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COMPARATIVE ASSESSMENT OF ABDOMINAL PAIN LEVEL AND HEMODYNAMIC SYMPTOMS IN LOW VS HIGH-PRESSURE CO2 IN SUBJECTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Background: Gallstones are usually treated with laparoscopic cholecystectomy which is also considered a gold-standard treatment modality for gallbladder stones. In laparoscopic cholecystectomy, for better visualization of surgical sites, carbon dioxide at a certain pressure is commonly used.

Aim: The present study aimed to comparatively assess the abdominal pain level and hemodynamic symptoms in low vs high-pressure Co2 in subjects undergoing laparoscopic cholecystectomy.

Methods: The study assessed 120 subjects in the age range of 18-70 years undergoing laparoscopic cholecystectomy divided into two groups of equal subjects where Group I subjects underwent laproscopic cholecystectomy with preset CO2 pressure of 7-10 mm Hg and Group II subjects with preset pressure of 12-14 mm Hg were given 12-14 mmHg. . In all the subjects, liver function tests, vomiting and nausea postoperatively, shoulder-tip pain, abdominal pain, and hemodynamic symptoms were assessed statistically and were compared.

Results: Systolic blood pressure showed a significant difference in the two groups with $p<0.05$. During surgery and 1 hour following surgery, the mean heart rate was significantly higher in the high-pressure group ($p<0.05$). Abdomen pain and shoulder-tip pain were also higher in the high-pressure group. Nausea and vomiting showed a significant difference in the two groups after 12 hours of surgery ($p<0.05$). Mean alkaline phosphate levels were significantly higher in the low-pressure group ($p<0.05$).

Conclusions: The present study concludes that considering the lesser side effects and good performance of low-pressure laparoscopic cholecystectomy in comparison to the use of high pressure, low pressure should be used as an alternative and effective replacement of high pressure during laparoscopic cholecystectomy.

Keywords: cholecystectomy, gallstones, high-pressure pneumoperitoneum, laparoscopy, low-pressure pneumoperitoneum

INTRODUCTION

The presence of gallstones is a common complication seen in the biliary tract of human beings. These gallstones have been managed using the surgical approach since 1882 with surgery being a gold-standard and traditional approach to remove gallstones. Nearly 10% of the human population globally is estimated to have gallstones with the most common surgical approach used to remove the gallstones being cholecystectomy. Cholecystectomy is widely used in both developing and developed countries for removal of the gallstones.[1]

Presently, the gold standard surgical approach for gallstones is laparoscopic cholecystectomy. Laparoscopic cholecystectomy was first described in 1988 by Dubois and it gradually advanced by various video systems and monitors that helped in better visualization of the surgical field. Various advantages associated with laparoscopic cholecystectomy that encouraged the utility of this technique among patients and surgeons are lesser mortality rates of <1%, early return to routine activities, lower pain post-surgery, lesser side effects, shorter hospital stay duration, and shortcuts. [2,3]

In laparoscopic surgery, to attain better outcomes, clear visualization of the surgical field remains a vital aspect. This is achieved by various ways and methods with pneumoperitoneum being one of those methods. In pneumoperitoneum, carbon dioxide (CO2) is entered in the peritoneal cavity keeping the constant pressure till the end of the surgery till the removal of the ports. The standard pressure used in pneumoperitoneum is 12-14 mmHg.[4] Pressure during pneumoperitoneum is also associated with various complications usually encountered following difficult and prolonged surgeries owing to carbon dioxide transmission to the peritoneum and head down position. These complications include an increase in post-operative intra-abdominal venous pressure, renal failure, an increase in liver enzymes, hemodynamic complications, alterations in arterial blood gas concentrations, and reduction in lung capacity.[5,6]

To reduce these complications of constant pressure pneumoperitoneum in the present time, surgeons use the gases at a pressure of 7-10 mmHg despite of standard 12-14 mm Hg pressure. Using the gases at low pressure in subjects with cardiovascular diseases, chronic respiratory diseases, and in elderly subjects has been reported to have good outcomes. It has also been associated with other advantages including the improved quality of life post-surgery and lesser shoulder shoulder-tip pain along with other benefits.[7] However, the use of low-pressure gas hampers the clear view of the surgical site, increases complications, and prolongs surgical duration.

These limitations can make surgeons use high-standard pressure and covert laparoscopy cases to open surgery.[8]

Considering the various advantages associated with laparoscopic cholecystectomy, the present study aimed to comparatively assess the abdominal pain level and hemodynamic symptoms in low vs high-pressure Co2 in subjects undergoing laparoscopic cholecystectomy.

