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# Low Pressure Pneumoperitoneum vs. Normal Pressure Pneumoperitoneum In Relation To Shoulder Tip Pain Following Laparoscopic Cholecystectomy: A Randomized Clinical Trial

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**ABSTRACT**
**Background:** The origin of shoulder pain post laparoscopypain syndrome is only partly understood, but it is assumed that it is causedby overstretching of the diaphragmatic muscle fibers due to high pressure of pneumoperitoneum created during laparoscopy. This study aimed to compare the incidence and severity of post-operative shoulder tip pain between low pressure and normal pressure carbon dioxide pneumoperitoneum laparoscopic cholecystectomy.
**Methods and Material**: This is a prospective randomized study of 118 patients from were divided randomly into groups A and B. The laparoscopic cholecystectomy was performed according to the conventional four port technique, at a carbon dioxide pneumoperitoneum pressure of 8 to 10 mm Hg in group A, and 12 mm Hg in group B. During the post-operative period all patients were prescribed analgesia with intravenous tramadol (100 mg). The time of first dose of post-operative analgesic and total requirement of post-operative analgesic was recorded.The degree of post-operative pain and post-operative shoulder tip pain was assessed by means of visual analogue pain scale at 1, 6, 12 & 24 hours postoperatively.
**Results:** The overall incidence of shoulder tip pain was 24.6%. The patients in low pressure group had lower intraoperative gas consumption (51.7Lvs. 63.4L, p=0.000036), postoperative pain (p<0.001), shoulder tip pain (7 vs. 22, p=0.00134), and had longer duration to requirement of first dose of analgesia postoperatively (45 vs. 28 minutes, p=0.003).No significant difference was noted between the two groups with regard to intraoperative and postoperative complications.
**Conclusions:** Low pressure pneumoperitoneum laparoscopic cholecystectomy techniqueis better and safer alternative to traditional standardized pressure pneumoperitoneum laparoscopic cholecystectomy in reducing postoperative pain and shoulder tip pain.

**KEYWORDS:** Randomized clinical trial, Laparoscopic cholecystectomy, low pressure pneumoperitoneum, shoulder tip pain, minimal access surgery.

## I. INTRODUCTION

Today cholecystectomy is the commonest surgery of the biliary tract[1,2].It has become the gold standard operation for cholelithiasis and in September 1992 a National Institutes of Health (NIH) consensus conference in Bethseda concluded that laparoscopic cholecystectomy was the treatment of choice for gall bladder pathology,[1,4].

Worldwide, laparoscopic cholecystectomy is most often performed by creating pneumoperitoneum by insufflating carbon dioxide into the abdominal cavity using a pressure regulating automatic insufflators[5,6]. The pneumoperitoneum provides the space for maneuvering the instruments necessary for performing cholecystectomy laparoscopically.

However the maintenance of elevated intra-abdominal pressure for the duration of the surgery is associated with numerous adverse effects involving the circulatory & respiratory systems, as well as the kidneys – some of these side effects result from a positive intraperitoneal pressure itself, while others are associated with carbon dioxide absorption from the peritoneal cavity into the blood[7-11].The aetiopathogenesis of this type of pain are still not understood - some say that it may be the result of diaphragmatic irritation of a chemical nature caused by the insufflated carbon dioxide while others believe that shoulder pain after laparoscopy could be caused by overstretching of the diaphragmatic muscle fibers owing to the high pressure of insufflation. In the latter case it would be the volume of the gas utilized for pneumoperitoneum that caused the diaphragmatic irritation[5,12-15].

Hence, in order to minimize the adverse effects of pneumoperitoneum, the clinical practice

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was extended to include low pressure pneumoperitoneum [8 to 10 mm of mercury (Hg)].[6, 8, 16, 17].

The aim of the present study is to compare the effects of lowpressure Pneumoperitoneum with Normal Pressure Pneumoperitoneum In Relation To Shoulder Tip Pain Following Laparoscopic Cholecystectomy

## II. METHODS

This was a randomized clinical trial conducted in the Department of General surgery of S.M.S. hospital, Jaipur (Rajasthan). A total of 118 participants were included in the study after the following inclusion and exclusion criteria:

**Inclusion Criteria:**

1. Age 18 to 60 years
2. Either sex
3. Clinically and investigationally diagnosed as cholelithiasis
4. Consented for cholecystectomy
5. Consented for study
6. Fit for laparoscopy and general anesthesia

