Original Research Article

Comparison of low pressure versus standard pressure pneumoperitoneum for elective laparoscopic cholecystectomy in a tertiary care institute of western India

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ABSTRACT

Background: Laparoscopic cholecystectomy has proven beyond doubt to be the gold standard in the management of symptomatic cholelithiasis and other gall stone diseases. The aim of this study was to compare the use of the low-pressure pneumoperitoneum (defined as 7-9 mm Hg) with the use of standard pressure pneumoperitoneum (defined as 14 mm Hg) in patients undergoing laparoscopic cholecystectomy in a prospective randomized manner.

Methods: This randomized prospective study was carried out in the Department of General Surgery in a tertiary care PDU hospital, in Rajkot, India, from July 2014 to October 2016, with a sample size of 50 patients. Patients were randomized into two groups, one group with 25 patients was undergone laparoscopic cholecystectomy with standard pressure pneumoperitoneum at 14 mm hg (SPLC) while the other group with 25 patients was undergone laparoscopic cholecystectomy with low pressure pneumoperitoneum at 7-9 mm hg (LPLC).

Results: Incidence and intensity of post-operative pain were significantly lower in LPLC group compared to SPLC group. The average change in systolic BP and diastolic BP in patients who underwent LPLC and SPLC was not statistically significant. Average hospital stay for LPLC group are 1.92 days and for SPLC group its 2.48 days.

Conclusions: Though surgeon experience quite more difficulty in dissection during low pressure pneumoperitoneum and operative time is quite high, it is significantly advantageous in terms of post-operative pain, use of analgesics, less shoulder tip pain and hospital stay. It is feasible and safe. There was no significant change in SBP and DBP in both groups.

Keywords: Cholecystectomy, Gall bladder disease, LPSC, SPLC

INTRODUCTION

Laparoscopic cholecystectomy has become the gold standard treatment for gallstones disease. During laparoscopic cholecystectomy adequate working space is required in the abdomen for good exposure that contributes to satisfactory results and patient safety. Common methods to create working space in the abdomen are pneumoperitoneum and abdominal wall lifting methods such as the laparotensor and laparolift. 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.

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.5,5

An emerging trend has been the use of low pressures for pneumoperitoneum in the range of 7-10 mm Hg instead of the standard pressure pneumoperitoneum in an attempt to lower the impact of pneumoperitoneum on human physiology while providing adequate working space.6 This method appears to have little adverse effect on the cardiac and respiratory functions and is suitable for the elderly and for those with chronic cardiac or respiratory diseases. Other possible advantages of low pressures during pneumoperitoneum appear to be lower incidence of shoulder tip pain in the postoperative period and also better quality of life in the week following surgery.7

However, the lower pressures involved in the low pressure laparoscopic cholecystectomy might result in a 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 standard pressure laparoscopic cholecystectomy or open cholecystectomy.8

This study proposes to compare the use of the low pressure pneumoperitoneum (defined as 7-9 mm Hg) with the use of standard pressure pneumoperitoneum (defined as 14 mm Hg) in patients undergoing laparoscopic cholecystectomy in a prospective randomized manner.

METHODS

This randomized prospective study was carried out in the Department of General Surgery in a tertiary care PDU hospital, in Rajkot, India, from July 2014 to October 2016, with a sample size of 50 patients. Patients were randomized into two groups, one group with 25 patients was underwent laparoscopic cholecystectomy with standard pressure pneumoperitoneun at 14 mm Hg (SPLC) while the other group with 25 patients was undergone laparoscopic cholecystectomy with low pressure pneumoperitoneum at 7-9 mm Hg (LPLC).

All consecutive patients with uncomplicated symptomatic gallstone disease tagged for laparoscopic cholecystectomy were included in the study. At admission patient’s blood pressure and heart rate were noted. Ethical clearance from the Institute Ethics Committee was taken. The procedure was explained in detail and informed consent taken. Patients with previous abdominal surgeries and acute cholecystitis and with complications of gallstone disease like gallbladder perforation, empyema, and common bile duct stone were excluded from the study.

The surgeries were performed by experienced consultant surgeons. During the surgery the first port was inserted at a pressure of 14 mm hg.

In the standard pressure group, the pressure was taken up to 14 mm hg whilst in the low pressure group the pressure was reduced to 8 mm hg for the remaining duration of surgery. A standard laparoscopic cholecystectomy was performed with the insertion of four ports at the start of surgery. Intra-operative monitoring done by monitoring heart rate and blood pressure non-invasively every 10 minutes and average of it taken from three readings: one before creating pneumoperitoneum, one after creating it, one after skin closure. Closure of the rectus sheath done at 10 mm ports at the umbilicus site and at epigastric site using absorbable sutures. Skin was approximated at all the port sites using ethilon 2-0. Or 3-0. The anaesthetic protocol was same for both groups. Post-operative analgesia was administered in the form of diclofenac 12 hourly with additional dose where necessary. Patients were encouraged to become ambulatory yearly and were allowed oral intake six hours after surgery. Post-operative pain was measured at 6, 12 and 24 hours using a 0-10 pain scale. Need for additional analgesia over and above the 12 hourly diclofenac and incidence of shoulder tip pain were also noted.

