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Evaluation of hemodynamic changes with different abdominal pressure for laproscopic cholecystectomy using advanced cardiac output (Flo-Trac) monitoring

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ABSTRACT

Background and Aims: During laparoscopic procedures, hemodynamic stability is of great concern. This study was carried out to evaluate hemodynamic Changes with different intra- abdominal pressure (IAP) for laparoscopic cholecystectomy using Advanced Cardiac Output (FloTrac) Monitoring.
Materials and Methods: In this Prospective, randomized and observational study, total 90 patients ASA grade I, II scheduled for laparoscopic cholecystectomy were randomly allocated to three groups: Group I :10-12mm hg, groupII-13-15mmhg, Group III- $>$ 15mmhg. Central venous line and arterial cannula was secured before induction and connected to FloTrac monitor. Heart rate (HR), Cardiac index (CI), Systemic vascular resistance index (SVRI), Stroke volume variation (SVV), Oxygen saturation (SPO2) were monitored at various interval. For Statistical analysis student t-test and ANOVA test were used.
Results: At all time intervals, HR of Group I was found to be lower than Group II and Group III except at insufflation. CI (Cardiac Index) of Group I was also found to be lower than that of Group II and that of Group III was lower than that of Group II at all time intervals. At all time periods values of SVRI, SVV of Group I were found to be lower than that of Group II and Group III. SVRI, SVV of Group II were found to be lower than that of Group III.
Conclusions: IAP value above 15mm Hg seems to affect the hemodynamics significantly. Study showed that the IAP rise from 10-12 to 13-15 does not influence hemodynamics significantly, and could be adjudged relatively safe.

1. Introduction

The first report of Laparoscopic Cholecystectomy (LC) in medical literature originated simultaneously from France.[1] and the United States of America (USA).[2] The first laparoscopic cholecystectomy in India was performed in 1990.[3] Today, Laparoscopic cholecystectomy (LC) is one of the most common elective surgical procedures performed throughout the world.[4] With the advent of newer techniques in anesthetic and surgical management, up to 84% of elective laparoscopic cholecystectomy patients can be discharged on the day of surgery itself.[5]

During laparoscopic procedures, hemodynamic stability is of great concern. During the laparoscopic procedures, there are often hemodynamic and respiratory alterations. These alterations are derived from 3 factors: the first one is the intra-abdominal pressure created by the pneumoperitoneum; the second one is the existence of an insufflation gas that may be absorbed by the blood depending upon the gas used and; the third one is the positioning of the patients.[6]

Among different strategies to control the hemodynamics during laparoscopic cholecystectomy, variation in intra-abdominal pressure is somewhat less explored. One must understand that increased intra-abdominal pressure associated with pneumoperitoneum may compress venous capacitance vessels causing an initial increase, followed by a sustained decrease in pre-load. Compression of the arterial vasculature increased afterload might result in a marked increase in calculated systemic vascular

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resistance (SVR). Cardiac index might be significantly reduced, and the magnitude of this effect is proportional to intra-abdominal pressure achieved. In healthy subjects undergoing laparoscopic cholecystectomy the cardiac output has been shown to be depressed to a maximum of 28% at an insufflations pressure of 15 mm Hg but is maintained at an insufflation pressure of 7 mm Hg. In animal models, a cut-off value of 12 mm Hg IAP has been found to be optimal to minimize the effect of IAP on haemodynamic changes.[7]

There are limited studies on this issue despite the fact that procedures under low-pressure have been as effective as those under high pressure and reportedly have lesser impact on cardiovascular and hemodynamic parameters.

Initially Pulmonary Artery (PA) catheters were introduced for continuous monitoring of cardiac output.[8] In the present era, use of invasive PA catheter based cardiac output monitoring has been questioned. As an alternative, the FloTrac system can be used to monitor C.O. which is a practical, reliable, and minimally invasive option that provides dynamic and flow based hemodynamic parameters through an existing arterial line and central venous line.[9]

Hence the present study was planned to evaluate the effect of different abdominal pressures on hemodynamic changes using advanced cardiac output (FloTrac) monitoring.