**Exclusion Criteria:**

1. Any serious pre - existing cardiovascular, pulmonary or immunological disease
2. Pregnancy
3. Coagulopathies
4. Complicated gall bladder, which includes-

- Dense adhesions at triangle of calot's (frozen calot)
- Contracted and fibrotic gall bladder
- Gangrenous gall bladder
- Acutely inflamed gall bladder
- Empyema of gall bladder
- Mirrizi's syndrome
- Cholecysto-gastric or duodenal fistula
- Previous upper abdominal surgery

5. Patients having any neuralgic pain or any shoulder pathology causing pain
6. Patient's refusal to give informed consent
7. Patient who are converted to open cholecystectomy procedure/normal pressure laparoscopic cholecystectomy

All participants were educated preoperatively regarding the use of Visual Analogue Pain scale.
Before induction of anesthesia, patients were randomized into group A & group B. The laparoscopic cholecystectomy was performed according to the conventional four port technique- umbilical port, port below xiphoid & two ports below right costal margin. The working ports were introduced at a carbon dioxide pneumoperitoneum pressure of 15 mm Hg in both group A & B. The laparoscopic cholecystectomy was then performed according to the following study protocol:

- **GROUP A (Low pressure group)**: The patients in group A underwent laparoscopic cholecystectomy at a carbon dioxide pneumoperitoneum pressure of 8 to 10 mm Hg.
- **GROUP B (Normal pressure group)**: The patients in group B underwent laparoscopic cholecystectomy at a carbon dioxide pneumoperitoneum pressure of 12 mm Hg.

In all the cases the residual carbon dioxide was evacuated at the end of procedure by compressing the abdomen taking care to keep the trocar valves open.

The duration of surgery, intraoperative gas consumption, per operative findings(For e.g., adhesions in the vicinity of gall bladder), intraoperative complications (bile spillage, bleeding, visceral injury) along with reason for conversion, if any, to normal pressure laparoscopic cholecystectomy or open cholecystectomy was recorded. The cases converted to open cholecystectomy were excluded from the study.

During the post-operative period all patients were prescribed analgesia with intravenous tramadol (100 mg), if required. The time of first dose of post-operative analgesic as well as the total requirement of post-operative analgesic was recorded for each patient.
The degree of post-operative pain and post-operative shoulder tip pain (if any) was assessed by means of visual analogue pain scale (VAS) at 1, 6, 12 & 24 hours post operatively. The following outcome variables were assessed:

1. Duration of surgery
2. Intra operative gas consumption
3. Pressure at which procedure completed
4. Intra operative complications
5. Post-operative complications (vomiting, surgical site infection & CBD injury)
6. Frequency of post-operative shoulder tip pain
7. Intensity of post-operative shoulder tip pain on visual analogue pain scale
8. Intensity of post-operative pain on visual analogue pain scale
9. Analgesic requirement
10. Length of post-operative study

Statistical analysis was performed using IBM SPSS software. Chi square and t-tests were performed to assess the significance of association.

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## III. RESULTS

**Demographic Profile:**

The mean age of low pressure group was 39.75 years with a maximum and minimum age of 18 and 60 years,respectively. The mean age of normal pressure group was 38.61 years with a maximum and minimum age of 18 and 60 years.

Gender distribution in both the groups was similar.In low pressure group out of the 59 patients, 6 (10.2%) were males and 53 (89.8%) were females, while in normal pressure group 7 (11.9%) were males and 52(88.1%) were females.

**Duration of Surgery:**

The mean duration of surgery in low pressure group was 26.10 minutes while in normal pressure group the mean duration of surgery was 25.47 minutes with no significant difference between the two groups (p=0.485 by unpaired t-test).

