

Comparative analysis of hemodynamic changes and shoulder tip pain under standard pressure versus low-pressure pneumoperitoneum in laparoscopic cholecystectomy- a randomized controlled study

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Abstract

Introduction: Laparoscopic cholecystectomy is the standard treatment of choice for symptomatic cholelithiasis and is commonly performed under Enhanced Recovery After Surgery (ERAS) protocols to improve patient outcomes. Pneumoperitoneum, typically created using carbon dioxide (CO₂), facilitates the procedure but may lead to haemodynamic changes and postoperative shoulder tip pain, particularly at standard pressures (12–14 mmHg). Low-pressure pneumoperitoneum (8–10 mmHg) has emerged as a safer alternative, potentially reducing these complications.

Aims and Objectives: To compare the effects of standard versus low-pressure pneumoperitoneum on intraoperative haemodynamic parameters, including blood pressure, heart rate, and end-tidal CO₂ (EtCO₂), and on postoperative shoulder tip pain in patients undergoing elective laparoscopic cholecystectomy.

Materials and Methods: A prospective, randomised controlled trial was conducted at a tertiary care hospital in Chennai from March 2023 to February 2024. Sixty patients were randomly assigned to two groups: Group I (standard pressure) and Group II (low pressure), with 30 patients in each. Intraoperative vitals were monitored, and postoperative shoulder tip pain was assessed using the Visual Analogue Scale (VAS) at 12, 24, and 48 hours. Data were analysed using SPSS version 22.0.

Results: Group II showed better haemodynamic stability and significantly lower shoulder tip pain at 12 and 48 hours postoperatively compared to Group I.

Conclusion: Low-pressure pneumoperitoneum improves haemodynamic parameters and significantly reduces postoperative shoulder tip pain, supporting its integration into ERAS protocols for laparoscopic cholecystectomy.

Keywords: Laparoscopic cholecystectomy, low-pressure pneumoperitoneum, haemodynamic changes, shoulder tip pain, ERAS

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Introduction

Cholelithiasis is a common global health condition, with recent estimates indicating an overall prevalence of approximately 6% worldwide, and current data show that around 70–80% of individuals with gallstones remain asymptomatic throughout their lives [1]. In India, the prevalence of cholelithiasis shows considerable regional variation, these demographic differences are likely due to genetic, dietary, and environmental changes. The increasing prevalence of cholelithiasis in recent years has

also led to greater public health awareness, increased importance of ultrasonographic screening, and lifestyle changes characterized by decreased physical activity and increased sedentary behavior [2].

While most individuals with gallstones remain asymptomatic, recent data suggest that approximately 1–2% progress to symptomatic disease each year over long-term follow-up, about 20–30% may develop complications such as biliary colic, acute cholecystitis, or pancreatitis [3, 4]. In such interventions, surgical

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treatment in the form of laparoscopic cholecystectomy is the ideal treatment for cholelithiasis. Laparoscopic cholecystectomy has evolved as the definitive treatment of cholelithiasis, becoming the gold standard procedure due to its minimally invasive approach, immediate recovery, reduced hospital stays, and decreased postoperative complications [5].

The emergence of Enhanced Recovery After Surgery (ERAS) protocols has further resulted in better perioperative outcomes by promoting early recovery, minimizing the use of opioid analgesics, and streamlining surgical techniques [6]. An ideal component of laparoscopic surgery is the creation of a pneumoperitoneum during the procedure. It is usually prepared with carbon dioxide gas to enable exact exposure of the operative field. However, the insufflation of gas and resulting elevation of intra-abdominal pressure may lead to significant physiological changes, particularly affecting the cardiovascular and respiratory systems. These changes include elevated heart rate, increased mean arterial pressure, and elevated end-tidal carbon dioxide (EtCO₂) levels [7]. These effects are typically tolerated well by healthy people, but they can lead to issues in patients with compromised heart and lung function [6].

