

## Original Research Article

# Assessment of immediate postoperative complications in patients undergoing elective laparoscopic cholecystectomy for symptomatic cholelithiasis with pre-existing co-morbid conditions

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### ABSTRACT

**Background:** Elective laparoscopic cholecystectomy done by experienced surgeon continues to be a vary safe operation however from surgical point of view, presence of co-existing clinical conditions offer independent complication risk but the influence of these clinical conditions such , diabetes, hypertension, respiratory etc. has not been emphasized enough. This study is an effort to determine the influence of co-existing clinical conditions on morbidity and mortality following laparoscopic cholecystectomy.

**Methods:** This prospective observational study was conducted over a period of 1.8 years from August 2017 to April 2019. On the basis of selection criteria patients with symptomatic cholelithiasis were divided into two groups cases and control group. The evaluation of morbidity was done in terms of any wound infection, chest infection, cardiac complications, cholangitis, deep vein thrombosis, septicemia, etc.

**Results:** Distribution of complications was comparable between cases and controls. (Nil: 90% versus 92.50% respectively. Proportion of patients with complications was significantly lower in patients without history of previous attack as compared to with history of previous attack. Distribution of complications were comparable between diabetic and non-diabetic.

**Conclusions:** The presence of co- morbid conditions in the form of diabetes mellitus and hypertension does not increase the risk of immediate post operative complications. However, history of previous attack of acute cholecystitis can increased chances of intra-operative adhesions around calots triangle prolonging the duration of surgery which in turn can increase the risk of post operative complications.

**Keywords:** Coexistent conditions, Outcome of laparoscopic cholecystectomy, Diabetes and laparoscopic cholecystectomy

### INTRODUCTION

Gall bladder diseases adds burden to health care system it also contributors majorly to morbidity and about 10-15% of population in western population suffers from gall stones.<sup>1</sup> The patients of cholelithiasis have tendency to develop a wide variety of complication is well known.

Because of the complication associated with symptomatic cholelithiasis, cholecystectomy is now a frequently performed abdominal operation

The realisation of significance of gallstone, increasing use of USG and availability of good operating room facility have all contributed to large number of

cholecystectomy being performed today. Laparoscopic cholecystectomy offers safe and effective treatment for symptomatic gall stone disease patients. Its advantage includes early return to bowel function, less postoperative pain, cosmetically better scar, shorter length of stay, early return to full activity.<sup>2</sup>

Numerous reports in literature, confirms that cholecystectomy continues to be a very safe operation that can be performed with very low mortality.<sup>3</sup> Careful pre-operative evaluation of the patients, modern anaesthesia, improved operative technique and better postoperative care have contributed a lot to the low mortality and morbidity rates associated with operative procedures. However, a spectrum of varied factors may increase the morbidity and mortality rates. Since the incidence of gall bladder stones increases with advancing age and varied number of clinical condition may coexist with the gall stone disease such as diabetes mellitus, hypertension, cardiac, respiratory and renal disorders, etc. Many factors have been associated with increase postoperative morbidity and mortality. Turrill et al long back report-ed a strong correlation of increasing age and diabetes mellitus with high morbidity rates among patients with gall bladder disease.<sup>4</sup> However, the conclusions of Turrill et al contrasted sharply with those of Haff et al. they unable to demonstrate any age related increase in morbidity or mortality rate in patients with biliary tract disease, they also determined that the presence of diabetes mellitus alone didn't alter risk in their patient population.<sup>5</sup>

However reports from various authors confirms that cholecystectomy continues to be a vary safe operation that can be performed with near zero mortality, however from surgical point of view, diabetes is a risk factor for gall stone formation and complications.<sup>6</sup> Likewise other co-existing clinical conditions offer independent complication risk but the influence of the presence of co-existent clinical conditions such, diabetes, hypertension, respiratory etc. disorder has not been emphasized enough. This study is an effort to determine the influence of co-existing clinical conditions on morbidity and mortality following laparoscopic cholecystectomy.

## METHODS

This prospective observational study was conducted in VMMC and Safdarjung hospital, New Delhi over a period of 1.8 years from August 2017 to April 2019. The aim of the study is to know importance of co-existent clinical conditions diagnosed preoperatively and their influence on immediate postoperative morbidity.