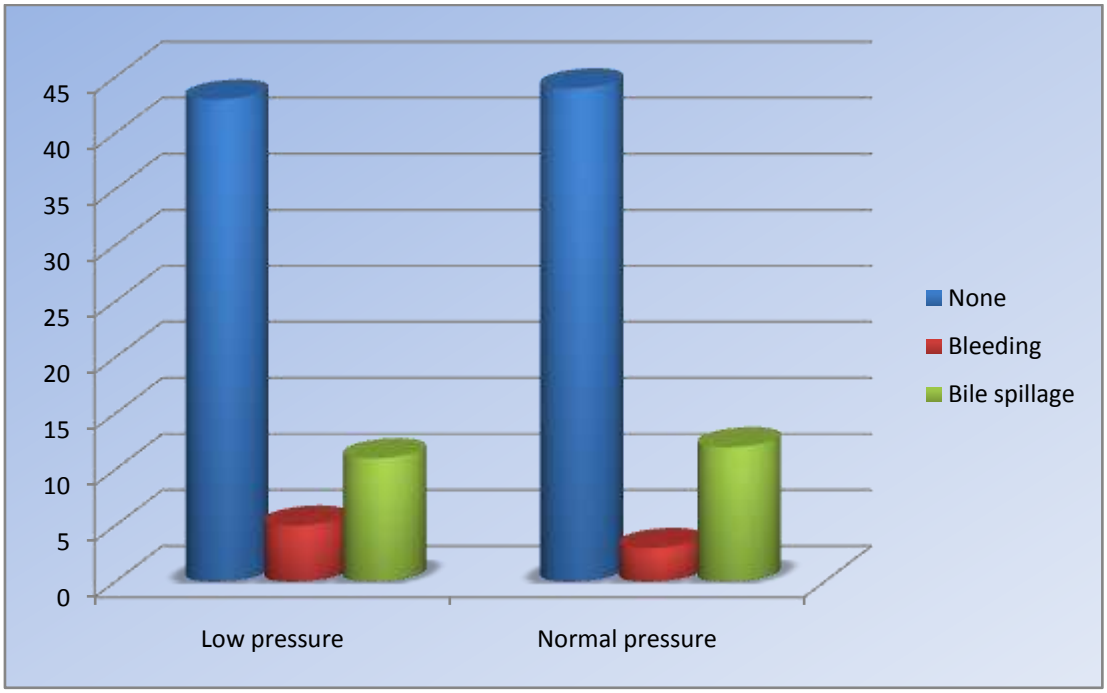


**Figure 1: Bar chart comparing intraoperative complications between both groups**

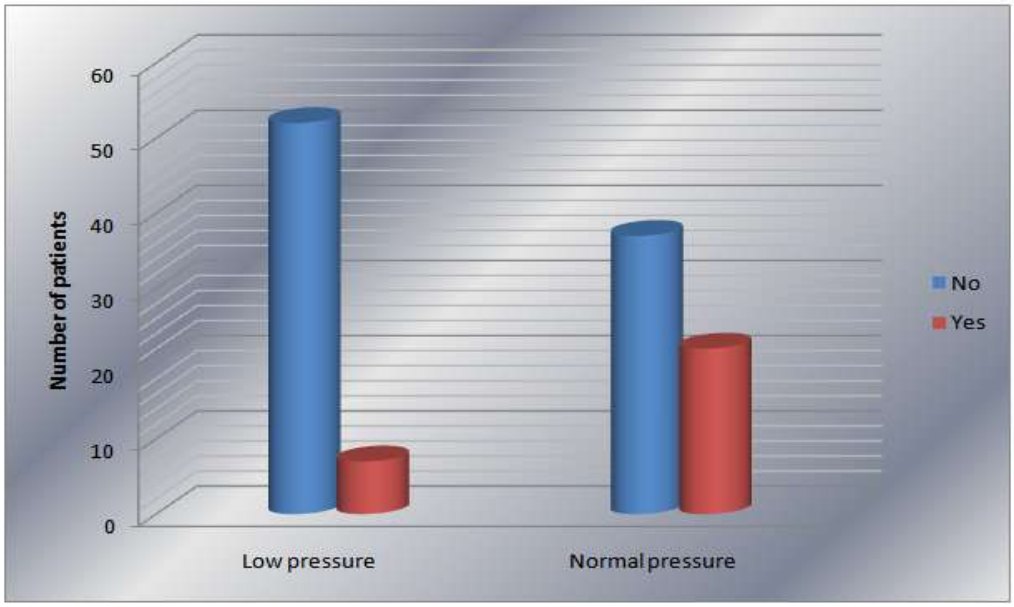


**Figure 2: Bar chart comparing postoperative shoulder tip pain between both pressure groups**

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| Group | Mean Visual Analogue Score of Postoperative Shoulder Tip Pain | | | |
|---|---|---|---|---|
| | 1 hr | 6 hr | 12 hr | 24 hr |
| Low pressure | 0.00 | 0.42 | 0.25 | 0.14 |
| Normal pressure | 0.10 | 1.97 | 1.25 | 0.97 |
| p value | 0.159 | 0.00024 | 0.00022 | 0.00004 |