Postoperative shoulder tip pain is a common clinical manifestation encountered by patients following a laparoscopic cholecystectomy. This is understood to result from diaphragmatic irritation due to residual CO₂, which stimulates the phrenic nerve and radiates pain to the shoulder region [8]. The intensity of this pain may alter with the pressure used to create the pneumoperitoneum. Given these challenges, there has been an increased interest in utilizing low-pressure

pneumoperitoneum, specifically in the range of 8–10 mmHg, as opposed to the conventional pressure range of 12–14 mmHg. Emerging evidence suggests that lowering insufflation pressure may aid in mitigating the adverse hemodynamic effects, reducing postoperative shoulder tip pain, and improving overall patient outcomes without compromising surgical visibility or procedural efficiency [9–11].

This study aims to evaluate the hemodynamic changes and intensity of shoulder tip pain in patients undergoing laparoscopic cholecystectomy using a standard and low-pressure pneumoperitoneum.

Materials and Methods

Study Design and Setting

This prospective, randomized controlled trial was conducted in the Department of General Surgery at a tertiary care medical college hospital in Chennai, India, from March 2023 to February 2024. Institutional Ethics Committee approval was obtained, and written informed consent was secured from all participants.

Study Population

A total of 60 participants aged 18–60 years with American Society of Anesthesiologists (ASA) physical status I–II undergoing elective laparoscopic cholecystectomy were enrolled. Patients with complicated cholecystitis, previous upper abdominal surgery, pregnancy, severe cardiopulmonary disease, or those requiring conversion to open surgery were excluded. Participants were randomized using a computer-generated sequence into two groups: Standard Pressure (14 mmHg, n = 30) and Low Pressure (8–10 mmHg, n = 30) (Figure 1).

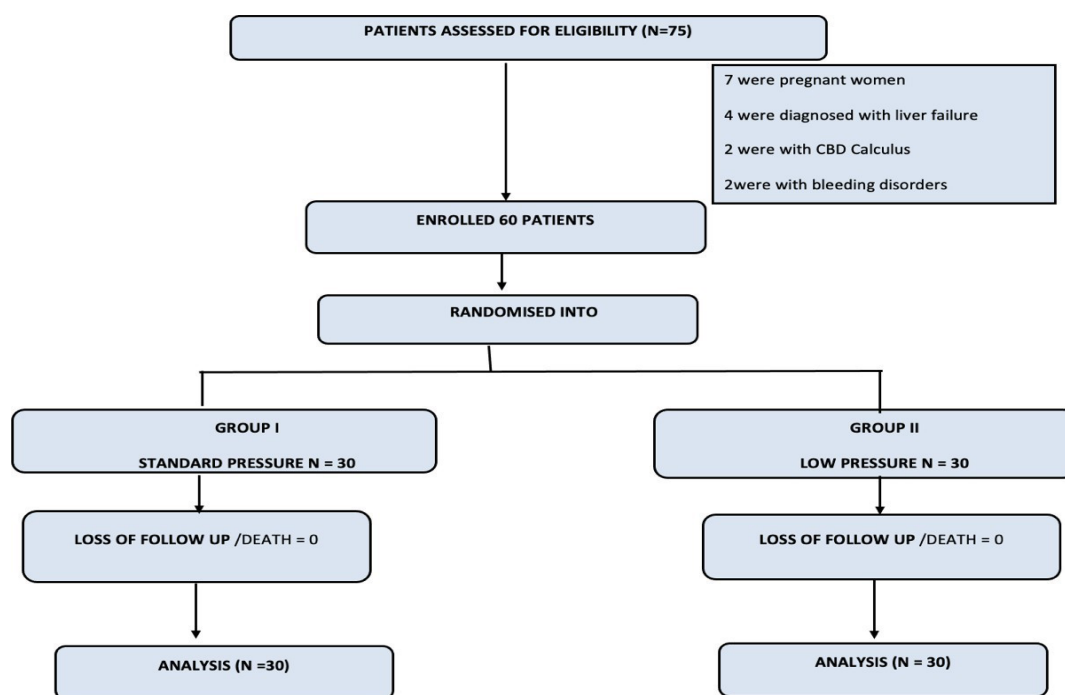


Fig 1: CONSORT diagram

Preoperative Evaluation

All patients underwent a detailed clinical assessment, including obtaining demographic data and upper gastrointestinal symptoms. Routine investigations like complete blood count, liver and renal function tests, and coagulation profile were recorded. Abdominal ultrasonography confirmed cholelithiasis and excluded acute cholecystitis, common bile duct stones, or biliary dilatation. Pre-anaesthetic clearance was obtained for all cases.

