E-ISSN: 2616-3470
P-ISSN: 2616-3462

www.surgeryscience.com
2022; 6(2): 40-44
Received: 27-10-2021
Accepted: 30-12-2021

Mohd. Abass
Department of Surgery, Government Medical College Jammu, Jammu and Kashmir, India

Amarjeet Singh
Department of Surgery, Government Medical College Jammu, Jammu and Kashmir, India

Manish Sharma
Department of Surgery, Government Medical College Jammu, Jammu and Kashmir, India

Suleman Chaudhary
Department of Surgery, Government Medical College Jammu, Jammu and Kashmir, India

Corresponding Author:
Manish Sharma
Department of Surgery, Government Medical College Jammu, Jammu and Kashmir, India

A prospective randomized, controlled study comparing low pressure versus standard pressure co2 pneumoperitoneum during laparoscopic cholecystectomy

Mohd. Abass, Amarjeet Singh, Manish Sharma and Suleman Chaudhary

DOI: https://doi.org/10.33545/surgery.2022.v6.i2a.884

Abstract
A prospective randomized controlled study was conducted to evaluate the feasibility and safety of low pressure co2 pneumoperitoneum versus standard pressure co2 pneumoperitoneum during laparoscopic cholecystectomy after receiving approval from ethical committee. Patients undergoing laparoscopic cholecystectomy were enrolled in the study after fulfilling eligibility criteria. According to surgical approach patients were randomly divided into two groups of 50 patients each, group A and group B respectively. Group a Patients underwent laparoscopic cholecystectomy with low pressure co2 pneumoperitoneum [less than 8 mmHg] while group B patients underwent laparoscopic cholecystectomy under standard pressure co2 pneumoperitoneum [12 to 15 mmHg]. The following parameters were assessed primarily in terms of incidence of pain in post-operative period, changes in cardiorespiratory, changes in the organ system functions and length of the hospital stay.
Results: Both groups were matched for the demographic parameters. We found that operative time was comparable in both groups whereas post-operative pain analgesic requirement, changes in cardiorespiratory, changes in organ system function and length of the hospital were flavouring low pressure co2 pneumoperitoneum in a statistically significant manner. ($p< 0.01$).
Conclusion: Low pressure co2 pneumoperitoneum is ideal for laparoscopic cholecystectomy in terms of post-operative pain, use of analgesics, and length of hospitals stay and minimizes the adverse hemodynamic effect of co2 insufflation.

Keywords: Prospective, randomized, comparing, pneumoperitoneum, cholecystectomy

Introduction
The annual incidence of gallstones is about one in 200 people (1). Only 2% to 4% of people with gallstones become symptomatic with biliary colic (pain), acute cholecystitis (inflammation), obstructive jaundice, gallstone pancreatitis within a year [1]. Cholecystectomy is the preferred option in the treatment of symptomatic gallstones [2]. Every year more than 0.5 million cholecystectomies are performed in the US and 60,000 in the UK [3]. Approximately 80% of the cholecystectomies are performed laparoscopically [4]. During the last hundred years cholecystectomy has remained the gold standard for the definitive management of patients with symptomatic cholelithiasis. The revolution in laparoscopic surgery began three decades ago when laparoscopic cholecystectomy was introduced. It did not take long for a consensus to develop and for the National Institutes of health to pronounce Laparoscopic cholecystectomy as, the treatment of choice for many patients with symptomatic cholelithiasis [5].
Traditionally, one of the first steps in laparoscopic cholecystectomy is the creation of pneumoperitoneum**,** using carbon dioxide (CO2) through a veress needle [6] or through a port [7] (hole) in the abdominal wall. Carbon dioxide is insufflated into peritoneal cavity at the rate of 4-6 liters / min to a pressure of 10 -20 mmHg. The pneumoperitoneum is maintained by a constant gas flow of 200-400 mI/min. The conventional laparoscopic cholecystectomy uses a higher intra-abdominal pressure between 12-15mmHg and low-pressure pneumoperitoneum laparoscopic cholecystectomy uses a pressure of less than 8mmHg. There are certain advantages of low pressure pneumoperitoneum laparoscopic cholecystectomy over conventional laparoscopic cholecystectomy in terms of post-operative pain, requirement of analgesics,

preservation of cardio-pulmonary functions and length of hospital stay.

