

Original Article

Comparison of Oro-Pharyngeal airway cap and tracheal intubation on systemic stress responses and hemodynamic parameters in pediatric laparoscopic procedures

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Abstract: *Objective:* The adverse events caused by intubation may contribute to serious cardiovascular and systemic stress responses, especially in pediatric patients. Alternative airway maintenance techniques may attenuate these hemodynamic and systemic stress responses. This study aimed to compare the hemodynamic and systemic stress responses of the insertion of Oro-Pharyngeal airway cap (OPLAC) and Endotracheal Intubation (ETT) in pediatric laparoscopic surgery patients. *Methods:* Eighty-six pediatric laparoscopic surgery patients were randomly divided to receive either OPLAC (Group OPLAC) or ETT (Group ETT). Respiratory and hemodynamic parameters, inflammatory responses, oxidative stress, anesthesia recovery variables, and adverse events during emergence were compared. *Results:* Respiratory parameters including peak airway pressure (PAP) and end-tidal carbon dioxide pressure ($P_{ET}CO_2$) were similar intraoperative. Heart rate and mean arterial, plasma β -endorphin, cortisol, interleukin-6, TNF- α , malondialdehyde (MDA) levels, and blood glucose in Group OPLAC were significantly lower than those in Group ETT. Postoperative bucking, laryngospasm and serious hypoxemia were seen in Group ETT but not in Group OPLAC. *Conclusion:* Maintaining the airway using OPLAC is associated with less inflammatory or oxidation stress which can yield more stable hemodynamic profile compared to direct tracheal intubation.

Keywords: Endotracheal intubation, hemodynamics, inflammation, laryngeal mask airway, oxidation stress

Introduction

Systemic and hemodynamic changes induced by intubation and extubation from anesthesia may cause tachycardia and arrhythmias. These complications can be a threat for pediatric patients undergoing laparoscopic surgeries [1, 2]. Endotracheal intubation has been proven to be a reliable method for maintaining the airway and is considered to be the standard technique for airway management during pediatric laparoscopic surgery [3]. Recent studies, however, have reported endotracheal intubation increases the risk of hemodynamic and physical stresses compared to the use of a laryngeal mask airway (LMA). Additionally, LMA is shown to reduce the incidence of respiratory failure and adverse events during emergence from anesthesia and extubation [4]. Systemic stress is mainly manifested as metabolic and hormonal reactions to injury, and closely linked with

endocrinological, immunologic, and hematological effects [5]. Serious physical stress during surgery leads to poor outcomes. Blood glucose, the plasma β -endorphin (β -EP) and cortisol (Cor) levels triggered by inflammation or immune activation are indicators of stress responses during anesthesia and surgery [6, 7]. Inflammation-mediated cytokines release, namely, interleukin-6 (IL-6), and tumor necrosis factor-alpha (TNF- α) negatively influence patients' outcomes, especially for pediatric patients [7]. Accumulating studies have demonstrated that anesthesia and surgery-related physical stress lead to increased ATP consuming, immune suppression and even multiple organ failure in pediatric patients [8]. Therefore, modification of the circulating blood glucose, Cor, β -EP levels, inflammatory cytokine, and oxidative stress are needed to improve the surgical outcome [9].

So far, many studies have been conducted on the use of LMA available in different forms due to its simple operation, low stimulation and stress response [1, 10, 11]. Oro-Pharyngeal airway cap (OPLAC) is a noncuffed supraglottic airway device designed especially for the oriental population. OPLAC is made of special thermoplastic elastomer and does not need to be inflated. It has a built-in epiglottis blocker system, navigating the epiglottis to slide over the tube aperture and to be fixed under the epiglottic compressor to reduce the airway obstruction [12]. The application of OPLAC in adults surgery patient has been well established, little is known of the OPLAC application in pediatric surgery patients. The aim of this study was to perform a clinical trial to compare the effects of OPLAC and endotracheal intubation in pediatric laparoscopic surgery patients by identifying respiratory and hemodynamic variables, the inflammatory and oxidation stress, and adverse events incidence during the induction and emergence.

