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Original Research

Can Positive-Pressure Ventilation be Administered with Laryngeal Mask to Pediatric Patients Undergoing Laparoscopic Inguinal Hernia Operation?

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Abstract

Objectives: We aimed to investigate the effects of intubation and laryngeal mask airway (LMA) use by evaluating the results of blood gas tests, end-tidal CO_2 measurements, and airway changes during laparoscopic inguinal hernia repair in children.

Methods: This study was designed to be a prospective randomized study enrolling 150 ASA-I patients, aged 1–8 years; who were scheduled for laparoscopic inguinal hernia repair. Group 1 (n=75) received general anesthesia with fentanyl, propofol, and rocuronium and they were orotracheally intubated. Group 2 (n=75) received general anesthesia with fentanyl and propofol and were inserted an LMA. Demographical data were recorded. Arterial blood gas test results at baseline, in the 10th min after the insufflation, and in the 10th min after the end of the insufflation were noted. The end-tidal CO_2, HR, SPO_2, inspiratory pressure, plateau pressure, tidal volume (TV), and respiratory frequencies were recorded. The duration of anesthesia, operation, and insufflations was noted. Emergent complications were recorded.

Results: The duration of both anesthesia and recovery was longer in Group 1 compared to Group 2. Hemodynamical parameters, end-tidal CO_2 values, TVs, airway pressures, and respiratory frequencies were not statistically significantly different between the groups. There were no statistically meaningful differences in the levels of pH, PCO_2, and PO_2 between the groups.

Conclusion: Compared to orotracheal intubation during laparoscopic inguinal surgery; LMA did not cause any statistically significant differences in the blood gas test results or airway pressures and recovery was faster with LMA. Therefore, LMA can be used in pediatric laparoscopic surgery as a safe tool for maintaining the airway.

Keywords: Laparoscopic surgery, Laryngeal mask airway, Pediatric patient

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Laryngeal mask airway (LMA) is used in several anesthetic practices today. The advantages of LMA include reduced anesthetic drug consumption and associated faster recovery, and reduced frequency of postoperative nausea and vomiting. However, there are some concerns about LMA use; including the risks of inappropriate ventilation, increased intragastric pressure, hypercarbia secondary to CO_2 insufflation, and hemodynamic changes secondary to increased intra-abdominal pressure (IAP).[1,2]

The number of studies investigating the safety of LMA

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ProSeal™ during pediatric laparoscopic surgery is limited. These studies compared LMA use and intubation by evaluating ventilation and gastric pressure values during laparoscopic surgery in pediatric patients, reporting similar results with either method.[3-6] However, there are no studies in the literature comparing LMA use with intubation by evaluating the results from arterial blood gas (ABG) tests and end-tidal CO_2 exchange in pediatric laparoscopic inguinal hernia operations.

The aim of the present study was to compare the effects of intubation and laryngeal mask use on ABG test results and end-tidal CO_2 and airway pressure changes in children undergoing a laparoscopic inguinal hernia operation.

Methods

This study was carried out in the Pediatric Surgery Department in the period from May 2015 to July 2015. Institutional medical Ethic Committee approval was received for the conduct of this study (17.03.2015/462). The study has been registered on http:clinicaltrials.gov (NCT03352375). The study was conducted in compliance with the Declaration of Helsinki. After obtaining the Ethics Committee approval, 150 pediatric patients in the age range from 1 to 8 years with the ASA physical Status-I; who were scheduled for undergoing an elective laparoscopic inguinal hernia operation were enrolled in the study. Our study had a prospective and randomized design.

Oral and written consent was obtained from the parents of the participants. The patients; who did not volunteer to participate in the study; who had airway anomalies, gastroesophageal regurgitation risk, reactive airways, hiatal hernia, peripheral vascular diseases, and neuropsychiatric diseases; mentally retarded patients or patients; and who had a history of pulmonary infection within the last 6 weeks were excluded from the study.

Demographic data including age, weight, and gender were recorded in all groups. All patients were premedicated with oral midazolam 0.5 mg/kg. The patients were randomly assigned to two groups in the premedication unit by the anesthesia technician; who was unblinded to the study. The study groups were as follows:

- Group 1 (n=75): Orotracheal intubation group.
- Group 2 (n=75): ProSeal LMA group.

