

series of Kauver et al. (13), the operative complications were (17% vs. 9%) in elderly. Polychronidis et al. (15) also noted a higher complication (37% vs. 6%) in patients over 75 years. The score at 6 hours was significant ($P < 0.001$). It was also significant at 24 hours ($P < 0.050$) but the pain score at 48 hours was although less in the LC group it was statistically not significant. This finding was in similarity with other researchers such as Enes et al. (16) and Agnifili et al. (17). Reasons for less post-operative pain in LC could be: Shorter length of incision (1 cm in LC vs. 5-7 cm or more in OC) and less operative trauma as forceful retraction of the wound edges for exposure to the operative field in OC which is not requires in LC. Number of analgesics requested was also significantly different in the two groups at $P < 0.001$. Patients of LC group took on an average of 1.56 doses postoperatively, and OC group requires 3.08 doses. This is similar to McMahan et al. which showed less analgesic consumption in LC group (22 vs. 40 mg) (18).

In our study patients were kept NPO in the post-operative period till the bowel sounds appeared or flatus is passed whichever came first, which was similar to the protocol in the study conducted by KAYA et al. (19). In our study in LC group, the mean period of NPO was 34.8 hours, and in OC group it was 44.16, and the difference was statistically significant at $P < 0.050$. Ido et al. (14) had a mean of 1.3 days (31.2 hours) in the elderly group. This significant effect can be due to: Less operative stress, less post-operative pain, and earlier mobilization. In our study patients of LC group could be comfortably discharged after an average of 79.52 hours postoperatively and in those in the OC group after 92.16 hours and this difference was statistically significant at $P < 0.050$. Theodoros et al. (12) observed a hospital stay of 4.9 (117.8 hours) days in the elderly group (> 80 years). In the patients of the series of Ido et al. (14), the average stay of 9.3 (223.2 hours) was recorded in patients > 70 years. Polychronidis et al. (2) observed a mean hospital stay of 3 (72 hours) days in the elderly patients > 75 years of age. Spiezia et al., (20) in their series saw a post-operative stay of 4 days in patients > 75 years of age.

As proposed by Mayol et al., post-operative complications of cholecystectomy in elderly were divided into four grades (3). In our study, there were no complications of Grade 2, 3, or 4. According to Baldini et al. (21), post-operative retention requiring catheterization was based on USG; if bladder volume > 600 ml, then catheterization is indicated. But as USG was not feasible thus as guided by Baldini et al.,

inconvenient retention beyond 1-2 hours catheterization was done (21). There were 2 cases of urinary retention needing catheter, and 1 case of umbilical port infection managed conservatively in our LC group. In the OC group, there were 3 cases of urinary retention (22). The difference was insignificant in both the groups (12% Grade 1 morbidity). In their study, Mayol et al. had a morbidity of 11-20% which also included Grades 2 and 3 complications (3). Dennis et al. (23) had a total of 24% complications in which 12% were of Grade 1 and 12% of Grade 2. This was the central query of this study. PFTs were done on 1st and 6th post-operative days, and the results were compared between the two groups. Alteration in pulmonary function after abdominal surgery and general anesthesia has already been well studied. General anesthesia typically impaired gas exchange as the result of altered lung mechanics. The effect of upper abdominal surgery on lung function, however, is more pronounced, lasting up to 10 days. It is characteristically restrictive in pattern and may lead to atelectasis, pneumonia and hypoxemia and thus can be clinically significant (24). LC is associated with reduced pain, pulmonary dysfunction, morbidity, and duration of convalescence as compared to OC (24).

There was a significant difference of PEFr, FEV₁, and FVC between LC and OC on the first POD, but this difference was reduced on the 6th POD. The percentage loss of various factors in lung function depicts the morbidity of a procedure in its post-operative period and percentage loss between experimental group on day 1 (18.13; 16.80; 23.04) and control group on day 1 (47.75; 40.36; 44.12) were significantly higher in experimental group, thus proving the increased morbidity of OC as compared to LC in elderly patients. In this context, other studies for other age groups have also demonstrated similar results: Ravimohan et al. (24) observed a range of 21-31% after LC and 40-60% in OC. Among the studies conducted by our western counterparts Freeman et al. found a range of around 23% reduction after OC and 45% reduction after LC, a study had a similar inclusion criteria of > 65 years had a result of lung function reduction of 13-17% in LC and 21-38% in OC, which are quite similar to our findings (25). It is proving that increased age does not cause much of a difference. In their study, Frazee et al. (26) also had a similar result of loss of 47-48% in OC and 27-28% in LC on the 1st post-operative day. In our study PH was in normal range immediately postoperatively in both the groups (7.39 in experimental group and 7.40 in control group) with statistically no difference. HCO₃ was also similar in experimental group and B (25.27 vs. 27.12) and was very close to the normal values thus showing no metabolic component involved to imbalance the equation. In previous studies, some reported respiratory acidosis due to the transperitoneal absorption of CO₂ (27)

and others reported metabolic acidosis due to the degree of tissue hypoperfusion leading to anaerobic metabolism (28,29) but in our study, it was not the case. The difference can be due to small sample size, no measurement recorded intraoperatively, and serum lactate was not measured to rule out the metabolic component.

As a conclusion, LC should be advised for elderly patients as an elective procedure safely as the intraoperative morbidity is similar to OC, whereas post-operative morbidity is much less in LC compared to the OC. Various advantages of LC as compared to OC even in the elderly can be cited after the study as less post-operative pain, less analgesics requirement, less derangement of pulmonary functions and thus fewer chest complications, less duration of hospital stay and better patient compliance.

Conflict of Interests

Authors have no conflict of interests.

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