

Low-Pressure Laparoscopic Surgery is a Viable and Risk-Free Alternative to Standard Pressure for the Treatment of Benign Gall Stone

IMRAN ALI¹, GUL NAZ², SAULEHA SAYYED³, ZAHID RASHEED⁴, MUHAMMAD RIZWAN⁵, FAWAD HAMEED⁶, MUHAMMAD KHURRAM JAMEEL⁷

¹Consultant General Surgeon, THQ Hospital, Phalia

²Senior Registrar Surgery, Ghulab Devi Hospital Lahore

³Women Medical Officer, Farooqui Dental & Medical Centre, Lahore

⁴Registrar Surgery, Farooq Hospital Rawalpindi Branch, Rawalpindi

⁵Consultant General Surgeon, DHQ hospital, Jhelum

⁶Associate Professor surgery, Azra Naheed Medical College, Lahore

⁷Assistant Professor of Surgery, Azra Naheed Medical College, Lahore

Corresponding author: Imran Ali, Email: dr_imran500@yahoo.com

ABSTRACT

When compared to the open cholecystectomy, laparoscopic cholecystectomy (LC) has the benefits of less post-operative pain and quicker return to work. However, up to 80% of individuals after laparoscopic surgery still experience significant pain and needing pain relief.

Methodology: The reason for this research was to compare the results of LC performed with and without LPP. LC requires the surgeon to choose a pneumoperitoneum pressure that maximizes working space while avoiding unintended side effects. This study used a Randomized Controlled Trial (RCT) design, and it was done at the West Surgical Ward at Mayo Hospital in Lahore. The study enrolled 60 participants who met the inclusion criteria. The patients were split in two groups: Low-pressure pneumoperitoneum-LPP (Group A) (06-10 mm of Hg) and pneumoperitoneum at standard pressure (SPP) is part of Group B. (12-16 mm of Hg). All had opted for a LC to treat their symptomatic gallstone disease. At 4, 8, and 24 hours following surgery, the severity of postoperative shoulder pain (if present) was evaluated using a visual analogue pain scale (VAS). The frequency of postoperative nausea and vomiting was assessed at 4, 8, 12, and 24 hours.

Results: The patients were 35.63 years old on average. Majority of these two groups has no complications. Based on the data, we discovered that the frequency of episodes of nausea/vomiting in both groups was very low and that only a few patients had bouts of nausea/vomiting in the 4 hours and 24 hour time intervals.

Conclusion: We have come to the conclusion that LP laparoscopic surgery is a viable and risk-free alternative to SP laparoscopic operation for the treatment of benign gall stone disorders. Our findings lead us to the conclusion that LPP is a superior option for the LC since it reduces the post-operative pain in the shoulder and the risk of PONV while not significantly increasing the risk of intraoperative complications.

Keywords: Benign Gall Stone, Treatment, Low-Pressure Laparoscopic Surgery,

INTRODUCTION

When compared to the open cholecystectomy, LC has the benefits of less post-operative pain and quicker return to work. However, up to 80% of individuals after laparoscopic surgery still experience significant pain and needing pain relief.^[1, 2] In order to do a LC, pneumoperitoneum must be created by insufflating the abdominal cavity with CO₂ through a pressure-regulating automated insufflator. The abdomen is inflated with pneumoperitoneum, revealing the organs therein and facilitating instrument access. Complications from pneumoperitoneum include acid-base imbalances, reduced lung compliance, nausea, and shoulder pain after surgery.^[3]

Numerous researches has demonstrated the advantages of LC over traditional methods. Instantaneous and effective pain control to reduce the pain (VAS) scores (ranges from zero to ten cm) and no additional treatment required after discharge are also acceptable outcomes. As a result, wound infiltration with local anesthetic medicines after surgery is being studied.^[4]

The precise pathogenesis of shoulder pain is unknown. Carbon dioxide insufflation causes postoperative pain of the shoulder. After the procedure, carbon dioxide gas lingers in the sub-diaphragmatic region for more than 24 hours.^[5]