After the transfer of the patient to the operation room, all patients were monitored with electrocardiogram in lead D2 and with non-invasive measurements of blood pressure, and SpO_2 values. Hydration of the patient was maintained with isotonic saline through the established intravenous line. The patients in Group 1 underwent orotracheal intubation with a cuffed intubation tube in an appropriate size to the age and weight of the patient after the anesthesia induction with 1 µg/kg fentanyl, 3 mg/kg propofol, and 0.6 mg/kg rocuronium administered intravenously. Rocuronium administration was not repeated in Group 1 after anesthesia induction. A ProSeal LMA in the appropriate size to the age and weight of the patient was inserted in the patients in Group 2 after the anesthesia induction with the intravenous administration of 1 µg/kg fentanyl and 3 mg/kg propofol. The cuff of the endotracheal tube was inflated to a maximum pressure of 60 cmH_2O.[7] Gastric aspiration was performed in all patients before the procedure. Anesthesia was maintained with 1–2% sevoflurane and 50% oxygen – 50% air mixture. All patients were monitored for the end-tidal CO_2.

Following induction, all patients were ventilated in the P-controlled mode. The inspiratory pressure (Pinsp) and frequency appropriate for the age of the patient were set to a tidal volume (TV) of 6–8 mL/kg. All patients received positive end-expiratory pressure of 4 cm H_2O.[8,9] The end-tidal CO_2 value was aimed to be maintained in the range from 35 to 45 mmHg. The heart rate (HR), SpO_2, end-tidal CO_2, Pinsp, plateau pressure (Pplat), respiratory frequency (f), and TV values were recorded as the baseline values. Following the Allen test, the radial artery was cannulated and blood samples were collected to determine the baseline ABG test results. Then, the surgery team took the patient over. Another sample for the ABG test was taken 10 min after the intraperitoneal CO_2 insufflation. The HR, SpO_2, end-tidal CO_2, Pinsp, Pplat, f, and TV values were recorded again in the 10th min. The IAP during the operation was aimed to be maintained in the range from 8 and 12 mmHg. Pinsp was increased when there was a decrease in TV during the operation. When there was a rise in the end-tidal CO_2 value and TV was reduced, Pinsp was increased. When the TV was adequate and the end-tidal CO_2 value increased, the frequency was increased. The third sample for the ABG tests was taken 10 min after intra-abdominal CO_2 sufflation. The HR, SpO_2, end-tidal CO_2, Pinsp, Pplat, f, and TV values were recorded. The levels of pH, pCO_2, pO_2, HCO_3, base excess (BE), and SO_2 were noted according to the results obtained from the analysis of the third ABG sample.

For analgesia, 15 mg/kg paracetamol was administered intravenously to all patients in the operation room. At the end of the operation, the effect of the neuromuscular blockers was antagonized with 2 mg/kg sugammadex in Group 1. The patients with adequate spontaneous ventilation and return of airway reflexes were extubated. In Group 2, the LMAs were removed in patients achieving adequate spontaneous ventilation and return of airway reflexes. A modified aldrete score of 9 and over was accepted to indicate

recovery and patients achieving recovery were discharged from the operation room.

The duration of anesthesia (the time from the induction to the recovery of the patients), the duration of operation (the time from the skin incision to the last suture), the insufflation duration (the time from the onset to the end of intra-abdominal CO_2 insufflation), and the duration of recovery were recorded. The recovery duration was described as the time to achieve a modified aldrete score of 9 and over. The emerging complications associated with the administration of anesthesia (cough, stridor, laryngospasm, aspiration, nausea, vomiting, regurgitation, and airway trauma) and surgery (subcutaneous emphysema and pneumothorax) were noted.

Sample Size

The sample size was estimated at the alpha significance level of 0.05 with 90–95% power by predicting that the moderate effect size among groups (effect size = 0.5) would be considered as a difference. The study was planned to include 150 patients for a 92% power. The statistical analyses were performed with IBM SPSS Statistics 22 (SPSS IBM, Turkey). The conformity of the data to the normal distribution was evaluated with the Shapiro–Wilks test. The study data were summarized with descriptive statistics (mean, standard deviation, and frequency). For the analyses of the quantitative data, the Student's t-test was used for comparing two-groups with normally distributed data and the Mann–Whitney U-test was used for comparing two-groups having non-normally distributed data. For the intra-group comparisons of normally distributed parameters, variance analysis was used in repetitive measurements and the paired sample t-test was used in binary comparisons. For the evaluation of the non-normally distributed parameters, the Friedman test was used for the intra-group comparisons and the Wilcoxon signed-rank test was used for the binary comparisons. The significance was evaluated at $P<0.05$ level.

Results

This study was planned to enroll 150 pediatric patients in the age range from 1 to 8 years. However, the data from two patients in Group 2 were excluded because adequate blood samples for blood gas analyses could not be obtained. The data of 148 patients were included in the study statistics.