MATERIALS AND METHODS

The present randomized clinical study was aimed to comparatively assess the abdominal pain level and hemodynamic symptoms in low vs high-pressure Co2 in subjects undergoing laparoscopic cholecystectomy. The study was done at Department of General Surgery of the Institute. Verbal and written informed consent were taken from all the participants in verbal and written form.

The study included 120 subjects that were randomly divided into two groups of 60 subjects each. The study subjects were in the age range of 18-70 years. The inclusion criteria for the study were subjects having gall stones, of age 18 years or more, undergoing laparoscopic cholecystectomy at the institute, and were willing to participate in the study. The exclusion criteria for the study were subjects having elevated liver enzymes before surgery, Grade 3 or 4 fatty liver, BMI (body mass index) of <19 or >30, pregnant females, subjects undergoing extensive upper abdomen surgery, empyema, and subjects with rupture of the gall bladder.

After the final inclusion of the study subjects, detailed history was recorded for all the subjects including the demographic data. After the history recording, a physical examination was done. After randomly dividing the subjects into two groups of 60 subjects each, Group I subjects pneumoperitoneum was made having PaCO2 of 7-10 mmHg and Group II subjects with pneumoperitoneum having PaCO2 of 12-14 mmHg. In both groups, the same general anesthesia, surgical method, and standard four-port technique were used. In both groups, 12 hours after surgery, subjects were allowed to change their position and movement and started eating. The subjects and allotted nurses were blinded to the group of subjects.

After 1, 3, 6, 12, and 24 hours of surgery, VRS (verbal rating scale) was used to assess shoulder-tip pain and abdominal pain at the surgery site. VRS utilizes the scores from 0-4 where 0, 1, 2, 3, and 4 depicted no pain or moderate pain. Medium pain, severe pain, and intractable pain respectively. Nausea and vomiting levels were also assessed at 1, 3, 6, 12, and 24 hours postoperatively on scores of 0-3 where 0, 1, 2, and 3 signified no nausea or vomiting, slight nausea, and vomiting, need for the anti-nausea drug, and intractable vomiting respectively. Also, blood samples were collected from all the subjects using an aseptic and sterile approach after 24 hours of the surgery to assess liver enzymes including bilirubin, ALP (alkaline phosphatase), ALT (alanine transaminase), and AST (aspartate transaminase). Body temperature, heart rate, and arterial blood pressure were recorded in all the subjects during surgery, 1, 3, and 6 hours postoperatively.

The data gathered were analyzed statistically using the SPSS software version 21.0 (IBM Corp., Armonk, NY, USA) and the chi-square test. The data were expressed as mean and standard deviation and frequency and percentage. Statistical significance was kept at a p-value of <0.05. To evaluate the change in parameters of any group before and after surgery, repeated measurements and ANOVA (analysis of variance) were used.

RESULTS

The present randomized clinical study was aimed to comparatively assess the abdominal pain level and hemodynamic symptoms in low vs high-pressure Co2 in subjects undergoing laparoscopic cholecystectomy. The study included 120 subjects that were randomly divided into two groups of 60 subjects each. Group I subjects were given pneumoperitoneum with 7-10 mm Hg $PaCO_2$ and Group II subjects were given 12-14 mmHg $PaCo_2$ respectively. The demographic data between the two groups of study subjects was statistically comparable. The mean age of the study subjects in Groups I and II was 39.2±13.1 and 36.6±15.6 years respectively with p=0.471. There were 26.6% (n=16) males and 73.3% (n=44) females in Group I, whereas, there were 96.6% (n=58) males and 3.33% (n=2) females in Group II showing a statistically non-significant difference with p>0.05. The mean height in the two groups was comparable with 161.4±4.5 and 158.7±7.7 cm in Groups I and II respectively with p=0.161. The mean weight of study subjects in Group I and II was 68.4±7.3 and 73.3±8.2 kg respectively which was non-significant with p=0.125 as shown in Table 1.

The study results showed a statistically significant difference in the mean systolic pressure of the two groups on comparison of hemodynamic parameters using repeated measure ANOVA with p=0.01. Concerning diastolic blood pressure, a non-significant difference between the two groups was seen at different time intervals with p=0.07 with comparable mean values in the two study groups. In a specific assessment interval, a significant difference was seen in the mean heart rates of study subjects in the two groups with p=0.001. The mean heart rate at different assessment times was not similar with a more marked difference in the two groups noticed during the surgery and 1 hour following the surgery.

