LATEST INNOVATIONS &TRENDS IN MEDICAL SCIENCE - "SINGLE INSTITUTIONAL COMPARATIVE STUDY ON THE IMPACT OF THE STANDARD PRESSURE AND LOW PRESSURE PNEUMOPERITONEUM ON POST - OPERATIVE PAIN FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY - A STRATIFIED RANDOMIZED CONTROLLED TRIAL"

Abstract

Background and Objectives: Gastro-Intestinal surgery has undergone a revolution in the recent years by the introduction of laparoscopic techniques. The most common complaint following laparoscopic surgery, initially being recognized by gynaecologists during early experience with laparoscopic sterilization is shoulder pain. The concept of "Keyhole Surgery" created an immediate disparity between the potential of the new technique and training of surgeons to perform it. Now modern surgical methods are aimed at giving cure along with minimal invasive techniques with patient in mind and safety never being compromised.

Cholelithiasis, which is one of the most common gastrointestinal disorders seen, was traditionally treated by conventional or open cholecystectomy. Currently laparoscopic cholecystectomy is the standard procedure as it is less painful, needs shorter recovery period and short hospital stay.

Recovery after laparoscopic cholecystectomy depends upon several factors such as: Abdominal pain, Shoulder tip pain, Nausea, Vomiting and Fatigue. These side-effects are due to peritoneal stretching and diaphragmatic irritation caused by high intra-abdominal pressure and by CO_2. Among the

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causes for shoulder pains are: Stimulation of the sympathetic nervous system by hypercarbia, the residual pneumoperitoneum after the surgery, and rapid distention of the abdomen by carbon dioxide. Keeping this in mind, it was assumed that lower intra-abdominal pressure will decrease these complications. Traditionally, the pressure used to create pneumoperitoneum is around 15mm Hg. There are a few studies done using low pressure pneumoperitoneum (less than 12 mm Hg) and showed decrease in pain post- operatively. But, all the studies are not equivocal in this respect. Further, the safety of low- pressure pneumoperitoneum is not established.

There were no Stratified RCT studies conducted before on this topic. So, our aim was to compare impact of the Standard Pressure and Low-Pressure pneumoperitoneum technique on post-operative pain following conventional laparoscopic cholecystectomy

Materials and methods: A stratified study to compare
impact of the Standard Pressure and Low-Pressure pneumoperitoneum technique on post-operative pain following conventional laparoscopic cholecystectomy was performed 143 patients during the period of Jan 2018-Dec 2019. Individuals fulfilling the inclusion and exclusion criteria were assigned to 2 groups as per methodology.

1. Group: A patients will be undergoing laparoscopic cholecystectomy with low pressure pneumoperitoneum –LPP (7-8 mm Hg) while,
2. Group: B will be undergoing laparoscopic cholecystectomy with standard pressure pneumoperitoneum -SPP (12-14 mm Hg).

The duration of surgery was carefully

recorded using the wall mounted OT timers. The time of arrival in the postoperative ward was defined as 0 h postoperatively. Presence of shoulder pain, port site pain and / or diffuse abdominal pain was measured at 2, 4, 6, 12, 24, and 48 hours, respectively. Pain score VAS (Visual Analogue Score) according to scale was used to detect the intensity of the pain postoperatively. World Health Organization (WHO) analgesic step ladder was used as a frame work for providing symptomatic pain relief to the patients. Statistical analysis was done using standard tools. Mean of two groups were compared using independent t-test. Chi square test was used to analyse the significance of difference between frequency distribution of the data. P value < 0.05 was considered as statistically significant

Results: Standard Pressure Pneumoperitoneum was done in 51% patients and Low Pressure Pneumoperitoneum was done in 49% patients. Majority of the patients belong to the age group of 28-37 years (39.2%). Surgeon visibility was good in 98.6% patients and poor in 1.4% patients. Bile spillage was seen in 7.7% patients. Post-operative mobilization was earlier in patients belonging to Low Pressure Pneumoperitoneum group. Post-operative opioid consumption was significantly lower in the Low Pressure group. There is no statistical significance among age, surgeon visibility and bile pillage.

Keywords: Standard Pressure, Low-Pressure Pneumoperitoneum, Laparoscopic Cholecystectomy, Post - Operative Pain, Stratified Randomized Controlled Trial Gastro-Intestinal surgery, Keyhole Surgery, Hospital Stay, Recovery, Pain , Control, early recover , Opioid Analgesia
Visual Analogue Score, Shoulder Pain.