Material and methods

Ethics

This prospective, randomized clinical trial was approved by the Ethics Committee of Yancheng Maternity and Child Health Hospital (file number, 2016-SR-009). Written informed consent was obtained from the parents of each patient. The study protocol was conducted in accordance with the Declaration of Helsinki and its amendments. All experiments were performed in accordance with relevant guidelines and regulations.

Subjects

A total of 86 children ages 6 months to 7-year-old, in ASA physical status I-II, undergoing laparoscopic surgery under general anesthesia in our hospital from Jan 2016 to Oct 2016 were recruited and randomized to either the OPLAC (n=43) or the ETT (n=43) groups. Types of surgery included 32 cases of inguinal hernia, 14 cases of hydrocele, 20 cases of cryptorchidism, 5 cases of appendicitis, 6 cases of pyloric obstruction, 5 cases of intestinal obstruction, and 4 cases of recurrent intussusception. Random allocation software version 1.0.0 was used for randomization. The anesthesiologist

inserting the device could not be blinded, but the researchers who recorded the data and patients were blinded to the group allocation. Exclusion criteria included heart diseases, recent upper respiratory tract infection (with 48 h and not resolved), gastro esophageal reflux, and patients who need respirator for assisted ventilation after operation.

Study design and anesthesia procedure

Anesthesia procedure complied with the standards for children. Children under 6 years old were usually anesthetized by inhalational induction with sevoflurane in oxygen by mask for sufficient time. Standard monitoring included heart rate (HR), mean arterial pressure (MAP), electrocardiography, SpO_2 , $P_{ET}CO_2$, adequate depth of anesthesia was assessed by the lack of motor response to jaw thrust. Intravenous (I.V.) line is established for fluids and drugs administration. Older children who are co-operative with the anesthesiologist received I.V. induction with propofol (1% 1-2 mg/kg) plus fentanyl (1-2 μ g/kg) and atropine (0.04 mg/kg). The endotracheal tube was inserted with the help of direct laryngoscope in Group ETT. For patients in Group OPLAC, Oro-Pharyngeal airway cap sizes for different weight were used as appropriate. Anesthesia maintenance was provided by sevoflurane in oxygen. The successful placement criteria of OPLAC were confirmed by regular bag movement synchronous with chest movement, symmetric lung respiratory sound, and adequate ventilation ($SpO_2 \geq 92\%$). The patient's age, weight, type of surgical procedure, time of surgery, airway quality and any manipulation of the OPLAC or endotracheal intubation was recorded. We evaluated our patients for persistent cough, sore throat, hypoxemia, and laryngospasm postoperative. Failure of OPLAC insertion within three attempts was excluded from the study.

Hemodynamic and respiratory variables

Hemodynamic (MAP, HR) parameters were measured at the subsequent stages: after anesthesia induction (before airway instrument) (T0); endotracheal tube or OPLAC intubation (T1); 5 min after intubation (T2); before tube removal (T3); extubation or OPLAC removal (T4); and throughout emergence from anesthesia at 1, 5, 15, and 30 min after extubation

Table 1. Baseline demographic and clinical characteristics

Characteristics	Treatment groups		P
	Group ETT (n=43)	Group OPLAC (n=43)	
Age (months)	46±38	43±31	0.342
Weight (kg)	13±5	15±6	0.245
Mean anesthetic time (min)	73±31	69±24	0.163
Duration of insertion (s)	15.3±5.66	9.42±4.02	0.024
Procedures			
Inguinal hernia	18 (41.9%)	14 (32.6%)	0.372
Hydrocele	8 (18.6%)	6 (14.0%)	0.559
Cryptorchidism	9 (20.9%)	11 (25.6%)	0.610
Appendicitis	2 (4.65%)	3 (6.98%)	NS
Pyloric obstruction	2 (4.65%)	4 (9.30%)	NS
Intestinal obstruction	2 (4.65%)	3 (6.98%)	NS
Recurrent intussusception	2 (4.65%)	2 (4.65%)	NS

Values are given as mean (SD), or number of patients (%). Group ETT: endotracheal tube intubation group; Group OPLAC: Oro-Pharyngeal airway cap intubation group.

or OPLA removal (T5-T8). Respiratory parameters (PAP, $P_{ET} CO_2$) were evaluated at T3 and T4. Anesthesia recovery was measured by spontaneous breathing recovery time, eye opening time.