Surgical Procedure and Intraoperative Monitoring

All surgeries were performed by experienced surgeons following Enhanced Recovery After Surgery (ERAS) protocols. Standard four-port laparoscopic cholecystectomy was conducted in both groups. Hemodynamic parameters, pulse rate, systolic and diastolic blood pressure, and end-tidal carbon dioxide (EtCO₂), were recorded at baseline, at creation of pneumoperitoneum, intraoperatively, at exsufflation,

and before extubation. Operative duration and need for pressure adjustment were documented.

Postoperative Assessment and Statistical Analysis

Shoulder tip pain was assessed using the Visual Analogue Scale (VAS; 0–10) at 12, 24, and 48 hours postoperatively. Data were analyzed using IBM SPSS Statistics version 22.0. Descriptive statistics were expressed as mean ± standard deviation and percentages. The Chi-square test and Student’s t-test were applied, with $p < 0.05$ considered statistically significant.

Results: A total of 60 patients meeting the inclusion criteria were randomized equally into Group I (standard pneumoperitoneum pressure of 14 mmHg) and Group II (low pneumoperitoneum pressure of 8–10 mmHg). Baseline demographic characteristics, including age, gender distribution, and age-group stratification, were comparable between the two groups and are depicted in (Table 1).

Table 1: Baseline Demographic Characteristics of the Study Participants (N = 60)

Parameter	Group I (14 mmHg)	Group II (8–10 mmHg)	Total
Age (Mean ± SD)	44.8 ± 11.7	43.6 ± 9.15	44.2 ± 10.4
Gender (M:F)	1:9	1:14	—
Age Distribution (years)			
29–39	7 (11.67%)	12 (20%)	19 (31.7%)
40–49	14 (23.33%)	6 (10%)	20 (33.3%)
50–59	8 (13.33%)	7 (11.67%)	15 (25%)
≥60	1 (1.67%)	5 (8.33%)	6 (10%)

Intraoperative findings revealed a higher frequency of minor complications in the standard-pressure group. Two patients in the low-pressure group required conversion to standard pressure due to suboptimal visualization. No patients required conversion to open

cholecystectomy. Operative duration was similar between the groups, indicating that lower insufflation pressure did not significantly affect surgical time, and is presented in (Table 2).

Table 2: Intraoperative Parameters (N=60)

Parameter	Group I	Group II	P value
Duration of surgery (min)	75 ± 15.2	75 ± 15.25	0.081
Intraoperative complications (n)	18	10	0.038*
Conversion to standard pressure (n)	0	2	0.15
*P value < 0.05 is considered statistically significant			

Hemodynamic parameters were comparable at baseline. During the intraoperative period, both groups exhibited expected physiological variations; however, the low-pressure group demonstrated improved stability during exsufflation and in the early postoperative period. Statistically significant differences were observed in

selected parameters following exsufflation, favoring the low-pressure group. End-tidal CO₂ levels remained comparable intraoperatively, with a significant reduction noted post-exsufflation in the low-pressure group, as listed in the following (Table 3).

Table 3: Comparative Analysis of Hemodynamic Parameters Between Group I and Group II (N = 60)

Parameter	Time Point	Group I (Mean ± SD)	Group II (Mean ± SD)	P Value
Duration of Surgery (minutes)	–	75 ± 15.25	75 ± 15.25	1.00
Heart Rate (beats/min)	Before Insufflation	79.8 ± 9.02	81 ± 7.7	0.45
	At Insufflation	83.5 ± 6.5	86 ± 6.3	0.67
	During Surgery (15 mins)	85.2 ± 6.8	82.8 ± 6.9	0.96
	At Exsufflation	82.7 ± 5.8	78.6 ± 3.9	0.36