I. INTRODUCTION

There are no Stratified RCT studies conducted before on this topic. Therefore, we conducted a stratified randomization in this pilot study to compare the impact of the Standard Pressure and Low- Pressure pneumoperitoneum technique on post-operative pain following conventional laparoscopic cholecystectomy

In recent years we are witnessing a revolution with the innovation and introduction of laparoscopic techniques. Early experience of gynaecologists suggests that they noticed shoulder pain post-surgery, in at least 30% of patients undergoing laparoscopic sterilisation. Subsequently even the "Keyhole Surgery" brought with it a discrepancy due to the challenges involved in training of surgeons to carry out surgery[1-3].Today the latest techniques in surgical methods aim at curing the ailments with the help of minimal invasive techniques to ensure patient safety and at the same time ensure operations are conducted successfully.

We have observed that post laparoscopic cholecystectomy there are 3 kinds of pain namely: Visceral Pain, Parietal Pain and Shoulder Pain. Gastrointestinal disorders such as Cholelithiasis was treated or by open cholecystectomy. Today it is a standard procedure as it results in less pain, less hospital stays and fast recovery time. This of course depends on multiple factors such as: Shoulder tip pain, Vomiting and Nausea coupled with fatigue because of stretching of peritonea & diaphragmatic exasperation caused by abdominal pressure inside abdomen and by carbon dioxide[3-5]. It is to be noted that stimulation of sympathetic nervous by hypercarbia are the main reasons for shoulder pain.

Cholelithiasis, which is one of the most common Gastrointestinal disorders seen, was traditionally treated by conventional or open cholecystectomy. Currently laparoscopic cholecystectomy is the standard procedure as it is less painful, needs shorter recovery period and short hospital stay[6-8].

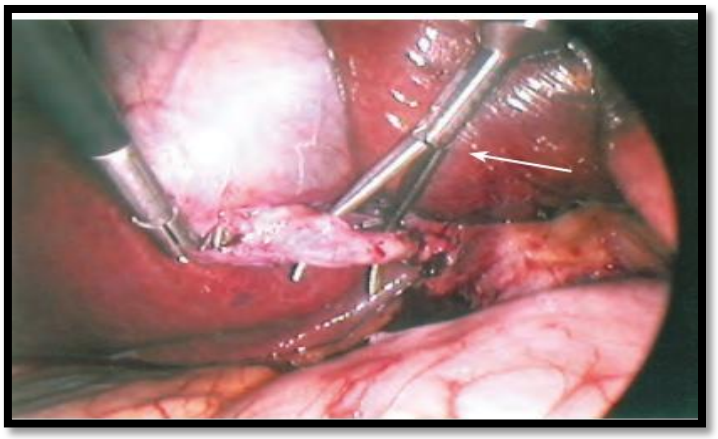


Figure 1: Operative image of a laparoscopic cholecystectomy. Laparoscopic forceps (arrow) are used to dissect "Calot's triangle" [7]

II. MATERIALS AND METHODS

1. Primary Objective

- Assessment of intensity and frequency of post-operative pain using VAS score (Visual Analog Scale).

2. Secondary Objective

- Assessment of the Duration of the Surgery.
- To measure the number of bile spillage in both the Standard and Low-Pressure pneumoperitoneum technique.
- Post-operative Opioid consumption.
- To Assess Time for Patient Mobilization Post Surgery

This study was carried out in a tertiary care hospital with over 750 beds, and lasted for a period 2 years.

3. Inclusion Criteria

- Patients between 18 to 70 Years
- Planned surgery was done for gall stone
- Normal CPD anatomy
- USG confirmed gall stone disease with at least one episode of epigastric pain.

4. Exclusion Criteria

- Above 70 years
- Pregnant Patients those with extra hepatic pathology
- ASA III / IV
- Conversion to open cholecystectomy.
- Portal hypertension, Coagulopathy and Malignancy
- CBD stones
- Past Abdominal surgery.
- Patients without consent

A total of 143 patients were randomly selected, during the period of Jan 2018- Dec 2019. The patients were divided into 2 groups namely:

1. Group – A, low pressure pneumoperitoneum –LPP (7-8 mm Hg) while,
2. Group – B, standard pressure pneumoperitoneum -SPP (12-14 mm Hg).

