Effects of Haemodynamic Changes Caused by Different Pneumoperitoneum Pressures on Cerebral Oxygenation in Laparoscopic Cholecystectomy: Prospective Randomised Controlled Trial

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ABSTRACT

Objective: To evaluate the role of different pneumoperitoneum pressure ranges on cerebral oxygenation.
Study Design: Prospective, randomised controlled trial.
Place and Duration of the Study: Karadeniz Technical University, Turkiye, from January to September 2020.
Methodology: Seventy patients (aged 18-65 years, ASA I-IIII) scheduled for laparoscopic cholecystectomy were divided into two groups; low pressure (LP, 10-12 mmHg) and high pressure (HP, 13-15 mmHg). The heart rate, peripheral oxygen saturation, systolic, diastolic, and mean arterial pressure, BIS, end-tidal carbon dioxide, and left and right regional cerebral oxygen saturation (rSO_2) were recorded during induction, at the beginning, and after 5, 10, 15, 30, 60, and 90th minutes of pneumoperitoneum, after the surgical and anaesthesia procedures.
Results: The findings did not demonstrate a significant difference between the haemodynamic parameters of the groups. However, there were differences (fifth [p=0.022], fifteenth minutes [p=0.035], at the end [p=0038] of pneumoperitoneum in right rSO_2, and similarly at the end [p=0.038] of pneumoperitoneum in left rSO_2 between mean variation of rSO_2 when compared to the baseline; cerebral oxygenation was better preserved in LP. While no patient had more than 20% rSO_2 reduction in LP, a total of three patients had cerebral desaturation in HP.
Conclusion: Although <15 mmHg pressure for pneumoperitoneum was usually well-tolerated by patients, it had been observed that cerebral oxygenation may be affected with this range. The pathophysiological effects of pneumoperitoneum and possible consequences of this situation should be considered while performing laparoscopy.

Key Words: *Cerebrovascular circulation, Haemodynamics, Laparoscopic cholecystectomy, Near- infrared spectroscopy, Pneumoperitoneum.*

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INTRODUCTION

Laparoscopic cholecystectomy is performed with pneumoperitoneum which is a result of iatrogenic insufflation of an inert gas (usually carbon dioxide) into the abdomen. The pathophysiological results of increased intra-abdominal pressure (IAP) and hypercapnia on cardiovascular, respiratory, renal, hepatic, endocrine and neurological systems had been the subject of many studies.

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It is emphasised that intraoperative cardiac and respiratory deteriorations occur during pneumoperitoneum (especially at the initial stage) in laparoscopic procedures.[1,2]

Although IAP below 15 mmHg for pneumoperitoneum are considered to be relatively 'safe', it is possible to encounter significant haemodynamic fluctuations and pathophysiological results even in laparoscopic procedures performed in this range.[2,3]

The near-infrared spectroscopy (NIRS) can measure oxygenation in the prefrontal cortex and detect increases in oxygen extraction caused by reduced oxygen delivery within a very short reaction time.[4] It is known that intraoperative cerebral oxygenation monitoring with the NIRS can be used in patient groups (especially elderly, and children) for the assessment and follow-up of postoperative neurological outcomes.[5-7]

The aim of this study was to investigate the effects of carbon dioxide pneumoperitoneum on haemodynamics and cerebral oxygenation in laparoscopic cholecystectomy at IAP ranges classified as low (10-12 mmHg) and high (13-15 mmHg) using NIRS technique. Other objectives were investigating the correlations between haemodynamic variables and NIRS values, and analysing the differences in haemodynamic variables between groups.

METHODOLOGY

This prospective, randomised trial was conducted at the University Hospital after obtaining the approval from the ethics committee (Karadeniz Technical University Scientific Research Ethics Committee, 2020/11). Written informed consent was obtained from all the patients according to the Declaration of Helsinki and Patient Rights Regulation between January and September 2020. In addition, the study was registered at the publicly accessible trial registry of the United States National Library (www.clinicaltrials.gov, identifier NCT: 04309318).

