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Original Research Article

Low pressure versus standard pressure pneumoperitoneum in laparoscopic cholecystectomy: a comparative study

Arnab Mandal, Arindam Ghosh*, Sabyasachi Bakshi

Department of General Surgery, Bankura Sammilani Medical College and Hospital, Bankura, West Bengal, India

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***Correspondence:**
Dr. Arindam Ghosh,
E-mail: arinsunny@gmail.com

ABSTRACT

Background: With the establishment of laparoscopic cholecystectomy as gold standard management of cholelithiasis, the current stress is being given on increasing patient safety and reducing the post-operative morbidity associated with this procedure. An emerging trend is to use of low-pressure pneumoperitoneum in an attempt to lower the impact of pneumoperitoneum while providing adequate working space.
Methods: In this prospective randomized study 66 participants were allocated into two arms i.e. low-pressure pneumoperitoneum (LPP) and standard pressure pneumoperitoneum (SPP). The necessary data were collected using laboratory investigations, clinical examination and perioperative findings. Data were analyzed using suitable statistical software.
Results: Mean duration of surgery, surgical difficulty and field visualization difficulty were insignificantly greaterin LPP group than SPP group. CO_2 consumption was significantly less in LPP. Incidence of bile spillage, usage of drain was insignificantly increased in LPP. Post-operative pain was significantly greater in SPP group. Time for per oral tolerance of food and incidence of nausea were significantly greater in SPP group. Standard pressure group needed significantly more tramadol injection than LPP. There were no significant haemodynamic changes in SPP group compared to LPP group. Length of hospital stay was significantly greater in SPP.
Conclusions: Laparoscopic cholecystectomy in low pressure pneumoperitoneum is safe and feasible. Intra-operative complications like operative field visualization, operative difficulties, conversion rates, duration of surgery are not affected moreover, low-pressure pneumoperitoneum, decreases consumption of intra-operative CO_2, post-operative pain, shoulder tip pain, need of analgesia, nausea and promotes early per oral feeding, thus reduces hospital stay.

Keywords: Laparoscopic cholecystectomy, Low-pressure pneumoperitoneum, Pneumoperitoneum, Standard pressure pneumoperitoneum

INTRODUCTION

The history of gall stone disease is very old and evidenced in archaeological remains of a 2000th BC young Egyptian women.[1] Although first recorded laparoscopic cholecystectomy was performed by Philip Mouret, in 1987 in Paris, France but in September 1988, Reddick and Oslen performed laparoscopic cholecystectomy by a method which was accepted and rapidly developed into a procedure that is now being used.[2,3] Now laparoscopic cholecystectomy is the treatment of choice for symptomatic cholelithiasis. The physiological consequences of increased intra-abdominal pressure by gas insufflation were very little observed until 1960. In 1966, Kurt Semm invented an automatic insufflation device, which was capable of monitoring intra-abdominal pressure.[4] Today, intra-abdominal pressure is conventionally set at 12-15 mmHg.[5]

International guidelines recommend that the use of "the lowest intra-abdominal pressure allowing adequate exposure of the operative field rather than a routine pressure" should be used due to minimize the impact of pneumoperitoneum on normal physiology and the positive impact on postoperative pain.[6] Low pressure pneumoperitoneum is defined as a pressure of 6-10 mmHg.[7] The main concern about low-pressure pneumoperitoneum is its safety in terms of inadequate exposure resulting in the longer than usual operating time, increased rate of intra-operative complications and also possibly increased frequency of conversion to open cholecystectomy.[8] Therefore, attempts are made to use low-pressure pneumo-peritoneum in the range of 6-10 mmHg in an attempt to minimize alteration of normal physiology and simultaneously to provide an adequate working space.