The increased intra-abdominal pressure by creation of pneumoperitoneum with CO2 leads to certain changes in the function of organ systems and also leads to post-operative pain. Degree of intra-abdominal pressure is directly related to such change. The laparoscopic cholecystectomy can be performed at low pressure pneumoperitoneum. Though available space for dissection is less than the standard pressure pneumoperitoneum but an uncomplicated gallstones disease can be treated by low pressure laparoscopic cholecystectomy with reasonable safety by an experienced surgeon [8]. Post-operative pain syndrome is well recognized in laparoscopic cholecystectomy and characterized by abdominal and particularly shoulder tip pain which is not a feature seen in low pressure pneumoperitoneum laparoscopic cholecystectomy [9]. However the lower pressure involved in the low pressure laparoscopic cholecystectomy might result in less than adequate exposure of operating field resulting in longer than usual operating time, higher rate of conversion to standard pressure or open cholecystectomy [10].

With the safety of laparoscopic cholecystectomy having been established, the current stress is on reducing the postoperative morbidity associated with this procedure. Hence, this study was conducted to document the feasibility of low pressure laparoscopic cholecystectomy.

Aims and Objectives

To evaluate the feasibility and safety of low pressure CO2 pneumoperitoneum versus standard pressure CO2 pneumoperitoneum during laparoscopic cholecystectomy with respect to Incidence of pain in the post-operative period, changes in organ system functions and length of hospital stay

Materials and Methods

After obtaining approval from institutional ethical committee and informed written consent the study was conducted in patients admitted in the Post Graduate Department of Surgery Govt, Medical College Jammu over a period of one year for elective cholecystectomies. All patients of symptomatic gall stone diseases and gall bladder polyps (> 10mm) and patients with normal common bile duct (on pre-operative ultrasound) were included in the study and exclusion criteria was

Patients with choledocholithiasis, Age <15 years and > 65 years and patients not fit for general anaesthesia. The patients were randomly divided into 2 groups of 50 patient each. The patients were allocated to receive either in standard or low-pressure pneumoperitoneum upon investigation to participate in the study. The randomization plan was drawn by independent investigator

Group A: Consisted of patients who underwent low pressure pneumoperitoneum laparoscopic cholecystectomy [less than 8mmHg].

Group B: Comprised of patients who underwent conventional pressure pneumoperitoneum laparoscopic cholecystectomy [12-15mmHg].

All the patient admitted for cholecystectomy were fully evaluated by clinical examination, blood investigation and radiological investigation to confirm the diagnosis. Preoperative antibiotic dose was given and surgery performed under general anaesthesia by a single surgeon on both groups.

Technique

A conventional 4 port laparoscopic cholecystectomy was performed using CO_2 gas as pneumoperitoneum. Two 10mm port made one in the umbilical and another in the Epigastrium and two 5mm ports made one in the anterior axillary line and one in the mid axillary line according to surgeon ease. For creation of pneumoperitoneum the Intra-abdominal pressure in group A was kept less than or equal to 8mmHg and in group B it was kept between 12-15mmHg. The patients were observed in both groups for changes in cardio respiratory parameters intraoperative, postoperative, for pain and observations were noted and recorded.

Statistical Analysis

The results were compared using student's t-test or Mann Whitney U-test whichever appropriate, were employed to analyze the statistical difference in parametric data. Chi-square or fisher's exact test whichever appropriate were applied for categorical data. A p value less than 0.05 was considered statistically significant.