There is no consensus on how to manage postoperative shoulder pain effectively. For comprehensive pain reduction after LC, multimodal analgesia is required. There have been a few trials using LPP that have shown a reduction in discomfort after surgery.^[6]

LPP helps the patient by reducing postoperative pain intensity, although it does not influence intraoperative hemodynamics, LPP was both practical and safe, with less postoperative pain and a similar operating time to SPP.^[6] The use of LPP has been stressed in several studies. However, surgeons who use low pressure have encountered technical challenges such as limited working space, longer operating times, a greater

happening of the intraoperative problems, more conversion to standard pressure, and many professionals continue to question its efficacy, and there is no reference of pneumoperitoneum pressure as an ideal pressure for LC in the literature.^[7]

In light of this, this study will compare shoulder pain, intraoperative complications, nausea, and vomiting following LC using low pressure (LP) (06-10mm Hg) against standard pressure (SP) (12-16mm Hg) to determine an optimal working pressure for LC that allows adequate working space while reducing postoperative shoulder pain, intraoperative problems, nausea, and vomiting

METHODOLOGY

The reason for this research was to compare the results of LC performed with and without LPP. LC requires the surgeon to choose a pneumoperitoneum pressure that maximizes working space while avoiding unintended side effects. This study used a Randomized Controlled Trial (RCT) design, and it was done at the West Surgical Ward at Mayo Hospital in Lahore after approval of synopsis in March 2021.

Duration of study was 06 months with a sample size of the 60 patients (thirty patients in each group) is estimated by using the 5 percent level of significance, 95 percent power of the test with the expected mean pain score value for low pressure as 0.24±0.822 and standard pressure 1as 2.16±3.2269. This study employed a 'Non-Probability' sampling strategy. We systematically assigned patients at random to two groups (A and B). Group A contains patients who received LPP (pressures between 6 and 10 mm Hg) while Group B included patients who received SPP (12-16 mm Hg).

Patients in this study were selected if they were between the ages of 20 and 60, in ASA physical status classes 1 and 2, and scheduled to have LC for asymptomatic gallstone disease. Patients undergoing LC with CBD exploration, patients undergoing

LC converted to open surgery, and patients with a history of shoulder pain are ineligible. Patients with additional co-morbid illnesses, such as diabetes and hypertension, are also excluded.

The conventional four-port laparoscopic method had been used for the cholecystectomy that had been performed by an expert. Documentation was created for the duration of the procedure, the intra-operative findings, the intra-operative complications (including (1) bile leaking, (2) bleeding, (3) visceral injury), and the hospital stay. The decision to switch to a standard pressure cholecystectomy or an open surgery of cholecystectomy was documented, along with the reasons for making the switch. During the postoperative period, every patient was given the identical medication for pain relief and to prevent nausea and vomiting. The visual analogue scale was used to evaluate the degree of postoperative shoulder discomfort (if there was any) at 4, 8, 12, and 24 hours after surgery. The rate of nausea and vomiting was reported at 4, 8, 12, and 24 hours after the start of the study.

The statistical software SPSS version 26 was used to enter and evaluate data. The mode was used to portray quantitative values like age. Gender was expressed as a frequency and percentage for qualitative variables such as gender. The chi-square test was used to compare both research groups' low and standard pressures, with a p-value of 0.05 considered significant.

RESULTS

A total of 60 patients were enrolled in this trial. The patients' average age was 35.63 years, a minimum and maximum age of 20 and 60 years, respectively (maximum people in their 40s). According to this study it was divided into two groups like Group A, the maximum age of the patients was 60 years, while the maximum age from group B was 56 years and minimum age of group A was 20 years while minimum age of group B was 23 years old.

Data analysis of the frequency of intraoperative complications i.e. bile Spillage, bleeding and visceral injury, clearly stated that majority of these two groups has no complications. In graphical representation of data we come to know that very rare patients got episode of nausea/vomiting in 4 hours and 24 hours time intervals. However in 8 hours and 12 hours time intervals more patients faced this condition.