Patients with ASA I-III, 18-65 years of age and undergoing general anaesthesia for elective laparoscopic cholecystectomy were eligible. The exclusion criteria included cerebrovascular pathology, uncontrolled diabetes, hypertension, anaemia, coagulopathy, cirrhosis, peritonitis, asthma, chronic obstructive pulmonary disease, and related respiratory diseases, morbidly obese (BMI >35 kg/m^2) patients and emergency operations.

The preoperative fasting period of the cases was planned to be eight hours. Premedications, 0.1 mg/kg midazolam and 0.01 mg/kg atropine sulfate, were administered intramuscularly. Peripheral venous access was established with a 20 Gauge cannula, and then 0.9% saline (4 mg/kg/h) infusion was initiated to the patients who were taken to the operating room.

The patients included in the study were taken to the operating table and electrocardiography, heart rate, non-invasive arterial pressure (NIBP), peripheral oxygen saturation (SpO_2), end-tidal CO_2 ($EtCO_2$) bispectral index (BIS), and NIRS (Cerebral/Somatic Oximeter) monitoring was applied.

Basal measurements of the patients (in a relaxed, calm position, and without oxygen support) were recorded in the patient follow-up form and, afterwards, preoxygenation was administered with 100% oxygen for three minutes. Anaesthesia induction was performed with 1 µg/kg fentanyl, 1 mg/kg lidocaine, 2-3 mg/kg propofol, and 0.6 mg/kg rocuronium. Endotracheal intubation was accomplished after sufficient time had passed for the muscle relaxation, and the BIS value was monitored in the range of 40-60. Following endotracheal intubation, tidal volume was adjusted between 6-8 ml/kg (based on the ideal weight) and respiratory rate between 10-12/min, to keep the $EtCO_2$ within the limits of 32-40 mmHg. In the maintenance of anaesthesia, sevoflurane at 2% was used in a mixture of 50% air-50% oxygen, and an additional 0.1 mg/kgrocuronium was administered for the maintenance of muscle relaxation if required. Remifentanil infusion (0.5-2 µg/kg/min) was administered as an analgaesic during the operation. The required depth of anaesthesia was adjusted so that the BIS value was between 40-60, and additional hypnotic and analgaesic drugs were added when needed. In case of rSO_2 decreased by more than 20%, after necessary checks, 100% oxygen was administered and the cerebral oxygenation were brought into the safe range.

The patients were divided into two groups by computer-assisted randomisation method: Group Low Pressure received LP (n=35) and Group High Pressure received HP pneumoperitoneum (n=35). The patients and anaesthesiologists were blinded to the group assignments. The CONSORT flow diagram is shown in Figure 1. The surgical team was informed before the operation according to the randomisation, and appropriate pneumoperitoneum was applied by the same team.

The pneumoperitoneum was initiated at an insufflation rate of 40 lt/min. Patients were placed in the reverse Trendelenburg position (20-30°, without side) on the operating table. Heart rate, SPO_2, NIBP, BIS, $EtCO_2$, and rSO_2 (right and left frontal region) were measured of all patients before induction (baseline), after induction, at the beginning of pneumoperitoneum, 5,10, 15, 30, 60, 90 minutes after pneumoperitoneum, at termination of pneumoperitoneum, end of surgical procedure and end of anaesthesia procedure (before the patient was sent to the recovery unit).

Power analysis was performed for two groups in the sample size of the study based on the primary objective. Accordingly, in the t-test study of independent samples, when the significance level of the differences was 6 and the type 1 error was 0.05, the sample size was calculated as 28 (twenty-eight) for each group with 80% power. Sampling was computed with OpenEpi (Open Source Epidemiologic Statistics for Public Health, Version 3).