Observations and Result

Table 1: Showing Age distribution of study patients among two groups

Age (years)	Group A		Group B		P-value
	No.	% Age	No.	% Age	
20-34	19	38	21	42	0.728
35-49	21	42	17	34	
50-64	10	20	12	24	
Mean±SD	38.9±11.70		38.1±12.37		

Both groups were comparable in age distribution. [P value = 0.728]

Table 2: Showing Gender distribution of study patients among two groups

Gender	Group A		Group B		P-value
	No.	%age	No.	%age	
Male	14	28	9	18	0.235
Female	36	72	41	82	
Total	50	100	50	100	

Both groups were comparable with respect to sex

Table 3: Showing comparison based on analgesic requirement in two groups

Analgesic	N	Mean	SD	Range	P-value
Requirement					
Group A	8	2.13	0.641	1-3	0.018
Group B	15	2.94	0.772	2-4	

*Statistically Significant Difference (P-value<0.05)

The analgesic requirements for postoperative shoulder tip pain were less in group A as compared to group B. The mean number of analgesics requirement in group A was 2.13+0.641 and in group B was 2.94+ 0.772 with statistically significant difference [P-value<0.05]

Table 4: Showing interoperative heart rate (beats/min) changes among two groups

Time Interval	Group A		Group B		P-value
	Mean	SD	Mean	SD	
Just before induction	84.08	12.37	86.42	16.84	0.461
During larynges & intubation	93.56	12.06	98.82	17.35	0.016*
Immediately during insufflation	94.68	11.96	99.74	16.76	0.037*
5 min. after insufflation	95.20	11.08	102.80	14.76	0.004*
10 min. after insufflation	96.12	11.14	105.92	14.64	<0.001*
20 min. after insufflation	96.17	10.67	105.25	10.06	<0.001*
30 min. after insufflation	93.75	11.29	112.40	11.50	0.003*
At exsufflation	92.36	10.28	104.52	12.67	<0.001*
10 min. after exsufflation	88.04	10.92	100.56	12.02	<0.001*

The Statistically Significant Difference (P-value<0.05) was observed on inter-group comparison of heart rate [beats/min] between group A and group B at various intervals during laryngoscopy and intubation, immediately during insufflation, at 5, 10, 20, 30, minutes after CO2 insufflation, at exsufflation and 10 minutes after CO2 exsufflation.

Table 5: Comparison based on LFT's changes postoperatively among two groups

Change in LFT's	Group A		Group B		P-value
	Mean	SD	Mean	SD	
T.B	0.12	0.064	0.234	0.082	<0.001*
SGOT	4.08	2.546	11.92	4.198	<0.001*
SGPT	4.42	2.935	15.64	5.896	<0.001*
ALP	4.46	4.921	15.41	7.384	<0.001*

Statistically Significant Difference (P-value<0.05) was observed in values of LFTs post operatively between both groups.

Table 6: Showing comparison based on operative time (minutes) among two groups

Operative time(minutes)	N	Mean	SD	Range	P-value
Group A	30	22.6	4.81	12-32	0.465
Group B	30	21.8	5.78	12-33	

The mean operative time [minutes] in group A was 22.6 ± 4.81 and in group B was 21.8 ± 5.78 with p value = 0.465 which was statistically insignificant

Table 7: Showing comparison based on hospital stay (Days) among two groups

Hospital Stay(Days)	N	Mean	SD	Range	P-value
Group A	50	1.1	0.303	1-2	<0.001*
Group B	50	2.3	0.405	2-3	

The mean duration of hospital stay [days] in group A was 1.1 ± 0.303 and in group B was 2.3 ± 0.405 which was statistically significant [P-value <0.05]

Discussion

In our study the mean age of patients in group A was 38.9 + 11.70 and in group B 38.1 ± 12.37, the difference was not statistically significant (p=0.728) (Table 1) and the gender distribution in both groups was inclined towards female with 72% in group A and 82% in group B were females, although the difference between the two groups was not significant statistically (p=0.235) (Table 2). Our study was consistent with Shaffer EA 2005 [11] and Novacek G11 2006 [12] concluding females have 2 to 3 times higher risk of gallstones in premenopausal age.