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	15 min Post-Exsufflation	81.5 ± 5.7	80.6 ± 3.06	<0.01*
Systolic Blood Pressure (mm Hg)	Before Insufflation	124.3 ± 12.5	125.6 ± 11.04	0.99
	At Insufflation	127.3 ± 14.1	130 ± 14.3	0.47
	During Surgery (30 mins)	128 ± 15.6	128 ± 15.1	0.45
	At Exsufflation	123.6 ± 13.5	123 ± 5.9	0.00*
	15 min Post-Exsufflation	124.3 ± 9.7	126.6 ± 6	0.00*
Diastolic Blood Pressure (mm Hg)	Before Insufflation	79.3 ± 9.4	80.3 ± 9.6	0.85
	At Insufflation	83.3 ± 8.4	83.6 ± 10.3	0.11
	During Surgery (30 mins)	82.6 ± 8.6	80.3 ± 8.5	0.18
	At Exsufflation	80.3 ± 8	75.6 ± 5	0.79
	15 min Post-Exsufflation	78.3 ± 8.7	81 ± 5.4	0.01*
End Tidal CO₂ (mm Hg)	Before Insufflation	33.9 ± 5.4	32.9 ± 4.8	0.10
	At Insufflation	35.7 ± 4.8	35.9 ± 4.3	0.22
	During Surgery (15 mins)	36.6 ± 4.3	35.8 ± 5.6	0.06
	At Exsufflation	35.5 ± 3.4	33.2 ± 4.8	0.09*
	15 min Post-Exsufflation	33.6 ± 4.7	31.1 ± 4.08	0.05*

*P value < 0.05 is considered statistically significant

Postoperative shoulder tip pain, assessed using the Visual Analogue Scale, was lower in the low-pressure group at multiple time intervals. Statistically significant reductions were observed at 12 and 48 hours postoperatively, while differences at 24 hours were not significant; these results are demonstrated in (Table 4).

Table 4: VAS Scores for Shoulder Tip Pain (Mean ± SD)

Time Point	Group I	Group II	P value
12 hours	1.47 ± 0.86	0.37 ± 0.61	0.02*
24 hours	1.23 ± 0.93	0.87 ± 0.86	0.42
48 hours	0.47 ± 0.68	0.00 ± 0.00	0.00*

*P value < 0.05 is considered statistically significant

Discussion

Laparoscopic cholecystectomy is the gold standard treatment for the management of symptomatic cholelithiasis. Pneumoperitoneum, typically created using carbon dioxide (CO₂), facilitates the laparoscopic approach but is known to cause certain intraoperative physiological alterations. These changes, including acid-base imbalance, decreased pulmonary compliance, and haemodynamic fluctuations, are particularly associated with the standard intra-abdominal pressure of 12–14 mmHg. Our study evaluated the intraoperative haemodynamic changes and postoperative outcomes associated with low-pressure (8–10 mmHg) versus standard-pressure pneumoperitoneum during laparoscopic cholecystectomy.

According to the existing literature, a higher prevalence of cholelithiasis was identified in the Korean health-screening cohort. It significantly demonstrated a higher rate of asymptomatic gallstones in women younger than 40 years among females, aligning with our study's female-to-male ratio [12]. A large nationwide Chinese study reported an age-standardized prevalence of 5.41% in women vs. 4.85% in men [13]. The mean age of participants in Group I and Group II was 44.8±11.7 years

and 43.6±9.15 years, respectively. Intraoperative complications were more frequent in the standard pressure group (Group I) compared to the low-pressure group (Group II). However, none of the cases required conversion to open surgery, according to the findings of Bhattacharjee et al [14].

Based on heart-rate dynamics, while there were no significant differences pre-insufflation, the low-pressure group (Group II) demonstrated lower heart rates during surgery, at exsufflation, and 15 minutes post-exsufflation; this mirrors results from other randomized and prospective studies [15, 16]. The systolic blood pressure and diastolic blood pressure values showed minimal variation between the groups during the initial intraoperative phase. However, a significant reduction in both parameters was noted in Group II at exsufflation and post-exsufflation. These results are consistent with the study by Goel et al. [15].