There were no significant differences in age, gender, and body weight distributions between the groups (Table 1). No statistically significant differences were found in the operation duration and insufflation duration between the groups. The mean duration of anesthesia for Group 1 was statistically significantly higher compared to Group 2 (p=0.014). The mean recovery time was significantly longer in Group 1 compared to Group 2 (p=0.001) (Table 2).

Table 1. Demographic data

	Group 1 (n=75) Mean±SD	Group 2 (n=73) Mean±SD	p
Age (Years)	4.97±3.18	5.03± 2.87	0.914
Weight (KG)	19.57±9.32	19.03±6.96	0.688
Male/Female ratio	32/43	35/38	0.678

Student's t-test; SD: Standard Deviation.

There were no statistically significant differences in the mean values of HR, baseline end-tidal CO_2, and SPO_2 when the values obtained at baseline, insufflation, and insufflation-end were compared between the groups (Table 3). Again, no statistically significant differences were found in the mean Pinsp, P, f, and TV values when the baseline, insufflation, and insufflation-end values were compared between the groups (Tables 4, 5). Similarly, no statistically significant differences were found between the groups

Table 2. Procedure time

	Group 1 (n=75) Mean±SD	Group 2 (n=73) Mean±SD	p
[1]Anesthesia duration (min)	44.07±9.51	40.55±7.56	0.014*
[1]Operation duration (min)	26.32±9	26.67±7.72	0.799
[2]İnsufflation duration (min)	18.44±8.77	18.71±7.21	0.426
[2]Recovery duration (min)	7.99±1.78	4.21±1.92	0.001**

[1]Student's t-test; [2]Mann–Whitney U-test; *P<0.05; **P<0.01; SD: Standard Deviation; Min: Minute.

Table 3. Hemodynamic changes

	Group 1 (n=75)	Group 2 (n=73)	P
Heart rate			
Beginning	120.88±15.48	121.83±16.18	10.716
Insufflation	110.52±12.23	109.99±15.48	10.817
End	104.47±12.3	107.65±15.79	10.174
End-Tidal CO^2			
Beginning	33.84±4.44	33.92±3.73	10.900
Insufflation	37.95±3.99	37.89±4.52	10.941
End	34.6±3.42	34.45±3.17	10.783
SPO^2			
Beginning	99.75±0.57	99.61±0.59	20.061
Insufflation	99.47±0.75	99.48±0.66	20.861
End	99.51±0.96	99.53±0.55	20.310

[1]Student's t-test; [2]Mann–Whitney U-test; SD: Standard Deviation.

Table 4. Changes in the ventilation pressure parameters

	Group 1 (n=75)	Group 2 (n=73)	p
P inspiratory			
Beginning	15.12±2.58	15.27±2.1	10.711
Insufflation	18.08±2.8	17.95±2.49	10.756
End	17±2.61	16.97±2.6	10.951
P plat			
Beginning	7.01±1.07 (7)	7.12±0.73 (7)	20.395
Insufflation	8.12±1.09 (8)	8±0.84 (8)	20.452
End	7.77±1.03 (8)	7.73±0.83 (8)	20.736

[1]Student's t-test, [2]Mann–Whitney U-test; SD: Standard Deviation; Pinsp: Inspiratory pressure; Pplat: Plateau pressure.

Table 5. Changes in the ventilation frequency and tidal volume parameters

	Group 1 (n=75)	Group 2 (n=73)	P1
f			
Beginning	19.52±2.39	19.4±2.72	0.,417
Insufflation	20.82±2.47 (20)	20.83±3.1 (20)	0.664
End	20.1±2.5 (20)	20.04±2.95 (20)	0.593
TV			
Beginning	188.86±69.59	189.01±84.69	0.314
Insufflation	172.51±63.04	172.61±71.79	0.698
End	186.64±70.99	186.68±81.72	0.464

[1]Mann–Whitney U-test; SD: Standard Deviation; f: Frequency; TV: Tidal volume.

in the mean pH, PCO_2, PO_2, HCO_3, and BE levels measured at the baseline, insufflations, and insufflation-end times (Table 6). The mean IAP was 11.64 mmHg in Group 1 and 11.54 mmHg in Group 2. No complications were observed in association with surgery or the anesthetic procedures administered.