### Inclusion criteria

Patient aged above 18 years and below 65 years undergoing elective laparoscopic cholecystectomy with confirmed co morbidities were included. While otherwise healthy individuals were included in control group.

### Exclusion criteria

All those patients- undergoing emergency cholecystectomy, acute cholecystitis, pregnancy, morbid obese patients, patients undergoing open cholecystectomy.

### Sample size

The study of Stinton, et al observed that prevalence of gallstones was 10-15%.<sup>7</sup> Taking this value as reference, the minimum required sample size with 8% margin of error and 5% level of significance is 77 patients. To reduce margin of error, total sample size taken is 80 with 1:1 ratio for cases and controls. (40 cases and 40 controls)

Formula used is:

$$N = (p(1 - p)) \div (ME \div Z\alpha)^2$$

Where  $Z\alpha$  is value of Z at two sided alpha error of 5%, ME is margin of error and p is prevalence rate.

### Calculations

Prevalence rate as 10%

$$n \geq ((0.1 \times (1 - 0.1)) \div (0.08 \div 1.96))^2 = 54.02 = 55 \text{ (approximately)}$$

Prevalence rate as 15%

$$n \geq ((0.15 \times (1 - 0.15)) \div (0.08 \div 1.96))^2 = 76.53 = 77 \text{ (approximately)}$$

A total of 80 patients undergoing elective laparoscopic cholecystectomy were divided in two groups of 40 each as patients with co morbidities (case group) and without co morbidities (control group). An ethical clearance sought and then a written informed consent is taken from all the patients. Detailed history was followed by meticulous physical examination. Biochemical analysis and blood chemistry was done like a routine preoperative protocol. Every patient under-went complete abdominal ultrasonographic examination, which was done to confirm diagnosis along with the evidence of (if any) additional intra-abdominal pathology. All patients were asked about the history previous attack of pain abdomen due to acute cholecystitis requiring hospital admission and the same is noted in study proforma

Co-existent conditions included are: The diagnosis of diabetes mellitus was made for patients with persistently elevated levels of blood sugar or glucosuria and for those with an abnormal 2-hour post prandial glucose level (those having fasting serum glucose level > 126 mg/dl or more and random serum glucose level 200 mg/dl or more).<sup>8,9</sup> This group included patients with newly

discovered diabetes and long term diabetic patients. The diagnosis of chronic renal disease was made for patients with two or more serum creatinine levels in excess of 1.5 mg/dl. Postoperative renal dysfunction was defined by similar criteria. The diagnosis of arteriosclerotic heart disease was determined by verified history of coronary occlusion, a history of coronary artery reconstruction, a previous myocardial infarction documented electrocardiographically, a current electrocardiographic evidence of myocardial ischemia, and a history or clinical evidence of cardiac decompensation requiring digitalis. The diagnosis of hypertensive cardiovascular disease was made if systolic and diastolic blood pressures were repeatedly in excess of 140 and/or more than or equal to 90 mmHg respectively.<sup>10</sup> The patient who were taking antihypertensive medication also included.

Patients with co-existent clinical conditions were optimally investigated, treated and then subjected to surgery. Standard conventional four port laparoscopic cholecystectomy is done by one surgeon. All wounds were closed with simple suture using monocryl.

Operative findings including duration of surgery, adhesions at calots triangle any intraoperative event or complications were recorded in proforma.

Early mobilization, post-operatively was encouraged. Patients were kept on intravenous fluids and similar spectrum of antibiotics therapy usually (third generation cephalosporin) and analgesic given to patient. All patients were allowed orally once gut motility returns. The postoperative complications included are: wound infection; evaluated by standard techniques. Wound was considered infected if there was drainage of purulent material from wound regardless of microbiological findings or if non-purulent discharge with positive microbiologic findings. Chest infection; purulent sputum with typical auscultation signs with or without microbiological confirmation was accepted as indicating chest infection. Cardiovascular problem included myocardial infarction (based upon ECG and/or enzyme changes), congestive cardiac failure or new and

significant arrhythmia which required treatment or monitoring in postoperative period. The postoperative complications were monitored each day before discharge and again 15 day and one month after discharge in surgical Outpatient department.

The evaluation of morbidity was done by assessing any wound infection, chest infection, cardiac complications, cholangitis, deep vein thrombosis, septicemia, etc. The outcome of the patients were recorded in a proforma which was filled by the operating surgeon.

