

COMPARISON OF OPEN CHOLECYSTECTOMY WITH LAPAROSCOPIC CHOLECYSTECTOMY USING LATEST VARIABLES OF PULMONARY FUNCTIONS AS PARAMETERS

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ABSTRACT

Objectives: To compare open cholecystectomy with laparoscopic cholecystectomy using latest variables of pulmonary functions as parameters.

Study Design: Randomized controlled trial.

Place and Duration of Study: Department of Surgery, CMH Rawalpindi from May 2010 to Nov 2010.

Patients and Methods: Patients with symptomatic cholelithiasis subjected to elective cholecystectomy were studied. The patients were divided into two groups. Open Cholecystectomy was performed on patients in group I, and laparoscopic cholecystectomy was performed in patients in group II. Respiratory function tests were performed preoperatively and on the morning of the 1st post-operative day.

Results: Preoperative pulmonary function tests were normal and did not differ significantly between the two groups. After operation a significant reduction in the FEV1 (Forced Expiratory Volume in first second), FEV6 (Forced expiratory volume in first six seconds) and their ratio FEV1/FEV6 occurred after both open and laparoscopic cholecystectomy. However, mean reductions in FEV1, FEV6 and FEV1/FEV6 in the laparoscopic cholecystectomy group were significantly ($p < 0.05$) less as compared with those after open cholecystectomy.

Conclusion: Laparoscopic cholecystectomy causes less impairment of lung function than cholecystectomy performed through a subcostal incision.

Keywords: Laparoscopic cholecystectomy, Open cholecystectomy, Randomized controlled trial, Spirometry.

INTRODUCTION

All types of abdominal surgeries result in impairment of pulmonary functions in the immediate post-operative period. The reduction in pulmonary functions may lead to closing capacity impinging upon the tidal breathing range. This results in closure of small airway during normal tidal ventilation. Gas trapping occurs in the affected airways and subsequent absorption of air may lead to the development of small, discrete areas of atelectasis¹. Spirometry is the most widely used pulmonary function test¹ available to measure such impairments. The values of different parameters used in spirometry vary according to age, height and gender². The procedure related postoperative pulmonary

complications depend on the site and size of surgical trauma³. Risk of postoperative pulmonary complications increase as the incision approaches the diaphragm³.

Gall stone disease is a major health problem worldwide⁴. Cholecystectomy is the treatment of choice for symptomatic gall stones and is the most common operation of the biliary tract and the second most common operative procedure performed today⁴. The surgical management of gallstones has been revolutionized after the advent of laparoscopic cholecystectomy in 1985⁵. This technique has virtually become the gold standard in the management of cholecystitis/symptomatic cholelithiasis^{6,7}.

Open cholecystectomy performed through a subcostal incision might be associated with significant alterations in pulmonary functions. A restrictive breathing pattern with reduced inspiratory capacity is evident immediately after surgery⁸. Although the etiology of pulmonary dysfunction after upper abdominal surgery is not

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completely elucidated but post-operative pain and diaphragmatic dysfunctions are considered to be the major contributing factors^{8,9}.

This study is designed to compare open cholecystectomy with laparoscopic cholecystectomy using latest variables of pulmonary functions like FEV6 and FEV1/FEV6 as parameters. Therefore, this study is unique and first of its kind which would compare both types of gall bladder surgeries using the new variables. We hope that this study would encourage new research into the topic and therefore, would benefit both the patients and doctors around the world.

PATIENTS AND METHODS

Design of the study was "Randomized Control Trial" and was conducted at CMH Rawalpindi from May 2010 to Nov 2010. A total of 113 patients were finally studied which were divided into two groups. Sample size was calculated using Open Epi sample size calculator version 2.3. The level of significance was kept at 5% and the power of the study 90%. The values of mean and standard deviation for the variable (FEV1) in both the groups were selected from a previous study¹². As there was no study found in the literature which compared FEV6, therefore to calculate the sample size, another study comparing FEV1/FVC (Forced Vital Capacity) was selected¹².

All patients of both genders with symptomatic cholelithiasis, undergoing elective cholecystectomy from May 2010 to Nov 2010 were considered for entry in the study. Exclusion criteria included patients of acute cholecystitis and choledocholithiasis, patients with a history of previous pulmonary disease or any thoracic cage deformity, patients with previous history of thoracic or abdominal surgery, patients smoking more than 10 cigarettes per day and patients with age less than 15 years or more than 75 years. A second stage exclusion was planned for all those patients who developed complications during or after surgery.

