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Original Research Article

Outcome analysis of low pressure versus high pressure pneumoperitoneum laparoscopic cholecystectomy: a randomized clinical study

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ABSTRACT

Background: Laparoscopic cholecystectomy is established as gold standard for management of cholelithiasis. Intraoperative pneumoperitoneum affects the postoperative outcomes. The current stress is on increasing patient safety. Hence, this prospective study was undertaken to compare the effect of low pressure pneumoperitoneum (LPP <10 mm Hg) versus high pressure pneumoperitoneum (HPP > 14 mm Hg) on postoperative pain and ileus.
Methods: 120 patients undergoing laparoscopic cholecystectomy were randomized into the LPP (<10mm Hg) group (n=60) and the HPP (>14 mm Hg) group (n=60). Total duration of surgery, intra-operative gas consumption, occurrence of bile spillage during operation, shoulder pain and abdominal pain in postoperative period, additional requirement of analgesia in postoperative period and postoperative ileus were assessed.
Results: There was no significant difference in terms of operative duration, consumption of CO_2 gas, intraoperative bile spillage, total hospital stay and tolerance to early feeding. The incidence of shoulder pain was higher in patients who underwent HPP laparoscopic cholecystectomy ($p<0.05$). There was early recovery and early return of bowel activity in LPP which was statistically significant.
Conclusions: Low-pressure pneumoperitoneum is feasible and safe and results in reduced postoperative shoulder tip pain and near-equal operative time with early return of bowel activity compared with high-pressure pneumoperitoneum.

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

INTRODUCTION

Surgeons use "available tools" to the best of their knowledge and skills, with the goal of promoting the safest and most rapid return of patient to self-sufficiency and return to work while reducing mortality, morbidity, dysfunction and pain. Laparoscopy suits these requirements and currently holds the centre stage. Pneumoperitoneum for laparoscopic cholecystectomy is created by insufflating carbon dioxide gas into the peritoneal cavity and then holding it at constant pressure till the end of surgery.[1]

Pneumoperitoneum, 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.[2,3] The duration of convalescence after uncomplicated laparoscopic cholecystectomy depend on several factors of which shoulder tip pain is more important.[4]

Other are nausea, vomiting, ileus, postoperative fatigue, postoperative hospital stays, recovery time. Shoulder tip pain frequently occurs after laparoscopic cholecystectomy making postoperative recovery less comfortable. The etiology of postoperative pain is extremely complex, and a precise evaluation of the various causes is still difficult to achieve. Carbon dioxide insufflation is the commonest means of achieving pneumoperitoneum and carbon dioxide gas is widely considered to be responsible for postoperative pain. In particular shoulder tip pain is presumed to be linked to carbon dioxide insufflation and its intensity is so strong that analgesics must be administered frequently. The reported incidence of this particular, uncomfortable type of pain varies from 35 to 63% following gynaecological procedures.[5] In addition, the reported incidence of shoulder tip pain following laparoscopic cholecystectomy varies between 30 to 50%.[6]

Therefore, a 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. This prospective randomized study compared the use of the low-pressure pneumoperitoneum (LPP defined as <10mm Hg) to high pressure pneumoperitoneum (HPP defined as >14mm Hg) in patients undergoing laparoscopic cholecystectomy. The main areas of interest were operative duration, intraoperative gas consumption, bile spillage, post-operative shoulder tip and abdominal pain and postoperative ileus assessed by return of bowel sounds, passage of flatus and tolerance of oral feed.

METHODS

The study was carried out 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 duration. All consecutive patients in age group from 18 to 70 years, 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, prior history of acute cholecystitis, cholangitis and pancreatitis, history of multiple abdominal surgery, 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. 120 prospective patients, who satisfied the inclusion-exclusion criteria, were randomized into two groups using the random number table. The general anesthesia 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 10-mm 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 fascial defect of the umbilical incision was closed with No 1 Vicryl. The skin of the incisions was closed with Nylon sutures. Following extubation, patients were shifted to the recovery room: For comparison between groups special attention was paid on following outcomes

- Operative time was noted starting from time of making the incision to time of closure of skin
- Post-operative shoulder tip pain and abdominal pain using Numeric Pain Rating Scale (NRS). This was done at 2 hours, 8 hours,24 hours and 48 hours after surgery. Both groups were administered equal dose of analgesia. Any additional analgesic requirement was noted
- Post-Operative Ileus was measured with three parameters taking Return of Bowel Sounds, Passing of Flatus and Tolerance of Oral Feeds as three independent parameters at 6 hours, 12 hrs., 24 hrs. and 48 hrs. post-surgery in both groups. Any episode of vomiting, abdominal distension within 48 hrs. post operatively was noted
- Intraoperative carbon dioxide (CO_2) consumption, bile spillage, visceral/vessel injury during operation were noted.