It was reported that with α 0.239 ($X^2= 67\%$) with likelihood ratio 66.55%, SPP is strongly associated with shoulder pain at 4 hours as compare to low pressure pneumoperitoneum (likelihood ratio 42%). Similarly, we elaborated that α 0.007 ($X^2 = 125\%$) with likelihood ratio 83% which means SPP was strongly associate with shoulder pain at 8 hours as compare to low pressure pneumoperitoneum which is likelihood ratio 50%.

We analyzed the data to evaluate either if there is a statistically important relationship between the factors, with α 0.264 ($X^2= 98\%$), likelihood ratio 77%, SPP was seen strongly associates with shoulder pain at 8 hours as compare to low pressure pneumoperitoneum. In this table, we easily elaborate that on the behalf of α 0.31 ($X^2= 111\%$) with likely hood ratio 82.8%.

DISCUSSION

The prevalence and vigour of postoperative pain of the shoulder are reduced markedly when LC is performed under low-pressure CO₂ (06 to 10 mmHg). When compared to the SPCP group, the LPCP group had a 2.5-fold lower incidence of shoulder pain. This is consistent with past research. Furthermore, meta-analyses of the previous trials show that LPCP is effective at causing the reduction in the occurrence and severity of pain of the shoulder following LC. The growing body of research supports the theory that CO₂ pneumoperitoneum-induced peritoneal stretching and diaphragmatic injury are to blame for post-LC shoulder pain. Shoulder pain begins 2–6 hours after surgery and gradually increases in intensity until it peaks at around 12 hours when it starts to fade. The degree of pain of the shoulder in the SPCP group was markedly higher at 8 & 24 hours after the procedure.^[8]

Our observation of delayed shoulder discomfort and pain, as well as the significance of this phenomenon in the first eight and twenty-four hours after surgery, is supported by a large number of studies that were conducted in the past. The SPCP group required extra analgesics due to shoulder pain; however, this change was not statistically significant after 8 hours, but it was ($p = 0.05$) after 24 hours. The fact that this was the case shows that the patients in the SPCP group did not have a smooth recovery. Pain in the shoulder following surgery was experienced similarly by both groups, with duration of around 2.7 days on average being the norm.^[9]

It would indicate that the total amount of time spent in surgery is a factor in determining how long postoperative shoulder pain will last. People who have shoulder surgery that lasts more than 45 minutes, in comparison to those who have shoulder surgery that lasts less than 45 minutes, have shoulder pain for a longer period of time after the procedure. It's possible that the shorter length of shoulder pain is due to the fact that both groups of patients underwent their surgeries at roughly the same time (average time of 38 minutes). Pneumoperitoneum residual volume can potentially have an effect on post-operative stomach discomfort as well as pain in the shoulder that occurs after LC. Sarvestani et al. determined the amount of pneumoperitoneum that was still present 24 hours after LC by using chest X-rays in their calculation.^[10]

Several further randomised studies revealed that the operating periods of SPCP and LPCP LC were comparable. According to a meta-analysis, LPCP LC surgery takes two minutes longer than SPCP. LPP reduces exposure and operational area. There was no RCT that looked at the long-term safety of LC in LPCP patients.^[11,12]

According to Willam K¹³ minimal invasive hysterectomy done under LPCP and SPCP can be graded as bad, fair, good, and extraordinary as per surgeon's comfort depending on the level of pelvic visibility. The LPCP group, with the exception of one patient, had good or excellent visualization; nonetheless, this group reported significantly less shoulder pain than the SPCP group. There is only one study that looks at surgeon's ease levels during LC with LPCP and SPCP. LPCP reduced overall visibility, visibility at suction, and dissection space, they discovered. We analyzed the surgeon's satisfaction level on the Likert scale across six unique categories in a pre-defined proforma. None of the surgeons thought any of the categories were "very difficult" or "extremely bad." In both groups, individual scores for each parameter, as well as the total score, were comparable. Without raising pressure, all of the patients in the LP group could be operated satisfactorily.^[14]