In present study outcome of the use of the low pressure pneumoperitoneum (LPP defined as 10 mmHg in our study) in comparison to the use of standard pressure pneumoperitoneum (SPP defined as 14 mmHg in this study) in patients undergoing laparoscopic cholecystectomy was studied. Aim of the present study was to evaluate safety, time difference, difficulty, and conversion rate to open cholecystectomy done under low pressure versus standard pressure pneumo-peritoneum and also to find out the complications, specially pain and morbidity in per-operative and post-operative period. Different parameters were evaluated in the present study, like - duration of surgery, surgical difficulty, surgical field visualization and conversion to open cholecystectomy / standard pressure cholecystectomy, intra-operative gas consumption, peri-operative complications like bile spillage, post-operative complication like shoulder tip pain, requirement of post-operative analgesia, late tolerance of food, nausea, haemodynamic changes taking place during per-operative period and the length of stay in hospital after operation..

METHODS

This is an institution based (single center) prospective, observational study. The study population comprised of 66 patients, satisfying the inclusion and exclusion criteria. They were studied at General Surgery Department of BSMCH, West Bengal, India. After taking the informed consent from the participants, data were collected. The final sample size was 33 in each group.

Inclusion criteria

Age of 18 years or more of both gender and uncomplicated symptomatic cholelithiasis were included.

Exclusion criteria

Patients with gall bladder malignancy, acute cholecystitis, cholelithiasis associated with choledocholithiasis, history of ERCP and stent in situ, patients with other preoperative causes of shoulder pain like bursitis, rheumatoid arthritis, tendinitis and other musculoskeletal conditions, coronary artery diseases, COPD, asthma, previous malignancy, jaundice or any other co-morbidity, previous upper abdominal surgery, BMI<18.5, >29.9, ASA grade III, IV, V and patients with cognitive impairments and patients on chronic analgesic use or history of addiction to alcohol were excluded from the study.

Study procedure

Pre-operative

All routine pre-operative investigations were done. Blood pressure and pulse were measured at night before the operation, before intubation on operation table. Randomization of the subjects were done into two study arms viz- low pressure pneumoperitoneum and standard pressure pneumoperitoneum. Both surgical team and patients were blinded.

Operative

All the patients underwent general anesthesia using same drug, procedure and protocol. Injection ceftriaxone (1 g) was given intravenously to all the patients irrespective of study group during induction. In low pressure pneumoperitoneum group (LPP) the set pressure of pneumoperitoneum was 10 mmHg for the rest of intraoperative period and in standard pressure pneumoperitoneum group (SPP) the set pressure of pneumoperitoneum was 14 mmHg. This fact was hidden to the operating surgeon. At any point of surgery if surgeon complained of surgical difficulties/problem in surgical field visualization, he was informed about gas pressure of pneumoperitoneum and he was asked for opinion to convert it to standard pressure pneumoperitoneum (in case of low-pressure pneumoperitoneum) or to convert it to open cholecystectomy (in case of both pressure situations). Closure of ports were done in a standard procedure for all participants. Port site skin was infiltrated with 0.25% bupivacaine. The operating surgeons were experienced and had more than 100 laparoscopic cholecystectomies to their credits. All patients underwent same laparoscopic procedure by same surgical team. Blood pressure, pulse were noted just after intubation, just before starting pneumoperitoneum, every 10 minutes interval during operation and just after releasing pneumoperitoneum.

All the patients were given 1 g (if weight <50 kg then 15 mg/kg dose) of Paracetamol infusion intravenously before extubation and 6 hourly thereafter.

Post-operative

Blood pressures and pulses of all the patients were measured at 6th hour post-operatively then 12 hourly during hospital stay. 6 hours after the operation, patients were allowed sips of water, which if tolerated well and intestinal peristaltic sound returned at 12-hour post-

operatively, they were then allowed liquid diet. Only after then patients were allowed normal diet at 24 hour post-operatively. If not tolerated well and intestinal peristaltic sound was absent, then steps were subsequently delayed. After starting liquid diet intravenous paracetamol was changed to Tablet Paracetamol 1 g (if weight <50 kg then 15 mg/kg dose) 6 hourly per-orally. Numeric pain rating scale of pain scoring was taught to study population before operation and nursing staffs of post-operative wards was also taught the same. NPRS scoring was done 2 hourlies by nursing staffs in first 48-hour post-operative period and noted. NPRS scoring was not recorded when patients were sleeping. If hospital stay >48 hours then NPRS score was recorded when patient complaints of pain. If NPRS score were >3 without movement and NPRS score were >6 with movement, next schedule dose of paracetamol was given, if it was scheduled within next 30 minutes or at any other point injection Tramadol was given to the patient at a dose of 1 mg/kg body weight. The minimum interval between 2 doses of tramadol injection was 6 hours.

