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Original Research Article

Intraoperative safety of low pressure pneumoperitoneum cholecystectomy: a comparative study

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ABSTRACT

Background: With the establishment of laparoscopic cholecystectomy as gold standard for management of cholelithiasis, the current stress is on increasing patient safety. Hence, this study was undertaken to compare the effect of low pressure pneumoperitoneum (LPP <10mm Hg) versus high pressure pneumoperitoneum (HPP >14mm Hg) in a prospective randomized manner on intraoperative safety, assessing the working space and safety by seeing contact of parietal peritoneum to underlying viscera during secondary port insertion.
Methods: 120 patients undergoing laparoscopic cholecystectomy were randomized into the LPP (<10mm Hg) group (n=60) and the HPP (>14mm Hg) group (n=60) prospectively. Available working space assessed directly, safety by contact of parietal peritoneum to underlying viscera during secondary port insertion and operative difficulty assessed by visualization, dissection and grasping, total duration of surgery; intra-operative gas consumption, and bile spillage were assessed.
Results: There was no significant difference in terms of available working space, operative duration, consumption of carbon dioxide, surgeon's operative difficulty and intraoperative bile spillage. Out of 180 secondary ports inserted, there was evident contact of 20 (11.1%) secondary ports in high pressure groups and 14 (7.7%) secondary ports in low pressure group, which is suggestive of adequate exposure and working space available for surgery at both pressures.
Conclusions: Low-pressure cholecystectomy did not compromise intraoperative safety and should be the standard of care in day care surgery.

Keywords: High-pressure pneumoperitoneum, Laparoscopic cholecystectomy, Low-pressure pneumoperitoneum, Postoperative shoulder pain

INTRODUCTION

While performing any laparoscopic procedure, adequate working space is a major requirement, like in every surgery. As abdomen is a closed space, this assumes a top requisite for better ergonomics and patient safety. Pneumoperitoneum for laparoscopic cholecystectomy is most often created by insufflating carbon dioxide gas into the peritoneal cavity and then holding it at constant pressure till the end of surgery when it is released at the time of withdrawal of the ports.[1] Literature is abundant that standard pressure pneumoperitoneum, employing a pressure range of 12-14 mm Hg, over prolonged periods has been associated with adverse effects such as decreased pulmonary compliance, altered blood gas parameters, impaired functioning of the circulatory system, raised liver enzymes and renal dysfunction and even increased intra-abdominal venous pressures.[2-6] Therefore, a rising trend has been the use of low pressures for pneumoperitoneum in the range of 8-10 mm Hg in an attempt not to alter the physiological parameters and also providing adequate working space at the same time.

One important advantage of low pressure pneumoperitoneum appears to be lower incidence of shoulder tip pain in the postoperative period and also better quality of life in post- operative period. However, the lower pressures have also been linked to less than adequate exposure of the operating field resulting in longer than usual operating time, higher rate of intraoperative complications and also possibly higher frequency of conversion to open cholecystectomy. This study proposes to compare the use of the low-pressure pneumoperitoneum (LPP defined as <=10mm Hg) with the use of high pressure pneumoperitoneum (HPP defined as >=14mm Hg) in patients undergoing laparoscopic cholecystectomy in a prospective randomized manner. The main areas of analysis were the contact of parietal peritoneum to the underlying viscera during secondary port insertion (indirectly indicating available working space and potential for injury), operative difficulty (visualization, grasping and dissection), operative duration, intraoperative gas consumption and bile spillage.

METHODS

The study was conducted in the department of minimal access and general surgery, Fortis Escorts hospital and research centre, Faridabad, Haryana in India, over a period of 13 months. All consecutive adult patients, with uncomplicated symptomatic gallstone disease and ASA Grade I to IV were included in the study. Exclusion criteria included BMI >30kg/m^2, history of ERCP and stent in situ, known shoulder disease, empyema gallbladder, history of cholangitis and pancreatitis, history of multiple abdominal surgeries, coagulopathy, previous malignancy, patients requiring other concomitant procedures, patients who do not give consent for participation in the study or patient with cognitive impairments and patients on chronic analgesic use or history of addiction to alcohol.

Ethical clearance from the Institute Ethics Committee was taken. The details of procedure were explained and informed consent taken before enrolment. The study was done in a randomized prospective manner with a sample size of 120 patients. Randomization into the two groups was done using Random Number Table. The general anesthetic protocol was the same for both groups. A standard laparoscopic cholecystectomy was performed according to the American ‘four punctures’ technique described by Dubois et al. A single experienced consultant surgeon performed all surgeries. After induction of general anesthesia, open method was used to gain entry into the abdomen in all patients in both study groups and a 10mm laparoscope was inserted into the abdomen through the umbilical port.

