



## Clinical Study of Complications of Laparoscopic Cholecystectomy and Open Cholecystectomy

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### ABSTRACT

*This is clinical study of 440 patients undergoing elective laparoscopic and open cholecystectomy in a tertiary care hospital during the period from June 2013 to June 2016. Out of the 440 patients, 50% underwent laparoscopic surgery and 50% open cholecystectomy. The incidence of gall bladder disease was highest in the age group of 41-50 years, showing incidence of 33 %. The mean age incidence in present study was 44.71 years. Incidence of Complication was also highest in age group 41-50 yrs. Majority patients were females, which were found to be 282 patients, while male were 158 patients. Ratio of male to female was 1: 1.78. Complication rate in male and female was 10.12% and 9.21% respectively. Male and females had no significant statistical difference for the incidence of complications in both Laparoscopic and open cholecystectomy groups. Pre operative ultrasonographic finding of gall bladder wall thickness > 3mm was associated with an increased risk of complication and conversion of laparoscopic cholecystectomy to open cholecystectomy. Obesity [BMI > 30 kg/m<sup>2</sup>] and acute cholecystitis was associated with increased risk of complication as well as conversion. The mean operating time increased in the cases which complicated intraoperatively. Complication rate among both groups in Laparoscopic and open cholecystectomy was 8.18 % and 10.9% respectively. Thus there was no significant difference in the incidence of complications. Spillage of gall stone was most common complication in laparoscopic cholecystectomy followed by intraoperative gall bladder perforation and biliary duct injury. Whereas following open cholecystectomy, post operative wound infection was the most common complication, followed by post operative bile leakage. Complication rate among both study groups was similar but, intra operative morbidity and severity of complications was more in laparoscopic cholecystectomy.*

### INTRODUCTION

Laparoscopic cholecystectomy has become the treatment of choice for chronic cholecystitis and cholelithiasis around the world. Laparoscopic cholecystectomy is still reported as having a higher complication rate for acute cholecystitis than for chronic cholecystitis, with a currently

reported postoperative complication rate of about 9% to 17% in some published series<sup>[1]</sup>.

### Aims and Objectives

To study, analyze and compare the perioperative results and final outcome of patients undergoing laparoscopic cholecystectomy and open cholecystectomy (OC) with regards to incidence

and occurrence of complications, factors responsible for complications, modalities of treatment explored for its management, and to set up guidelines for selection of patients for open or laparoscopic cholecystectomy.

### Methodology

All patients undergoing open and laparoscopic cholecystectomy at Department of General surgery, Medical College with group of Tertiary care hospital centers from July 2013 to July 2015, and includes 440 patients. Most of the operations were performed by professors and assistant professors of surgery, but resident surgeons participated in surgery under supervision. This was a prospective study conducted over 3 years. Patients with gallstone disease were eligible to participate in the study comparing conventional open cholecystectomy and laparoscopic cholecystectomy according to exclusion and inclusion criteria. The Hospital Ethics Committee approved the study protocol and written informed consent was obtained before the study from all patients.

We analyzed 440 patients, diagnosed with gallstone disease randomly assigned to laparoscopic cholecystectomy or open cholecystectomy. We included all patients aged >18 years with symptomatic gallstone disease (cholelithiasis, acute and chronic cholecystitis). Patients with confirmed choledocholithiasis, previous upper abdominal surgeries, pregnant women and patients with malignant tumors were excluded from study. Demographic data such as age, sex, surgical risk (ASA score), history of previous hospitalization for common bile duct stones and if underwent preoperative Endoscopic Retrograde Cholangio Pancreatography, comorbid conditions, body mass index, ultrasound of abdomen and duration of surgery were computed. Respiratory complications (pneumonia, broncho-pneumonia, pleural effusion, pulmonary embolism), surgical site infections, urinary infections, deep vein thrombosis and other complications were recorded from the immediate postoperative period until the time of hospital discharge. We evaluated length of postoperative hospital stay and the clinical

conditions at the time of discharge. Data were statistically analyzed using the chi-square test, considering the significant differences at  $p < 0.05$ . Operation time was taken as indicator of difficult surgery. The time required for surgery was noted from time of insertion of umbilical port to removal of all ports and skin closure. A policy of converting if there is no progress in dissection of Calot's triangle within 30 minutes was adopted in our study. If converted to open method, the cause of conversion, step at which converted and time after which conversion was done, were noted. Ryles tube were removed immediately after surgery in all cases. Patients were kept nil by mouth till return of the bowel sounds. All patients were ambulated as early as possible. Drains when kept were removed if output was less than 5-10 cc. with no bile leak. Complications directly related to the surgical technique were graded according to Clavien's classification<sup>(2)</sup>. Injury of the bile ducts were graded as per Hannover classification<sup>(3)</sup>

### RESULTS

#### a) Age Incidence:

Maximum numbers of patients were in the group of 41 – 50 yrs with mean as 44.71 years. Mean for females was 42.67 years and 46.62 years for males.

