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SHORT TERM OUTCOMES IN PATIENTS UNDERGOING NORMAL PRESSURE PNEUMOPERITONEUM IN PATIENTS OF LAPROSCOPIC CHOLECYSTECTOMY VERSUS CHOLELITHIASIS USING LOW PRESSURE PNEUMOPERITONEUM: A COMPARISON STUDY

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ABSTRACT

Objectives: To compare short-term outcomes in patients undergoing laproscopic cholecystectomy using low pressure pneumoperitoneum versus normal pressure pneumoperitoneum in patients of cholelithiasis. **Methodology:** this randomized controlled trial study was conducted at Surgical Department Bolan Medical College from 27th June 2019 to 26th December 2019. A total of 140 patients aged 18-60 years old both males and females with uncomplicated symptomatic gall stones were included. Patients suffering from acute cholangitis, acute biliary pancreatitis, Hep B & C, multiple abdominal surgeries and malignancy were excluded. Group A: low pressure pneumoperitoneum technique was used by keeping the Pressure at 8-10 mmHg. Group B: normal pressure pneumoperitoneum technique was used by keeping the pressure at normal range i.e. 12-15mmHg. All the surgeries were done by consultant surgeon. Operative time in both groups was noted. After cholecystectomy, pain in the patients was observed at 6 hrs using visual analogue pain scale after giving a standard dose of and patients were auscultated for bowel sounds by senior resident at 6 hours to record return of bowel activity. **Results:** Mean operative time in Group A (low pressure pneumoperitoneum) was 50.71 ± 3.67minutes while in Group B (normal pressure pneumoperitoneum) was 43.06 ± 5.71minutes (p-value=0.0001). Mean post-operative pain in Group A (low pressure pneumoperitoneum) was 2.09 ± 0.70 while in Group B (normal pressure pneumoperitoneum) was 4.0 ± 0.73 (p-value=0.0001). Return to bowel activity in Group A (low pressure pneumoperitoneum) was 8.57% while in Group B (normal pressure pneumoperitoneum) was 2.86% (p-value=0.303).

Conclusion: This study concluded that the patients undergoing laparoscopic cholecystectomy using low pressure pneumoperitoneum technique have better outcome than normal pressure pneumoperitoneum technique.

KEYWORDS: laparoscopic cholecystectomy, low pressure Pneumoperitoneum, outcome.

INTRODUCTION

Laproscopic cholecystectomy is one of the most frequently performed surgeries global and is undergoing regular amendments with growing technology in order to make it more safe and beneficial. Laproscopic cholecystectomy has revolutionized the treatment of uncomplicated gall stones since its introduction and it has widely replaced open cholecystectomy as gold standard treatment.[1]

Cholelithiasis is currently one of the most common diseases dealt in surgery. Cholecystectomy is one of the most commonly performed abdominal surgical procedures, and in developed countries many are performed laparoscopically. As an example, 90% of cholecystectomies in the United States are performed laparoscopically.[2] Laparoscopic cholecystectomy is considered the "gold standard" for the surgical treatment of gallstone disease. This procedure results in less postoperative pain, better cosmesis, shorter hospital stays and disability from work than open cholecystectomy.[3]

Like every laparoscopic procedure surgical team requires safe access to abdominal cavity therefore creating large working space. CO2 insufflation for creating pneumoperitoneum is recommended technique for adequate working space and patient safety.[2-3] Standard pressure for pneumoperitoneum is 12 -15 mmHg. Pneumoperitoneum (i.e. maintaining high intrabdominal pressure) is associated with adverse effects like increase pulmonary compliance, decreased cardiac output, altered blood gases, impaired liver and renal functions along with circulatory system compromise and increase in abdominal venous pressure.[4-8] Duration of ailment after uncomplicated laproscopic cholecystectomy depends upon several factors including post-operative shoulder tip pain and return of post - operative ileus which is assessed by bowel sounds along with post-operative recovery time.