Antibiotic regimen and other drugs using post-operatively were same for all patients. Patients were released from hospital after tolerance of normal diet orally and NPRS score <6 with movement with oral paracetamol 1 g (if weight <50 kg then 15 mg/kg dose) 6 hourly. Any complication aroused post-operatively was treated as per standard guideline and release from hospital was delayed as needed. Patients were encouraged for early ambulation post-operatively. Any incidence of shoulder tip pain was recorded separately.

All data were analysed using appropriate statistical procedures with the help of standard statistical software (MS. Excel, SPSS). Data were described by estimating mean, standard deviation, percentage etc, and displayed by the help of tables and different charts. Relationship between variables was established by different statistical tests. P value of less than 0.05 was considered as significant.

RESULTS

Baseline characteristics

Table 1 shows distribution of study subjects as per gender and groups of allocation, distribution of study subjects according to their age groups, distribution of study subjects according to their BMI (n=66) and distribution of study subjects according to the number of calculus in USG (n=66).

There was clear preponderance of female (83.33%) among the participants. However, the groups were found to be comparable in respect of distribution of gender across the groups (Table 1). Majority of the participants of both the groups were young adults (51.52% vs 54.55%), closely followed by middle aged adult (42.42% vs 39.39%). However, the groups were found to be comparable in respect of distribution of age category across the groups. Majority of the participants of SPP are overweight (51.52%) and LPP are normal weight (54.55%). However, the groups were found to be comparable in respect of distribution of BMI across the groups. Majority of the participants of SPP & LPP having multiple calculi in USG (60.61% vs 72.73%). However, the groups were found to be comparable in respect of distribution of calculi in USG across the groups.

Table 1: Baseline characteristics.

	Pneumoperitoneum			χ^2, df, p value
	SPP No. (%)	LPP No. (%)	Total No. (%)	
Gender				
Male	6 (18.18)	5 (15.15)	11 (16.67)	0.11,1,0.741
Female	27 (81.82)	28 (84.85)	55 (83.33)	
Age groups (years)				
18-35 (young adult)	17 (51.52)	18 (54.55)	35 (53.03)	
35-55 (middle aged adult)	14 (42.42)	13 (39.39)	27 (40.91)	0.07, 2, 0.968
≥55 (older adult)	2 (6.06)	2 (6.06)	4 (6.06)	
Mean age (years)	37.27	36.12	36.7	0.351, 64, 0.726*
SD	13.57	12.63	13.12	
BMI				
Normal	16 (48.48)	18 (54.55)	34 (51.52)	0.24, 1, 0.622
Overweight	17 (51.52)	15 (45.45)	32 (48.48)	
Mean BMI	24.58	24.14	24.36	0.578, 64, 0.565*
SD	2.95	3.25	3.11	
No. of calculus in USG				
Single	13 (39.39)	9 (27.27)	22 (33.3)	1.09, 1, 0.296
Multiple	20 (60.61)	24 (72.73)	44 (66.7)	

Table 2: Parameters in respect to duration of surgery.

Groups	Mean (in min.)	SD	Upper range (min.)	Lower range (min.)	Independent t test, df, p value
SPP	53.31	7.39	70	40	
LPP	55.34	6.65	65	45	1.137,62,0.260
Total	54.33	7.1	70	40	
Groups	Number	Percentage	Type of conversion		
SPP	1	3.03	Open		
LPP	1	3.03	Open		
Total	2	3.03	Open		
Groups	Number	Percentage	P value (Fisher exact test (two tailed))		
SPP	2	6.25	1		
LPP	3	9.38			
Total	5	7.81			
Groups	Surgical field visualisation difficulty	Percentage	P value (Fisher exact test (two tailed))		
SPP	2	6.25	0.671		
LPP	4	12.5			
Total	6	9.38			

Table 3: Distribution of study subject according to intra-operative gas consumption.