2. Materials and Methods

The sample size was taken as 90 allocated randomly to three groups comprising of 30 patients each. It was a prospective randomized observational study. The Institutional Ethical Board approved this study and written informed consent was obtained from all participants.

2.1. Inclusion criteria

Patients undergoing elective laparoscopic cholecystectomy procedures with American Society of Anesthesiologists (ASA) Grade I & II , Aged 18 to 60 years of either sex.

2.2. Exclusion criteria

Patients with significant portal hypertension, suspected gall bladder carcinoma, cirrhosis, and generalized peritonitis, Patients with communication difficulties (preventing reliable assessment), Patients with co- existing disease like diabetes mellitus or cardiac disease etc.

2.3. Sample size estimation

The sample size estimation was projected on the basis of study done by targeting a mean change in cardiac index to the tune of 10±13% to be clinically significant for differentiation among groups. The sample size was calculated using the following formula

$n = 16\, s^2/d^2 + 1$

Where, s=13; and d=10,

So the required sample size

n = 27.04+1 ~ 28 samples in each group.

After adding two samples in each group for drop out, the sample size was taken as 90 allocated randomly to three groups comprising of 30 patients each.

2.4. Randomization method

Randomization was done using computer generated random number table.

A total of 90 patients were enrolled in the study to three study groups as follows:

Group I: Intra-abdominal pressure was maintained between 10-12 mm Hg

Group II: Intra-abdominal pressure was maintained between 13-15 mm Hg

Group III: Intra-abdominal pressure was maintained above 15 mm Hg

After taking the patient in operation theatre all standards monitors were attached and monitored. Intravenous line secured on the right dorsum of the hand with 18 gauge cannula. Injection 1 mg midazolam and 50 mg Fentanyl was given to reduce pain and anxiety. 22 gauge arterial cannula was secured in Right/left radial artery after local infiltration of 2 ml of 2% lignocaine. Central venous line (7 Fr) was inserted inside the right internal jugular vein under aseptic condition by Seldinger's technique.

CVP and invasive Blood pressure measurement was started and connected to FloTrac monitor. Following baseline parameters were monitored – Heart rate (HR), Cardiac index (CI), Systemic vascular resistance index (SVRI), Stroke volume variation (SVV), Oxygen saturation (SpO_2).

Patient was oxygenated with 100% oxygen for 3 minutes and then induced with Midazolam 1-2 mg, Fentanyl 1-2 mg/kg, and Propofol 1-2 mg/kg. After induction patients were intubated with vecuronium 0.08-0.12 mg/kg and maintained with 50%O_2 and 50% air, Isoflurane , Vecuronium and Fentanyl as per standard protocol. Patients were put on controlled ventilation using closed circuit with low flow balanced anesthesia. HR, CI, SVRI, SVV, SpO_2, E_TCO_2 were monitored at following interval: Baseline (before induction), immediately after insufflation, 10 minutes after insufflation and thereafter every 10 minutes, at immediate post ex-sufflation and 10 minutes after ex-sufflation.

During surgery patients were placed in reverse trendelenberg's position (head up) at 15 degree with right side of the table elevated.

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The values were represented in Number (%) and Mean ±SD. For Statistical analysis student t-test and ANOVA test were used.

3. Observations and Results

Heart Rate (HR) of Group II was maximum followed by of Group III and minimum in Group I at all time intervals, except at 30 minutes post-insufflation and at 10 minutes after exsufflation (Figure 1).

At 30 minutes of insufflation and at 10 minutes after exsufflation HR of Group III was maximum followed by Group II and minimum in Group I.

