Section: General Surgery

Original Research Article

THE FEASIBILITY OF PERFORMING SAFE LAPAROSCOPIC CHOLECYSTECTOMY USING LOW PERITONEAL PRESSURE

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Received : *14/01/2023*
Received in revised form : *20/02/2023*
Accepted : *05/03/2023*

Keywords:
Low Pressure Pneumoperitoneum, Standard Pressure Pneumoperitoneum, Laparoscopic Cholecystectomy.

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DOI: 10.47009/jamp.2023.5.2.190

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (2); 895-899

Abstract

Background: A Laparoscopic cholecystectomy as called lap cholecystectomy is a common but major surgery with serious risk and potential complications. Laparoscopic surgeries have attended the status of a gold standard for most of abdominal pathology; we therefore performed this study to assess the feasibility and safety of major laparoscopic surgeries similar to laparoscopic cholecystectomy (LC). Laparoscopic cholecystectomy (LC) at pnemoperitoneum (PP) pressures of 12-15 mm Hg is established for symptomatic gallstones. Metabolic and cardiopulmonary concerns and, pain may be minimized by low pressure PP. **Materials and Methods:** This prospective, randomized and triple blended observational study was done in Department of Surgery in a Tertiary care Hospital. The study duration was 12 months from February 2021 to January 2022. A total of 80 patients were included, who fulfilled the inclusion criteria and who gave consent to participate in the study. **Result:** Total Eighty patients of symptomatic gallstone disease planned for laparoscopic cholecystectomy were included in the study. After randomization, there were 40 patients in both groups, i.e. group 1 (LPLC or 8 mm Hg group), and, group 2 (SPLC or 12 mm Hg group). In group 1 the ratio of male and female is 33:7 and in group 2 the ratio of the male and female is 36:4. Both groups were similar with respect to age, sex and BMI. There were no associated co-morbidities in any of the patients. **Conclusion:** Laparoscopic surgeries with low pressure CO2 pneumoperitoneum are feasible and safe under. Laparoscopic cholecystectomy is feasible and safe at 8 mmHg pressure with slight modification of technique, and is associated with less pain compared to surgery at 12 mmHg. Studies with compromised cardiopulmonary or hepatic reserve are required to better quantify the benefits.

INTRODUCTION

Laparoscopic cholecystectomy (LC) has been established as the gold standard for the treatment of uncomplicated symptomatic gallstone. Creation of pneumoperitoneum (PP) by carbon dioxide (CO_2) insufflations is the most widely accepted technique for adequate working space and patient safety.[1-3] The standard pressure for PP lies between 12-15 mm Hg; however, decreased pulmonary compliance, altered blood gas parameters, decrease in cardiac output, impaired renal perfusion and raised liver enzymes have been observed at these pressures.[4-6] These effects may be explained by decrease in renal, hepato-portal and splanchnic blood flows, along with impairment of venous return during PP. Several studies have compared the effects of reduced pressure (7-9 mm Hg) with standard pressure (12-15 mm Hg) during LC.[7-11] These studies illustrate the feasibility of low pressure PP, along with some advantages in terms of postoperative pain. However, it is still unclear whether changes in metabolic and physiologic parameters viz. liver function tests and cardiopulmonary parameters, have any clinical significance.[11] The present study was designed to compare low pressure and standard pressure pneumoperitoneum used during LC in terms of intra-operative parameters (cardiopulmonary, metabolic), operative difficulty, postoperative pain, consumption of analgesics and liver profile derangement