It was seen that on assessing the LFT (liver function test) values preoperatively and postoperatively in two study groups, a significant difference was seen in bilirubin levels in Group I preoperatively and postoperatively with respective p-values of 0.002 and 0.02. However, a non-significant intergroup difference was seen with p=0.6. A significant improvement was seen for ALP, ALT, and AST levels in Group I postoperatively with a marked reduction in all parameters and p-values of 0.001, 0.001, and 0.001 respectively. Similar results were seen with high-pressure usage in Group II with significant reduction in ALT, and AST levels and respective p-values of 0.001 and 0.001. On intergroup assessment, a significant difference was seen for ALP with p=0.02 showing that all other liver function variables were comparable in the two groups as depicted in Table 2.

On comparing the various study parameters in two groups at different time intervals, it was seen that shoulder tip pain and abdominal pain using the chi-square test showed no significant difference in pain frequency after 1 hour of surgery in the two study groups utilizing low pressure and high pressure. However, a statistically significant intergroup difference was seen at 3, 6, 12, and 24 hours after surgery for abdominal pain with respective p-values of 0.001, 0.03, 0.001, and 0.001.

At all the assessment times, pain in Grade 3 or 4 was not seen in any subject of the low-pressure group. For shoulder tip pain, a significant difference was seen in two groups at 1, 3, 6, 12, and 24 hours after surgery with p-values of 0.02, 0.02, 0.02, 0.001, and 0.001 respectively. For nausea and vomiting significant difference was only seen at 12 hours with p=0.01 as summarized in Table 3.

DISCUSSION

The present study included 120 subjects that were randomly divided into two groups of 60 subjects each. Group I subjects were given 7-10 mm Hg $PaCO_2$ and Group II subjects were given 12-14 mmHg $PaCO_2$ respectively. The demographic data between the two groups of study subjects was statistically comparable. The mean age of the study subjects in Groups I and II was 39.2±13.1 and 36.6±15.6 years respectively with p=0.471. There were 26.6% (n=16) males and 73.3% (n=44) females in Group I, whereas, there were 96.6% (n=58) males and 3.33% (n=2) females in Group II showing a statistically non-significant difference with p>0.05. The mean height in the two groups was comparable with 161.4±4.5 and 158.7±7.7 cm in Groups I and II respectively with p=0.161. The mean weight of study subjects in Group I and II was 68.4±7.3 and 73.3±8.2 kg respectively which was non-significant with p=0.125. These data were similar to the studies of Baraka A et al[9] in 1994 and Joris J et al[10] in 1992 where authors assessed subjects with demographic data comparable to the present study.

It was seen that there was a statistically significant difference in the mean systolic pressure of the two groups on comparison of hemodynamic parameters using repeated measure ANOVA with p=0.01. Concerning diastolic blood pressure, a non-significant difference between the two groups was seen at different time intervals with p=0.07 with comparable mean values in the two study groups. In a specific assessment interval, a significant difference was seen in the mean heart rates of study subjects in the two groups with p=0.001. The mean heart rate at different assessment times was not similar with a more marked difference in the two groups noticed during the surgery and 1 hour following the surgery. These results were consistent with the previous studies of Vezakis A et al[11] in 1999 and Kanwer DB et al[12] in 2009 where authors reported hemodynamic alterations comparable to the present study in their respective studies.

The study results showed that on assessing the LFT (liver function test) values preoperatively and postoperatively in two study groups, a significant difference was seen in bilirubin levels in Group I preoperatively and postoperatively with respective p-values of 0.002 and 0.02. However, a non-significant intergroup difference was seen with p=0.6. A significant improvement was seen for ALP, ALT, and AST levels in Group I postoperatively with a marked reduction in all parameters and p-values of 0.001, 0.001, and 0.001 respectively. Similar results were seen with high-pressure usage in Group II with significant reduction in ALT, and AST levels and respective p-values of 0.001 and 0.001. On intergroup assessment, a significant difference was seen for ALP with p=0.02 showing that all other liver function variables were comparable in the two groups. These findings were in agreement with the findings of Hasukiae S[13] in 2005 and Sayadi S et al[14] in 2013 where authors reported a significant reduction of liver enzymes post laparoscopic cholecystectomy.