Pneumoperitoneum was created and intra-abdominal pressure of <10mmHg was kept in low pressure group and intra-abdominal pressure of 14mmHg was kept in high pressure group and the whole surgery was carried out at those pressures in both groups. Intra-operative monitoring was performed by monitoring heart rate and blood pressure non-invasively every 5 minutes. The patient was then placed in a reverse Trendelenburg position of 30 degree while rotating the table to the left by 15 degrees. Three additional ports were then placed under direct vision. First, either a 10 mm or a 5-mm trocar was placed in the epigastrium (Epigastric Port). Second 5 mm port was placed along the right anterior axillary line between the twelfth rib and the iliac crest (Right Iliac Fossa Port). Another 5-mm port was inserted in the right subcostal area in the midclavicular line (Right Subcostal Port) (Figure 1).

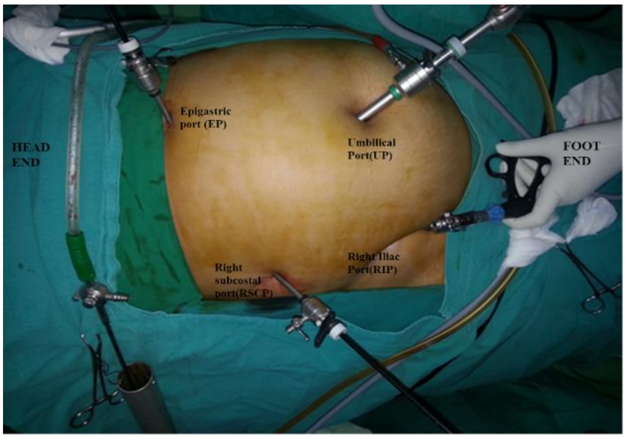

Figure 1: Primary and secondary port sites.

The fascial defect of the umbilical incision was closed with No 1 Vicryl. The skin incisions were closed with Nylon. Following extubation, patients were shifted to the recovery room.

For comparison between groups special attention was paid on following outcomes:

- Number of secondary ports inserted during the surgery and number of secondary ports with contact of parietal peritoneum to the underlying viscera This was taken as a measure of safety during secondary port insertion, as a contact would put a viscera at risk (Figure 2, Figure 3)
- Operative time was noted starting from time of making the incision to time of closure of skin
- Intra-operative gas consumption
- The occurrence of bile spillage during operation
- Operative difficulty during surgery assessed by grading visualization, grasping and dissection by operating surgeon.

Statistical analysis

- Quantitative variables were compared using Unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups
- Qualitative variable was compared using Chi-Square test /Fisher's exact test
- Regression analysis was used to assess the effect of pressure on duration of surgery.

A p-value of <0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysed using Statistical Package for Social Sciences (SPSS) version 21.0.

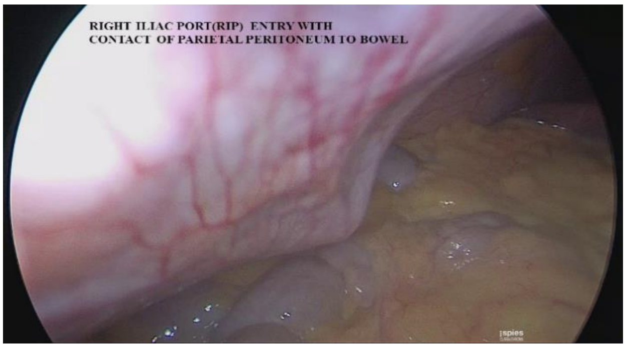

Figure 2: Right iliac port showing contact of parietal peritoneum to underlying bowel.

Figure 3: Right subcostal port showing contact of trocar tip to underlying bowel.

RESULTS

Both groups were matched for age, sex and BMI (Table 1). There were no conversions in either group. LPP laparoscopic cholecystectomy took an average one minute more than HPP laparoscopic cholecystectomy [63.17±7.7 minutes (range 45-90 minutes) versus 62±9.4 minutes (range 45-85 minutes)] but this difference was not statistically significant (p>0.05).

However, mean consumption of CO_2 gas was less in LPP compared to HPP laparoscopic cholecystectomy with no statistical significance (103±11.5 liters versus 108±14.5 liters; p>0.05) (Table 2).

Contact of parietal peritoneum to the underlying viscera during secondary port insertion, was taken as indirect indicator of compromise of intraoperative safety and potential for injury. A total of 180 secondary ports were inserted in each study group, 3 in each case. Out of 180 secondary ports inserted, there was evident contact of 20 (11.1%) secondary ports in high pressure groups and 14 (7.7%) secondary ports in low pressure group with p value 0.699 which was statistically insignificant.