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 analyzed using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS

Both groups were matched for age, sex and BMI (Table 1). There were no conversions to open surgery. Laparoscopic cholecystectomy with HPP took an average of 62±9.4 minutes (range 45-85 minutes) compared to 63.17±7.7 minutes (range 45-90 minutes) for LPP, 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 difference (103±11.5liters versus 108±14.5liters; p>0.05). There was no statistical difference in terms of bile spillage and visceral/vessel injury in between the groups (Table 2).

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.

	HP (n=60)	LP (n=60)	P value
Operative time (in minutes)			
Mean±St dev	62±9.4	63.17±7.7	n.s
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
Postoperative shoulder tip pain			
2 hours	4.2	2.5	<0.005
8 hours	3.5	1.9	<0.005
24 hours	2.5	1.2	<0.005
48 hours	1	0	<0.005
Postoperative abdominal pain			
2 hours	5	2.47	<0.005
8 hours	3.5	1.5	<0.005
24 hours	2.5	1	<0.005
48 hours	1	0	<0.005
Post-operative ileus			
Return of bowel sounds	**Yes**	**Yes**	
6 hours	0	21	<0.005
12 hours	30	45	<0.005
24 hours	50	58	n.s
48 hours	60	60	n.s
Passage of flatus			
6 hours	5	20	<0.005
12 hours	15	30	<0.005
24 hours	55	60	n.s
48 hours	60	60	n.s
Tolerance of oral feed			
6 hours	60	60	n.s
12 hours	60	60	n.s
24 hours	60	60	n.s
48 hours	60	60	n.s
Bile spillage			
Yes	3	1	n.s
No	57	59	
Need for additional analgesia			
Yes	0	0	n.s

Five patients (8%) who underwent LPP laparoscopic cholecystectomy and eighteen patients (30%) who underwent HPP laparoscopic cholecystectomy had postoperative shoulder tip pain at any point in time during the peri-operative period ($p<0.05$). Amongst these right-sided shoulder tip pain occurred in 19 patients and pain on both sides, moving from one shoulder to the other in 4 patients. Shoulder tip pain was present at 2 hours postoperatively and peaked in both the groups at 8 hours with significant improvement after this time. The frequency of shoulder-tip pain was significantly lower in patients with LPP laparoscopic cholecystectomy at 2, 8, 24 and 48 hours in the postoperative period. Pain scores as recorded on NRS revealed that postoperative shoulder-tip pain was significantly less intense at 12 and 24 hours in the LPP group. Mean scores approached zero in LPP laparoscopic cholecystectomy at end of observed postoperative period whereas patients who underwent HPP laparoscopic cholecystectomy, reported comparative higher score. The frequency of abdominal pain was less in patients who underwent LPP cholecystectomy at 2, 8, 24 and 48 hours in the postoperative period which was statistically significant and mean scores approached zero at the end of observed postoperative period in low pressure group. Abdominal pain was present in upper abdomen above umbilicus and at the port sites in all patients in both groups. Standard diclofenac sodium in dose of 225mg/day (75 mg i.v 8hourly) was given to all patients in both groups starting immediately postoperatively. There was no requirement of additional analgesia in either groups.

There was early return of bowel sounds in LPP group at 6-hour post operatively in twenty-one patients and compared to none in HPP cholecystectomy group. This reduced post-operative ileus was statistically significant at 12 hours and 24 hours also with p value>0.005. All patients in both groups had return of their bowel sounds at 48 hours postoperatively. The similar trend was observed for early passage of flatus in LPP group at 6, 12 and 24 hours. Patients were started orally at 6 hours in both groups, which was accepted well by all patients. There was no episode of vomiting and abdominal distention in any patient in either study groups.