Biochemical measurements

Venous blood was obtained at the indicated time points: T0, T2, T3, and T5. One drop of blood was taken to determine blood glucose level. The rest was taken for serum separation, the separated serum was used to detect β -EP and Cor at T0, T2, T3, and T5; IL-6, TNF- α , MDA and Superoxide Dismutase (SOD) at T0 (pre-incubation) and T5 (extubation). Serum SOD was tested by colorimetry, β -EP, Cor, IL-6, TNF- β , and MDA levels were assayed by enzyme-linked immunosorbent assay (ELISA). All assays were performed according to manufacturer's instructions.

Statistical analysis

SPSS 19.0 was employed for analysis of data, Independent t-test analyses were used for demographic data. The χ^2 test was used to analyze categorical variables. Data are presented as mean (SD) or number (%). Student t test and ANOVA were used for statistically analyzing quantitative data. P value <0.05 was considered statistically significant.

Results

Baseline demographic and clinical characteristics

In this prospective randomized study, 43 patients were included in the ETT group and 43 patients in the OPLAC group. Patient and procedural characteristics of both groups are shown in **Table 1**. Patients in two groups were similar in terms of age, weight, mean anesthetic time and procedural characteristics. The duration of insertion in Group OPLAC was significantly lower than Group ETT. There were no drop-outs from the study, and all the subjects received the intended management.

Hemodynamic and respiratory data

There were no significant differences of baseline HR and MAP between the two groups. Comparing MAP and HR at subsequent time points during intraoperative period, Group OPLAC had a lower MAP and HR, especially at the time of tube intubation ($P=0.043$, $P=0.001$). Of note, Group OPLAC had lower MAP and HR than those observed in Group ETT during emergence from anesthesia ($P<0.001$). The highest mean intergroup difference was 8.64mmHg and 18.37 beats/min ($P=0.011$, $P<0.001$). The differences of MAP and HR narrowed 30 min after extubation or OPLAC removal (**Figure 1**).

Intergroup comparison of $P_{ET} CO_2$ and peak airway pressure (PAP) before (T3) and at on and device removal (T4) points, $P_{ET} CO_2$ ($P=0.555$, $P=0.874$) and PAP ($P=0.815$, $P=0.481$) levels did not change significantly between the groups with respect to time (**Figure 2**).

Systemic stress responses related to airway instruments

Both groups had significant reduction in plasma β -EP concentration from their respective baseline values during the whole operation procedure ($P<0.001$). The change in β -EP concentration between the groups was insignificant ($P>0.05$), except for at 1 min after extubation. Group ETT had higher β -EP concentration than that in Group OPLAC ($P=0.032$) (**Figure 3A**). Plasma Cor concentration was lower dur-

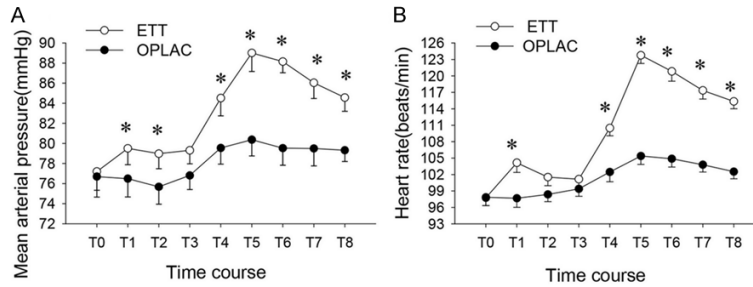


Figure 1. Changes in hemodynamic variables during the study. After anesthesia induction (before airway instrument) (T0); endotracheal tube or OPLAC intubation (T1); 5 min after intubation (T2); before tube removal (T3); extubation or OPLAC removal (T4); throughout emergence from anesthesia at 1, 5, 15, and 30 min after extubation or OPLA removal (T5-T8). A: Mean arterial pressure. B: Heart rate. Values are mean (SD). * $P < 0.05$ intergroup. $n = 43$ for each group.