In an attempt of minimizing the adverse effects of pneumoperitoneum and decreasing the duration of ailment, a technique of low pressure pneumoperitoneum has been developed which allows adequate exposure and minimal hemodynamic effects while keeping the

pressure between 8 -10 mm Hg. Studies have shown less post-operative shoulder tip pain of 8% in Low pressure pneumoperitoneum group as compared to 30% in Normal pressure pneumoperitoneum group and return of bowel sounds at 6 hours in 17% of patients in Low pressure pneumoperitoneum group as compared to none in Normal pressure pneumoperitoneum gr oup at 6 hours along with operative time of 62±9.4 min in low pressure group as compared to 63±7.7min in high pressure group.[9] while another study showed Mean of total VAS score of low pressure pneumoperitoneum group was 0.36 ±1.24, 0.24±0.82 and 0.08±0.27 at 4hrs, 12hrs and 24 hrs respectively as compared to 1.44±2.19, 2.16±3.22 and 1.00±1.56 observed at the same intervals for Normal pressure pneumoperitoneum group and took about 39.16 ± 5.14 min for low pressure group and 39.36 ± 5.43min for normal pressure group.[10]

Hence this study is designed to compare the short term outcomes, postoperative pain , return of bowel activity and mean operative time after low pressure, pneumoperitoneum and normal pressure pneumoperitoneum with a larger sample size as compared to previous studies (largest being 140 patients). By doing this research we will be able to study this technique in our local population and will be able to implement it in future. Besides there is also scant research work done in our local setup (Pakistan) before this.

METHODOLOGY

a. Inclusion Criteria.

b. Exclusion Criteria.

METROLOGY

After approval by the Ethical Review Board, Bolan Medical College, a study was conducted on all patients between the age of 18-60 yrs fulfilling the inclusion criteria and admitted through OPD and after taking informed consent they were divided randomly into two groups by lottery method.

Group A: low pressure pneumoperitoneum technique was used by keeping the Pressure at 8-10 mmHg.

Group B: normal pressure pneumoperitoneum technique was used by keeping the pressure at normal range i.e. 12-15mmHg.

Patients aged 18-60 years old both males and females with uncomplicated symptomatic gall stones (ultrasound proven gall stones causing recurrent attacks of right hypochondric pain for

≥ 3months) included in this study, exclusion criteria was applied on Patients suffering from acute cholangitis, acute biliary pancreatitis, Hep B and C positive patients, History of ERCP, History of prior multiple abdominal surgeries and Malignancy.

All the surgeries were done by consultant surgeon. Operative time in both groups was noted as per-operational definition. After cholecystectomy, pain in the patients was observed at 6 hrs using visual analogue pain scale after giving a standard dose of analgesic (inj. Provas 1g 8h° + inj. Toradol 30mg 12h°) and patients were auscultated for bowel sounds by senior resident at 6 hours to record return of bowel activity (as per-operational definition).

The data was entered and analyzed in SPSS version 21. Quantitative variables like age, pain scores, operative time were presented as mean and standard deviation, while qualitative variables like gender and return of bowel activity were presented as frequency and percentages. Mean score of the pain, operative time between the two groups was compared using independen t sample's t-test and return of bowel activity by chi square test. P value ≤ 0.05 was considered significant. Data was stratified for age, gender, DM, HTN and IHD. Post -stratification, both groups were compared for mean score of the pain, operative by in dependent sample's t-test and return of bowel activity by chi square test for each strata taking p-value≤0.05 as significant.

RESULTS

Majority of the patients 84 (60.0%) were between 18 to 40 years of age. In this study age range was from 18 to 60 years with mean age of 35.67 ± 9.78 years. The mean age of patients in group A was 34.91 ± 9.10 years and in group B was 37.11 ± 10.26 years as shown in Table I.

Out of 140 patients 94 (67.14%) were males and 46 (32.86%) were females with male to female ratio of 2.16:1 as shown in Figure XIII. Distribution of patients according to DM, HTN & IHD is shown in Table II respectively.