**Table 1: Postoperative shoulder tip pain score of low and normal pressure groups**

| Group | Duration of Postoperative Stay (Days) | | |
|---|---|---|---|
| | N | Mean | Standard Deviation |
| Low pressurecount %within group | 59 | 1.47 | 0.89 |
| Normal pressure count %within group | 59 | 1.47 | 0.56 |

**Table 2: Postoperative hospital stay of low pressure and normal pressure group**

**Intraoperative Gas Consumption:**

The mean carbon dioxide gas consumption for insufflation was 51.73 litres in low pressure group while in normal pressure the mean carbon dioxide gas consumption for insufflation was 63.39litres. The mean carbon dioxide gas consumption for insufflations was significantly higher in the normal pressure (12-14 mm of Hg) group (p=0.000036 by unpaired t-test).

**Intraoperative Complications:**

In low pressure group, there were no intraoperative complications in 43 (72.9%) patients while intraoperative bile spillage and bleeding occurred in 11 (18.6%) and 5 (8.5%) patients respectively. In normal pressure group there were 3 (5.11%) patients in which there was intraoperative bleeding and bile spillage occurred in 12 (20.3%) patients. There was no significant difference between the two groups in terms of intraoperative complications (p=0.758 by chi square test) and hence operating at a low pressure carbon dioxide pneumoperitoneum is safe [Figure 1].

**Postoperative Pain:**

The mean visual analogue pain score of postoperative pain at 1, 6, 12, and 24 hours postoperatively was significantly higher in normal pressure(12-14mm hg) group than in low pressure (8-10 mm Hg) group (p<0.001 by unpaired t-test).

**Shoulder Tip Pain:**

The proportion of patients who reported postoperative shoulder tip pain at any point in the post-operative period was 24.6% (29 out of 118 patients) [table 7]. All of the 29 patients reported right shoulder tip pain. The frequency was significantly lower in the low pressure group than in normal pressure group: 7 (11.9%) patients versus 22 (37.3%) patients respectively (p=0.00134 by Chi square test). The shoulder tip pain started in the postoperative period and peaked in both the groups at 6 hours and improved as the time passed by. [Figure 2]

The mean visual analogue pain score of postoperative shoulder tip pain was significantly less intense at 6, 12, 24 hours in the low pressure group than in normal pressure group (p<0.001 by unpaired t-test) [Table 1].

**Postoperative Complications:**

During the postoperative period there was one patient in each group in which there was persistent leakage of bile in the abdominal drain. The biliary leak closed spontaneously and no surgical intervention was required. There was 1 patient in low pressure group who had surgical site infection of the epigastric port. The proportion of patients having vomiting in the postoperative period was similar in both the groups: 23.7% (14 out of 59 patients) in low pressure group and 22% (13 out of 59 patients) in normal pressure.

However the vomiting was less intense in the low pressure group and the postoperative period was more tolerable in the low pressure group. There was no significant difference between the two groups in terms of postoperative complications (p=0.781 by Chi square test).

**Analgesic Requirements:**

In both the groups there were some patients who did not require analgesic in the postoperative period: 45.8% (27 out of 59 patients) in low pressure group [figure 16] and 28.8% (17 out of 59 patients) in normal pressure group. Though the patients who did not require analgesics

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in the postoperative period was more in the low pressure group it did not reach statistical significance (p=0.057 by Chi square test).

The mean time at which first postoperative dose of analgesic requirement was 45 minutes in the low pressure group and 27.9 minutes in the normal pressure group. The need of first dose of postoperative analgesia was later in the low pressure group than in the normal pressure group (p=0.042 by unpaired t-test).

The mean total analgesic requirement of ampoules of tramadol (1 ampoule of tramadol= 100 mg of tramadol) was significantly less in the low pressure group (1.13 ampoule) than in the normal pressure group (1.69 ampoule) with a p value of 0.003 by unpaired t-test.

**Postoperative Stay:**

The mean duration of postoperative hospital stay was same in both the groups [Table 2]

## IV. DISCUSSION

Laparoscopic cholecystectomy is the preferred surgical technique for uncomplicated cholecystectomies. In comparison to the open cholecystectomy, laparoscopic cholecystectomy is associated with diminished surgical trauma, more tolerable postoperative period, shorter convalescence and early return to work. However early postoperative pain after laparoscopic cholecystectomy is a frequent complain. The pain after laparoscopic cholecystectomy vary in quality, localization and is reported in several trials to be incisional, intra-abdominal (visceral) or referred to shoulder as shoulder tip pain.