Groups	Parameters in respect to intra-operative gas consumption.				Mann-Whitney U, p value
	Mean (in lit.)	**SD**	**Upper range (in lit.)**	**Lower range (in lit.)**	
SPP	109.13	11.8	135	96	358, 0.038
LPP	103.56	9.22	129	93	
Total	106.34	10.95	135	93	
Groups	Bile spillage	Percentage	χ^2, df, p value		
SPP	6	18.75	0.10, 1, 0.756		
LPP	7	21.88			
Total	13	21.31			
Groups	Other complications				
SPP	6	18.75			
LPP	6	18.75			
Total	12	18.75			
Groups	Drain used		χ^2, df, p value		
SPP	10	31.25	0.07, 1, 0.790		
LPP	11	34.38			
Total	21	32.81			

Distribution of study subject according to the Intra-operative gas (CO_2) consumption (in litres) (n=64), according to number of participants having Bile spillage during surgery (n=64), according to number of participants having other complications during surgery. (n=64), and according to number of participants needed Drain during surgery (n=64) (Table 3).

Distribution of study subject according to the Post-operative pain score (NPRS score) in 1st 6 hours without movement (n=64), with movement (n=64), according to the post-operative shoulder tip pain (NPRS Score) in 1st 6 hours (n=64), according to the occurrence of post-operative shoulder tip pain in 1st 6 hours (n=64), and according to the post-operative pain score (NPRS Score) in 6 - 12 hours without movement (n=64) (Table 4).

Distribution of study subject according to the post-operative pain score (NPRS score) in 6 -12 hours (n=64), with movement (n=64), according to the occurrence of post-operative shoulder tip pain in 6-12 hours (n=64), according to the post-operative pain score (NPRS score) in 12-18 hours without movement (n=64), and according to the post-operative pain score (NPRS score) in 12-18 hours with movement (n=64) (Table 5).

Table 4: Distribution of study subject according to post-operative NPRS score with movement in first 6 hours.

Groups	Parameters in respect to post-operative NPRS score with movement in first 6 hours				Mann-Whitney U, p value
	Mean	**SD**	**Upper range**	**Lower range**	
SPP	4.13	1.24	7	2	337.50, 0.015
LPP	3.44	1.12	7	2	
Total	3.78	1.23	7	2	
Groups	Occurrence of post-operative shoulder tip pain	Percentage	P value (Fisher exact test (two tailed))		
SPP	7	21.88	0.148		
LPP	2	6.25			
Total	9	14.06			
Groups	Parameters in respect to post-operative Shoulder tip pain (NPRS Score) in 1st 6 hours.				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	0.72	1.5	5	0	435.50, 0.089
LPP	0.28	1.1	5	0	
Total	0.5	1.33	5	0	
Groups	Parameters in respect to post-operative NPRS Score without movement in 1st 6 hours.				Mann-Whitney U, P value
	Mean	SD	Upper range	Lower range	
SPP	2.75	0.83	5	2	345.00, 0.015
LPP	2.22	0.78	4	1	
Groups	Parameters in respect to post-operative NPRS score without movement in 6-12 hours.				Mann-Whitney U, P value
	Mean	SD	Upper range	Lower range	
SPP	2.63	1.11	6	1	394.50, 0.095
LPP	2.22	0.89	5	1	
Total	2.42	1.03	6	1	

Table 5: Parameters in respect to post-operative NPRS score with movement in 6-12 hours.