### Statistical analysis

The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means±SD and as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using Kolmogorov-Smirnov test. The cases in which the data was not normal, we used non parametric tests. The following statistical tests were applied for the results: the comparison of the variables which were quantitative and not normally distributed in nature were analysed using Mann-Whitney Test (for two groups), the comparison of the variables which were qualitative in nature were analysed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used. The data entry was done in the Microsoft excel spreadsheet and the final analysis was done with the use of Statistical package for social sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0. For statistical significance, p value of less than 0.05 was considered statistically significant.

## RESULTS

In this study on the basis of selection criteria two study groups were defined with 40 patients in each arm, patients with co-morbidities (cases) in one arm and patient without co-morbidities (control) in another arm.

**Table 1: Comparison of socio-demographic characteristics between cases and controls.**

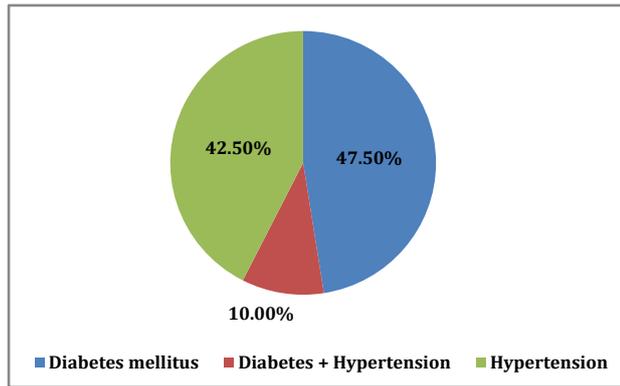
Socio-demographic characteristics	Cases (n=40)	Controls (n=40)	Total	P value
<b>Age (years)</b>				
Mean±SD	49.78±8.26	43.05±7.72	46.41±8.63	
Median (25th-75th percentile)	51(41-55)	41.5(38-50.25)	45.5(39-54.25)	0.0007*
Range	34-63	30-59	30-63	
<b>Gender</b>				
Female	29 (72.50%)	29 (72.50%)	58 (72.50%)	1‡
Male	11 (27.50%)	11 (27.50%)	22 (27.50%)	
<b>History of previous attack</b>				
Absent	15 (37.50%)	19 (47.50%)	34 (42.50%)	0.366‡
Present	25 (62.50%)	21 (52.50%)	46 (57.50%)	

\*Mann Whitney test, ‡ Chi square test

**Table 2: Comparison of complications between cases and controls.**

Complications	Cases n=40 (%)	Controls n=40 (%)	Total (%)	P value
Nil	36 (90)	37 (92.50)	73 (91.25)	1†
Wound infection	4 (10)	3 (7.50)	7 (8.75)	
<b>Total</b>	40 (100)	40 (100)	80 (100)	

† Fisher's exact test



**Figure 1: Distribution of co-morbidity in cases.**

Table 1 shows the comparison of socio-demographic characteristics between cases and controls. The median (25th-75th percentile) of age (years) in cases was 51 (41-55) which was significantly higher as compared to controls (41.5 (38-50.25)). (p=0.001). Distribution of

gender was comparable between cases and controls. (Female: 72.50% versus 72.50% respectively, Male: 27.50% versus 27.50% respectively) (p=1). Distribution of history of previous attack was comparable between cases and controls. (Absent: 37.50% versus 47.50% respectively, Present: 62.50% versus 52.50% respectively) (p=0.366).

Figure 1 shows distribution of co morbidity in cases. In present study, in majority (47.50%) of patients, co-morbidity was diabetes mellitus followed by hypertension (42.50%). Co-morbidity was Diabetes + Hypertension in only 4 out of 40 patients (10.00%).

All patient underwent laparoscopic cholecystectomy none of the patient required conversion to open cholecystectomy.

Distribution of presence of adhesions at calots triangle was comparable between cases and controls. (No adhesion: 57.50% versus 50% respectively, Adhesions: 42.50% versus 50% respectively) (p=0.501). Median (25th-75th percentile) of duration of surgery (minutes) in cases was 41 (35-62.25) and controls was 55 (37.75-78) with no significant difference between them (p=0.283).