Concerning the comparison of the various study parameters in two groups at different time intervals, it was seen that shoulder tip pain and abdominal pain using the chi-square test showed no significant difference in pain frequency after 1 hour of surgery in the two study groups utilizing low pressure and high pressure. However, a statistically significant intergroup difference was seen at 3, 6, 12, and 24 hours after surgery for abdominal pain with respective p-values of 0.001, 0.03, 0.001, and 0.001. At all the assessment times, pain in Grade 3 or 4 was not seen in any subject of the low-pressure group. For shoulder tip pain, a significant difference was seen in two groups at 1, 3, 6, 12, and 24 hours after surgery with p-values of 0.02, 0.02, 0.02, 0.001, and 0.001 respectively. For nausea and vomiting significant difference was only seen at 12 hours with p=0.01. These results were in line with the results of Al Dabbagh A et al[15] in 2010 and Imani F et al[16] in 2012 where authors reported a significant difference in low-pressure and high-pressure laparoscopic cholecystectomy concerning pain as seen in the present study.

CONCLUSION

Considering its limitations, the present study concludes that considering the lesser side-effects and good performance of low-pressure laparoscopic cholecystectomy in comparison to the use of high pressure, low pressure should be used as an alternative and effective replacement of high pressure during laparoscopic cholecystectomy. Further studies with a larger number of subjects and longer study duration are needed to reach a definitive conclusion.

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TABLES

Characteristics	**Group I**		**Group II**		**p-value**
	n=60	**%**	**n=60**	**%**	
Mean age (years)	39.2±13.1		36.6±15.6		0.471
Gender					
Males	16	26.6	2	3.33	>0.05
Females	44	73.3	58	96.6	
Height (cm)	161.4±4.5		158.7±7.7		0.161
Weight (kg)	68.4±7.3		73.3±8.2		0.125

Table 1: Demographic data in the two groups of study subjects

LFT parameter	**Group I**		**p-value**	**Group II**		**p-value**	**Intergroup p-value**
	Preop	**Postop**		**Preop**	**Postop**		
Bilirubin D	0.3±0.3	0.23±0.07	0.002	0.3±0.3	0.2±0.2	0.02	0.6

Bilirubin T	0.68±0.4	0.63±0.18	0.01	0.7±0.4	0.6±0.2	0.007	0.2
ALP	147±61.4	169.5±57.3	0.001	187±78.4	185±63.2	0.6	0.02
ALT	34.7±15.6	18.4±6.9	0.001	31±12.4	20.5±13.9	0.001	0.26
AST	45±29.3	20.6±7.3	0.001	37.7±13.5	20.8±6.6	0.001	0.21

Table 2: Mean LFT (liver function test) values preoperatively and postoperatively in two study groups

Postop time	**Adverse effect (pain)**	**Group**	**Score 0**	**Score 1**	**Score 2**	**Score 3**	**Score 4**
1 hour	**Nausea and vomiting**	Low (I)	16	24	12	9	-
		High (II)	10	20	28	2	0
	p-value	0.3					
	Abdominal	Low (I)	0	8	40	12	0
		High (II)	0	12	24	22	2
	p-value	0.16					
	Shoulder-tip	Low (I)	8	32	20	0	0
		High (II)	4	16	32	8	0
	p-value	**0.02**					
3 hours	**Nausea and vomiting**	Low (I)	20	24	16	0	-
		High (II)	16	22	20	2	0
	p-value	0.6					
	Abdominal	Low (I)	0	16	44	0	0
		High (II)	0	2	38	18	2
	p-value	**0.001**					
	Shoulder-tip	Low (I)	28	24	8	0	0
		High (II)	4	22	26	8	0
	p-value	**0.02**					
6 hours	**Nausea and vomiting**	Low (I)	32	16	12	0	-
		High (II)	22	20	16	2	-
	p-value	0.4					
	Abdominal	Low (I)	0	32	28	0	0
		High (II)	0	16	34	8	2
	p-value	**0.03**					
	Shoulder-tip	Low (I)	20	24	16	0	0
		High (II)	8	20	20	12	0
	p-value	**0.02**					
12 hours	**Nausea and vomiting**	Low (I)	44	4	12	0	-
		High (II)	14	36	8	2	-
	p-value	**0.001**					
	Abdominal	Low (I)	8	8	44	0	0

		High (II)	0	0	14	44	2
	p-value	**0.001**					
	Shoulder-tip	Low (I)	40	20	0	0	0
		High (II)	20	14	24	2	
	p-value	**0.001**					
24 hours	**Nausea and vomiting**	Low (I)	52	8	0	0	-
		High (II)	42	16	2	0	-
	p-value	0.25					
	Abdominal	Low (I)	16	44	0	0	0
		High (II)	0	48	12	0	0
	p-value	**0.001**					
	Shoulder-tip	Low (I)	44	16	0	0	0
		High (II)	32	18	10	0	0
	p-value	**0.01**					

Table 3: Comparison of various study parameters in two groups at different time intervals