On observing the respiratory parameters, a mild reduction in end-tidal CO₂ (EtCO₂) was observed in Group II during the postoperative period. This differs from the study by Ortenzi M et al. [11], which reported elevated EtCO₂ with standard-pressure pneumoperitoneum. Furthermore, postoperative

shoulder tip pain is commonly associated with laparoscopic procedures and was significantly lower in the low-pressure group at 12, 24, and 48 hours postoperatively. These findings correlate with prior studies conducted by Bolat H et al. and Arun RC et al. [17, 18]. Additionally, a recent randomized clinical trial by Serrano AB et al. [19] demonstrated that low-pressure pneumoperitoneum was associated with a reduced peritoneal inflammatory response while maintaining surgical feasibility, further supporting the physiological advantages of lower insufflation pressures.

However, our study had a few limitations; considering the sample size was small and a single-centre study, the findings may not reflect outcomes in other settings. The usage of the VAS scale to determine the pain assessment is subjective and can vary from patient to patient. An extended follow-up is necessary to assess the duration of recovery and any long-term complications. This randomised controlled study enhances the reliability and validity of its findings by including clearly defined groups (standard vs. low pressure).

This study ensured a focused analysis of the haemodynamic changes and postoperative outcomes in patients with laparoscopic cholecystectomy. The prompt use of intraoperative monitoring at multiple time points allowed for detailed analysis of heart rate, blood pressure, and end-tidal CO₂. Also, the continued application of ERAS protocols minimised confounding variables related to perioperative care. Importantly, this study also had a strong focus on addressing the reduction in postoperative complications and enhancing a better quality of life. Based on these observations, our study supports that low-pressure pneumoperitoneum is associated with improved haemodynamic stability and reduced postoperative shoulder pain, making it a potentially safer and more patient-friendly alternative to standard pressure settings during laparoscopic cholecystectomy.

Conclusion

Reducing intra-abdominal pressure to 8 to 10 mmHg during laparoscopic cholecystectomy significantly improves hemodynamic stability and lowers postoperative shoulder tip pain without affecting surgical outcomes. The results support adding low-pressure pneumoperitoneum to Enhanced Recovery After Surgery (ERAS) protocols. This inclusion can improve patient comfort and recovery, making it a practical and effective strategy in regular surgical practice.

Authors' Contributions: Dr. Lakshmi Nivedha Lakshmi Raja conceptualized the study, participated in data collection, and prepared the initial manuscript draft. Dr. Vijay Rahul Johnson contributed to patient recruitment, data acquisition, and statistical analysis. Prof. Dr. R. Anantharamkrishnan Dr.senthilkumar and Dr.Shahid ibrahim supervised the study, provided critical intellectual input, and reviewed the manuscript. All authors read and approved the final manuscript.

Ethics Approval and Consent to Participate: The study was approved by the Institutional Ethics

Committee of Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Chennai. Written informed consent was obtained from all participants prior to enrollment.

Consent for Publication: Written informed consent for publication was obtained from all participants. All authors consent to the publication of this manuscript.

Code availability: Not applicable

Availability of Data and Materials: The data generated and analyzed during the current study are available from the corresponding author on reasonable request.

Funding: None

Conflicts of interest: None declared

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for Student Research (CARE IHEC-I)**
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16.03.2023

To

Dr. Vijay rahul. J
Department of General Surgery
Chettinad Hospital and Research Institute

Sir/Madam,

Sub: Your proposal Reviewed - Communication of decision - Regarding

Ref No : IHEC-I/1842/23

The Institutional Human Ethics Committee (CARE IHEC-II) has reviewed your proposal titled "**Comparative Study of Hemodynamic Changes and Shoulder Tip Pain Under Standard Pressure Versus Low-pressure Pneumoperitoneum in Laparoscopic Cholecystectomy**" on **16.03.2023** and the following decision has been taken based on the deliberations and discussions.

Decision: Approved

Comments :

Yours Sincerely

Dr Suruliraman S M MD
Member Secretary
CARE-IHEC for Students
(CARE IHEC-I)