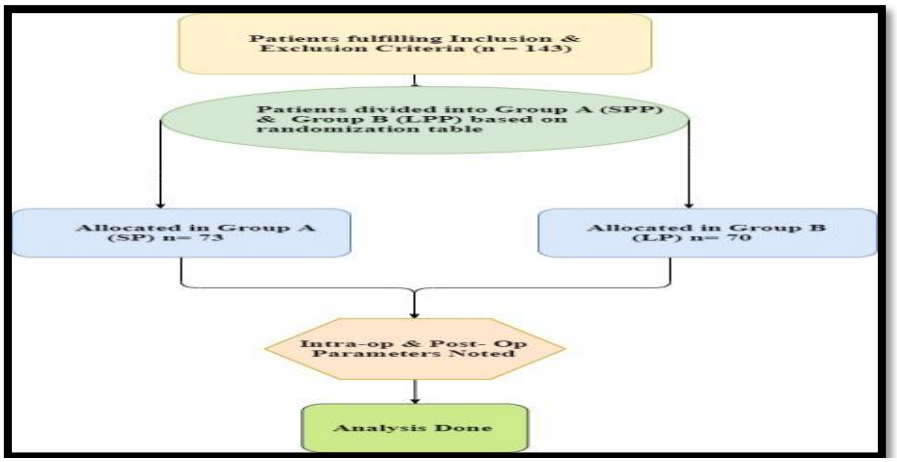
Shoulder pain, Port site pain and / or diffuse abdominal pain was measured at 2, 4, 6, 12, 24, and 48 hours, respectively. Pain score VAS (Visual Analogue Score) according to scale was used to detect the intensity of the pain postoperatively

World Health Organization (WHO) analgesic step ladder was used as a framework for providing symptomatic pain relief to the patients. Statistical analysis was done using standard tools. We compared the two groups with the help of independent t-test and Chi square test to understand statistical significance.

III. STUDY PROCESS FLOW DIAGRAM

1. Pre-Operative Parameters

- Pressure of pneumoperitoneum: Standard Pressure Pneumoperitoneum (SPP) was done in 51% patients and Low Pressure Pneumoperitoneum (LPP) was done in 49% patients.



2. Distribution according to Patient Age Group

- Most of them were between of 28-37 years (39.2%) followed by 38-47 years (18.2%), 18-27 years (16.1%), 48-57 years (15.4%) and >58 years (11.2%). Mean age in SPP is 39.34±12.015, and mean age in LPP is 38.73±12.41. Overall mean age was 39.04±12.171.
- In patients receiving Standard Pressure Pneumoperitoneum, most of them were in 28-37 years (38.4%) and in patients receiving low pressure Pneumoperitoneum, were between 28-37 years (40%). The association was found to be statistically not significant.

3. Intra-Operative Parameters

- **Surgeon visibility:** Surgeon visibility was good in 98.6% patients and poor in 1.4% patients. In patients receiving Standard Pressure Pneumoperitoneum, surgeon visibility was good in all the patients (100%) and in patients receiving Low Pressure Pneumoperitoneum, surgeon visibility was poor in 2.9% patients only. The association was found to be statistically not significant.

- **Bile spillage:** Bile spillage was seen in 7.7% patients. In patients receiving Standard pressure Pneumoperitoneum, bile spillage was seen in 4.1% patients and in patients receiving Low Pressure Pneumoperitoneum, bile spillage was seen in 11.4% patients indicating statistical insignificance.

4. Post-Operative Parameters

- **Post- operative Pain Score:** We noticed statistical significance at different time intervals as can be seen from the Table -1
- **Post Operative Patient Mobilization Time:** It was noted that patients belonging to LP group exhibited early post-operative mobilization with a mean of 8.39 $\pm$ 0.967 Hrs as compared to patients belonging to SP group in whom the mean duration of postoperative mobilization was 9.67 $\pm$ 1.001 Hrs.

This can be attributed to the fact that early postoperative pain relief is associated with early mobilization and increased patient satisfaction.