Mean operative time in Group A (low pressure pneumoperitoneum) was 50.71 ± 3.67minutes while in Group B (normal pressure pneumoperitoneum) was 43.06 ± 5.71minutes as shown in Table V (p-value=0.0001). Mean post-operative pain in Group A (low pressure pneumoperitoneum) was 2.09 ± 0.70 while in Group B (normal pressure pneumoperitoneum) was 4.0 ± 0.73 as shown in Table III (p-value=0.0001). Return to bowel activity in Group A

(low pressure pneumoperitoneum) was 8.57% while in Group B (normal pressure pneumoperitoneum) was 2.86% as shown in Figure XIV (p -value=0.303).

Stratification of operative time with respect to age, gender, DM, HTN & IHD is shown in Table VII. Stratification of post -operative pain with respect to age, gender, DM, HTN & IHD is shown in Table VII. Stratification of return to bowel activity with respect to age, gender, DM, HTN & IHD is shown in Table VIII.

Table I: Age distribution for both groups (n=140).

Age (years)	Group A (n=70)		Group B (n=70)		Total (n=140)	
	No. of patients	%age	No. of patients	%age	No. of patients	%age
15-40	48	68.57	36	51.43	84	60.0
41-60	22	31.43	34	48.57	56	40.0
Mean ± SD	**34.91 ± 9.10**		**37.11 ± 10.26**		**35.67 ± 9.78**	

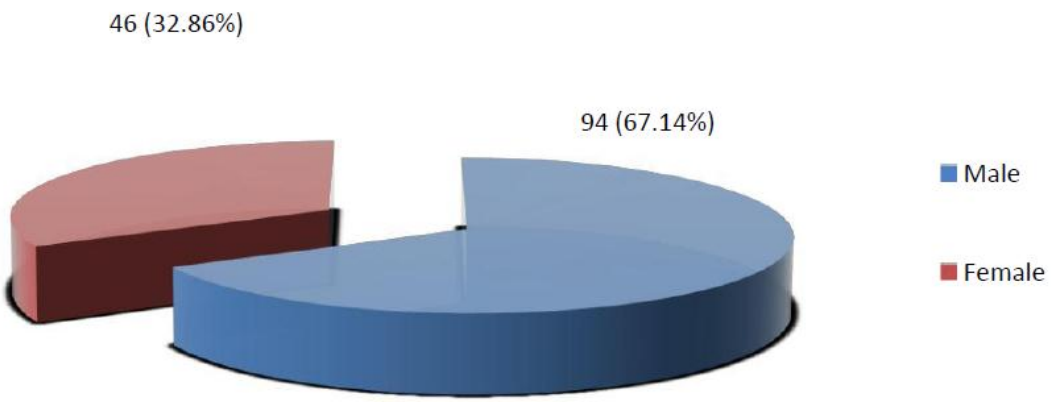

Figure-XIII: Distribution of patients according to Gender (n=140).

Table-II: Distribution of patients according to DM, HTN, IHD.

DM	Group A (n=70)		Group B (n=70)		Total (n=140)	
	No. of patients	%age	No. of patients	%age	No. of patients	%age
Yes	16	22.86	16	22.86	32	22.86
No	54	77.14	54	77.14	108	77.14
HTN						
Yes	18	25.71	20	28.57	38	27.14
No	52	74.29	50	71.43	102	72.86
IHD						
Yes	16	22.86	16	22.86	32	22.86
No	54	77.14	54	77.14	108	77.14

Table-III: Comparison of operation time and post-operative pain.