Discussion

The lack of clear information about the risk/benefit ratio in pediatric laparoscopic surgery has been a concern for many years. However, the demonstration of the advantages of laparoscopic surgery; including the small size of incisions, small quantities of volume and heat loss, minimum tissue damage, reduced post-operative pain, improved visualization of difficult-to-access regions, post-operative early mobilization, and maintenance of oral intake in patients leads to increased interest in this type of procedures.[10-12]

The volume of gas required for generating pneumoperitoneum in laparoscopic surgery is considerably less in children compared to adults. In adults, there is a need for 2.5–5 l of gas while a volume of 0.9 l is needed for a child weighing 10 kg. The insufflation pressure is recommended to be limited in the range from 6 and 12 mmHg during pediatric laparoscopic surgery.[13] The insufflation pressure was maintained in the range from 8 and 12 mmHg in our study and the mean IAP level was measured to be 11.64 mmHg in the intubation group and 11.54 mmHg in the LMA group.

Table 6. Changes in arterial blood gas test results

	Group 1	Group 2	P1
Ph			
Beginning	7.4±0.06	7.4±0.06	0.765
Insufflation	7.36±0.05	7.36±0.06	0.813
End	7.39±0.05	7.39±0.05	0.973
PCO_2			
Beginning	34.79±5.85	34.63±5.96	0.873
Insufflation	37.84±5.72	37.45±7.64	0.728
End	35.76±6.31	35.74±5.9	0.985
PO_2			
Beginning	253.44±77.23	257.31±83.22	0.770
Insufflation	274.75±91.09	275.19±105.38	0.978
End	272.74±105.8	273.63±96.62	0.957
HCO_3			
Beginning	20.41±1.48	20.7±1.62	0.267
Insufflation	21.58±1.99	21.69±1.83	0.734
End	21.32±1.76	21.57±1.81	0.388
BE			
Beginning	−2.53±1.48	−2.56±1.3	0.906
Insufflation	−2.63±1.6	−2.65±1.62	0.963
End	−2.64±1.42	−2.65±1.59	0.960

[1]Student's t-test; SD: Standard Deviation.

Adverse respiratory and cardiovascular changes secondary to intra-abdominal CO_2 insufflation, increased intra-abdominal pressure, and Trendelenburg position were reported during laparoscopic surgery of adolescents. Similar changes were shown rarely for children aging from 10 to 12 years. Knowing the cardiorespiratory changes created by the increased intra-abdominal pressure and CO_2 insufflation during laparoscopic surgery in children is crucial for anesthesia management.[14-16] Increased intra-abdominal pressure impairs diaphragm movements and reduces functional residual capacity, compliance, TV, and minute volume; whereas it increases airway resistance, alveolar arterial oxygen gradient, alveolar dead space, and hypoxia.[13,16-18]

A significant amount of CO_2 is absorbed during laparoscopy. Tobias et al.[16] examined the changes in the airway pressure and end-tidal CO_2 levels on 55 children during laparoscopic surgery sessions lasting <10 min. They detected an increase of more than 5 cm H_2O in the airway pressure in 11% of the patients and an increase of more

than 5 mmHg in the end-tidal CO_2 levels in 33% of the patients. Bergesio et al.[19] found a 26.6% increase in the peak airway pressure, 20.2% increase in resistance, and a 38.9% decrease in compliance under an insufflation pressure of 10–12 mmHg during laparoscopic surgery in children aged from 8 months to 11 years. In our study, no significant differences were found in the Pinsp, Pplat, f, and TV values at all times between the groups. Approximately an increase of 2 cm H_2O was observed in the Pinsp values of both groups after insufflation. However, minimal increases in the Pinsp, Pplat, and f values during insufflation returned to the baseline values at the end of insufflation. The TV values also showed a decline during insufflation. There were no differences between the end-tidal CO_2 measurements at all times between the groups. However, the end-tidal CO_2 levels were elevated after insufflation in both groups. This increase was at a level of 4 mmHg. Despite the increase, the end-tidal CO_2 values remained within normal limits.

In laparoscopic surgery, cardiac output is reduced secondary to the decrease in venous return and the increase in systemic vascular resistance.[14] Gueugniaud et al.[20] measured the continuous esophageal aortic blood flow with echo Doppler to monitor the hemodynamic changes during laparoscopic surgery in healthy infants. The intra-abdominal pressure was fixed at 10 mmHg. Significant reductions in the aortic blood flow, stroke volume, and a significant rise in the systemic vascular resistance were reported. However, the authors noted that the observed changes were reversed at the end of the insufflation.

Gentili et al.[21] evaluated hemodynamic responses with echocardiography in children during peritoneal insufflation. They observed an increase in the peak HR, mean arterial pressure, and left ventricular systolic and diastolic end volumes but the ejection fraction was preserved. We measured HR in the present study. There were no significant differences in HR measured at all times between the groups. However, contrary to expectations, there was a decrease in HR during insufflation in both groups. The reduced but not the elevated HR in our study can be explained by the maintenance of IAP at a fixed level and of the end-tidal CO_2 and pCO_2 levels within the normal limits. The reduced HR can be attributed to the effects of anesthetic agents.

