SCIENTIFIC ARTICLE

Prospective randomized trial of low pressure versus standard pressure pneumo-peritoneum in laparoscopic cholecystectomy

P. Shivhare, P.Dugg, S.Mittal, H.Singh, A.Kumar, P.Jain
Department of Surgery, Govt. Medical College, Patiala, Punjab, India

Key words: Low pressure laparoscopic cholecystectomy (LPLC); standard pressure laparoscopic cholecystectomy (SPLC); cholelithiasis; pneumoperitoneum.

Abstract

Background

Low pressure pneumo-peritoneum in laparoscopic cholecystectomy is of advantage in patients with cardio-pulmonary co-morbidity. This study aimed to compare low pressure (LP- 7 mmHg) pneumo-peritoneum with standard pressure (SP-12mm Hg) pneumoperitoneum in a prospective randomized clinical trial.

Methods

100 Consecutive patients who qualified for laparoscopic cholecystectomy (LC) for uncomplicated symptomatic gallstones were randomized to either standard pressure laparoscopic cholecystectomy (SPLC) or low pressure laparoscopic cholecystectomy (LPLC). They were comparable for sex, mean age, body mass index (BMI), ASA grade, operative time, complication rate, conversion rate, postoperative pain assessed by the Visual Analogue Scale of Pain (VAS), including the incidence of shoulder-tip pain, postoperative hospital stay, recovery time, and the quality of life (QOL) within 7days following LC. Statistical analysis was done using chi-square and student's t-test.

Results

Mean operative time was longer in LPLC compared with SPLC, but this difference was not significant ($p<0.05$). Tachycardia was present in both groups after creation of pneumo-peritoneum; the difference was not significant. Conversion to open cholecystectomy occured in 8.0% in LPLC and 4 % in SPLC ($p<0.05$). Shoulder tip pain was similar in both groups, while the difference in mean hospital stay (2.56 days in SPLC vs. 2.72 days in LPLC), and consumption of analgesics in the two groups, was not statistically significant.

Conclusion

Laparoscopic cholecystectomy, though safe to perform at low intra-peritoneal pressure (7mm Hg), took a longer time to complete compared with standard pressure pneumo-peritoneum of 12mm Hg. Post-operative pain and analgesic requirement were not altered at low pressure.

Introduction

Cholelithiasis continues to be a national and international health disorder. Gall stones found in a young Egyptian mummy have confirmed that cholelithiasis plagued mankind for over 2000 years (1). In the last one hundred years open cholecystectomy remained the gold standard and the definitive management of symptomatic cholelithiasis. Nevertheless high costs, prolonged hospitalization, prolonged recovery time, pain and morbidity associated with open major surgery resulted in laparoscopic cholecystectomy emerging as the preferred option (2).

Laparoscopic surgery is not risk free as it requires creation of pneumo-peritoneum. Carbon dioxide is used which may cause hypercarbia that can only be avoided

Correspondence: P.Dugg
E-mail: dr_dugg@hotmail.com

by compensatory hyperventilation by increasing the tidal volume during ventilation. Increase in intra-abdominal pressure during pneumo-peritoneum triggers several patho-physiological mechanisms independent of the type of gas used. Furthermore, when laparoscopic cholecystectomy was performed at 15 mm Hg or greater, cardiovascular changes resulting in increased systemic and pulmonary vascular resistance and reduction of cardiac index were reported [2].This prospective study was performed to compare laparoscopic cholecystectomy at low versus high pressure pneumo-peritoneum in an Indian hospital.

Materials and method

One hundred patients comprising mainly women, mean age (standard deviation) 45.5 (12.3) years and 43.6 (14.5) years, were randomized to undergo low pressure laparoscopic cholecystectomy (LPLC) or standard pressure laparoscopic cholecystectomy (SPLC) respectively. The ration of men and women and body mass index of patients was comparable in both groups (Table 1).

Inclusion criteria were those patients with symptomatic gall stones between 18 and 70 years old, who were fit to undergo laparoscopic cholecystectomy under general anaesthesia and who gave fully informed consent. Exclusion criteria in this study were ; pregnant women, lactating women, previous open abdominal surgery, prolonged administration of non-steroidal anti-inflammatory drugs, patients with cirrhosis of the liver, bleeding disorders, acute cholecystitis, and a previous history of peritonitis. Furthermore, those with an empyema of the gall bladder and suspected gall bladder cancer with stones were excluded.