CI of Group II was found to be lower than that of Group I at all time intervals and Cardiac Index of Group III was found to be lower than that of Group II at all periods. In all the three groups a gradual decline in CI was observed at all periods of observations post insufflations. CI was observed to increase after exsufflation and reached to baseline at 10 minutes post exsufflation in all the groups (Table 1). Differences in Cardiac Index (CI) among the groups (Table 1) were found to be statistically significant at 20 minutes post insufflation, 30 minutes post insufflation and at post exsufflation (Table 1).

At all time intervals post insufflation, SVRI of Group III was maximum followed by that of Group II and minimum was in Group I. Differences were significant at 20 and 30 minutes post insufflation (Table 2). On intergroup comparison by using Post Hoc Tukey HSD Test, it was found that differences were significant only between Group I and Group III at 10, 20, 30 minutes post-insufflation and at exsufflation (Table 3).

At all time intervals, except baseline and 10 minutes post exsufflation, SVV of group III was maximum followed by that of group II and group I in descending order. Differences were found to be significant at all time periods post insufflation (Table 4). On further intergroup analysis by using Post Hoc Tukey HSD Test (Table 5), it was found that differences were statistically significant between Group I & Group III as well as between Group II & Group III at all time periods.

SpO_2 of all the patients ranged from 98-100%. Though intergroup differences in oxygen saturation levels were found to be statistically significant at immediately after insufflation, 10 minutes after insufflation and 20 minutes after insufflation, but these differences were not of any clinical significance hence no further analysis was done.

4. Discussion

The present study was carried out to evaluate hemodynamic changes with different abdominal pressure for laparoscopic cholecystectomy using advanced cardiac output (FloTrac) monitoring. In present study, we used three abdominal pressure variants – 10-12 mm Hg, 13-15 mm Hg and >15 mm Hg for this purpose. The groups were matched for age, gender and baseline hemodynamic characteristics and it was ascertained that there was no confounding effect of demographic characteristics.

As far as effect on HR is concerned, it was found to be affected by abdominal pressure throughout the study period. The effect was pronounced after abdominal pressure reached 12 mm Hg and the pattern of response did not vary substantially between 13-15 mm Hg and above 15 mm Hg. Although, these variations were significant statistically, however, this difference has little clinical relevance, as the maximum increase in heart rate in any group at any time was 16.95%, which is within the acceptable clinical limits. Similar observations were also made by Rishimani and Gautam (1996).[10] Who also observed that reduced intra-abdominal pressure does not clinically affect the heart rate. Observations to similar effect were also made by other workers too.[11] Although the changes in present study did not hold clinical significance yet they were significant statistically, however, a number of studies have not found a significant difference in different abdominal pressure conditions.[12] But some studies have also obtained results similar to our study.[13] These findings indicate that in general heart rate is not much influenced to have a clinical impact and thus increased IAP can be used safely at least in normotensive patients.

In present study, cardiac index was seen to be decreasing soon after insufflation, with mean decline ranging from 2.51% to 32.17% at different post-insufflation intervals (Table 1). Although decrease in cardiac index was noticed in all the three groups, however, it was most pronounced in >15 mm Hg group and least pronounced in 10-12 mm Hg group. Despite these trends, the intergroup differences were significant only at 20 minutes and 30 minutes post-insufflations intervals and at the time of exsufflation. One must understand that increased intra-abdominal pressure associated with pneumoperitoneum may compress venous capacitance vessels causing an initial increase, followed by a sustained decrease in pre-load[7] Similar to our study, Korkmaz et al. (2002)[14] also observed no significant difference in cardiac index of patients undergoing laparoscopic cholecystectomy under gasless and gaseous (14 mm Hg) conditions. Although, in present study insufflations was done in all the cases, however, significant differences were observed between two extremes and the middle IAP condition, thus showing that the pattern of CI change has a systematic change, which is not directly proportional to change in IAP. In another study, Wallace et al. (1997)[15] on comparing the difference in intraoperative CI changes between 7.5 mmHg and 15 mm Hg insufflations groups did not find them to be significant statistically. In present study, we also did not observe any significant difference in pattern of change in CI between 10-12 mm Hg and >15 mm Hg groups.