Data were analysed with SPSS (Statistical Package for the Social Sciences, Version 23, IBM, United States of America). The conformity to the normal distribution was evaluated using the Shapiro-Wilk test. Chi-square test was used to compare the categorical variables according to the groups. Independent samples t-test was used to compare the normally distributed data according to the groups and the Mann-Whitney U test was used to compare the non-normally distributed data. Repeated measures analysis of variance was used to compare the normally distributed data according to time within the groups, and the Friedman test was used to compare the data that was not normally distributed. Spearman's rho correlation coefficient was used to examine the relationship between normally distributed quantitative data. The analysis results were presented as mean±standard deviation and median (minimum – maximum) for the quantitative data and as frequency (percent) for the categorical data. While the mean value was based on the independent two-sample t-test and repeated analysis of variance, the median values were based on the Mann-Whitney U and Friedman tests. The level of significance was considered as <0.05.

RESULTS

There were seventy patients, in two equal groups, included in the study. Two patients from the low pressure group and six patients from the high pressure group were excluded from the study after switching to laparotomy for surgical reasons.

Table I: Patient characteristics and procedural variables of groups.

	Low Pressure (n = 31)	High Pressure (n = 29)	p-value
Age (years) **	49.45 ±12.58	47.32±12.83	0.514
Gender* (Female/Male)	22/9	19/10	0.650
Height (m)***	1.67 ± 0.10	1.68 ± 0.06	0.653
Weight (kg)***	78.23 ± 13.20	79.86 ± 6.60	0.543
Body Mass Index (kg/m^2)***	27.8± 3.55	28.3± 2.61	0.634
ASA score (n) 1/2/3	3/24/4	3/26/0	0.134*
Anaesthesia time (min)**	78.90 ± 21.64	73.14 ± 16.33	0.386
Surgery time (min)**	58.03 ± 19.37	55.24 ± 17.09	0.739
Insufflation time (min)**	46.87 ± 17.81	42.66 ± 16.36	0.378

Chi-square test, **Mann Whitney U test, * Student t-test (mean ±SD).*

Table II. Cerebral oxygen saturation variation at different measurement times according to the baseline.