Outcome	Group A (n=70)	Group B (n=70)	p-value
	Mean ± SD	Mean ± SD	
Operation time (minutes)	43.06 ± 5.71	50.71 ± 3.67	**0.0001**
Post-operative pain	2.09 ± 0.70	4.0 ± 0.73	**0.0001**

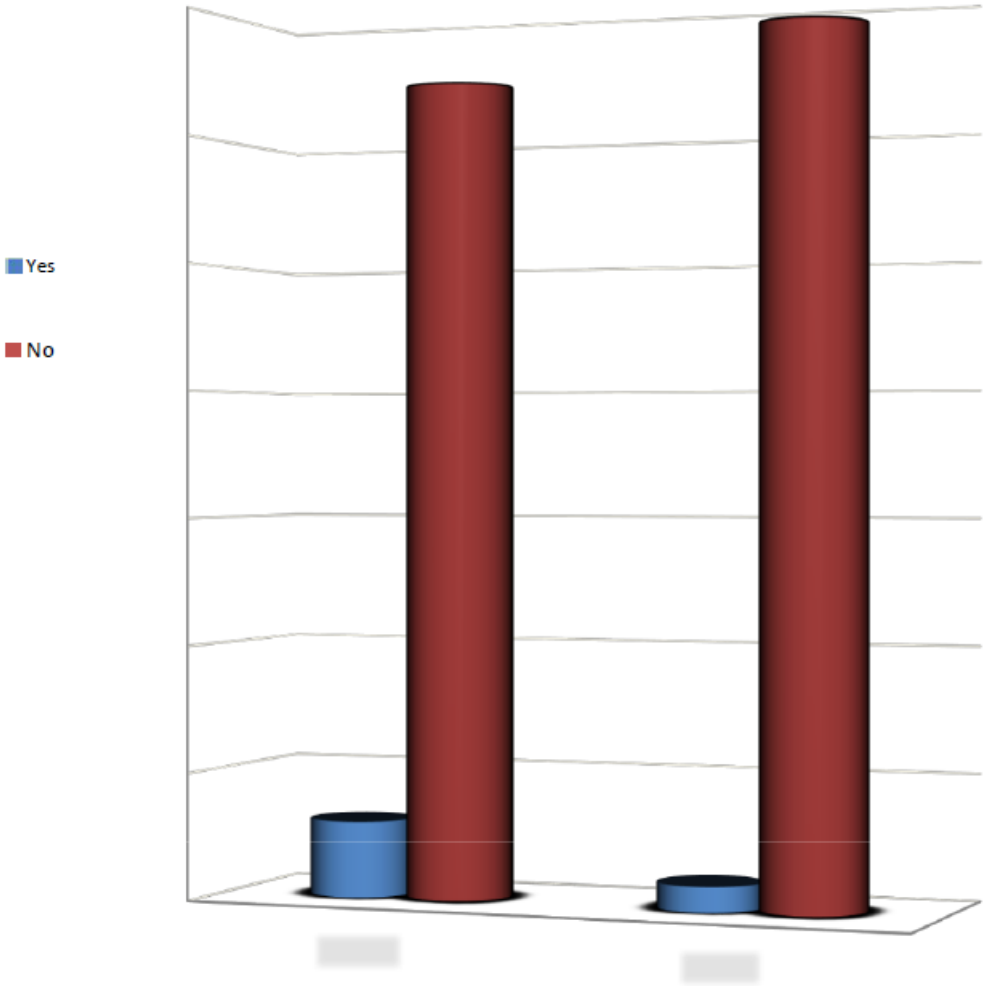

Figure XIV: Percentage of return of bowel activity in both groups.

Table VI: Stratification of operating time with respect to age, gender, DM, HTN & IHD.

Co-morbid conditions		Group A (n=70) operating time (min)		Group B (n=70) operating time (min)		P-value
		Mean	SD	Mean	SD	
Age (years)	**18-40**	51.0	3.26	43.75	5.99	**0.0001**
	41-60	50.41	4.17	41.55	4.95	**0.0001**
Gender	**Male**	51.22	3.57	43.83	5.88	**0.0001**
	Female	49.75	3.84	41.36	5.16	**0.0001**
DM	**Yes**	53.0	3.25	40.50	4.41	**0.0001**
	No	50.04	3.57	43.81	5.90	**0.0001**
HTN	**Yes**	52.70	3.40	41.33	6.58	**0.0001**
	No	49.92	3.53	43.65	5.39	**0.0001**

IHD	**Yes**	53.0	3.25	40.50	4.41	**0.0001**
	No	50.04	3.57	43.81	5.90	**0.0001**

Table VII: Stratification of post-operative pain with respect to age, gender, DM, HTN & IHD.