According to the findings of our study, a LC carried out at an intra-abdominal pressure of 9 to 10 mmHg is just as successful and safe as an SPP procedure. This is substantiated by the fact that both approaches take around the same length of time, result in approximately the same number of problems during the operation, and do not significantly impact the surgeon's ease score. These findings call into question the long-held belief that an SPP is required for adequate visualization and exposure during LC, and emphasize the need of using LPP (9 to 10 mm of Hg) for the procedure. Patients with a BMI of more than 30 and those with significant gallstones were excluded. So our cases were straight and free of adhesions. As a result, these results should be regarded with caution in patients who have not been pre-screened. Likert scale used to gauge surgeon satisfaction is another topic of disagreement.^[15,16]

It is a randomized study in which both the patient and the pain assessor are blind to the assigned groups. We enrolled a subset of patients. On the one hand, this is strength because it enabled us to test the theory without being confounded by technological concerns. On the other hand, it presents the findings from being generalized to non-selected patients, which could be considered a study flaw. The surgeon was not blinded to the intra-abdominal pressure used during surgery, which is another study weakness. For a surgeon who is used to a 14 mmHg intra-

abdominal pressure, a lower pressure is intuitively acceptable. The study's main discovery is that we were able to show for the first time that surgeon satisfaction with exposure and working space is not affected by lower pressures (9–10 mmHg), and that LC may be conducted safely in selected patients. As a result, LPP may be indicated regularly in these patients.^[17]

Numerous research published over the last decade have shown that pneumoperitoneum development causes numerous physiological abnormalities in individuals having laparoscopic procedures. The mechanical influence of gas in the peritoneal cavity, as well as the chemical makeup of the gas used, such as carbon dioxide, can explain these alterations. The difference in serum bilirubin levels between people who had LC under low and standard pressure was statistically negligible (p -value=0.2562).^[18]

Pneumoperitoneum has no substantial effect on bilirubin levels, according to AN Singh et al. postoperatively, serum levels of AST & ALT were higher ($p=0.0001$) in people who had a SP LC. As a result, it's possible that using standard pressure during LC has a negative impact on AST and ALT levels. Patients having HPPLC exhibited higher AST and ALT values, according to a comparable study conducted by Ahmad NZ. Ahmad NZ et al., discovered significant increases in AST and ALT, but not in ALP. It was previously debated if the squeezing pressure effect on the liver, diathermy, and general anesthesia all played a role in liver disease. In LC conducted at low or standard pressure, however, the same parameters are present.^[19]

Furthermore, the changes are seen in operations other than LC that do not involve liver manipulation, implying that a single component common to all laparoscopic surgeries is to blame. CO₂ insufflation and increased intra-abdominal pressure cause reduced portal blood flow, resulting in sublethal ischemia of hepatocytes. Reperfusion damage could be one of the causes. The neuro-humoral response of the rennin-angiotensin-aldosterone system is activated when intra-abdominal pressure rises. Because of these considerations, the group getting high-pressure pneumoperitoneum has a substantially higher spike in liver enzymes.^[20]

Guruswamy S, et. al.^[21] conducted research and they discovered that the low-pressure group experienced less pain intensity. Additionally, analgesic consumption was decreased. All experiments were done on ASA grade 1 and 2 cases. Further research is needed to determine the cardiovascular stability of LPP in cases having cardiac issues or ASA grade 3 and 4 cases with additional issues.^[35] After scrutinizing the findings of our study, we conclude that LPP causes marked reduction in occurrence, severity of pain after surgery and a decreased need for analgesia, in comparison to SPP.

CONCLUSION

Based on prior research and a current study of patients of all ages, LPP is preferable for LC, allowing us to simply overcome any issues. LP laparoscopic surgery for benign gall stone diseases is possible and safe. LP laparoscopic surgery is a safe alternative to SP laparoscopic surgery for benign gall stone disorders. LPP reduces post-operative shoulder soreness, PONV, and intraoperative problems, making it a better option for the LC.

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