Measurement period	Low Pressure		High Pressure		Test Statistic	p-value
	Avg. ± SD	Avg. (min - max)	Avg. ± SD	Avg. (min - max)		
Right rSO_2 (Induction)	-3.4 ± 5.9	-4.0 (-17.0 – 13.0)	-5.0 ± 7.3	-6.0 (-18.0 – 12.0)	t=0.927	0.358
Right rSO_2 (Pneu.)	-4.0 ± 7.0	-1.0 (-19.0 – 5.0)	-2.0 ± 7.0	-3.0 (-14.0 – 15.0)	t=-1.127	0.264
Right rSO_2 (Pneu. 5min)	-3.3 ± 6.5	-3.0 (-17.0 – 8.0)	2.0 ± 10.0	2.0 (-1.0 – 33.0)	t=-2.455	0.017
Right rSO_2 (Pneu. 10min)	-4.6 ± 7.8	-3.0 (-22.0 – 7.0)	0.0 ± 9.7	-1.0 (-17.0 – 19.0)	t=-2.004	0.050
Right rSO_2 (Pneu. 15min)	-5.3 ± 7.9	-3.0 (-25.0 – 5.0)	0.0 ± 9.5	0.0 (-16.0 – 19.0)	t=-2.351	0.022
Right rSO_2 (Pneu. 30min)	-4.6 ± 5.9	-4.0 (-18.0 – 3.0)	-1.4 ± 9.3	-4,0 (-16,0 - 23,0)	t=-1.835	0.162
Right rSO_2 (Pneu. 60min)	-3.3 ± 3.0	-5.0 (-6.0 – 2.0)	4.8 ± 11.3	2.0 (-6.0 – 24.0)	t=-1.835	0.096
Right rSO_2 (Pneu. end)	-7.1 ± 7.7	-6.0 (-25.0 – 4.0)	-2.4 ± 9.1	-2.0 (-23.0 – 20.0)	t=-2.157	0.035
Right rSO_2 (Surgery end)	-7.7 ± 7.9	-6.0 (-27.0 – 4.0)	-3.5 ± 10.7	-5.0 (-18.0 – 25.0)	t=-1.754	0.085
Right rSO_2 (Anaes.end)	-10.7± 6.8	-11.0 (-31.0 – 1.0)	-7.6 ± 9.3	-7.0 (-22.0 – 13.0)	t=-1.51	0.136
Left rSO_2 (Induction)	-3.4 ± 5.2	-3.0 (-13.0 – 6.0)	-5.8 ± 7.5	-5.0 (-24.0 – 8.0)	t=-1.413	0.156
Left rSO_2 (Pneu.)	-3.9 ± 6.9	-3.0 (-22.0 – 7.0)	-0.8 ± 10.0	-2.0 (-18.0 – 28.0)	t=-1.413	0.163
Left rSO_2 (Pneu. 5min)	-3.0 ± 8.6	-2.0 (-24.0 – 15.0)	1.0 ± 10.0	0.0 (-19.0 – 20.0)	t=-1.673	0.100
Left rSO_2 (Pneu. 10min)	-3,1 ± 8,5	-2.0 (-25.0 – 17.0)	-0.6 ± 9.8	1,0 (-21,0 – 14,0)	t=-1.061	0.293
Left rSO_2 (Pneu. 15min)	-4.9 ± 8.0	-4.0 (-25.0 – 8.0)	-1.0 ± 10.0	-1.0 (-22.0 – 15.0)	t=-1,698	0.095
Left rSO_2 (Pneu. 30min)	-5.2 ± 7.1	-4.0 (-24.0 – 4.0)	-1,7 ± 10,5	1.0 (-23.0 – 17.0)	t=-2.757	0.174
Left rSO_2 (Pneu. 60min)	-6.6 ± 4.4	-5.0 (-13.0 - -2.0)	4.6 ± 9.6	2.0 (-5.0 – 17.0)	t=-2.119	0.057
Left rSO_2 (Pneu. end)	-7.0 ± 7.1	-5.0 (-24.0 – 4.0)	-2.6 ± 9.1	-4.0 (-20.0 – 18.0)	t=-2.119	0.038
Left rSO_2 (Surgery end)	-6.5 ± 7.1	-6.0 (-24.0 – 6.0)	-3.9 ± 9.7	-4.0 (-22.0 – 21.0)	t=-1.182	0.242
Left rSO_2 (Anaes. end)	-10.4± 7.7	-10.0 (-24.0 – 6.0)	-8.2 ± 10.1	-8.0 (-26.0 – 16.0)	t=-0.946	0.348

t: Two sample independent t-test; Pneu: Pneumoperitoneum; Anaes: Anaesthesia.

Table III. Correlations between rSO_2 and haemodynamic parameters in the high pressure group.

Haemodynamic Parameter		Right rSO_2				Left rSO_2			
		P	5min	10min	15min	P	5min	10min	15min
Heart rate	r	-0.323	-0.234	-0.044	-0.112	-0.524	-0.307	0.061	-0.106
	p	0.088	0.221	0.822	0.563	0.003	0.105	0.755	0.585
Systolic arterial pressure	r	-0.108	-0.031	0.252	0.301	-0.047	-0.009	0.151	-0.066
	p	0.577	0.873	0.187	0.113	0.811	0.963	0.434	0.734
Diastolic arterial pressure	r	-0.011	0.147	0.340	0.224	0.005	0.103	0.365	0.045
	p	0.957	0.448	0.071	0.242	0.981	0.594	0.051	0.817
Mean arterial pressure	r	-0.110	0.110	0.314	0.245	-0.056	0.110	0.288	-0.025
	p	0.570	0.569	0.098	0.201	0.775	0.570	0.130	0.896
Peripheral saturation	r	-0.139	-0.299	-0.183	-0.209	-0.192	-0.358	-0.318	-0.242
	p	0.471	0.115	0.343	0.276	0.319	0.057	0.092	0.205
$EtCO_2$	r	-0.201	-0.354	-0.312	-0.157	-0.280	-0.532	-0.521	-0.502
	p	0.296	0.060	0.100	0.416	0.141	0.003	0.004	0.005
BIS	r	0.129	0.045	-0.206	-0.047	0.188	-0.074	-0.203	0.184
	p	0.506	0.818	0.284	0.809	0.328	0.701	0.290	0.341

r: Spearman's rank correlation coefficient (P: onset of pneumoperitoneum).