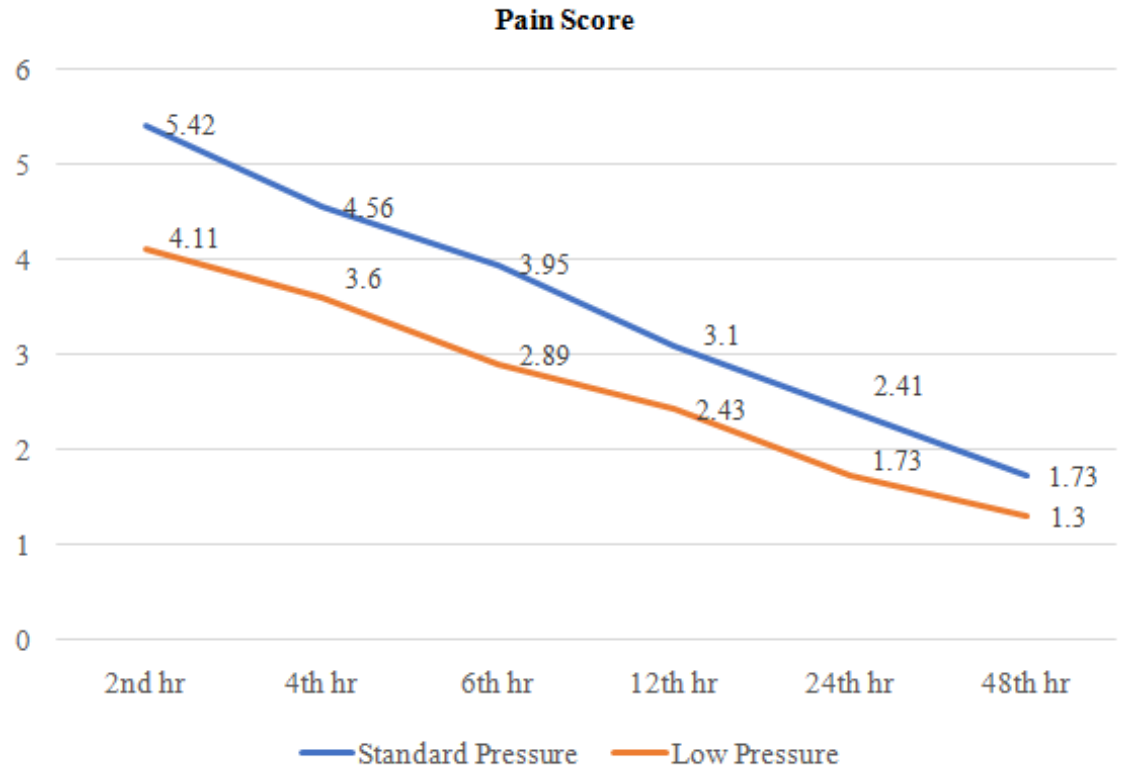
5. Post- Operative Opioid Consumption

- It was noted that post-operative opioid consumption was significantly less in the LP group. The Analgesia was given to the patients according to WHO Pain Stepladder Approach. Opioids (Inj Tramadol 50mg) was given when the VAS Score was more than 5.
- It was noted, that there was a fall in the use of opioid in LP group in the 2^{nd} and 4^{th} hr and no additional use of opioid in the LP group in 6^{th} , 12^{th} and 48^{th} hr.
- When comparing the Post- Op Opioid Consumption between the two groups, there was a statistical significance at 2^{nd}, 4^{th}, 6^{th}, and 12^{th} hour.
- There was statistical significance, when we compared the mean score of pain among two Group and at different time intervals.

Table 1: Group Statistics showing Pressure of Pneumoperitoneum & Pain score

Group Statistics						
Pressure of Pneumoperitoneum		**N**	**Mean**	**SD**	**T test**	**P value**
Pain Score-2nd hr	SP	73	5.42	0.644	12.32	0.001*
	LP	70	4.11	0.627		
Pain Score-4th hr	SP	73	4.56	0.850	7.69	0.001*
	LP	70	3.60	0.623		
Pain Score-6th hr	SP	73	3.95	0.896	7.97	0.001*
	LP	70	2.89	0.671		
Pain Score-12th hr	SP	73	3.10	1.120	4.10	0.001*
	LP	70	2.43	0.791		
Pain Score-24th hr	SP	73	2.41	0.998	4.58	0.001*
	LP	70	1.73	0.760		
Pain Score-48th hr	SP	73	1.73	0.786	3.86	0.001*
	LP	70	1.30	0.492		

Chart Line Diagram: scatter plot pain score at different intervals between lp and sp group



IV. CONCLUSION

We would like to conclude that Low pressure pneumoperitoneum is feasible, safe and results in less pain and early mobilisation after surgery that resulted in less requirement of post operative opioids. Consequently, it reduced opioids related complications like drowsiness and constipation.

There is a need for more stratified RCT studies and investigation on this topic to understand the potential benefit.

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