MATERIALS AND METHODS

This study was a prospective, randomized, triple blinded trial conducted in a tertiary care Hospital. The study was undertaken after approval by the institutional ethics committee, and after obtaining informed written consent from all the subjects. For the purpose of the study, low-pressure pneumoperitoneum laparoscopic cholecystectomy (LPLC) was denoted when insufflations pressure was kept at 8 mmHg; and high-pressure pneumoperitoneum laparoscopic cholecystectomy (HPLC) when insufflations pressure was kept at 12 mmHg after the introduction of all four ports. Patients with a diagnosis of symptomatic uncomplicated gallstone disease, scheduled for elective laparoscopic cholecystectomy were enrolled in the study. Patients with deranged liver function tests (including serum alkaline phosphatase), history of chronic liver disease or liver malignancy, history of chronic alcohol intake, history of jaundice, cardiopulmonary disease, morbid obesity, choledocholithiasis, biliary obstruction, cholangitis, carcinoma gallbladder, a recent (< 3 weeks)or ongoing episode of acute gallstone pancreatitis or acute cholecystitis, ongoing pregnancy, bleeding diathesis, or upper abdominal surgical scars were excluded from the study. After admission, the following information was recorded on the case record form – age, sex, weight, height, body mass index (BMI), pre-operative ultrasound findings (wall thickness, pericholecystic fluid, common duct anatomy and diameter, and number of calculi), and, liver function tests (serum total bilirubin, serum alanine aminotransferase, serum alkaline phosphatase). The subjects were randomized using computer generated random numbers into one of two groups depending on the insufflations pressure used – group 1 (LPLC or 8 mm Hg group), and, group 2 (HPLC or 12 mm Hg group). Allocation concealment was achieved by the sealed envelope technique. The envelopes were opened in the operating room by technical staff responsible for setting the insufflations pressure. After overnight fasting, patients received premedication with oral diazepam 0.2 mg/kg 2 hours before surgery, and, a single dose of prophylactic antibiotic (intravenous cefazolin) at induction of anaesthesia. Intra-operative monitoring included continuous lead II electrocardiography, pulse oximetry, capnography, and spirometry (S5 monitor, DatexOhmeda®, USA). Radial artery cannulation was performed after confirming adequate collateral flow in the ulnar artery by the modified Allen's test. The arterial cannula was connected to a FloTracTM sensor and VigileoTM monitor (Edwards Lifesciences®, USA). This enabled minimally-invasive measurement of mean arterial pressure, heart rate, and, cardiac index, using a validated pulse waveform analysis.[13,14] The principle involved is that aortic pulse pressure is proportional to stroke volume and inversely proportional to aortic compliance. Following establishment of monitoring, an intravenous crystalloid infusion (Ringer's lactate) was initiated at 10 mL/ kg/hour. Anesthesia was induced using intravenous fentanyl 1-2 μg/kg with intravenous propofol 1-2.5 mg/kg, and tracheal intubation was facilitated by intravenous vecuronium 0.1 mg/kg as muscle relaxant. Anesthesia was maintained with a mixture of O_2 and N_2O along with isoflurane (1 ± 0.1 MAC). Intra-operative drug dosages, fluids, and FiO_2 were titrated to maintain heart rate and blood pressure at ±20% of baseline values, and SpO_2 greater than 97%. Intra-operative ventilation was standardized in both groups using volume-controlled mode initiated at a tidal volume of 8 mL/kg, I: E ratio of 1:2 and a respiratory rate of 10 breaths per minute. Keeping tidal volume constant, eucapnia (end-tidal CO_2 =35-40 mmHg) was maintained by varying the respiratory rate. Hemodynamic variables viz. mean arterial pressure; heart rate and cardiac index were recorded prior to induction of anesthesia (basal), post-induction, and then every 10 minutes following creation of pneumoperitoneum until completion of the procedure. Ventilatory parameters viz. end-tidal CO_2, mean airway pressure, peak airway pressure, SpO_2, tidal volume, respiratory rate and I:E ratio were recorded post induction following intubation, and at 12 minute-intervals until completion of the procedure. Arterial blood gases analysis was performed post-induction (baseline), and then at 24 minutes post-pneumoperitoneum. Muscle relaxation was reversed with intravenous neostigmine 0.06 mg/kg and atropine 0.03 mg/ kg. Ondansetron 8 mg and ranitidine was administered for postoperative nausea and vomiting. The standard four-port technique was used; pneumoperitoneum was created by the open method and the pressure was set to the randomized value from the outset. Patients were placed in a reverse Trendelenberg position (30°) with 15° elevation of the right shoulder after introduction of the four ports. If the surgeon was unable to proceed further due to poor visualization, he/she requested for an increase in pressure. The pressure was increased by the same technician to 12 mm Hg (if 8 mm Hg earlier), or was kept at 12 mm Hg ('sham' increase). This ensured continuation of blinding throughout the procedure. Conversion to open surgery was done only after the surgeon was convinced that further dissection was not possible at the second pressure, or there was another anatomical/ technical difficulty in the case (during grasping of fundus, dissection of Calot's triangle, clipping of duct or artery, separation from liver bed, or extraction of the organ). All such events and the time at which the eletrocautery burns to parietal wall/ viscera were recorded. Intra-operative outcome parameters recorded were operating time (laparoscopic time only), conversion to higher pressures, conversion to open surgery, reasons for conversion, intra-operative injuries or mortality, and use of additional ports. Postoperative analgesia in the form of intramuscular diclofenac 1.30 mg/kg 8 hourly for 24 hours was administered to all patients. Patients requesting for additional pain relief were prescribed intravenous tramadol (50 mg). The numbers of additional doses of analgesic, as well as the total additional dose used were recorded. Postoperative pain was also assessed by a visual analogue pain scale (VAS) at 3 hours, 12 hours, 24 hours and 48 hours after surgery. Pain scores were graded from 0 (no pain) to 10 (unbearable pain). The patients were discharged 24 hours after surgery if the course was unremarkable. Liver function tests were repeated on postoperative day 1 and day 6.