There was high incidence of contact of parietal peritoneum to underlying viscera in Right Iliac Fossa Port (RIP) in both groups. The contact of peritoneum to viscera was found less in LPP at all secondary port sites as compared to HPP with Epigastric port site (LPP versus HPP; 3% versus 5%), Right Subcostal Port site (2% versus 6%) and Right Iliac Port site 21.6% versus 23.3%) which was statistically insignificant.

Low pressure group was found safe in terms of intraoperative organ injury potential and working space was also not compromised to the extent to cause intraoperative organ injury or to interfere with dissection.

Comparing surgeon's operative difficulty between the two groups, there was no significant difference in terms of visualization, grasping and dissection at Calot's triangle. There was no statistical difference in terms of bile spillage and visceral/vessel injury in between the groups.

Table 1: Baseline characteristics of two groups.

	HPP (n=60)	LPP (n=60)	p value
Age			
Mean±SD	40.32±9.89	38.32±8.78	n.s
BMI			
Mean±SD	23.12±2.37	23.68±2.5	n.s
Sex (M:F)	15:45	20:40	n.s

Table 2: Comparison of outcome variables between two groups.

	HPP (n=60)	LPP (n=60)	p value
Operative time (in minutes)			
Mean±St. dev	62±9.4	63.17±7.7	n.s
Contact of parietal peritoneum to viscera			

Epigastric port (EP)			
yes	3	2	n.s
no	57	58	
Right subcostal (RSCP)			
yes	4	2	n.s
no	56	58	
Right iliac port (RIP)			
yes	13	10	n.s
no	47	50	
Total (yes)	20	14	n.s
Operative difficulty			
Visualisation			
Good/easy	55 (91%)	54 (90%)	n.s
Bad/difficult	5 (9%)	6 (10%)	
Grasping			
Good/easy	57 (95%)	58 (96%)	n.s
Bad/difficult	3 (5%)	2 (4%)	
Dissection			
Good/easy	55 (91%)	58 (96%)	n.s
Bad/difficult	5 (9%)	2 (4%)	
Bile spillage			
Yes	3	1	n.s
No	57	59	
Total gas consumption (in litters)			
Mean±St. dev	108±14.5	103±11.5	n.s
Visceral injury/vessel injury			
yes	0	0	n.s

DISCUSSION

With the establishment of laparoscopic cholecystectomy as gold standard for the management of cholelithiasis, there have been a series of untiring efforts to evolve and increase its safety. The aim has been to reduce the trauma especially during access, increasing surgeon and patient satisfaction and decreasing operative difficulty during the procedure. Despite the relative safety of laparoscopic techniques, inadvertent injuries to bowel, bladder and vascular structures do occur. It is recognized that the most common cause of serious laparoscopic complications is related to primary trocar insertion. Secondary port entry complications are mostly witnessed as the secondary port is inserted under direct vision, so, most of these secondary port complications are identified intraoperatively. Some are identified after the patient discharge from hospital, although the incidence is very low.[7] The complications include port-related direct organ injuries, such as abdominal organ or major and minor vascular injury; abdominal wall complications related to laparoscopic port insertion such as vascular injury, infection, and hernia; abdominal wall complications related to specimen removal, such as port site tumor seeding and endometriosis.[8-12] Probably no needle-trocar system can guarantee avoidance of injury during laparoscopic entry, especially when the trajectory of insertion puts great vessels at risk. Bowel injuries occur during open as well as closed techniques of insertion, and with optical trocar systems as well. Vascular injury is usually obvious, but delayed recognition of loss of bowel integrity is related to increased mortality and morbidity, especially in patients over 60 years of age.[13] Although lower insufflation pressures is recognized as a factor causing lesser physiological changes during laparoscopic surgery, there is lack of published scientific data on the safety of low insufflation pressure during port insertion. The safety of low pressure pneumoperitoneum cannot be assessed directly, hence the contact of parietal layer of peritoneum to the underlying viscera during secondary port insertion at a particular pressure under direct vision after the primary port insertion, served as an indirect indication of loss of safety window, adequacy of working space and potential of complication at particular pressure of pneumoperitoneum. A meta-analysis of 760,890 closed laparoscopy (blind entry of 1st port) and 22,465 open laparoscopy (open entry of 1st port) cases reported the incidence of vascular injury rate in closed laparoscopy was 0.44% compared with 0% in open laparoscopy. The incidence of bowel injury was 0.7% compared with 0.5% respectively. Krishnakumar and Tambe concluded that the open (Hasson) technique eliminated the risk of vascular injury and gas embolism and reduced the risk of bowel injury and recommend the open technique to be adopted for primary laparoscopic entry.[14] In our study, in both groups, first port was inserted using open entry with no injuries.