Randomizaton was based on each patient receiving a sealed envelope containing a random number selected from a table assigning a given individual to one of two equal groups of 50 ; LPLC, where a low pressure 7 mm Hg pneumo-peritoneum was employed, and SPLC, where standard 12 mm Hg pneumo-peritoneum was used. The study was approved by the local Ethics Committee.

All procedures were performed by a single team of experienced laparoscopic surgeons involved in the study. In brief, in all patients, access was achieved using four ports - a 10 mm port created below the umbilicus (camera port), two 5 mm ports at subcostal (midclavicular line) and right anterior axillary line, at the level of the umbilicus, and another 10 mm port, which was inserted from just below the xiphoid process (working port). The patient was placed supine on the operating table. Nasogastric intubation was performed after induction of anaesthesia to decompress the stomach and the urinary bladder was previously emptied by patients passing urine before entering the operating room. The operating surgeon stood on the left side of the patient with the first assistant and scrub nurse on the patient's right side and camera operator to the left of the main surgeon. Pneumo-peritoneum was created using a Veress needle inserted through a skin incision in the infra-umbilical / supraumbilical region. After creating the 12 mm Hg pneumo-peritoneum, a 10 mm port was inserted at the umbilicus. The remaining ports were inserted under laparoscopic direct vision. After introducing all four ports, in the LPLC group, the pressure of pneumo-peritoneum was decreased to 7 mm Hg, while in the SPLC group, pneumo-peritoneum remained unchanged. The rest of the operative procedure was performed as per standard.

Data obtained were sex, age, BMI, medical history prior to operation, gall bladder thickness, the quality of surgical field exposure, the ability to use the LP pneumo-peritoneum technique, the need for placing the patient in the reversed Trendelenberg position, increasing the pressure of the pneumo-peritoneum and the duration of surgery. Postoperative pain using a visual analogue scale [VAS] and the course of rehabilitation and quality of life in the early

postoperative period were assessed. The number of patients needed to treat was estimated based on the principle of detecting a 10% difference in pain intensity with a 90% probability at p assumed to be < 0.05. Statistical analysis was based on the chi- square and student`s t -test.

Postoperative pain was assessed using VAS, with evaluation at 2, 8, 24 and 48 h postoperatively which was marked on a vertical line, with 0 described as no pain at all and 10 described as insufferable pain. Neither the patients nor the nurses knew the group assignment; also, the patient did not know the pressure the pneumo-peritoneum had been set at. Nursing staff recorded episodes of vomiting and nausea. Patients were allowed to sit up, mobilized and fed 12 hours after surgery. All subjects were seen by the surgeons involved in the study at follow–up visits at the outpatient surgical department one week and three weeks after the operation.

Statistical analysis was done using percentages, mean values, standard deviation, standard error, $\chi 2$ test [Chi-square test] [with Yates correction], and t-test [unpaired]. The level of significance used was 0.05 levels for the corresponding degree of freedom to draw the inference. A p-value < 0.05 was considered statistically significant and <0.01, highly significant.

Results

Of 100 patients studied, 50 underwent LPLC procedure (Group A) and 50 underwent SPLC procedure (Group B). The sex ratio in both groups was similar (Table 1). Mean age in group A was 45.58 years as compared to 43.62 years in group B (Table1). Group A had a mean BMI of 26.74 (+3.66) Kg/meter^2 while the mean BMI of group B was 25.67(+4.15) Kg/meter^2. Blood pressure recorded before and during procedure in group A (125.4/74.44 & 124.4/72.26) was not statistically different to group B (122.4/74.42 & 120.52/75). The radial pulse rate recorded before and during procedure in group A was also similar to group B. Laparoscopic cholecystectomy was completed in 46 (92%) patients in group A compared with 48 (96 %) in group B (Table 2).

Gall bladder perforation occurred in 16% in the LPLC group [Group A] and 22% in the SPLC group (Group B). Some cases were managed by placing the gallbladder in an endo-bag before extraction, while in others the grasper was repositioned to occlude the perforation. All spilled stones were removed and peritoneal lavage was performed with normal saline until clear fluid drained out.