Groups	Parameters in respect to post-operative NPRS score with movement in 6-12 hrs				Mann-Whitney U, p value
	Mean	**SD**	**Upper range**	**Lower range**	
SPP	4.06	1.32	8	2	371.00, 0.046
LPP	3.41	0.82	5	2	
Total	3.73	1.15	8	2	
Groups	Parameters in respect to post-operative shoulder tip pain (NPRS Score) in 6-12 hrs.				Mann-Whitney U, P value
SPP	0.91	1.91	6	0	429.00, 0.04
LPP	0.09	0.52	3	0	
Total	0.5	1.46	6	0	
Groups	Occurrence of post-operative shoulder tip pain		Percentage	P value (Fisher exact test (two tailed))	
SPP	6		18.75	0.057	
LPP	1		3.13		
Total	7		10.94		
Groups	Parameters in respect to post-operative NPRS score without movement in 12-18 hrs.				Mann-Whitney U, p value
SPP	2.34	0.64	4	1	403.50, 0.096
LPP	2.06	0.61	3	1	
Total	2.2	0.64	4	1	
	Parameters in respect to post-operative NPRS score with movement in 12-18 hours.				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	3.66	0.81	5	2	308.00, 0.003
LPP	3	0.79	5	2	
Total	3.33	0.87	5	2	

Table 6 shows distribution of study subject according to the Post-operative Shoulder tip pain (NPRS score) in 12-18 hours (n=64), according to the occurrence of Post-operative Shoulder tip pain in 12-18 hours (n=64), according to the post-operative pain score (NPRS score) in 18-24 hours without movement. (n=64), according to the Post-operative pain score (NPRS Score) in18-24 hours with movement (n=64).

Table 6: Distribution of study subject according to post-operative shoulder tip pain (NPRS Score) in 12-18 hours.

Groups	Parameters in respect to post-operative Shoulder tip pain (NPRS Score) in 12-18 hours.				Mann-Whitney U, P value
	Mean	SD	Upper range	Lower range	
SPP	0.63	1.43	6	0	432.00, 0.047
LPP	0.09	0.52	3	0	
Total	0.36	1.11	6	0	----------
Groups	Occurrence of post-operative shoulder tip pain	Percentage	P value (Fisher exact test (two tailed))		
SPP	6	18.75	0.057		
LPP	1	3.13			
Total	7	10.94			
Groups	Parameters in respect to post-operative NPRS score without movement in 18-24 hours.				Mann-Whitney U, P value
SPP	2.25	0.56	3	1	365.00, 0.015
LPP	1.88	0.6	3	1	
Total	2.06	0.61	3	1	
Groups	Parameters in respect to post-operative NPRS score with movement in 18-24 hours.				Mann-Whitney U, P value
SPP	4.53	1.3	7	2	151.00, 0.000
LPP	2.94	0.7	4	2	
Total	3.73	1.31	7	2	

Table 7: Distribution of study subject, and according to the post-operative shoulder tip pain (NPRS score).

Groups	Parameters in respect to post-operative shoulder tip pain (NPRS Score) in 18-24 hours.				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	0.44	0.97	3	0	416.00, 0.011
LPP	0	0	0	0	
Total	0.22	0.72	3	0	----------
Groups	Occurrence of post-operative shoulder tip pain	Percentage	P value (Fisher exact test (two tailed))		
SPP	6	18.75	0.024		
LPP	0	0			
Total	6	9.38	------		
Groups	Parameters in respect to post-operative NPRS score without movement in 24-48 hours.				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	2.06	0.56	4	1	370.00, 0.019
LPP	1.72	0.57	3	1	
Total	1.89	0.59	4	1	
Groups	Parameters in respect to post-operative NPRS score with movement in 24-48 hours.				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	2.97	1.21	7	1	416.00, 0.173
LPP	2.56	0.79	4	1	
Total	2.77	1.04	7	1	

Concluded.

Groups	Parameters in respect to post-operative shoulder tip pain (NPRS Score) in 24-48 hours.				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	0.22	0.7	3	0	464.00, 0.078
LPP	0	0	0	0	
Total	0.11	0.5	3	0	

Table 8: Distribution of study subject according to the occurrence of post-operative shoulder tip pain.