RESULTS

Total Eighty patients of symptomatic gallstone disease planned for laparoscopic cholecystectomy were included in the study. After randomization, there were 40 patients in both groups, i.e. group 1 (LPLC or 8 mm Hg group), and, group 2 (SPLC or 12 mm Hg group). In group 1 the ratio of male and female is 33:7 and in group 2 the ratio of the male and female is 36:4. Both groups were similar with respect to age, sex and BMI [Table 1]. There were no associated co-morbidities in any of the patients.

In the LPLC group, difficulty was encountered by all the operating consultants in placing the 2nd-4th ports (1st port by open technique) using the standard 100 mm trocars. This was partly circumvented by making slightly oblique tracts. Other areas of difficulty were – while grasping the gall bladder fundus in 16 patients, during dissection of Calot's triangle in 21 patients, while clipping the cystic duct in 2 patients, and, while dissecting the gallbladder off the liver bed in 8 cases. Despite this, 31 of 40 cases were completed at 8 mm Hg pressure. Minor adjustments were made in a few instances (like using 30° telescope); however, additional ports were not required in any case. In 8 cases, the pressure was raised to 12 mm Hg, and 2 of these were converted to open cholecystectomy despite raising the pressure. Three patients needed conversion to open cholecystectomy for other reasons. Hence, the overall conversion rate to open procedure was 8/30 (20%) and 2/40(5%) were attributable to low pressure and poor visualization.

In the SPLC group too, there was difficulty encountered at various stages (creation of pneumoperitoneum: 4 cases, grasping gallbladder fundus: 6 cases, dissection of Calot's: 6 patients, clipping of cystic duct: 2 case, and, dissection of gall bladder from bed: 12 cases. Here, 36 cases were completed at 12 mm Hg. Hence, the overall conversion rate to open procedure was4/40 cases (10%) was converted to open cholecystectomy due to difficult anatomy and adhesions. No significant intra- or postoperative complications were observed in either group. There were no significant differences between the groups in operating time, conversion rate (due to factors other than pressure), and, the length of postoperative hospital stay [Table 1].

Cardiopulmonary Parameters

For statistical analysis of the repeated intraoperative cardiopulmonary parameters, readings have been truncated at 48 minutes post-pneumoperitoneum. Beyond this time, there was a significant attrition of data due to completion of surgery in several patients.

Heart rate decreased significantly after induction and creation of pneumoperitoneum in both groups; a slight increase was seen with the duration of pneumoperitoneum, however, there was no significant difference between the two groups. In both the groups, mean arterial pressure (MAP) was reduced after induction but increased above the baseline after creation of pneumoperitoneum; however, there was no significant difference between the two groups. In both groups, cardiac index decreased after induction, but was seen to increase gradually with the duration of pneumoperitoneum. The absolute values of all parameters were within the clinically normal range.

Table 1: Demographic features, intra-operative difficulty and postoperative course in both groups.

	LPLC group	SPLC group	p value (significant if <0.05)*
Sex ratio (male: female)	33:7	36:4	
BMI (kg/m2)	20:78±4.12	20:51±3.56	0.813
Length of postoperative hospital stay (days)	1.32±0.83	1.30±0.70	0.85
Operating time (minutes)	66±12.56	59±18.23	0.843
Conversion rate(open cholecystectomy)	20%(8/40)	10%(4/40)	0.166
Number of additional doses of analgesic	0.50±0.80	1.56±0.94	0.000
Total extra dose of analgesic (mg of tramadol)	11±22.36	45±80.33	0.000

Table 2: Changes in heart rate mean arterial pressure and cardiac index during surgery in both the groups.