In our study, need of analgesia was more in group B than group A and the difference was statistically significant (p=0.018) (Table 3). Our study was consistent with Sarli L *et al.* 2000 [13] study in which mean shoulder pain scores at 12 and 24 hours and post-operative analgesia requirements were also significantly lower in low pressure laparoscopic cholecystectomy group (p< 0.001). Our study was also consistent with Sandoval Jimenez *et al.* 2009 [14] and Kandil *et al.* 2010 [15] concluding more frequent shoulder pain was seen in standard pressure group.

In our study, rise in intraoperative heart rate was more in group

B than group A. Rise in intraoperative heart rate with statistically significant difference started at laryngoscopy and intubation (p=0.0 1 6) with further rise immediately during insufflations (p=0.037) and (p=0.045) with further continuous rise during insufflations; immediately during insufflations (p=0.034), 5, 10, 20, 30 minutes after insufflation, at exsufflation and remained till 10 minutes after exsufflation ($p<$ 0.001). Our study was consistent with Asif U *et al.* 2013 [16] (Table 4).

In our study liver functions tests were done both pre and postoperatively and the results were compared, statistically significant difference was seen between the two groups ($p<$ 0.001) with greater elevation of enzymes in group B (Table 5). The mechanism of rise in liver functions tests is explained by rise in pressure upto 14 mmHg leading to decreased blood flow to liver and increased postoperative 1st hour serum AST and ALT levels. Our study was consistent with Erymilaz *et al.* 2012 [17] in which there was statistically significant difference between low and high pressure group in respect to serum ALT and AST ($p<$ 0.05). Although there was no statistically significant difference in serum bilirubin level (p>0.05). Similar results were seen in study by Gupta R *et al.* 2013 [18] with significant rise in liver function tests in high pressure group compared to low pressure [AST (p= 0.0001) and ALT (p=0.0001)].

In our study the mean operative time in group A was 22.6 ± 4.81 minutes and in group B 21.8 ± 5.78 minutes (p value =0.465) with no statistically significant difference (Table 5). Our study was consistent with Kanwer DB *et al.* 2009 [19] in which laproscopic cholecystectomy with standard pressure took an average of 46.4 ± 6.9 minutes and in low pressure took an average 49.1 ± 5.7 minutes. Low pressure took an average 3 minutes more than standard pressure; but this difference was not significant statistically (p=0.1). Similar results were seen in Joshipura *et al.* 2009 (8) and Jie Hua *et al.* 2014 [20] studies with no significant difference in low pressure and high pressure group.

In our study, mean duration of hospital stay in group a was 1.1 + 0.303 days and in group b 2.3 ± 0.405 days with statistically significant difference ($p<$ 0.001) (Table 13). Our study was consistent with Jie Hua *et al.* 2014(20) which concluded shorter length of hospital stay and early recovery in low pressure pneumoperitoneum.

Conclusion

On the basis of the findings of the present data it can be easily established that low pressure co2 pneumoperitoneum is ideal for laparoscopic cholecystectomy in terms of post-operative pain, use of analgesics, length of hospitals stay and minimizes the adverse effect of co2 insufflation. Hence laparoscopic cholecystectomy being established as a mainstay of treatment for gallstones it can be further improved by reducing pressure for pneumoperitoneum thereby reducing the complications related to organ system.