Groups	Occurrence of post-operative shoulder tip pain	Percentage	P value (Fisher exact test (two tailed))
SPP	3	9.38	0.238
LPP	0	0	
Total	3	4.69	

Groups	Parameters in respect to post-operative clear fluid tolerance orally				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	7.88	3.81	24	6	430.50, 0.095
LPP	6.56	1.75	12	6	
Total	7.22	3.03	24	6	
Groups	Parameters in respect to post-operative liquid diet tolerance orally				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	16.88	6.61	36	12	361.00, 0.006
LPP	12.94	3.04	24	12	
Total	14.91	5.51	36	12	
Groups	Parameters in respect to post-operative normal diet tolerance orally				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	28.88	6.61	48	24	351.00, 0.003
LPP	24.75	2.9	36	24	
Total	26.81	5.51	48	24	----------

Table 9: Distribution of study subject according to the number of participants having post-operative nausea.

Groups	Number of participants having post-operative nausea.			Percentage	χ^2, df, p value
SPP	10			31.25	4.73,1, 0.02
LPP	3			9.38	
Total	13			20.31	------
Groups	No of patient needed post-operative tramadol injection.				
SPP	14			43.75	7.73,1,0.005
LPP	4			12.5	
Total	18			28.13	------
Groups	Parameters in respect to the difference of Pulse (/ min) after 30 min of pneumoperitoneum from base pulse.				Independent t test, df, p value
SPP	1.5	4.09	8	-7	1.484,62,0.143
LPP	-0.34	5.58	12	-10	
Total	0.58	4.98	12	-10	
Groups	Parameters in respect to the difference of Pulse (/ min) after release of pneumoperitoneum from base pulse.				Mann-Whitney U, P value
	Mean	SD	Upper range	Lower range	
SPP	0.38	3.76	8	-6	483.50, 0.7
LPP	0.13	3.98	10	-5	
Total	0.25	3.87	10	-6	

Distribution of study subject, and according to the post-operative shoulder tip pain (NPRS Score) in 18 - 24 hours (n 64), according to the occurrence of post-operative Shoulder tip pain in 18 - 24 hours. (n = 64), according to the Post-operative pain score (NPRS Score) in 24-48 hours without movement (n=64), according to the Post-

operative pain score (NPRS Score) in 24 - 48 hours with movement (n=64), and according to the post-operative shoulder tip pain (NPRS Score) in 24-48 hours (n = 64) Table 7. Distribution of study subject according to the occurrence of post-operative shoulder tip pain in 24 - 48 hours (n=64), according to the time of tolerance (minutes) of clear fluid orally (n=64), according to the time of tolerance (minutes) of liquid diet orally (n=64), according to the time of tolerance (minutes) of normal diet orally (n=64) (Table 8).

Distribution of study subject according to the number of participants having post-operative nausea (n=64), according to the number of patients needed Post-operative Tramadol injection (n=64), according to the difference of pulse (per min) after 30 min of pneumoperitoneum from base pulse (n=64) and according to the difference of pulse (per min) after release of pneumoperitoneum from base pulse (n=64) (Table 9).

Table 10: Distribution of study subject according to the difference of mean arterial pressure.

Groups	Parameters in respect to the difference of mean arterial pressure (mm of hg) after 30 min of pneumoperitoneum from base value.				Mann-Whitney U, p value
	Mean	SD	Upper range	Lower range	
SPP	1.1	2.1	5.6	-3.7	485.00, 0.716
LPP	0.93	1.88	4.7	-3	
Total	1.02	1.99	5.6	-3.7	
Groups	Parameters in respect to the difference of mean arterial pressure (mm of hg) after release of pneumoperitoneum from base value.				Independent t test, df, p value
SPP	0.59	1.58	4.6	-2.6	0.2,62,0.842
LPP	0.52	1.23	2.3	-2.4	
Total	0.55	1.42	4.6	-2.6	
Groups	Parameters in respect to the length of stay (hours) in hospital after the operation.				Mann-Whitney U, p value
SPP	41.25	6.67	60	36	335.00,0.001
LPP	36.75	2.9	48	36	
Total	39	5.61	60	36	--

Distribution of study subject according to difference of Mean arterial pressure (mm of Hg) after 30 mins. of pneumoperitoneum from base value (n=64), according to the difference of mean arterial pressure (mm of Hg) after release of pneumoperitoneum from base value (n=64) and according to the length of stay (hours) in hospital after the operation (n=64) (Table 10).