Table 2 depicts the comparison of complications between cases and control. Distribution of complications was comparable between cases and controls. (Nil: 90% versus 92.50% respectively, wound infection: 10% versus 7.50% respectively) (p=1). Wound infection is the most common complication observed. However, all these were minor wound infections. There was no mortality in this study.

**Table 3: Association of complications with presence of adhesions.**

Complications	Cases (n=40) (%)	Controls (n=40) (%)	Total (%)	P value
Nil	36 (90)	37 (92.50)	73 (91.25)	1†
Wound infection	4 (10)	3 (7.50)	7 (8.75)	
<b>Total</b>	40 (100)	40 (100)	80 (100)	

† Fisher's exact test

**Table 4: Association of complications with history of previous attack.**

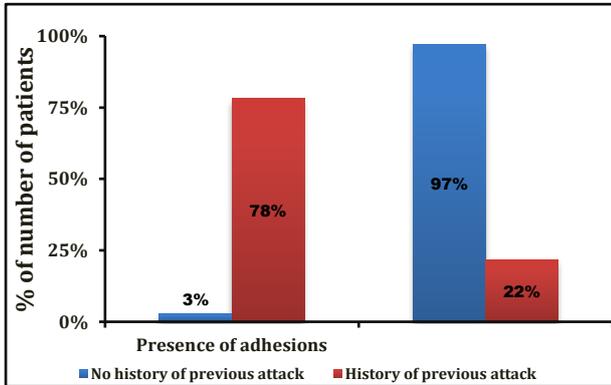
Complications	No history of previous attack (n=34) (%)	History of previous attack(n=46) (%)	Total (%)	P value
Nil	34 (100)	39 (84.78)	73 (91.25)	0.019†
Wound infection	0 (0)	7 (15.22)	7 (8.75)	
<b>Total</b>	34 (100)	46 (100)	80 (100)	

† Fisher's exact test

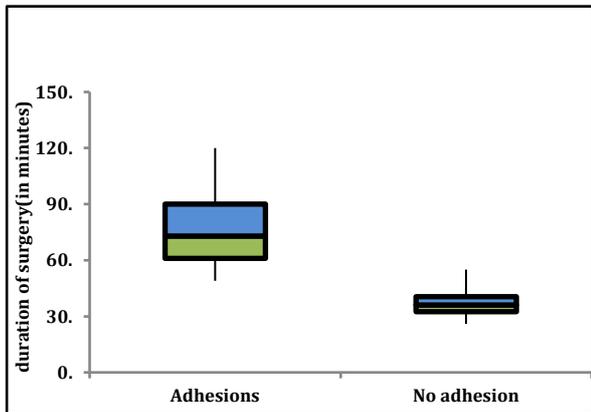
**Table 5: Association of duration of surgery (in minutes) with complications.**

Duration of surgery (in minutes)	No complications (n=73) (%)	Wound infection (n=7) (%)	Total (%)	P value
Mean±SD	52.42±22.14	82.29±22.97	55.04±23.64	0.003*
Median (25th-75th percentile)	41 (35-63)	79 (64.5-96)	47.5 (35-69.25)	
Range	26-120	56-120	26-120	

Distribution of complications was comparable between diabetic and non-diabetic. (Nil: 91.30% versus 91.23% respectively, wound infection: 8.70% versus 8.77% respectively) (p=1).



**Figure 2: Association of presence of adhesions with history of previous attack.**



**Figure 3: Association of duration of surgery with adhesions.**

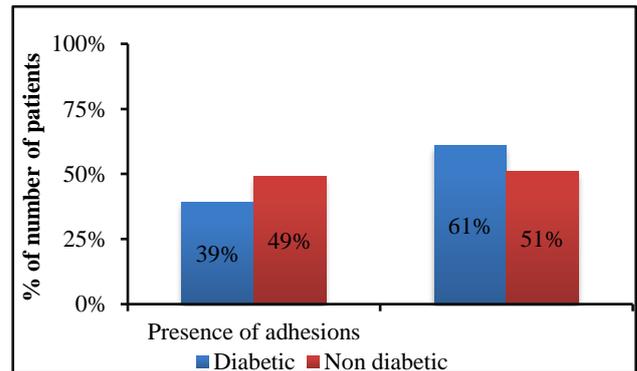
Table 3 shows association of complications with presence of adhesions. The proportion of patients with complications was significantly higher in patients with adhesions as compared to patients without adhesion. (wound infection: 18.92% versus 0% respectively). (p=0.003).