Another reason for unorthodox pattern of CI changes in different groups in present study could be attributed

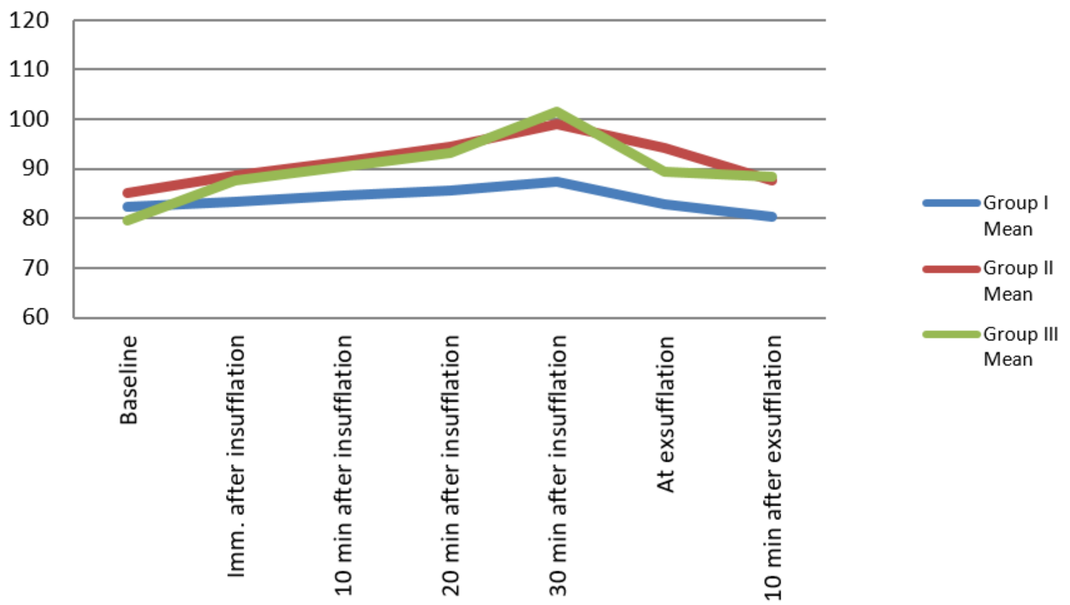

Fig. 1: HR changes in 3 Groups

Table 1: Comparison of C.I. at different time intervals

	Group I			Group II			Group III			Statistical significance (ANOVA)	
	n	Mean	SD	n	Mean	SD	n	Mean	SD	F	p
Baseline	30	3.50	0.43	30	3.58	1.01	30	3.90	0.38	2.900	0.060
Imm. after insufflation	30	3.32	0.41	30	3.49	0.38	30	3.45	0.32	1.766	0.177
10 min after insufflation	30	3.22	0.41	30	3.39	0.37	30	3.21	0.26	2.546	0.084
20 min after insufflation	30	3.11	0.40	30	3.28	0.36	30	3.03	0.25	4.054	0.021
30 min after insufflation	26	3.03	0.38	27	3.21	0.37	11	2.82	0.24	4.955	0.010
At exsufflation	30	3.20	0.36	30	3.49	0.36	30	3.33	0.28	5.454	0.006
10 min after exsufflation	30	3.41	0.37	30	3.58	0.35	30	3.55	0.35	1.941	0.150

Table 2: Comparison of SVRI at different time intervals

	Group I			Group II			Group III			Statistical significance (ANOVA)	
	n	Mean	SD	n	Mean	SD	n	Mean	SD	F	p
Baseline	30	1441.90	78.65	30	1479.21	142.64	30	1487.08	423.54	0.255	0.776
Imm. after insufflation	30	1447.65	78.87	30	1490.36	142.09	30	1520.69	158.56	2.351	0.101
10 min after insufflation	30	1452.45	79.04	30	1497.42	143.07	30	1535.11	158.15	2.980	0.056
20 min after insufflation	30	1455.04	79.00	30	1510.70	143.03	30	1549.85	159.06	3.929	0.023
30 min after insufflation	26	1473.45	72.88	27	1536.34	134.90	11	1634.53	167.11	7.032	0.002
At exsufflation	30	1447.82	79.33	30	1503.64	144.05	30	1531.16	160.36	3.076	0.051
10 min after exsufflation	30	1441.09	79.49	30	1497.03	143.54	30	1501.59	103.03	2.722	0.071