Co-morbid conditions		**Group A (n=70)**		**Group B (n=70)**		
		Pain		**Pain**		**P-value**
		Mean	SD	Mean	SD	
Age (years)	**15-40**	1.94	0.64	4.00	0.78	**0.0001**
	41-60	2.24	0.75	4.00	0.63	**0.0001**
Gender	**Male**	2.0	0.67	4.13	0.68	**0.0001**
	Female	2.25	0.75	3.73	0.79	**0.0001**
DM	**Yes**	1.75	0.89	3.88	0.64	**0.0001**
	No	2.19	0.62	4.04	0.76	**0.0001**
HTN	**Yes**	1.60	0.52	3.67	0.71	**0.0001**
	No	2.28	0.68	4.12	0.71	**0.0001**
IHD	**Yes**	1.75	0.89	3.88	0.64	**0.0001**
	No	2.19	0.62	4.04	0.76	**0.0001**

Table VIII: Stratification of return of bowel activity with respect to age, gender, DM, HTN & IHD.

Co-morbid conditions		**Group A (n=70) return of bowel activity**		**Group B (n=70) return of bowel activity**		**P-value**
		Yes	No	Yes	No	
Age (years)	**15-40**	01	23	01	17	**0.834**
	41-60	02	09	00	17	**0.068**
Gender	**Male**	02	22	00	23	**0.157**
	Female	01	10	01	11	**0.949**
DM	**Yes**	00	08	00	08	**----**
	No	03	24	01	26	**0.299**
HTN	**Yes**	01	08	01	09	**0.157**
	No	02	24	00	25	**0.937**
IHD	**Yes**	00	08	00	08	**----**
	No	03	24	01	26	**0.299**

DISCUSSION

Laparoscopic operative procedures have revolutionized abdominal surgery. There are several advantages of it like: a smaller and more cosmetic incision, reduced blood loss and shorter postoperative hospital stay.[11] Laparoscopic cholecystectomy is the treatment of choice for symptomatic cholelithiasis. Although there are clear benefits compared with open surgery, postoperative pain after Laparoscopic cholecystectomy remains an issue. Pain can prolong hospital stay and lead to increased morbidity.[11,12] After laparoscopic cholecystectomy

patients complain more of visceral pain as a result of stretching of the intra-abdominal cavity, peritoneal inflammation and phrenic nerve irritation caused by residual carbon dioxide in the peritoneal cavity.[13] In open cholecystectomy the type of pain results mostly is parietal pain.[14]

There is no general agreement on effective postoperative pain control. Different regimens have been proposed to relieve pain after laparoscopic surgery, such as non-steroidal anti-inflammatory drugs, local wound Anaesthetics, intra peritoneal Anaesthetics, intra peritoneal saline, gas drainage, heated gas, low-pressure gas and nitrous oxide pneumoperitoneum.[15] High pressure pneumoperitoneum for laparoscopy brings certain changes in the function of organ system and causes postoperative pain, but using low pressure has signify cant advantages in terms of postoperative pain, number of analgesics used, preservation of pulmonary function and hospital stay.[16] Although using low pressure pneumoperitoneum for laparoscopy has many advantages in terms of postoperative outcome, but surgeons experience more difficulty in dissection of tissues.[16]