	LPLC group			SPLC group		
	Heart rate (bpm)	Mean arterial pressure (mmHg)	Cardiac index (L/min/m2)	Heart rate (bpm)	Mean arterial pressure (mmHg)	Cardiac index (L/min/m2)
Basal	83±8	89±12	4.2±1.0	84±10	90±12	4.0±1.2
Post induction	78±11	84±12	3.9±1.1	83±14	89±12	3.8±1.0
12	75±8	90±12	3.8±0.9	75±10	93±6	4.0±1.0
24	76± 8	90±10	3.6±0.8	75±10	90±8	3.9±1.1
36	76±6	92±12	4.0±0.8	76±10	93±8	4.1±1.2
48	80±8	92±10	4.1±0.8	80±11	90±8	4.1±1.2

ISSN (O): 2687-5365; ISSN (P): 2753-6556

DISCUSSION

In the LPLC group, we did encounter difficulty in placing the 2nd-4th ports. As mentioned, this problem was partly circumvented by initially piercing the anterior abdominal fascia with a blade, and by sometimes using slightly oblique tracts. Anticipating this, others in similar situations have used a higher pressure initially for port placement.[7,9,12,16] We feel that the higher initial pressure might confound the cardiopulmonary variables in the LPLC group. Overall, port placement did not seem an insurmountable hurdle, as evidenced from the comparable operating times and conversion rates. Objective comparison of surgical difficulty at different pressures of PP has been performed by only one group.[11,12] They observed differences in favour of the higher pressure group in all three parameters, but these were not statistically significant.[12] In other studies, more than 85% of LCs was completed in patients randomized to the low pressure group. No differences have been reported in the requirement for additional ports, conversion rate, operating time, or complication rates.[10,11,17]

Cardiovascular changes in laparoscopic cholecystectomy occur due to anesthesia, CO_2 PP, and patient positioning. In our patients, the degree of tilt, both in the reversed Trendelenberg position and the right-up position, was kept constant for all patients. At the start of PP, increased intraabdominal pressure (IAP) compresses blood out of the splanchnic vasculature, increases the venous return and preload, and hence there is increase in the mean arterial pressure (MAP), systemic vascular resistance (SVR) and pulmonary vascular resistance (PVR), accompanied with a decrease in cardiac output (CO).[6,18] SVR elevation may also be due to increased plasma renin activity, increased antidiuretic hormone (ADH) production, and influence of the sympathetic system. Increased MAP is associated with elevated right atrial pressure (RAP) and pulmonary capillary wedge pressure (PCWP). Hypotension may occur in relatively hypovolemic patients, when increased IAP along with intermittent positive pressure ventilation (IPPV) compresses the inferior vena cava (IVC) and raises the intrathoracic pressure. The reverse Tredelenburg position also reduces venous return, leading to reduced CO and MAP. At lower IAP, cardiovascular changes are less pronounced. All the parameters have been shown to be reversible after peritoneal exsufflation without any residual effects.[19]

Only a few studies have dealt with comparison of cardiopulmonary parameters at different pressures of PP.[7,8,12,20] Wallace et al in a prospective, randomized double-blinded study of 40 patients showed that there were no significant differences in intraoperative heart rate or cardiac index, although the latter fell significantly soon after insufflation in both groups. The fall in cardiac index lasted longer (6 vs 2 minutes) and coincided with a slower rise in mean arterial pressure in the group with higher insufflation pressure. The authors felt that the hemodynamic effects of carbon dioxide are overshadowed by the mechanical effects of increased intra-abdominal pressure during laparoscopy.[8] Dexter et al found a moderate increase in heart rate after peritoneal insufflation which reached statistical significance for the high-pressure group. The MAP also rose significantly in both groups. Stroke volume (SV) and cardiac output (CO) were reduced after PP in both groups, however, both SV and CO were significantly higher ($p<0.04$) subsequently in the low-pressure group.[7] In our patients, the values of MAP and CI do suggest a similar trend of reduction after PP, however, no significant effects of differential pressure are observed.

CONCLUSION

Laparoscopic surgeries with low pressure CO_2 pneumoperitoneum are feasible and safe under. Laparoscopic cholecystectomy is feasible and safe at 8 mmHg pressure with slight modification of technique, and is associated with less pain compared to surgery at 12 mmHg. Studies with compromised cardiopulmonary or hepatic reserve are required to better quantify the benefits.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556

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