They were discharged on 1-3 days following surgery according to their condition. Statistical analysis was carried out using the chi square and independent student t tests. P value <0.05 was taken as statistically significant.

RESULTS

Patients were randomised into two groups, one group with 25 patients was undergone laparoscopic cholecystectomy with standard pressure pneumoperitoneun at 14 mm hg (SPLC) while the other group with 25 patients was underwent laparoscopic cholecystectomy with low pressure pneumoperitoneum at 7-9 mm hg (LPLC).

Table 1: Distribution of cases and controls according to age groups.

| Age (in years) | Cases (%) | Controls (%) |
|---------------|-----------|--------------|
| <20           | 0 (0)     | 0 (0)        |
| 20-29         | 4 (16)    | 0 (0)        |
| 30-39         | 7 (28)    | 11 (44)      |
| 40-49         | 4 (16)    | 3 (12)       |
| 50-59         | 4 (16)    | 6 (24)       |
| >60           | 6 (24)    | 5 (20)       |
| Total         | 25 (100)  | 25 (100)     |

Out of all, 7 (28%) cases belonged to 30-39 years age group while 11 (44%) controls belonged to this age group. Among total 50 study participants, 11 (22%) were males while 39 (78%) were females.

According to Table 2, low pressure laparoscopic cholecystectomy took on average more time than standard pressure laparoscopic cholecystectomy but this difference was not statistically significant (p = 0.1).
The operating surgeons had noted that there was little difference in the exposure at 8 mm Hg as compared to that at 14 mm Hg.

**Table 2: Comparison of operative time among cases and controls.**

| Operative time (in minutes) | Cases (%) | Controls (%) |
|-----------------------------|-----------|--------------|
| 1-50 | 0 (0) | 2 (8) |
| 50-75 | 10 (40) | 13 (52) |
| 76-100 | 13 (52) | 9 (36) |
| 101-125 | 2 (80) | 0 (0) |
| 126-150 | 0 (0) | 0 (0) |

Table 3 shows that incidence and intensity of post-operative pain were significantly lower in LPLC group compared to SPLC group.

Need of additional analgesia post-operatively and post-operative pain referred to the tip of the right shoulder were significantly lower in LPLC group in compare with SPLC group. For former difference was not statistically significant (p = 0.7). For later also difference was not statistically significant (p = 1.0).

**Table 3: Comparison of average pain scores at different intervals among cases and controls.**

| Average pain score | Cases | Controls |
|--------------------|-------|----------|
| 6 hours | 2.54 | 2.8 |
| 12 hours | 2.625 | 2.72 |
| 24 hours | 2.333 | 2.52 |

The average change in systolic BP and diastolic BP in patients who underwent LPLC and SPLC was not statistically significant. The average change in heart rate in patients who underwent LPLC compare to SPLC was not statistically significant.

**Table 4: Comparison of Blood pressure changes, pulse rate changes and post-operative hospital stay among case and controls.**

| Average BP changes | Cases | Controls |
|--------------------|-------|----------|
| Systolic BP (change in mmHg) | 0.69 | 0.9 |
| Diastolic BP (change in mmHg) | 1.54 | 2.64 |
| Average Pulse Changes (per minute) | 0.89 | 1.78 |
| Post-operative Hospital stay |     |          |
| 1 day | 3 | 1 |
| 2 days | 21 | 17 |
| ≥ 3 days | 1 | 7 |

Average hospital stay for LPLC group are 1.92 days and for SPLC group its 2.48 days. No any conversion seen in present study (laparoscopy converted to open cholecystectomy).

**DISCUSSION**

Low pressure pneumoperitoneum appears to have little adverse effect on the cardiac and respiratory functions and is suitable for the elderly and for those with chronic cardiac or respiratory diseases, lower incidence of shoulder tip pain in the post-operative period and also better quality of life in the week following surgery.4

If lower pressures are associated with favourable effects in terms of both success of the surgery and lower number of intra- and post-operative complications, the achievement of such pressures must be sought. On the other hand, if the use of lower pressures is shown to be harmful, surgeons ought to use standard levels of pressure. Therefore, our review will help in establishing optimal practices in terms of intraperitoneal pressure levels in laparoscopy. We do expect heterogeneity in study samples and surgery techniques, including different pressure levels.