DISCUSSION

Total 66 participants were in this study. 33 in each group (low pressure group and standard pressure group). In standard pressure group 18.18% were male, 81.82% were female, whereas in low pressure group 15.15% were male and 84.85% were female. So, in both the group clear preponderance of female was observed. When both the groups were statistically analysed, they found comparable in respect of gender distribution across the groups (p>0.05).

Majority of the participants of both the groups were young adults followed by middle aged adults followed by older adult. The age group distribution between the groups were also comparable (p>0.05). Standard pressure group had mean age of 37.27±13.57 and low-pressure group had mean age of 36.12±12.63. Which was also comparable (p>0.05).

Despite majority of participant of standard pressure group were overweight and low-pressure group were normal weight, the groups were comparable (p>0.05). Standard pressure group had mean BMI of 24.58±2.95 vs low-pressure group of 24.14±3.25, these were also comparable (p>0.05).

Majority of participants in both the groups had multiple calculi in USG and distribution according to the number of calculi (single/ multiple) was also comparable. So, independent variables in both the groups were comparable.

In present study, it was found that in standard pressure group there was one conversion to open cholecystectomy due to class I difficulty and in low-pressure group there was also one conversion to open cholecystectomy due to undiagnosed type I mirizzi's syndrome i.e. conversion rate is same in both the group (3.03% in both the group). Plenty of literature showed that increased frequency of conversion in low-pressure group.[9-15] Our results differed from these probably due to small sample size, good expertise and stringent exclusion criteria of present study. Furthermore, studies needed to conclude this.

After conversion, present sample size in both the group were 32 each and total 64. So, from now onward all the calculations and discussion would be based on total

sample size of 64, 32 in each group. In present study, we found that mean duration of surgery in low-pressure group was greater (average 2 minutes) than standard pressure group but this was not statistically significant (p=0.260). Hua et al found that slight statistical significance (weighted mean difference=2.07; p<0.001) in the mean duration of surgery.[16] This may due to they had a larger study sample and they were doing systemic review and meta-analysis.

In present study, we found that there was a greater number of surgical difficulty and surgical field visualization difficulty in low-pressure group, although both were statistically insignificant compared to standard pressure group. Kumar et al found that comparing surgeon's operative difficulty between the two groups, there was no significant difference in terms of visualization, grasping and dissection at Calot's triangle.[17] The findings were as per the findings.

It was also found that CO_2 consumption was less in LPP compared to SPP group with statistically significant difference (103.56±9.22 vs 109.13±11.8, p=0.038). Kumar et al, Mahajan Set al found in their study that LPP groups consumed less amount of CO_2 with no statistical difference.[17] This may due to mean BMI of standard pressure group in present study was greater than low-pressure group and some of the ports were leaky during present study, which leaked more CO_2 with increase of pressure. Further study needed with larger study group to make a comment on this.

In present study in low-pressure group incidence of bile spillage, usage of drain was more but that was not statistically significant and incidence of other complications during surgery was same in both the group. So, there was no significant difference between both the group in respect to intra-operative complications and usage of drain. Our results differed from these probably due to small sample size, good expertise and stringent exclusion criteria of present study. So, more studies with larger study group needed to conclude these findings.