Required numbers of patients from surgical out patient department at CMH Rawalpindi were

selected after permission from concerned authorities and Hospital Ethical Committee, and informed written consent was taken. Hospital registration number, date of admission, name, age, gender, height, weight and body mass index (BMI) was noted on the designed performa.

Patients were divided randomly in two groups using coin toss method. Group I included patients undergoing open cholecystectomy (OC) and group II included patients undergoing laparoscopic cholecystectomy (LC).

Anaesthetic technique was standardized for each group using multimodal analgesia and induction with Propofol and muscle relaxation with Atacurium. All operations were performed in the morning after an overnight fast and by a classified surgical specialist. Open cholecystectomy was performed through a transverse right sub-costal incision, 10 to 12 cm long with transection of the ipsilateral rectus abdominis muscle and in a classic antegrade manner. Laparoscopic cholecystectomy was performed via a standard four trocar technique, pneumoperitoneum was established with carbon dioxide insufflation and intra abdominal pressure was maintained at 12 to 14 mmHg. Both the procedures were done according to the recommended protocols.

Post-operative analgesia was also standardized for both the groups. To rule out any chance of post-operative pain interfering with the spirometry results patients were administered diclofenac sodium, 75 mg I/M 12 hourly and nalbuphine 5 mg I/V 12 hourly as analgesia for the first two days after surgery. Patients were kept in post-operative surgical wards after surgery.

Patients were taught technique of spirometry pre-operatively. Pre-operatively, all measurements were made with the patients in the sitting position with legs hanging down the right side of the bed. The tests were performed by a hand held electronic spirometer; "KoKo Peak Pro 6" (product code PDS 343110), manufactured by Ferraris Respiratory. (Fig-1). It electronically measures PEF, FEV1, FEV6 and FEV1/FEV6 ratio and its results are accurate and comparable with

standard spirometry¹⁰. It has a washable and reusable mouthpiece. Its windows based software allows patients data to be downloaded to a PC.

compare FEV1, FEV6, FEV1/FEV6 ratio pre and post-operative in both the groups. p value < 0.05 was considered to be as significant.

Table-1: Demographic features of the patients undergoing open and laparoscopic holecystectomy.

	Open Cholecystectomy (n=54)	Laparoscopic Cholecystectomy (n= 59)
Sex Ratio (M/F)	16/38	12/47
Age (years) *	46 (25-70)	47 (15-75)
Weight (kg) *	67.6 (53-88)	70 (48-93)
Height (m) *	1.63 (1.52-1.8)	1.63 (1.52-1.83)
BMI (kg/m ²) **	25.45 + 2.90	26.37 + 3.27

*Values given as mean (range), **Value given as mean +SD

Table-2: Comparison of Pulmonary Function tests Pre-operative and on first Post-operative day.

Parameters	Open Cholecystectomy (n=54)		Laparoscopic Cholecystectomy (n= 59)	
	Pre-operative	Post-op day 1	Pre-operative	Post-op day 1
FEV1 (Liter)	2.01 + 0.51	1.01 + 0.24*	1.99 + 0.69	1.35 + 0.57*
FEV6 (Liter)	2.41 + 0.62	1.22 + 0.28*	2.41 + 0.81	1.62 + 0.67*
FEV1/ FEV6 (%)	0.83 + 0.02	0.82 + 0.05)	0.82 + 0.03	0.83 + 0.05

* p < 0.05 compared with preoperative values (paired t test)

Table-3: Post operative changes in pulmonary function variables after Open Cholecystectomy and Laparoscopic Cholecystectomy.

Variable	Perioperative Change (Open Cholecystectomy)	Perioperative Change (Lap Cholecystectomy)
FEV1 (Liter)	-1.00 + 0.37 Ω	-0.64 + 0.26*
FEV6 (Liter)	-1.19 + 0.47 Ω	-0.78 + 0.30*
FEV1/ FEV6 (%)	-0.009 + 0.06	0.012 + 0.05

* p < 0.05 between groups (t-test)

All data with date and time stamped was presented in graphical or tabular format. Post-operative pulmonary function tests were carried out in both groups of patients in the post-operative ward on the morning of the first post operative day in the same position. FEV1/FEV6 ratio was calculated both pre and post operatively. To avoid technical errors both on the part of operator and patient's effort, multiple values were taken on each patient and the best values recorded were kept for study purpose.

