A Prospective Randomized Study on Comparison of Low Pressure Versus Standard Pressure Pneumoperitoneum for Elective Laparoscopic Cholecystectomy

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ABSTRACT

Introduction: This study proposes to compare the use of the low pressure pneumoperitoneum/LPLC (< 9 mm Hg) with the use of standard pressure pneumoperitoneum/SPLC (14 mm Hg) in patients undergoing laparoscopic cholecystectomy in a prospective randomized manner in an attempt to lower the impact of pneumoperitoneum on human physiology.

Method and Materials: The study was carried out with a sample size of 50 patients randomised into two groups, one with 25 patients - SPLC while the other group with 25 patients LPLC. To compare post-operative pain incidence of shoulder tip pain, average operation duration, need of additional analgesia post-operatively, duration of hospital stay, change in Pulse rate, SBP & DBP in both groups.

Result: Incidence and intensity of post-operative pain, post-operative pain referred to the tip of the right shoulder were significantly lower in LPLC group compared with SPLC group. The average change in SBP in patients who underwent LPLC was an increase of 0.83 ± 8.66 mm Hg and in SPLC group was an increase of 0.91 ± 14.67 mm Hg. Average change in DBP in patients who underwent LPLC was increase of 1.75 ± 8.33 mm Hg and in SPLC group was an increase of 2.64 ± 8.34 mm Hg and in LPLC group was a decrease of 0.8 ± 12.01 beats per minute and in SPLC group an increase of 1.8 ± 5.33 beats per minute. The average change in SBP, DBP & heart rate in patients who underwent LPLC & SPLC was not statistically significant. Average hospital stay for LPLC group are 1.92 days and for SPLC group its 2.48 days.

Conclusion: An uncomplicated gall stone disease can be treated by low pressure laparoscopic cholecystectomy with reasonable safety by an experienced surgeon. It is significantly advantageous in terms of post-operative pain, use of analgesics, less shoulder tip pain and hospital stay.

Keywords: Low Pressure Pneumoperitoneum, Laparoscopic Cholecystectomy

INTRODUCTION

Laparoscopic surgery has several advantages when compared to open surgery, including faster post-operative recovery and lower pain scores. An emerging trend has been the use of low pressures for pneumoperitoneum in the range of 7-8 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. It has been postulated that lowering intra-peritoneal pressure levels while performing general laparoscopic surgery would lower surgical complications including post-operative pain, but data remain scarce about significant operative complications.

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. This study proposes to compare the use of the low pressure pneumoperitoneum (as < 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.

METHOD AND MATERIALS

To compare post-operative pain incidence of shoulder tip pain, average operation duration, need of additional analgesia post-operatively, duration of hospital stay, change in Pulse rate, SBP & DBP in both groups.

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

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. The surgeries were performed by experienced consultant surgeons. A standard laparoscopic cholecystectomy was performed with the insertion of four ports at the start of surgery. Pre-operative, Intra-operative &...
post-operative monitoring of heart rate and blood pressure done. The anaesthetic protocol was same for both groups. 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 and incidence of shoulder tip pain were also noted. Statistical analysis was carried out using the chi square and independent student t tests. A p value <0.05 was taken as statistically significant.

RESULTS

Majority of patients in our study belonged to age group 30-40 years in both LPLC group and SPLC group (table-1). 39 out of 50 patients were female its 78%. (F>M) in both LPSC group and SPLC group.

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. LPLC took on average 10 minutes more than SPLC 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).

Incidence and intensity of post-operative pain were significantly lower in LPLC group compare with SPLC group.2 (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.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. For both difference was not statistically significant (p = 0.7) (table-3).

The average change in SBP 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 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. Average change in DBP 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 patients who underwent SPLC was an increase of 2.64 ± 8.34 mm Hg with a maximum rise of 10 mm Hg and a maximum fall of 7 mm Hg. 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. The average change in SBP, DBP & heart rate in patients who underwent LPLC & SPLC was not statistically significant. Average hospital stay for LPLC group are 1.92 days and for SPLC group its 2.48 days. No any conversion seen in our study. (Laparoscopy converted to open cholecystectomy)

DISCUSSION

Bearing in mind the potential negative impact of pneumoperitoneum on cardiopulmonary function and the positive impact on post-operative pain, international guidelines recommend that the use of “the lowest intra-abdominal pressure allowing adequate exposure of the operative field rather than a routine pressure” should be used. The advent of laparoscopic cholecystectomy is a milestone achieved in both the treatment of gallstones and in the evolution of minimal access surgery. The aim was to reduce the trauma during access and maintain appropriate exposure of the surgical field during surgery. Initial studies have indicated that the use of low pressure during pneumoperitoneum is associated with better intra-operative tolerance (including anaesthesia tolerance) and improved post-operative recovery with reduced intensity of the surgical pain. Many centres have reported that LPLC group shows better post-operative quality of life as compared to SPLC. In our study none of the patients had any major intra-operative or post-operative complications. The post-operative course was by and large uneventful in all patients. With increasing laparoscopic applications, surgeons should view the basic physiologic principles of the cardiac, respiratory, renal, and metabolic response in laparoscopy. As the complexity of general surgical cases performed laparoscopically increases, for a longer time durations of CO2 insufflation and elevated intra-abdominal pressure are required, further magnifying physiologic modifications in patients. Thus, the laparoscopist must be mindful from the each patient's fundamental cardiopulmonary status and anticipate the hemodynamic reaction to non-invasive surgery.

CONCLUSION

An uncomplicated gall stone disease can be treated by low pressure laparoscopic cholecystectomy with reasonable safety by an experienced surgeon. It is significantly

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**Table-1: Age distribution**

| Years | Case group | Control group |
|-------|------------|---------------|
| <20   | 0          | 0             |
| 20-29 | 4          | 0             |
| 30-39 | 7          | 11            |
| 40-49 | 4          | 3             |
| 50-59 | 4          | 6             |
| >60   | 6          | 5             |

**Table-2: Operative Time**

| Case (25) | Control (25) |
|-----------|--------------|
| 1-50 min  | 0            |
| 50-75 min | 10           |
| 76-100 min| 12           |
| 101-125 min| 2           |
| 126-150 min| 0           |

**Table-3: Average Pain Score**

| average pain score | 6 hours | 12 hours | 24 hours |
|--------------------|---------|----------|----------|
| Case/LPLC          | 2.54    | 2.625    | 2.3333   |
| Control/SPLC       | 2.8     | 2.72     | 2.52     |
advantageous in terms of post-operative pain, use of analgesics, less shoulder tip pain and hospital stay. It is feasible and safe. Some significant changes and results in cardio-vascular system components expected if study done through a more complex set up and probably a larger sample size that includes a significant numbers of patients with cardiovascular co morbidity conditions.

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