LMA has been used frequently in recent years as a tool for anesthesia in adult and pediatric patients. LMA use has both advantages and disadvantages. Its major advantages include reduced consumption of anesthetic agents, rapid recovery from anesthesia, and associated low incidences of nausea and vomiting. The major factors causing anesthesiologists to avoid LMA use include the potential for inadequate ventilation and increased intragastric pressure.[1,2] In our study, the duration of the operation and insufflation was similar in both groups and the duration of anesthesia and recovery was shorter in the LMA group.

Using LMA during laparoscopic gynecologic surgery reduces the consumption of anesthetic agents, reducing the likelihood of postoperative nausea and vomiting.[22] The use of ProSeal LMA during laparoscopic surgery was also demonstrated to reduce the stress response to intubation.[23] Aydogmus et al.[24] investigated the changes in the SpO_2 and end-tidal CO_2 values and the frequency of nausea and vomiting in laparoscopic surgery with ProSeal LMA in adult patients. They reported that ProSeal LMA might be an alternative to intubation in laparoscopic surgery.

However, there is no strong evidence supporting the use of LMA during laparoscopic surgery in the pediatric patient group. Galante et al.[3] reported that the application of ProSeal LMA might be an alternative to intubation in laparoscopic surgery in children. Mironov et al.[4] compared classical LMA use with intubation in pediatric laparoscopic procedures with a mean duration of 51 min and reported that LMA could be used in short-term laparoscopic surgery in children without respiratory diseases. Sinha et al.[5] compared the ProSeal LMA use with intubation and found that maximum Pinsp and end-tidal CO_2 levels were similar in short-term laparoscopic surgery. During carboperitoneum, they found an increase in Pinsp by 9 cm H_2O and an increase in end-tidal CO_2 levels by 6–7 mmHg. The complications including cough, stridor, and laryngospasm occurred more commonly in the intubation group whereas blood on the airway device was observed more commonly in the laryngeal mask group. Ozdamar et al.[6] compared the effects of LMA and endotracheal intubation on the gastric pressure in children and demonstrated that a correctly inserted LMA did not increase gastric pressure.

The studies showing the changes in CO_2 levels with blood gas analyses and end-TV measurements in children undergoing laparoscopic surgery are retrospective in design and they were conducted with a limited sample size mostly in urologic interventions and fundoplication operations. No significant changes were observed in CO_2 levels in these studies.[2,25] Sanders and Gerstein[25] conducted a correlation analysis between the end-tidal CO_2 levels and pCO_2 levels found in ABG tests in pediatric laparoscopic fundoplication. They showed that the end-tidal CO_2 values, especially in young children, were not reliable for follow-up in laparoscopic surgery. Thus, we considered that it would be appropriate to evaluate the safety of LMA use in our study not only with the end-tidal CO_2 levels but also with the PCO_2 measurements in the ABG analysis.

In our study, no significant differences were found in the

levels of pH, pCO_2, pO_2, HCO_3, and BE between the study groups based on the results obtained from ABG tests. Reduced pH was observed in both groups after insufflation but it remained within normal limits. The pCO_2 levels were elevated approximately by 3 mmHg in both groups after insufflation and reversed to the baseline values at the end of insufflation. A significant correlation was observed between the pCO_2 and end-tidal CO_2 levels.

Two recent studies investigated the need for neuromuscular blocker use in short-term pediatric laparoscopic surgery by evaluating intubated patients receiving neuromuscular blockers and LMA patients receiving no neuromuscular blocking agents during laparoscopic inguinal hernia operations in children. They showed that there was no need for neuromuscular blockers or the use of these agents at subparalytic doses would be appropriate. Those studies highlight that the use of LMA is a safe alternative in children undergoing laparoscopic inguinal hernia operations.[27,28] In our study, we inserted LMA without administering neuromuscular blockers and did not need to induce any muscle relaxation during the surgical procedure. The shorter recovery time observed in the LMA group can be attributed to the fact that neuromuscular blocking agents were not administered to these patients.

Conclusion

Laryngeal mask insertion can safely be used in pediatric laparoscopic surgery as an alternative option in airway maintenance.

Disclosures

Ethics Committee Approval: This study was carried out in the Pediatric Surgery Department in the period from May 2015 to July 2015. Institutional medical Ethic Committee approval was received for the conduct of this study (17.03.2015/462). The study has been registered on http:clinicaltrials.gov (NCT03352375). The study was conducted in compliance with the Declaration of Helsinki.

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