References

1. NIH. NIH consensus statement on gallstones and laparoscopic cholecystectomy. http://consensus.nih.gov/1992/1992GallstonesLaparoscopy090html.htm 1992 (accessed 7 August 2013).
2. Strasberg SM, Clavien PA. Overview of therapeutic modalities for the treatment of gallstone diseases. American Journal of Surgery. 1993;165(4):420-26.
3. Dolan JP, Diggs BS, Sheppard BC, Hunter JG. The national mortality burden and significant factors associated with open and laparoscopic cholecystectomy: 1997-2006. Journal of Gastrointestinal Surgery. 2009;13(1-2):2292-301.
4. Ballal M, David G, Willmott S, Corless DJ, Deakin M, Slavin JP. Conversion after laparoscopic cholecystectomy in England. Surgical Endoscopy. 2009;23(10):2338-44.
5. Craig AB, David B. Who did the first laparoscopic cholecystectomy? J Minim Acesss Surg 2011; 7(3):165-68.
6. Casati A, Valentini G, Ferrari S, Senatore R, Zangrillo A, Toni G. Cardiorespiratory changes during gynaecological laparoscopy by abdominal wall elevation: comparison with carbon dioxide pneumoperitoneum. British Journal of Anaesthesict. 1997;78(1):51-4.
7. Alijani A, Hanna GB, Cusehieri A. Abdominal wall lift versus positive-pressure pneumoperitoneum for laparoscopic cholecystectomy-randomized controlled trial. Annuals of surgery. 2004; 239(3):388-94.
8. Joshipura VP, Haribhakti SP, Patel NR *et al.* A prospective randomized, controlled study comparing low pressure versus high pressure pneumoperitoneum during laparoscopic cholecystectomy. Surgical Laparoscopic, Endoscopy and Percutaneous Techniques. 2009;19(3):234-40.
9. Krishnegowda U, Gupta AK, Sharma R *et al.* Hellenic J Surg. 2016;88(13):13-17.
10. Davides D, Birbas K, Vezakis A, Mcmahon MJ. Routine low pressure pneumoperitoneum during laparoscopic cholecystectomy. Surg Endosc. 1999;13(9):887-9.
11. Shaffer EA. Epidemiology and risk factors for gallstone disease: has the paradigm changed in the 21st century? curr Gastroenterol Rep. 2005;7:132-140.
12. Novacek G. Gender and gallstone disease. Wien Med Wochenschr. 2006;156(19-20):527-33.
13. Prevention of cholelithiasis (GREPCO). Hepatology. 1988;8(4):904-6.
14. Sarli 1, Costi R, Sansebastiano G, Trivelli M, Roncoroni L. Prospective randomized trial of low pressure pneumoperitoneum for reduction of shoulder tip pain following laparoscopy. British J Surg. 2000;87(9):1161-5.
15. Sandoval-Jimenez CH, Mendez-Sashida GH, Cruz-Marquez-Rico LM, Cardenas-Victoria R, Guzman-Esquivel H, Luna- Silva M, Diaz-Valero R. Postoperative pain in patients undergoing laparoscopic cholecystectomy with low versus standard pressure pneumoperitoneum. Rev Gast•oenterol Mex. 2009;74(4):314-20.
16. Kandil TS, El Hafnawy E. Shoulder pain following laparoscopic cholecystectomy: factors affecting the incidence and severity. J Laparoendosc Adv Surg. Tech A. 2010; 20(8):677-82.
17. Asif U, Kuldeep SM, Nandita M. Evaluation of hemodynamic changes using different Intra-Abdominal pressures for laparoscopic cholecystectomy. Indian j surg. 2013;75(4):284-89.
18. Eryilmaz HB, Menis D, Sezer A. The effects of different insufflation pressures on liver functions assessed with LIMON on patients undergoing laparoscopic cholecystectomy. Scientific world journal 2012, 12.
19. Gupta R, Kaman L, Dahiya D *et al.* Effects of varying intraperitoneal pressure on liver function tests during laparoscopic cholecystectomy. Journal of Laparoscopic and Advanced Surgical Techniques. 2013;23(4):339-342.
20. Kanwer DB, Kaman L, Nedousejiane M, Medhi B, Verma GR, Bala I. Comparative study of low pressure versus standard pressure pneumoperitoneum in laparoscopic

cholecystectomy. Trop Gastroenterol 2009;30(3):171-4.
21. Jie Hua, Jian Gong, Le Yao, Bo Zhou, Zhenshun Song. Low pressure versus standard pressure pneumoperitoneum for laparoscopic cholecystectomy: a systemic review and meta-analysis. The American Journal of Surgery. 2014;208(1):143-50.