In our study most patients experienced abdominal pain on the day of the surgery (74% in group A and 78% in group B; p>0.05). Pain was of low intensity at 2 hours and increased to a maximum at 8 hours postoperatively. After 8 hours the intensity of pain began to decrease such that very few patients had pain after 24 hours. The intensity of pain ranged between a pain score of 1to 6 in the first 24 hours, which did not exceed 6 at any time. In our study there were no statistically significant differences in consumption of analgesics in either group.

Discussion

Foremost of our concerns in this study was the limitation of visualization that may have occurred in patients undergoing low pressure pneumo-peritoneum laparoscopic cholecystectomy. Poor visualization,

Table 1 - Sex ratio, mean age (standard deviation) and body mass index (BMI) of patients (kg/m^2)

	Group A (LPLC)	**Group B (SPLC)**
Sex (M:F)	4:21	4:21
Age (years)	45.58±12.37	43.62 ± 14.5 53
BMI (kg/m2)	26.74±3.66	25.67±4.15

Table 2 - Indicating successful completion, operative time, shoulder pain and hospital stay.

	GROUP A (LPLC)	GROUP B (SPLC)
Completed successfully	46 (92%)	48 (96%)
Operating time (min)	80.90±20.9	65.40±22.6
Shoulder-tip pain	4%	4%
Mean hospital stay (days)	2.72	2.56

specifically of the structures around Calot's triangle, has the potential for surgical error resulting in injury to the common bile duct. However, in our study, there was no injury to the common bile duct. Wallace et al [3], Barczynski et al [4] and Chok et al [5], also reported no injury to the common bile duct in their studies. We believe that the chief reason for no bile duct injury in the present study are clear definition of the gallbladder neck cystic duct junction, the cystic duct and the cystic artery before ligation or cutting. Perforation of the gall bladder during dissection occurred in both groups and was not confined to the low pressure laparoscopic group.

The result in our study showed that most patients after laparoscopic cholecystectomy experienced abdominal pain on the day of surgery (74% in group A; 78% in group B). The post-operative pain score was low at two hours and increased to a maximum score of 6, eight hours after operation. After eight hours the intensity of pain decreased and very few patients had pain after 24 hours. The pattern of pain is similar to that shown by Chundrigar et al [6] Joris et al [7]. In our study, there was no difference in consumption of analgesics in both groups and in the rate of conversion to open cholecystectomy.

Hence it is concluded that laparoscopic cholecystectomy can be safely performed at low pressure (7mm Hg) pneumo-peritoneum, although it did not confer a specific advantage over standard pressure (12mm Hg) pneumo-peritoneum. By contrast, the time taken to complete the procedure is greater if pneumo-pressure is kept low. Thus standard pressure pneumo-peritoneum at 12 mm Hg. should be the preferred option during laparoscopic cholecystectomy for symptomatic gall stone disease that is uncomplicated.

References

1. Shehadi WH. The biliary system through the ages. Int Surg. 1979 Nov-Dec;64(6):63-78.

2. Redmond HP, Watson RWG, Houghton T, et al. Immune Function in Patients Undergoing Open vs Laparoscopic Cholecystectomy. Arch Surg. 1994;129(12):1240-1246

3. Wallace DH, O'dwyer PJ. Effect of a no-conversion policy on patient outcome following laparoscopic cholecystectomy. Br J Sur 1997;84(12):1680-1682.

4. Barczynski M, Herman RM. Low pressure pneumoperitoneum combined with intraperitoneal saline washout for reduction of pain after laparoscopic cholecystectomy: a prospective randomized study. Surg Endosc. 2004;18:1368–73.

5. Chok KS, Yuen WK, Hung L, Tat FS. Prospective Randomized Trial on Low-pressure Versus Standard-pressure Pneumoperitoneum in Outpatient Laparoscopic Cholecystectomy. Surgical Laparoscopy, Endoscopy & Percutaneous Techniques. 2006 Dec;16(6):383-386.

6. Chundrigar T, Morris R, Hedges AR, Starnatakis JD. Intraperitoneal bupivacaine for effective pain relief

after laparoscopic cholecystectomy. Ann R Coll Surg Engl 1993;75:437-439.

7. Joris J, Thiry E, Paris P, Weerts J, Lamy M. Pain after laparoscopic cholecystectomy: characteristics and effect of intraperitoneal bupivacaine. Anesth Analg. 1995;81:379–384.