**Table 1:** Mean age in various studies:

Sr No.	Study	Mean age in years
1	Bansal A et al. 2014 <sup>[4]</sup>	43.56
2	Hussain A et al. 2008 <sup>[5]</sup>	43.96
3	Palanivelu C. 2007 <sup>[6]</sup>	40.4

**Table 2 :** Incidence of Complications according to age groups

Age groups in yrs.	Laparoscopic cholecystectomy n=220	Open cholecystectomy n=220	P-value By fishers exact test
<20	0	2	
21-30	2	0	
31-40	10	8	0.810[NS]
41-50	4	10	0.173[NS]
51-60	0	4	
61-70	0	0	
71-80	2	0	

Complications in both groups were commonly observed in 3<sup>rd</sup> and 4<sup>th</sup> decade.

**b) Sex:**

In our study 158 patients were males and 282 were females. Females almost outnumbered males in each age group. The male: female ratio in our study is 1: 1.78 which well compares with the study of Kimura K et al [7] [1:1.52]. This ratio also well compares with the study of Leon Morgenstern et al [8] (1992) [1:1.5].

16 male [10.12%] patients developed complications while 26 female [9.21%] patients developed complications. Incidence of complications in our study was found out to have similar percentage of complications with no significant difference. Male and females had no significant statistical difference of incidence, of complications in both Lap and open cholecystectomy groups.

**Table 3 :** Complication rate sex distribution wise.

Sex	Laparoscopic cholecystectomy n=220	Open cholecystectomy n=220	Percentage
Male n=158	8	8	10.12%
Female n=282	10	16	9.21%

**Table 4 :** Concurrent illness (co-morbidities)

Disease	Laparoscopic cholecystectomy n=220	Open cholecystectomy n=220	Total n=440
Diabetes Mellitus	28	32	60
Hypertension	28	20	48
Asthma	8	4	12
Epilepsy	0	4	4

No significant difference was observed between the relation of complications and co morbidities in both study groups.

**c) Body Mass Index :**

There was association between obesity and incidence of complications between laparoscopic cholecystectomy and open cholecystectomy but the association was not significant statistically. This is because of limited sample size.

But there was a significant association between obesity and conversion of laparoscopic cholecystectomy into open cholecystectomy Non obese patients had a conversion rate of 6.9 % while in obese patients it went upto 21.42 %, which was significantly high with p value < 0.001.

Liu et al 2002 [9] and Micheal rosen [10] et al 2002 showed that obesity as independent predictor of conversion and difficult laparoscopic cholecystectomy. Total 34 obese patients participated in our study.

4 patients underwent open cholecystectomy. Among them 2 patient developed wound site infection.

30 patients underwent laparoscopic cholecystectomy. Among the 1 patient developed intra operative cystic artery hemorrhage. Other patient developed port incisional hernia.

**Table 5:** Complications in obese [BMI >30 kg/m<sup>2</sup>]

Basal Metabolic Index >30 kg/m <sup>2</sup>	Laparoscopic Cholecystectomy N=30	Open cholecystectomy N=4	P-value Chi square test
Complications	10	2	<0.001 [S]

**d) Ultrasonography:**

Our study indicates, strong association between gall bladder wall thickness (>3mm) and occurrence of complications in both laparoscopic cholecystectomy and open cholecystectomy.

A preoperative gallbladder ultrasonography for symptomatic cholecystitis, with a thick gallbladder wall (> or =3 mm) with calculi, is a clinical warning for the any surgeon for a difficult laparoscopic cholecystectomy procedure which may require conversion to an open cholecystectomy procedure. [11]

Jagadish Nachnani et. al. (2005) [12] in his study concluded that dissection of GB bed was more difficult in patients with past history of acute cholecystitis/pancreatitis (p<0.01) and in those with GB wall thickness exceeding 3mm(p<0.05).

**Table 6 :** Gall Bladder wall thickness and surgery done.

GB wall thickness	Total patients	Laparoscopic cholecystectomy	Open cholecystectomy
> 3mm	80	48	32
< 3mm	360	172	188

**e) Acute cholecystitis:**

Our study shows strong association between acute cholecystitis and incidence of complications in laparoscopic cholecystectomy and open cholecystectomy. Incidence of complications in laparoscopic cholecystectomy was twice that occurred in open cholecystectomy.(5:2)

One case of acute cholecystitis complicated into biliary duct injury during laparoscopic cholecystectomy. This result well compares with the study of Al Salamah<sup>[13]</sup>and Kum CK et al<sup>[14]</sup>Acute Cholecystitis is considered as a risk factor for Bile Duct Injury and the reported incidence varies from 0.2-2% <sup>[13],[14]</sup>.