I have conducted this study to compare short -term outcomes in patients undergoing laproscopic cholecystectomy using low pressure pneumoperitoneum versus normal pressure pneumoperitoneum in patients of cholelithiasis. In this study, mean operative time in Group A (low pressure pneumoperitoneum) was 50.71 ± 3.67minutes while in Group B (normal pressure pneumoperitoneum) was 43.06 ± 5.71minutes (p-value=0.0001). Mean post-operative pain in Group A (low pressure pneumoperitoneum) was 2.09 ± 0.70 while in Group B (normal pressure pneumoperitoneum) was 4.0 ± 0.73 (p-value=0.0001). Return to bowel activity in Group A (low pressure pneumoperitoneum) was 8.57% while in Group B (normal pressure pneumoperitoneum) was 2.86% (p-value=0.303). Studies have shown less post-operative shoulder tip pain of 8% in Low pressure pneumoperitoneum group as compared to 30% in Normal pressure pneumoperitoneum group and return of bowel sounds at 6 hours in 17% of patients in Low pressure pneumoperitoneum group as compared to none in Normal pressure pneumoperitoneum group at 6 hours along with operative time of 62±9.4 min in low pressure group as compared to 63±7.7min in high pressure group.[9] while another study showed Mean of total VAS score of low pressure pneumoperitoneum group was 0.36 ±1.24, 0.24±0.82 and 0.08±0.27 at 4hrs, 12hrs and 24 hrs respectively as compared to 1.44 ±2.19, 2.16±3.22 and 1.00±1.56 observed at the same intervals for Normal pressure

pneumoperitoneum group and took about 39.16 ± 5.14 min for low pressure group and 39.36 ± 5.43min for normal pressure group.[10]

Postoperative ileus has traditionally been accepted as a normal response to tissue injury. Postoperative ileus after abdominal operations is thought to be related to the degree of surgical trauma, and it has been shown that the simple act of opening the peritoneum can decrease gastrointestinal motility. Pathogenesis mainly involves inhibitory neural reflexes and inflammatory mediators released from the site of injury. Accordingly, some investigators have shown a reduction in the duration of postoperative ileus after laparoscopic procedures.[17] Post-operative ileus is characterized by the inability to tolerate a solid diet, delayed passage of flatus and formed stool and abdominal distention, nausea, vomiting, and accumulation of gas or fluids in the bowel.[18] Intestinal handling triggers mast cell activation and inflammation which is associated with prolonged postoperative ileus. This partly explain the faster recovery after minimal invasive surgery.[19] In a local study[20], the mean operative time in SPLC and LPLC groups was 35.4±8.95 and 37.4±7.89 minutes respectively, the mean operative time in both groups was statistically same, p-value > 0.05. The mean pain on visual analogue scale in SPLC and LPLC groups was 3.46±0.74 and 2. 84±0.75 respectively; the mean pain in LPLC was statistically less as compare to SPLC, p -value < 0.05. Shoulder tip pain in SPLC and LPLC was observed in 67 (74.44%) and 84 (93.33%) respectively, p-value < 0.05.[21]

The exact mechanism of pain related to pneumoperitoneum after laparoscopy may include diaphragmatic stretching, chemical irritation of peritoneum by carbonic acids from carbon dioxide, and sympathetic nervous system activation derived from hypercarbia and leading to amplification of local tissue inflammatory response as well as splanchnic mucosal ischemia.[22] The incidence of right shoulder pain in high pressure pneumoperitoneum may be related to diaphragmatic distention that causes irritation at the phrenic nerve distribution area. The removal of the remaining exogenous carbon dioxide at the end of operation reduced the incidence and severity of referred shoulder pain.[23,24] Gurusamy and Samraj carried out a review of various clinical trials evaluating low pressure and standard pressures and their effects on post operative recovery including postoperative shoulder tip pain. Their Cochrane Database review reported a lower incidence of shoulder tip pain reported in the low pressure groups.[23-28]

CONCLUSION

This study concluded that the patients undergoing laparoscopic cholecystectomy using low pressure pneumoperitoneum technique have better outcome than normal pressure pneumoperitoneum technique. So we recommend that low pressure Pneumoperitoneum carbon dioxide should be used instead of normal pressure in order to achieve better outcome.

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