Table 4 shows association of complications with history of previous attack. The proportion of patients with complications, wound infection was significantly lower in patients without history of previous attack as compared to with history of previous attack. (Wound infection: 0% versus 15.22% respectively). (p=0.019).

Table 5 depicts association of duration of surgery (in minutes) with complications. The median (25th-75th percentile) of duration of surgery (in minutes) in patients with wound infection was 79(64.5-96) which was significantly higher as compared to patients without complications (41(35-63)). (p=0.003).

Figure 2 shows association of presence of adhesions with history of previous attack. The proportion of patients with presence of adhesions was significantly lower in patients without history of previous attack as compared to with history of previous attack. (adhesions:- 2.94% versus 78.26% respectively ). (p<0.0001).

Figure 3 shows association of duration of surgery (in minutes) with adhesion. The median (25th-75th percentile) of du-ration of surgery (in minutes) in patients with adhesions was 73 (61-90) which was significantly higher as compared to patients without adhesion (36(32.5-40.5)). (p<0.0001).



**Figure 4: Association of presence of adhesions with diabetes.**

Figure 4 shows association of presence of adhesions with diabetes. The distribution of presence of adhesions was com-parable in diabetic and non-diabetic. (39.13% versus 49.12% respectively) (p=0.417).

**DISCUSSION**

Out of the eighty patients undergoing elective laparoscopic cholecystectomy 72.5% were females while 27.5% were males comparable to results in previous studies.<sup>11</sup> Mean age of the patient was 46.41±8.63 years with range of 30-63 years. History of previous attack of cholecystitis was present in 46% of the total number of patients. Of total 40 patients majority 19 (47.5%) were having diabetes mellitus alone as the co-morbidity while 4 (10%) of the patients had both diabetes and hypertension together, and 17 (42.5%) of patient had hypertension alone as the co- morbidity, these findings are consistent with studies done in past.<sup>12</sup> Out of total 80 patients, 7 (8.75%) developed wound infection and wound infection is the only complication noted in this study and distribution of complication is comparable in case and control group these results were also consistent with previous studies.<sup>13</sup> Similar to the observation by Al Mulhim et al this study also found no significant association of complication with diabetes mellitus, as only 2 (8.70%) diabetics in comparison to 5 (8.77%) in non-diabetics developed complication. Intraoperatively 37 (46.25%) found to have adhesions present around calots triangle, distribution of adhesions were found to be

comparable between cases and control group and also distribution of adhesions was comparable in diabetics and non-diabetics. However the incidence of complication is more in patients who had intraoperative adhesions 7 (18.92%) in comparison to 0 (0%) without adhesions and this association is found to be statistically significant the same result are also shown in study done by Chen et al.<sup>14</sup> However 36 (78.26%) of the patient who had adhesions found to have history of previous attack of acute cholecystitis present and this association was found to be statistically significant. The mean duration of surgery in cases was 51.95±22.36 minutes and 58.12±24.75 minutes in control group hence the mean duration of surgery found to be comparable between cases and control group, which is not statistically significant. Intraoperative adhesions around Calot's triangle is one of the predictor of difficult cholecystectomy prolonging duration surgery.<sup>15</sup> In our study also duration of surgery found to get prolonged in patients with adhesions 75.95±18.48 minutes in patients with adhesions and 37.05±6.51 minutes in patients without adhesions and in our study complications are found to be more in patients with increased duration of surgery as median of duration of surgery (in minutes) in patients with wound infection was 79 (64.5-96) which was significantly higher as compared to patients without complications 41 (35-63).

However, there is a need of more studies with larger sample sizes. If these studies can reduce confounding factors, they can help in confirming the results of this study and also in validation.

## CONCLUSION

On the basis of this study we conclude that elective laparoscopic cholecystectomy by experienced surgeon is a safe option for patients with symptomatic cholelithiasis in terms of immediate postoperative morbidity. The presence of co-morbid conditions in the form of diabetes mellitus and hypertension if are properly controlled does not increase the risk of immediate post-operative complications. However, history of previous attack of acute cholecystitis can increase chances of intraoperative adhesions around Calot's triangle prolonging the duration of surgery which in turn can increase the risk of post-operative complications.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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