While performing Laparoscopic Cholecystectomy in cases of acute cholecystitis, there are more chances of having bile duct injury. However, performing Lap Cholecystectomy during the acute phase requires more frequent modifications in operative technique and thus a longer operative time. In some cases, decompression of a tensely distended gall bladder by needle aspiration is necessary. In case of Acute Cholecystitis, the gall bladder may contain turbid bile or even pus. Thus, extra precautions must be taken, including the use of drains, in some cases, to avoid bile collection with its potential risk of infection.

**Table 7 :** Complications in patients with gall bladder wall thickness > 3mm (acute cholecystitis)

Complications	Laparoscopic cholecystectomy N=48	Open cholecystectomy N=32	P-value By Fisher test
Gall bladder perforation	4	0	0.292 [NS]
Gall stone spillage	4	0	0.292[NS]
Post op biliary leakage	0	2	0.168[NS]
Wound site infection	0	2	0.168[NS]

**f) Surgical Outcome:**

In our study, 220 patients were operated by open cholecystectomy and 220 patients were operated by laparoscopic cholecystectomy, while 18 of these laparoscopic cholecystectomy had to be converted into open cholecystectomy.

Total 42 complications occurred .18 complications occurred in patients operated by Laparoscopic cholecystectomy. Gall stone spillage was the most common complication in laparoscopic cholecystectomy in our study. No deaths occurred in patients undergoing laparoscopic cholecystectomy surgery. 24 complications occurred in patients operated by Open cholecystectomy. Wound infection was the most frequent complication in open cholecystectomy in our study. There were no deaths in patients undergoing open cholecystectomy.

Results in our study are comparable with the study of jatko et al.

In the comparative study by Jatzko<sup>[15]</sup> et al., open cholecystectomy was associated with a 7.7% morbidity rate, compared with 1.9% for laparoscopic cholecystectomy and a 5% mortality rate in open vs 1% for laparoscopic cholecystectomy.

In our study morbidity was seen more in laparoscopic group as compared to the study by Jatko et al. Reasons may be explained as our study having limited sized and with a learning curve in the teaching institute.

**Table 8:** Complication rate in various studies.

Sr.no	Study	Laparoscopic cholecystectomy	Open cholecystectomy
1	Jatco et al <sup>(15)</sup>	1.9%	7.7%
2	Buanes T et al <sup>(16)</sup>	9%	16%
3	Jan YY et al <sup>(17)</sup>	4.4%	2.2%
4	Present study	8.1%	10.9%

The course of complications with its management and resultant outcome were also studied. The factors affecting the incidence of complications and the corrective measures utilized to reduce the morbidity were noted. No complications like Pneumonia, Trocar injuries, Bowel injury or Pneumothorax were observed in our study.

No mortality was seen in both groups.

**Table 9:** Complications observed in patients undergoing laparoscopic and open cholecystectomy.

Complications	Laparoscopic cholecystectomy (n=220)	Open cholecystectomy (n=220)	P-value by Fishers exact test
Hemorrhage	2	6	0.284 (NS)
Spilled stones	6	0	0.030 (S)
Intraoperative Gall Bladder perforation	4	2	0.685 (NS)
Wound infection	0	8	0.007 (S)
Sub-hepatic abscess	0	2	0.498 (NS)
Bile duct injury	4	0	0.123 (NS)
Bile duct leakage	0	6	0.030 (S)
Port site hernia	2	0	0.498 (NS)

The significant p value is <0.05 with fisher exact test.

Mean duration of surgery was more in laparoscopic cholecystectomy as compared with open cholecystectomy as shown in table 10.

**Table 10:** Mean duration of cholecystectomy

Duration	Laparoscopic cholecystectomy	Open cholecystectomy	P-value
Operating time in min	84 ±34.5	74.55 ± 20.47	< 0.05

By Wilcoxon signed rank test, the p value is <0.05. Thus result is significant.

Mean duration in procedures which developed complication show a significant increase in the duration of surgery in laparoscopic group than open group.

**Table 11:** Mean duration of cholecystectomy in cases with complications:

Duration	Laparoscopic cholecystectomy	Open cholecystectomy	p value
Operating time in min	140 ±34.5	93.88 ± 20.47	< 0.05

By Wilcoxon signed rank test, the p value is <0.05. Thus result is significant.

**Table 12 :** Hospital stay.

Hospital stay	Laparoscopic cholecystectomy	Open cholecystectomy
Mean duration of hospital stay	4.42	6.61

By Wilcoxon Signed-Rank Test, the Z-value is 6.09. The p-value is <.0001 Thus result is significant.