Data analysis procedure:

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 16. All data was summarized as mean. Descriptive Statistics are provided for all variables. Quantitative data which includes age, FEV1, FEV6, FEV1/FEV6 ratio and BMI is presented as Mean \pm SD. Categorical data which includes gender is presented as frequency/ percentages. Paired sample t - test was used to

RESULTS

During the study period, all the patients fulfilling the inclusion criteria were admitted for elective cholecystectomy and were considered for the study. Informed consent for randomization was obtained from all the patients who agreed to participate in the study. Twenty six patients refused to participate in the study due to refusal to undergo open cholecystectomy. Following patients had to be excluded from the study:

- All those patients in whom pulmonary functions could not be recorded or were incompletely recorded.
- Patients in the laparoscopy group, which required conversion to open procedure due to difficulty in defining anatomy.
- All those patients in whom any iatrogenic injury or any complication of the surgery took place.

- d. Those patients who were scheduled for cholecystectomy but underwent any other procedure like common bile duct exploration.
- e. Those patients in whom pre-operative pulmonary functions revealed any form of COPD.
- f. Patients with BMI more than 30 kg/m².

All those patients in whom more analgesia was required than the standardized analgesia set for the study process.

Of the 120 cases inducted into the study 113 patients completed the study: 59 patients underwent laparoscopic and 54 open cholecystectomy. Of the 7 excluded patients 3 were dropped out because more analgesia had to be administered for their pain relief. Four patients had bile leak during the procedure and were excluded. Patient groups were almost similar with respect to age, height, and weight. The final demographic features of the patients of both groups are shown in Table-1.

Preoperative pulmonary function tests were normal and did not differ significantly between the two groups (Table-2). After operation a significant reduction in the FEV1, FEV6 and FEV1/FEV6 occurred after both open and laparoscopic cholecystectomy. However, mean reductions in FEV1, FEV6 and FEV1/FEV6 after laparoscopic cholecystectomy were significantly ($p < 0.05$) less as compared with those after open cholecystectomy. (Table- 3 and Table- 4).

DISCUSSION

Postoperative complications are very important in evaluating a surgical technique. Pulmonary complications are common and one of the leading causes of morbidity after major abdominal surgeries. General anesthesia has an important role in pulmonary complications and deterioration in pulmonary functions is directly related to time of anesthesia^{11,12}. Other factors which causes pulmonary function impairment in the post-operative period are types of surgery, type of incision, cutting of abdominal wall musculature and post-operative pain¹⁵.

A significant decrease in FEV1 and O2 saturation is observed in obese and morbidly obese patients. High BMI has a negative effect on respiration in both methods¹⁴. Therefore, in our study all those patients who had a BMI of more than 30 were excluded from the research process. A separate study on effect on pulmonary functions with raising BMI can be undertaken.

When this study was initially designed, it was thought that the pulmonary functions would be assessed by using the same parameters of FEV1 and FVC as already described by a number of authors, the so called "Tiffeneau Index". During the research process the upcoming importance of FEV6 was read about. It was noticed that this parameter is the latest and there was no study available which compared laparoscopic and open cholecystectomy using this parameter.

As we proceeded with the study, some ethical problems arose. The obvious advantages of laparoscopic cholecystectomy over open cholecystectomy resulted in high motivation among patients to undergo only laparoscopic cholecystectomy. This resulted in non acceptance to consent to the study. The highest rate of non-acceptance to open cholecystectomy was seen in the last two months of the study. Men were more readily willing to participate in the open cholecystectomy group and thus in the study. This fact can be easily observed in the relatively higher male to female ratio in our study.

After exclusion of the patients from our study sample it was observed that we needed more patients to complete our sample size of 120. Therefore, one more month was increased for the research process making the study span on 7 months time rather than the 6 months as initially planned.

To our knowledge there has been no other randomized study comparing pulmonary functions after laparoscopic and open cholecystectomy using FEV6 as a variable. Results from this study indicate that considerable impairment of pulmonary function occurred both after open and laparoscopic cholecystectomy. However mean reductions in FEV1 and FEV6

after laparoscopic cholecystectomy 13 were significantly ($p < 0.05$) smaller as compared with those after open cholecystectomy. FEV1/FEV6 ratio was just minimally changed in both groups and was not significant. Data summarized in Table- 2 and Table- 3.

CONCLUSION

Results of this study demonstrate that LC is essentially a superior procedure as compared to open cholecystectomy as far as the post-operative pulmonary functions are concerned. It is suggested that upper abdominal incisions affect pulmonary functions more than laparoscopic surgery. This can be attributed to postoperative pain and diaphragm dysfunction. Laparoscopy causes less damage to abdominal wall and less post-operative pain. The changes in ventilation mechanics and deterioration in postoperative oxygenation are reduced which leads to decrease in pulmonary complications.

Conflict of Interest

This study has no conflict of interest to declare by any author.

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