The increased intra-abdominal pressure due to the pneumoperitoneum causes several cardiopulmonary changes. The increased intra-abdominal pressure increases the absorption of CO_2, causing hypercapnia and acidosis, which has to be avoided by hyperventilation. It pushes the diaphragm upwards decreasing the pulmonary compliance and increases the peak airway pressure. Pneumoperitoneum increases the systemic vascular resistance and pulmonary vascular resistance. Carbon-dioxide pneumoperitoneum also predisposes to cardiac arrhythmias. During the early phase of pneumoperitoneum, there is a reduction in the cardiac output by decreasing the venous return. While these cardio-respiratory changes may be tolerated by healthy adults with adequate cardiopulmonary reserve, people with cardiopulmonary diseases may not tolerate these changes.[15] To negate these specific problems, the idea of LPP with carbon dioxide was introduced. Research studies have indicated that the use of LPP is associated with better intra-operative tolerance (including anesthesia tolerance) and improved postoperative recovery with reduced intensity of the surgical pain. Various authors have reported that laparoscopic cholecystectomy performed with LPP results in a better postoperative quality of life as compared to laparoscopic cholecystectomy performed with HPP.[16-18]

In our study contact of parietal peritoneum to the underlying viscera during secondary port insertion under vision after insertion of primary port, was taken as indirect indicator of potential of causing visceral injury at a particular intraabdominal pressure. Out of 180 secondary ports inserted, there was evident contact of 20 (11.1%) secondary ports in high pressure groups and 14 (7.7%) secondary ports in low pressure group, which is suggestive of adequate exposure and working space available for surgery at both pressures. Low pressure group was found safe in terms of intraoperative organ injury potential and working space was also not compromised to the extent to cause intraoperative organ injury. To our knowledge there is no earlier study done correlating the contact of parietal peritoneum to the underlying viscera as marker of loss of working space and potential of visceral injury. In our study, number of secondary ports causing contact of parietal peritoneum to the underlying viscera in low pressure group were comparable as compared to in high pressure group. This indirectly establish the safety of low pressure group Similar was found in study by Barczynski M, Herman RM, Wallace et al, where they concluded that there was no compromise of working space in low pressure group. Better intraoperative pO2 level, preservation of pulmonary function and intra operative safety favoring low pressure in a statistically significant manner was observed in a study by Joshipura VP et al.[19-21] Low pressure causes less cardiopulmonary changes during the surgery and is recommended in patients with history of cardiopulmonary disease. There was high incidence of contact of parietal peritoneum to underlying visera in Right Iliac Fossa Port (RIP) in both groups. During insertion of secondary ports surgeon should be extra cautious. Various measures like supporting the abdominal wall while insertion of secondary port externally and supporting with grasper intraperitoneally may reduce the chance of contact of parietal peritoneum to underlying viscera and increase the safety (Figure 4).

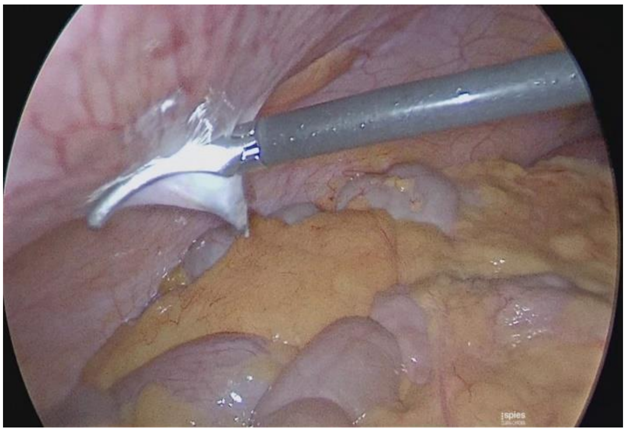

Figure 4: Supporting abdominal wall from inside using Maryland forceps during secondary port insertion.

CONCLUSION

The following conclusions have been drawn from our study: the intraoperative working space and safety of lower pressure group is established by lesser number of contact of secondary ports (parietal peritoneum) to the underlying viscera making low pressure laparoscopic cholecystectomy as feasible as standard pressure laparoscopic cholecystectomy, there was no significant difference in the total duration of surgery, complication rate and operative difficulty in both the groups establishing the safety of the low pressure for laparoscopic cholecystectomy.

On the basis of these results, the widespread use of low pressure pneumoperitoneum can be used in laparoscopic cholecystectomy and as it causes less physiological changes intraoperatively, it should be the procedure of choice in patients with ASA grade III/IV and in patients with history of cardio-pulmonary diseases.

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Ethical approval: The study was approved by the institutional ethics committee

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