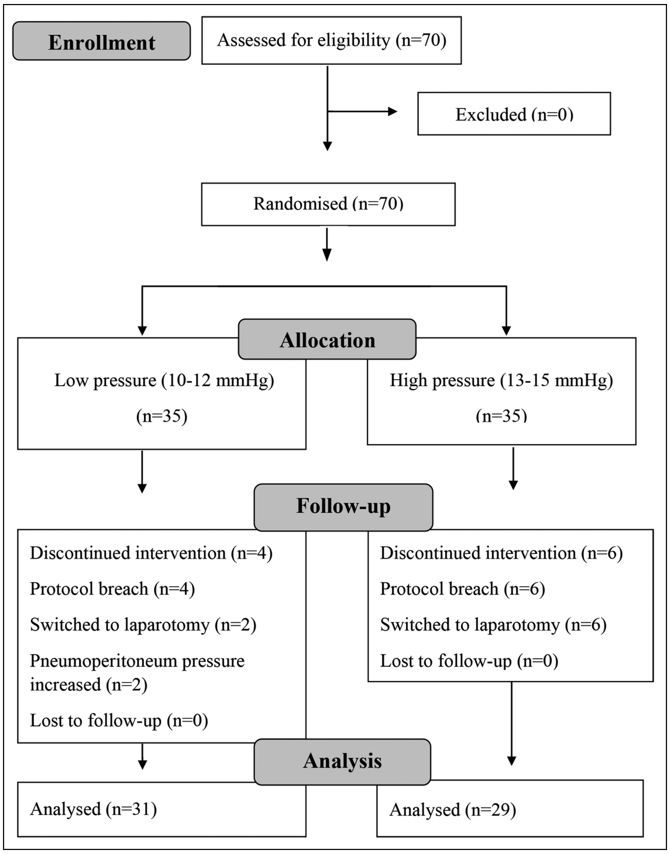

Figure 1: CONSORT diagram of patient recruitment.

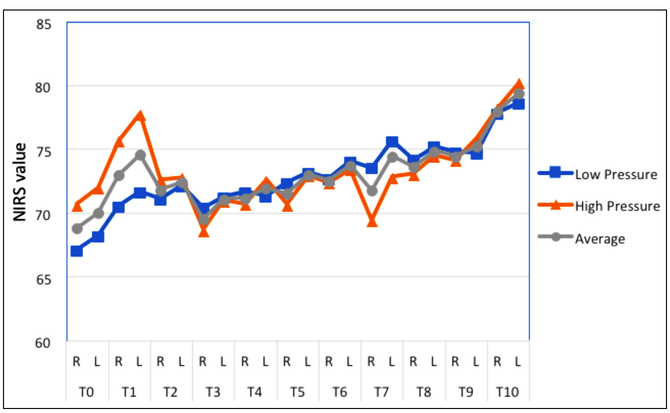

Figure 2: Distribution of the NIRS scores during the operation in the two groups.
T0: Baseline, T1: Induction, T2: Onset of pneu., T3: 5th min, T4: 10th min, T5: 15th min, T6: 30th min, T7: 60th min, T8: end of pneu., T9: End of surgery, T10: End of anaesthesia, pneu: Pneumoperitoneum.

Due to the requirement for pressure increase during surgery, two patients from the low pressure group were excluded. As a result, total of sixty patients data were analysed (Figure 1).

There were no statistical difference between the low-pressure and high-pressure groups in terms of age, gender, height, body weight, mean body mass index, ASA classification, and procedural variables (total anaesthesia time, total surgery time, and pneumoperitoneum insufflation time) (Table I).

When the mean variations of the right rSO_2 and left rSO_2 at different times according to the groups (Figure 2) were compared with the baseline (Table II), a statistically significant difference was found between the right rSO_2 values at the fifth minute after pneumoperitoneum as compared to the baseline ($p=0.017$). The mean of the low pressure group was -3.3 (3.3 units increase as compared to the baseline), while the mean for the high pressure group was 2.0 (2 units decrease as compared to the baseline).