DISCUSSION

Post-laparoscopy pain syndrome is well recognized and is characterized by abdominal and particularly shoulder tip pain; it occurs frequently following laparoscopic cholecystectomy. The etiology of post-laparoscopic pain can be classified into three aspects: visceral, incision, and shoulder. Lower pressures were used in many studies for their effect on shoulder tip pain. An emerging trend has been the use of low pressure pneumoperitoneum in the range of 7-10 mm Hg to lower the impact of pneumoperitoneum on the human physiology while providing adequate working space.[7] With the establishment of laparoscopic cholecystectomy as gold standard for the management of cholelithiasis, there has 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.[1] 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. 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 resulted in a better postoperative quality of life as compared to laparoscopic cholecystectomy performed with HPP.[7-18]

The proposed causes of post laparoscopy shoulder pain are peritoneal stretching, chemical irritation by CO2 and overstretching of diaphragmatic muscles owing to high rate of insufflation. Wallace, Kandil TS, demonstrated that the degree of stretching in the intra-abdominal cavity is a significant source of postoperative pain and it has been shown that a low insufflation rate significantly reduces shoulder tip pain.[12,17,19] In our study mean post-operative shoulder and abdominal pain were lower in low pressure group, the difference was statistically significant postoperatively at 2, 8, 24 and 48 hours. These findings were in accordance with Sarli L et al where low post-operative shoulder tip pain score at 6 hrs and 12 hrs were present (P value<0.001).[15] Yasir M et al assessed post-operative shoulder tip pain at 4, 8 and 24 h which was less in low pressure group, although statistical significance was seen only at 4 h.[20] Sandhu T et al observed higher incidence of shoulder pain in standard group (27.9% low pressure versus 44.3% standard pressure) (p=0.100).[17] Barczynski M, Herman RM8 reported 2.1 times lower incidence of shoulder pain after LPP than HPP ($p <0.05$).

In our study post-operative abdominal pain scores were less in low pressure group and the difference was statistically significant. These findings were in accordance with findings in studies by Kanwar et al and Topcu HO et al.[16,21] How far this would go in overall

recovery is debatable, but definitely would prove that patients following a fast track/day care protocol for laparoscopic cholecystectomy should be operated at low pressure. Guruswamy KS et al searched Cochrane central register of trials and collected data from fifteen randomized trials.[15,21] They found that intensity of pain was lower in low pressure Group.

In our study majority of the patient's post-operative pain could be managed by injection Diclofenac sodium 75 mg IV given 8 hourly. There was no need for any additional analgesia in both study groups. Similar was seen by Sarli L et al, Yasir M et al, Singhla S et al, Vijayaraghavan N et al.[5,15,20,22]

Postoperative ileus has traditionally been accepted as a normal response to tissue injury. Postoperative ileus after abdominal operations is thought to be related to the degree of surgical trauma, and it has been shown that the simple act of opening the peritoneum can decrease gastrointestinal motility. Pathogenesis mainly involves inhibitory neural reflexes and inflammatory mediators released from the site of injury.

Accordingly, some investigators have shown a reduction in the duration of postoperative ileus after laparoscopic procedures.[23] Post-operative ileus is characterized by the inability to tolerate a solid diet, delayed passage of flatus and formed stool and abdominal distention, nausea, vomiting, and accumulation of gas or fluids in the bowel.[24] Intestinal handling triggers mast cell activation and inflammation which is associated with prolonged postoperative ileus. This partly explain the faster recovery after minimal invasive surgery.[25]

In our study there was early return of bowel sound in LPP at 6 and 12 hours. All patients in both groups had return of their bowel sounds at 48 hours postoperatively. There was statistically significant early passage of flatus LPP cholecystectomy group. All the patients accepted oral feeds well without complaining of any nausea, vomiting or abdominal distension. at 6 hours, 12 hours, 24 hours and 48 hours of the surgery in both groups. From these findings it is clear that pneumoperitoneum does have effect on the gastrointestinal transit and post-operative ileus. Low pressure pneumoperitoneum causes early recovery of gastrointestinal system from the ileus and must be recommended as a standard procedure.

However, the fact needs to be considered that although not many had return of bowel sounds at 6 hrs, all the patients tolerated their feeds at 6 hrs. Studies need to be conducted whether this standard 6 hr post-operative fasting is essential or not. Infact, the fast-track protocol has tried to question this fact and has become the standard of care for Colo-rectal surgeries.[26] In our knowledge no study in literature has measured post-operative ileus by using return of bowel sounds, passage of flatus and acceptance of first oral feed.

CONCLUSION

This study demonstrates that use of the simple expedient of reducing the pressure of pneumoperitoneum to equal to or less than 10 mm Hg results in a significant reduction in both the intensity and frequency of postoperative shoulder tip pain and postoperative abdominal pain with early return of bowel activity in low pressure group. On the basis of these results, the widespread use of low pressure pneumoperitoneum can be used in laparoscopic cholecystectomy.

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