Table 3: Comparison of SVRI (Post-Hoc Tukey HSD test)

	Gr I Vs. Gr II			Gr I Vs. Gr III			Gr II Vs. Gr III		
	Mean diff.	**SE**	**'p'**	**Mean diff.**	**SE**	**'p'**	**Mean diff.**	**SE**	**'p'**
Baseline	-37.32	67.65	0.846	-45.18	67.65	0.783	-7.86	67.65	0.993
Imm. after insufflation	-42.71	33.85	0.421	-73.04	33.85	0.084	-30.34	33.85	0.644
10 min after insufflation	-44.97	33.90	0.384	-82.67	33.90	0.044	-37.70	33.90	0.509
20 min after insufflation	-55.67	33.99	0.235	-94.81	33.99	0.018	-39.15	33.99	0.485
30 min after insufflation	-62.89	33.10	0.147	-161.08	43.33	0.001	-98.19	43.09	0.066
At exsufflation	-55.82	34.24	0.239	-83.34	34.24	0.044	-27.52	34.24	0.702
10 min after exsufflation	-55.94	28.88	0.135	-60.51	28.88	0.097	-4.57	28.88	0.986

Table 4: Comparison of SVV at different time intervals

	Group I			Group II			Group III			Statistical significance (ANOVA)	
	n	**Mean**	**SD**	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**F**	**p**
Baseline	30	6.00	1.05	30	6.17	0.99	30	6.23	0.97	0.431	0.651
Imm. after insufflation	30	6.93	1.08	30	7.23	0.90	30	10.13	1.01	94.024	<0.001
10 min after insufflation	30	8.00	1.02	30	8.20	0.92	30	12.03	1.07	153.657	<0.001
20 min after insufflation	30	8.93	0.94	30	9.30	1.12	30	14.00	0.91	241.794	<0.001
30 min after insufflation	26	9.73	0.72	27	10.44	1.15	11	15.27	1.01	132.084	<0.001
At exsufflation	30	7.63	1.25	30	7.93	1.08	30	11.20	1.19	85.384	<0.001
10 min after exsufflation	30	5.90	1.09	30	6.53	1.04	30	9.17	1.02	81.310	<0.001

Table 5: Inter-group Comparison of SVV (Post-Hoc Tukey HSD test)

	Gr I Vs. Gr II			Gr I Vs. Gr III			Gr II Vs. Gr III		
	Mean diff.	**SE**	**'p'**	**Mean diff.**	**SE**	**'p'**	**Mean diff.**	**SE**	**'p'**
Baseline	-0.17	0.26	0.797	-0.23	0.26	0.641	-0.07	0.26	0.964
Imm. after insufflation	-0.30	0.26	0.478	-3.20	0.26	<0.001	-2.90	0.26	<0.001
10 min after insufflation	-0.20	0.26	0.722	-4.03	0.26	<0.001	-3.83	0.26	<0.001
20 min after insufflation	-0.37	0.26	0.332	-5.07	0.26	<0.001	-4.70	0.26	<0.001
30 min after insufflation	-0.71	0.27	0.026	-5.54	0.35	<0.001	-4.83	0.35	<0.001
At exsufflation	-0.30	0.30	0.585	-3.57	0.30	<0.001	-3.27	0.30	<0.001
10 min after exsufflation	-0.63	0.27	0.057	-3.27	0.27	<0.001	-2.63	0.27	<0.001

to selection of a relatively narrower range of IAP in different groups, being too narrow, it is difficult to state that whether the changes in cardiac parameters were being influenced by the IAP alone or were dependent on other factors like exposure period to variable IAP conditions. The cardiovascular changes resulting in change in haemodynamics take some time and as such the difference in duration of procedure might well affect the pattern of responses. We did not find a targeted clinically significant difference between group difference of 10% in any of the between group comparisons at different time intervals and as such derive the inference that the nominal IAP differences among groups did not provide a clinically significant difference as far as CI was concerned.