There was a statistically significant difference between the mean variations of the right rSO_2 values at the 15th minute after pneumoperitoneum according to the groups compared to the baseline ($p=0.022$). While the mean of the low pressure group was -5.3, it did not change in the high pressure group.

Regarding the assessment of the mean variables of the left rSO_2 values, consistent with other results, there was a difference between end of the pneumoperitoneum and the baseline ($p=0.038$). The mean of the low pressure group was -7.0, while the mean of the high pressure group was -2.6, correspondingly.

In the high pressure group, there was a moderate negative correlation between variation of $EtCO_2$ and variation of left rSO_2 at the 5th ($p=0.003$), 10th ($p=0.004$), and 15th ($p=0.005$) minutes of pneumoperitoneum (Table III). Furthermore, there was a moderate negative correlation between variation of heart rate and variation of left rSO_2 at the beginning of pneumoperitoneum ($p=0.003$). Besides, no correlation was measured between other haemodynamic variables in this group.

DISCUSSION

Considering the main findings of the study, when the mean of rSO_2 variations obtained at all measurement times was compared to the baseline (Table II), there were significant differences in right rSO_2 at the fifth, fifteenth minutes and at the end of the pneumoperitoneum. No significant haemodynamic depression was observed in either group. Hence, it was concluded that cerebral oxygenation was better preserved in the LP than in the HP.

Since the early 1970s, when the laparoscopy technique was in the mainstream, many animal and human studies based on the outcome of laparoscopy had been published. Although higher IAP (>20 mmHg) was used previously, pneumoperitoneum had been performed using usually lower IAP (<15 mmHg) in modern anaesthesia and surgical techniques since the 1990s. It was observed that the knowledge of the literature also developed in this direction.[1]

Umar *et al.,* in their study, classified the pneumoperitoneum pressures of 8–10 mm Hg, 11–13 mm Hg, 14 mm Hg in ASA I-II, aged 18-60 years patients who underwent elective laparoscopic cholecystectomy, and compared the intraoperative haemodynamic variations observed during the operation in these three groups.[8] They showed that there were significant differences among the groups in terms of heart rate, blood pressure, and $EtCO_2$. However, in the present study, no significant difference was found between the groups accord-ing to the haemodynamic variations.

Inal *et al*. classified the pneumoperitoneum pressure of 10 mm Hg and 14 mm Hg in one hundred of ASA I-III patients who underwent laparascopic cholecystectomy. As a conclusion, there were no haemodynamic variables between the two groups.[9] Nevertheless, the rSO_2 value changed over time with a statistically significant group difference. Overall, a high-pressure pneumoperitoneum was associated with a greater decrease in rSO_2 as compared to a low-pressure, in their results. Considering the absence of difference in haemodynamic variables between the two groups and the cerebral saturation decrease in the high pressure group, it was observed that the aforementioned study reported similar results as the current study. Therefore, they suggested use of a low--pressure pneumoperitoneum in patients with central nervous system pathologies.

Zuckerman *et al*. observed significant haemodynamic (cardiac index and stroke volume) depression, especially in the first ten minutes of pneumoperitoneum, in thirty-eight patients who underwent elective laparoscopic cholecystectomy with 15 mmHg IAP.[10] Again in this study, it was emphasised that the haemodynamic depression was compensated substantially after the tenth to fifteenth minutes of the pneumoperitoneum. As mentioned earlier, in the high pressure group in the current study, although haemodynamic depression was not observed, there was a significant deterioration in cerebral saturation in the first 15 minutes following the initiation of pneumoperitoneum.