The mean duration of hospital stay was of 4.42 days (2-7days) in Laparoscopic Cholecystectomy group and 6.61days (4-10days) in Open

Cholecystectomy group. The difference was statistically significant, p<0.0001.

The patients with complications and conversion or re-exploration had longer hospital stay in both group

**CONCLUSION**

- 1) The Incidence of Complication was highest in age group 41yrs-50 yrs.
- 2) Complication rate in male and female was 10.12% and 9.21% respectively. Male and females had no significant statistical difference for the incidence of complications in both Laparoscopic and open cholecystectomy groups.
- 3) Pre operative ultrasonographic finding of gall bladder wall thickness > 3mm was associated with increased risk of complication and conversion of laparoscopic cholecystectomy to open cholecystectomy.
- 4) Obesity [BMI > 30 kg/m<sup>2</sup>] and acute cholecystitis was associated with increased risk of complication as well as conversion.
- 5) In our study, the mean operating time required for laparoscopic cholecystectomy was 84 ±34.5 min; while mean time required for open cholecystectomy was 74.55 ± 20.47.
- 6) The mean time increased in the cases which complicated intraoperatively. This increase of surgical duration was high in patients with laparoscopic cholecystectomy i.e mean time 140 mins as compared to mean time of 93.88 mins with cases of open cholecystectomy.
- 7) Complication rate among both groups in Laparoscopic and open cholecystectomy was 10.21% and 8.1% respectively. Thus there was no significant difference in the incidence of complications. Spillage of gall stone was most common complication in laparoscopic cholecystectomy group. Followed by intraoperative gall bladder perforation and biliary duct injury. Where as, following open cholecystectomy, post

operative wound infection was the most common complication, followed by post operative bile leakage. Complication rate among both study groups was similar but, intra operative morbidity and severity of complications was more in laparoscopic cholecystectomy. Most of the complications were managed with conservative approach with antibiotics and close monitoring. While few required post operative endoscopic sphincterotomy and biliary stenting.

- 8) Mean duration of hospital stay for laparoscopic cholecystectomy is 4.42 days; while in open cholecystectomy it is 6.61 days.

Thus identifying preoperative variables predicting complications and conversion to open surgery improves patient counselling, planning of convalescence, and post operative expectations. In addition, the surgeon can appropriately predict intra operative difficulties related to complications and accordingly managing the surgical procedure to minimize the morbidity.

There was no significant difference in the incidence of complications in open cholecystectomy and laparoscopic cholecystectomy. Thus the post-operative outcome of patients operated for gall stone disease, depends more on the severity of the disease than on the type of the surgical procedure. In gall stone disease management, either acute or chronic condition, post-operative morbidity, mortality and hospital stay were reduced by laparoscopic cholecystectomy, hence post operative outcome was good in our study with laparoscopic cholecystectomy group .

Moreover pneumonia and wound infection rate were reduced. But the bile duct injuries were higher and the operation time was longer in elective laparoscopic cholecystectomy. This can be justified with learning curve in teaching institute.

According to our study, male sex, obesity, thickness of gall bladder wall more than 3 mm,

acute cholecystitis and instrumentation failure may be regarded as predictors of complications.

#### **Factors responsible for complications**

- Physical status of the patient,
- Degree of inflammation/ severity of disease,
- Pathology of gallbladder disease (e.g. thickness of gallbladder wall),
- Obesity,
- Co morbid conditions like diabetes mellitus, hypertension, asthma,
- Anatomical variations,
- Improper Surgical technique,
- Insufficient Surgical experience.

#### **Operative guidelines to be followed**

- Obese patients and patient with acute gall bladder disease with preoperative gallbladder ultrasonography for symptomatic cholecystitis, with a thick gallbladder wall (> or =3 mm) can be still considered as risk factors for operative complications.
- To avoid Cystic Duct Leaks, it is important to place clips accurately and avoid electro cautery in the vicinity of the cystic duct.
- Proper identification of anatomical variations is of prime important.
- Intra operative cholangiogram should be considered in, where-ever available, to delineate the biliary structure.
- Cholecystectomy in acute cholecystitis should be attempted laparoscopically first within 72 hrs of presentation, as if required it can be converted into open cholecystectomy.
- Conversion should be opted for in the beginning and at the time of recognition of a difficult dissection rather than after the occurrence of complication.
- Conversion from laparoscopic to open procedure should not be considered a complication but rather a reflection of sound surgical judgement in difficult case.

- Abdominal drain should be placed where ever suspicion of biliary tree injury is considered. It helps for drainage and early post operative clinical diagnosis.
- Early post operative ERCP and endoscopic sphincterotomy with biliary stenting prevents the morbidity of re-exploration and minimizes the hospital stay.

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