In present study, it was found that mean pain score, occurrence of shoulder tip pain, mean pain score of shoulder tip pain and all the parameters of post-operative pain were greater in standard pressure group and many of them were significantly greater. In 1st 6 hours of post-operative period, pain without movement, pain with movement were statistically significant higher in standard pressure group, whereas shoulder tip pain score and occurrence of shoulder tip pain were greater in standard pressure group but not statistically significant. In next 6 to 12 hours period, pain with movement, mean score of shoulder tip pain were statistically significant greater in standard pressure group. At 12 to 18 hours post-operative period there was statistically significant higher pain score with movement and post-operative shoulder tip pain score in standard pressure group. At 18 to 24 hours post-operative period, pain score without movement, with movement, post-operative shoulder tip pain occurrence and shoulder tip pain score all were statistically significant greater in standard pressure group. At 24 to 48 hours post-operative period pain without movement was significantly higher in standard pressure group. Different literatures showed that increased pressure of pneumo-peritoneum associated with post-operative early referred shoulder tip pain.[18-22] In present study it was found that mean time of tolerance of per oral clear fluid (7.88±3.81 hours in SPP vs 6.56±1.75 hours in LPP, p=0.095), liquid diet (16.88±6.61 hours in SPP vs 12.94±3.04 hours in LPP, p=0.006), normal diet (28.88±6.61 hours in SPP vs 24.75±2.90 hours in LPP, p=0.003) needed greater time in standard pressure group and the values were statistically significant in case of liquid diet tolerance and normal diet tolerance. In present study we found that in SPP 31.25% and in LPP 9.38% of participants experienced post-operative nausea and this difference was statistically significant (p=0.02).

In present study it was found that in standard pressure group needed more tramadol injection than LPP group (43.75% vs 12.5%) and this value was statistically significant (p=0.005). In present study it was found that these tramadol injections were needed extra than the normal paracetamol doses. So, more doses of analgesic were needed in present study than usual, this may be due to use of a subjective pain score (NPRS) and a fixed scoring was used to give a dose of tramadol. Moreover, most of the participants were female.

In present study blood pressure and pulse of the patient at the night before operation was taken as base blood pressure and pulse of that patient. Mean arterial pressure was calculated from blood pressure and used for further statistical calculations. Difference of pulse and mean arterial pressure (MAP) after 30 minutes of pneumoperitoneum and after release of pneumo-peritoneum from base pulse and base MAP was calculated for each patient. Mean difference of pulse and MAP from base lines after 30 minutes of pneumoperitoneum were higher in case of SPP but the differences were statistically insignificant. Mean difference of pulse and MAP from base lines after release of pneumoperitoneum were higher in case of SPP but the differences were statistically insignificant. So, comparison between both groups in respect to haemodynamic changes was statistically insignificant. One reason maybe that the actual difference of 4 mmHg in the intra-peritoneal pressures in our low-pressure pneumoperitoneum and standard pressure pneumo-peritoneum groups was not sufficient to influence the hemodynamic status. Further study with larger study population needed for a concrete conclusion.

The length of hospital stay, in present study was greater in SPP group (41.25±6.67 vs 36.75±2.90 in LPP, p=0.001) and it was statistically significant. Many studies concluded that in low-pressure group there was improved postoperative recovery.[23]

To conclude, laparoscopic cholecystectomy in low pressure pneumoperitoneum at 10 mm of hg pressure is safe and feasible in the hand of experienced surgeon. Intra-operative complications, operative field visualization, operative difficulties, conversion rates, duration of surgery are not affected by low-pressure pneumoperitoneum. Moreover, low-pressure pneumoperitoneum decreases consumption of intra-operative CO_2, post-operative pain, shoulder tip pain due to pneumoperitoneum, need of analgesia, nausea and promotes early per oral feeding, thus reduces hospital stay. So, low pressure pneumo-peritoneum imparts significant patientadvantages. This simple reduction of the pressure of pneumoperitoneum from 14 mmHg to 10 mmHg, imparts the extended benefits of laparoscopic cholecystectomy.

This study is a single institute-based study with small sample size. So, multicentric study with larger study group is needed. Moreover, detailed studies on physiological, biochemical and metabolic effect of low-pressure pneumoperitoneum are also needed.

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