The phenomenon of shoulder tip pain in the postoperative period is unique to laparoscopic cholecystectomy[5]. At the same time it is a frequent and a very distressing phenomenon. The etiology and pathogenesis of this type of pain is still not clearly understood and various theories have been proposed- some authors maintain that it is due to the irritation of the diaphragm of a chemical nature caused by the insufflated carbon dioxide[5,12] while there are others who believe that the shoulder pain after laparoscopy is caused by overstretching of the diaphragmatic muscle fibers owing to the high rate of insufflations[5, 14-15].

In order to reduce the frequency and the intensity of the shoulder tip pain several studies have been carried out and many perioperative analgesic schemes have been studied including subcutaneous and intramuscular anesthetic administration to the shoulder. However neither route of administration has shown sufficient positive results to justify routine clinical use[5]. There are reports of good results in reducing both the frequency and the intensity of shoulder tip pain by intraperitoneal irrigation with bupivacaine to both hemidiaphragms at the end of the surgery[18]. Some studies using heated carbon dioxide gas at 37$^{o}$C have shown favorable result in reducing shoulder tip pain[19], however, the use of heated carbon dioxide in laparoscopy requires specialized equipment.

Several randomized trials [table 3] have shown that the degree of stretching of the intra-abdominal cavity is a significant source of post-operative pain[14] and overstretching of the diaphragmatic muscle fibers due to the high rate of insufflation causes shoulder tip pain after laparoscopy. It has also been shown that a low insufflations rate significantly reduces shoulder tip pain[15].

In our study the overall incidence of shoulder tip pain was 24.6% which is comparable to the values reported in the literature.The frequency of shoulder pain was significantly lower in the 8 mm Hg group and also the intensity of pain recorded on visual analogue scale for pain was lower in the patients who underwent laparoscopic cholecystectomy at a low pressure of pneumoperitoneum. These observations are consistent with the results of other authors who had already found a correlation between the degree of pneumoperitoneum and postoperative pain. In the present study the mean carbon dioxide gas consumption for insufflation was significantly lower in the low pressure 8 mm Hg group.

The present prospective trial has also confirmed the observation of the earlier studies that low pressure pneumoperitoneum significantly decreases postoperative pain as evident by the marked difference in the mean visual analogue pain scale score of the two groups.

Although there was a significant difference in the pain scores between the 8 mm Hg and 12 mm Hg groups, the number of patients who did not require any analgesic medication was similar in both the groups. This lack of direct correlation may be due to the need for analgesics for pain other than shoulder tip pain in the early postoperative period such as abdominal (visceral) or incisional site pain and hence further research is needed to find out ways to improve the quality of the postoperative care of these patients. However at the same time the total analgesic requirement in terms of the number of ampoules of tramadol required was significantly less in the low pressure group than in the normal pressure group and also the need for the first postoperative dose of analgesic was later in the 8 mmHg group than in

the 12 mm Hg group. Thus a simple intervention of reducing the pressure of carbon dioxide pneumoperitoneum during laparoscopic cholecystectomy has resulted in marked decrease in the incidence and intensity of shoulder tip pain, intensity of postoperative pain and the need for analgesics in the postoperative period.

Low pressure carbon dioxide pneumoperitoneum laparoscopic cholecystectomy is a safe procedure as there was no significant difference in the proportions of intraoperative complications between the low pressure 8 mm Hg and normal pressure 12 mm Hg group. However the intraoperative use of suction for bleeding and bile spillage makes performing low pressure carbon dioxide pneumoperitoneum laparoscopic cholecystectomy difficult as with the use of suction there was acute reduction in the pneumoperitoneum thereby compromising the vision of the operative field and also hampering with the maneuverability of the laparoscopic instruments.

During the postoperative period there was no significant difference in the proportion of postoperative complications between the two groups, but the patients in the low pressure 8 mm Hg group had a more tolerable postoperative period thereby establishing the superiority of the low pressure carbon dioxide pneumoperitoneum laparoscopic cholecystectomy.

## V. CONCLUSION

Low pressure pneumoperitoneum laparoscopic cholecystectomy technique (8-10 mmHg) is better and safer alternative to traditional normal pressure pneumoperitoneum laparoscopic cholecystectomy (12-14 mmHg) in reducing postoperative pain and shoulder tip pain and postoperative hospital stay, with similar rates of intraoperative and postoperative complications.

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