There were also studies in the literature that concluded that low pneumoperitoneum pressures do not have advantage on haemodynamic variables and cerebral oxygenation.[11-13] Kaya *et al.* evaluated cerebral oxygen levels in sixty-two patients (aged 18-65 years; ASA I-III), who were equally divided into a low-pressure (8 mmHg) and standard-pressure (14 mmHg) groups, and scheduled for laparoscopic nephrectomy.[11] Both groups had similar rSO_2, arterial blood gas, haemoglobin values at all measurement times, and equal number (four) of cerebral desaturation events. As a result, they deduced that low insufflation pressure offered no advantages over standard pressure in terms of haemodynamics, arterial blood gases, cerebral oxygen saturation during the laparoscopic nephrectomy. In contrast to the present study, Kaya *et al*. observed significant advantages (Table II, Figure 2) in the preservation of cerebral oxygenation in the low pressure group, especially at the onset of pneumoperitoneum.

Decreased cerebral oxygenation may cause neurocognitive disorders and/or cerebrovascular events that may occur even at an early stage after anaesthesia.[2] Some patient populations were susceptible to these adverse changes in cerebral oxygenation, particularly the elderly, obese, and patients with impaired cardiovascular function.[5,14,15]

Gipson *et al*. evaluated the cerebral oxygenation of seventy patients in the ASA II and III groups who underwent elective laparoscopic surgery under 8-12 mmHg IAP, using the NIRS at 5-minute intervals.[16] After the pneumoperitoneum was initiated in the 12 patients included in the aforementioned study, it was shown that there was a 20% decrease in rSO_2 as compared to the baseline, and a 25% decrease in rSO_2 values when compared to the baseline in 6 patients. Correspondingly, Ruzman *et al.* reported a significant (20% or more from the baseline) decrease in rSO_2 during peritoneal insufflation in one-fifth of 65 patients in ASA I and II risk groups who underwent laparoscopic cholecystectomy with <15 mmHg pneumoperitoneum.[6]

According to this study's findings, there was no patient in the LP who had a decrease of more than 20% as compared to the baseline during the operation period when the right rSO_2 were compared with the baseline. Notwithstanding, a decrease of more than 20% in rSO_2 was observed in three patients in the HP.

Correlation analysis related to possible haemodynamic variations that may cause a decrease in rSO_2, especially in the HP, were applied by the current results. Strong negative correlations were detected between rSO_2 and $EtCO_2$ in the onset of pneumoperitoneum and in the first fifteen minutes in both groups (Table III). This result was interpreted as a serious relationship between hypercapnia and impaired cerebral oxygenation.

There were some limitations in this study. First, echocardiography measurements, which can evaluate the cardiovascular system in more detail and technically, could not be performed in the examination of haemodynamic changes.[17] Secondly, while the effects of carbon dioxide peritoneum were evaluated with $EtCO_2$ in the examination of haemodynamic changes, it may be necessary to use $PaCO_2$ analysis in blood gas for further interpretation. Third, the possible effects of changes in cerebral oxygenation on cognitive functions in the pre- and postoperative period of the patients could not be evaluated with a scale such as the Mini Mental State Examination test.[5] Finally, direct or indirect intracranial pressure measurement could not be performed to evaluate the correlation between increased IAP and increased intracranial pressure due to technical and ethical difficulties.

CONCLUSION

Cerebral oxygenation was significantly preserved in patients operated under IAP of 10-12 mmHg, compared to 13-15 mmHg. These results are important, especially in laparoscopic surgeries performed in patients with comorbid diseases and impaired compensation mechanisms, as they may set a precedent for future studies to review surgical and anaesthesia management.

ETHICAL APPROVAL:
The study was approved by the University Scientific Research Ethics Committee, submission number: 2020/11, dated 24.01. 2020.

PATIENTS' CONSENT:
Written informed consent was obtained from all the patients according to the Declaration of Helsinki and the Patient Rights Regulation.

COMPETING INTEREST:
The authors declared that there is no actual or potential conflict of interest related to this paper.

AUTHORS' CONTRIBUTION:
KO, SS: Substantial contributions to the conception, and design of the work, acquisition, analysis interpretation of data, drafting the work or revising it critically, and final approval of the version to be published.

Both authors agreed to be accountable for all aspects of the work ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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