In present study, statistically no significant difference among groups was observed with respect to SVRI at different intraoperative and postoperative intervals except at 20 min and 30 min after insufflations and at exsufflation when mean value in high IAP group were higher as compared to low IAP group. Statistically no significant differences in mean SVRI values of low IAP and mid IAP and mid IAP and high IAP groups were observed at any of the intraoperative, exsufflation or post-exsufflation intervals. As far as within group changes were concerned, mean values were above baseline values at all the follow up intervals in all the three groups except at 10 min post-insufflation interval in low IAP group where the mean value was lower than baseline. Thus in general, the changes in SVRI values were nominal and between group differences did not hold any clinical value. These observations are in agreement with the observations of Korkmaz et al. (2002)[14] who was also of the view that increased IAP did not affect the SVRI. SVRI in fact is a function of SVR and as such its change behavior was much the same as for SVR. As a matter of fact, body surface area remains a static and hence SVR trend is almost similar as observed for SVRI. Considering this relationship between SVR and SVRI, most of the researchers in past have studied only one of these parameters and excluded the other. In present study, we did undertake both the parameters but found no phenomenal difference.

However, stroke volume variation seemed to be affected substantially among the groups. At different intraoperative and exsufflation intervals, mean value in high IAP group was significantly higher as compared to that in mid IAP and low IAP groups. The percentage changes in stroke volume variation were phenomenal in present study. Even in low IAP group the peak rise in stroke volume was 84% whereas in high IAP group the peak rise in stroke volume was as high as 143.48%. Thus the findings suggest that with increased pressure and duration of exposure time, the SVV shows a phenomenal increase. Liu et al[16] also made findings similar to ours who observed that 5 mm, 10 mm and 15 mm Hg of IAP show an increase in SVV of nearly 10%, 53% and 98% respectively after 5 minutes of pneumoperitoneum creation, thus showing that SVV values are affected phenomenally at variable pressure conditions within a short span of time. In present study a steep decline in SVV was observed in all the three groups following exsufflation. This finding is endorsed by the observation of Wajima et al. (2015)[17] who also showed similar trends of increase after pneumoperitoneum creation and decrease after the release of pneumoperitoneum.

In present study, as such no clinically significant effect of IAP variation was observed on oxygen saturation levels, which remained from 98-100% in all the patients throughout the study. On evaluating the literature, we did not find any report suggesting a significant clinical impact of variable IAP on oxygen saturation among patients undergoing laparoscopic cholecystectomy.

The findings of present study in general showed that variation in IAP affects the hemodynamic parameters marginally when IAP is lesser than 15 mm Hg. However, at a higher IAP the hemodynamics is affected significantly. However, whether these changes have a clinical impact needs to be studied. In present study, no case of haemodynamic emergency occurred, hence despite variable effects of different IAPs on pulmonary, haemodynamics and stress response, all the IAP combinations used in present study were safe.

5. Conclusions

On the basis of above findings it can be concluded that although marginal increase in IAP does not affect haemodynamics substantially, however, IAP value above 15 mm Hg seems to affect the haemodynamics significantly in statistical terms. Thus, the present study showed that the IAP rise from 10-12 to 13.0-15 does not influence haemodynamics significantly, and could be adjudged relatively safe whereas rise of IAP above 15 mm Hg affects hemodynamic parameters significantly, so should be avoided specially in patients with compromised cardiovascular reserve.

6. Source of Funding

None.

7. Conflict of Interest

None.

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