Majority of patients in our study belongs to age group 30-40 years. Same ratio seen in both cases and control groups. 39 out of 50 (78%) patients were females (F>M). As it is seen that gall stones diseases are more common in female population. Similar age and sex distribution seen in other studies like Kanwer et al, Barczynski et al and Haribhakti SP et al.7,9,10

SPLC group took an average of 69.6 minutes with a minimum of 45 minutes and a maximum of 98 minutes. LPLC group took an average of 79 minutes with a minimum of 60 minutes and a maximum of 110 minutes. LPLC group took on average 10 minutes more than SPLC group. Our result is comparable with Kanwer et al study in that SPLC took 49.1 minutes with minimum of 35 minutes and max of 65 minutes.9 LPLC took 46.4 minutes with minimum of 40 minutes and max of 60 minutes. Present result is comparable with other studies like Sandhu T et al, Barczynski M et al, Haribhakti SP et al.7,10,12

Incidence and intensity of post-operative pain were significantly lower in LPLC group with fewer requirements of analgesics in the post-operative period. The average pain score at 6 hours for patients who underwent LPLC group was 2.5. The pain score at 6 hours for SPSC group was 2.8. This difference was not statistically significant. The average pain score at 12 hours for patients who underwent LPLC group was 2.6. The average pain score at 12 hours for patients who underwent SPLC group was 2.7. This difference was statistically significant. The average pain score at 24 hours for patients who underwent LPLC group was 2.3. Average pain score at 24 hours for patients who underwent SPLC group was 2.5. This difference was not statistically significant.

Our result is comparable with Kanwer et al, Trichak Sandhu et al, Barczynski et al, Haribhakti SP et al study.
in those SPLC group shows higher average pain score during all 6, 12, 24 hours post operatively than LPLC group.\textsuperscript{7,9,10,12} In those studies VAS (visual analogue score) was used as a pain score.

Two (8%) of the 25 patients who underwent LPLC group and 3 (12%) of the 25 patients who underwent SPLC group needed additional analgesia post-operatively. Our result is comparable with Kanwer et al study in that 3 (11.1%) patients in SPLC and 5 (19.7%) patients in SPLC shows requirement for additional analgesia.\textsuperscript{9} Present result is comparable with other studies like Trichak Sandhu et al, Barczynski et al, Haribhakti SP et al.\textsuperscript{7,10,12}

1(4%) of the 25 patients who underwent LPLC group and 3 (12%) of the 25 patients who underwent SPLC group had post-operative pain referred to the tip of the right shoulder. Our result is comparable with Kanwer et al study in it 1 (3.7%) patient in LPLC and 2 (7.1%) patients in SPLC shows post-operative pain referred to the tip of the right shoulder.\textsuperscript{9} Present result is comparable with other studies like Sandhu T et al, Barczynski et al, Haribhakti SP et al.\textsuperscript{7,10,12}

The average change in systolic BP in patients who underwent LPLC was an increase of 0.83±8.66 mm Hg with a maximum rise of 12 mm Hg and a maximum fall of 5 mm Hg. The average change in systolic BP in patients who underwent SPLC was an increase of 0.91±14.67 mm Hg with a maximum rise of 13 mmHg and a maximum fall of 16 mm Hg. This difference was not statistically significant. Our result is comparable with Kanwer et al study in that LPLC shows SBP increase 0.96 mmHg with maximum rise of 13 mmHg and max fall of 7 mmHg.\textsuperscript{9} SPLC shows SBP increase 0.8 mmHg with maximum rise of 18 mmHg and max fall of 16 mmHg.

Average change in diastolic blood pressure in patients who underwent LPLC was increase of 1.75±8.33 mm Hg with a maximum rise of 11 mm Hg and a maximum fall of 6 mm Hg. The average change in diastolic BP in patients who underwent SPLC was an increase of 2.6±8.34 mm Hg with a maximum rise of 10 mm Hg and a maximum fall of 7 mm Hg. This difference was not statistically significant. Our result is comparable with Kanwer et al study in that LPLC shows DBP increase 1.8 mmHg with maximum rise of 13 mmHg and max fall of 7 mmHg.\textsuperscript{9} SPLC shows DBP increase 2.8 mmHg with maximum rise of 10 mmHg and max fall of 7 mmHg.

The average change in heart rate in patients who underwent LPLC was a decrease of 0.8±12.01 beats per minute. Average change in heart rate in patients who underwent SPLC was an increase of 1.8 ± 5.33 beats per minute. This difference was not statistically significant. Our result is comparable with Kanwer et al study in that LPLC shows PR decrease 0.5 per min.\textsuperscript{9} SPLC shows PR increase 1.5 min.

Average hospital stay for LPLC group are 1.92 days and for SPLC group its 2.48 days. Sandhu T et al study shows similar post-operative hospital stay in both groups.\textsuperscript{12}

**CONCLUSION**

An uncomplicated gall stone disease can be treated by low pressure laparoscopic cholecystectomy with reasonable safety by an experienced surgeon. Though surgeon experience quite more difficulty in dissection during low pressure pneumoperitoneum and operative time is quite high, it is significantly advantageous in terms of post-operative pain, use of analgesics, less shoulder tip pain and hospital stay. It is feasible and safe. There was no significant change in SBP and DBP in both groups.

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**Conflict of interest:** None declared

**Ethical approval:** The study was approved by the Institutional Ethics Committee

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