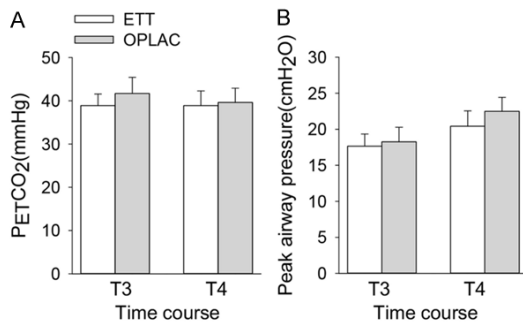


Figure 2. Changes of $P_{ET}CO_2$ and peak airway pressure in patients of two groups. Before tube removal (T3); extubation or OPLAC removal (T4). A: $P_{ET}CO_2$. B: Peak airway pressure. Values are mean (SD). $n = 43$ for each group. $P_{ET}CO_2$, end-tidal carbon dioxide pressure.

ing intraoperative period than at baseline in Group OPLAC ($P = 0.014$), but began to increase after the operation procedure in both groups, the plasma Cor concentration reached its maximum value at 1 min after extubation in Group ETT, which was higher than its baseline value ($P = 0.026$), whereas no differences were found among baseline value and postoperative time points in Group OPLAC ($P = 0.932$). Intergroup comparison, Group OPLAC had lower Cor concentration at 5 min after intubation ($P = 0.034$) and 1 min after extubation ($P = 0.013$) (Figure 3A). The change in blood glucose levels within time was insignificant ($P = 0.056$). The blood glucose level was higher in Group ETT as compared to that in Group OPLAC at 1 min after extubation or OPLAC removal ($P = 0.003$) (Figure 3A).

The plasma IL-6 and TNF- α during pre-operation and post-operation are displayed in Figure 3B. IL-6 and TNF- α levels were decreased in Group OPLAC, while increased in Group ETT. The difference was insignificant between groups pre-operation. However, IL-6 and TNF- α levels were remarkably lower in Group OPLAC post-operatively. ($P = 0.015$ and $P = 0.034$) (Figure 3B).

MAD and SOD levels were reduced over time in both groups, MDA level in Group OPLAC was significantly lower post-operatively compared to pre-operation value ($P = 0.015$). Between-group comparison, MDA level in Group ETT was higher than Group OPLAC during post-operation ($P = 0.042$). The change of SOD activity within time was insignificant ($P = 0.064$). However, SOD level in Group OPLAC was lower than that in Group ETT during post-operation ($P = 0.034$) (Figure 3C).

Anesthesia recovery parameters and postoperative adverse events

Spontaneous breathing recovery time and eye opening time were shorter in Group OPLAC than in Group ETT, but the differences were not significant ($P = 0.078$, $P = 0.325$) (Table 2). The incidence of postoperative cough (mild to moderate) was higher in Group ETT than in Group OPLAC ($P = 0.002$). However, no difference were noted in severe cough, laryngospasm or serious hypoxemia between the two groups ($P = 0.616$, $P = 0.202$ and $P = 0.494$, respectively) (Table 3). Morbidity due to aspiration or operation did not occur in either group.

Discussion

In the present study, we carried out serial measurement of hemodynamic and respiratory parameters in conjunction with inflammatory and oxidative response related variables. Our results show that OPLAC is effective in preventing the cardiovascular response, attenuating systemic stress response in pediatric patients undergoing laparoscopic surgery.

Airway device in pediatric laparoscopic procedure

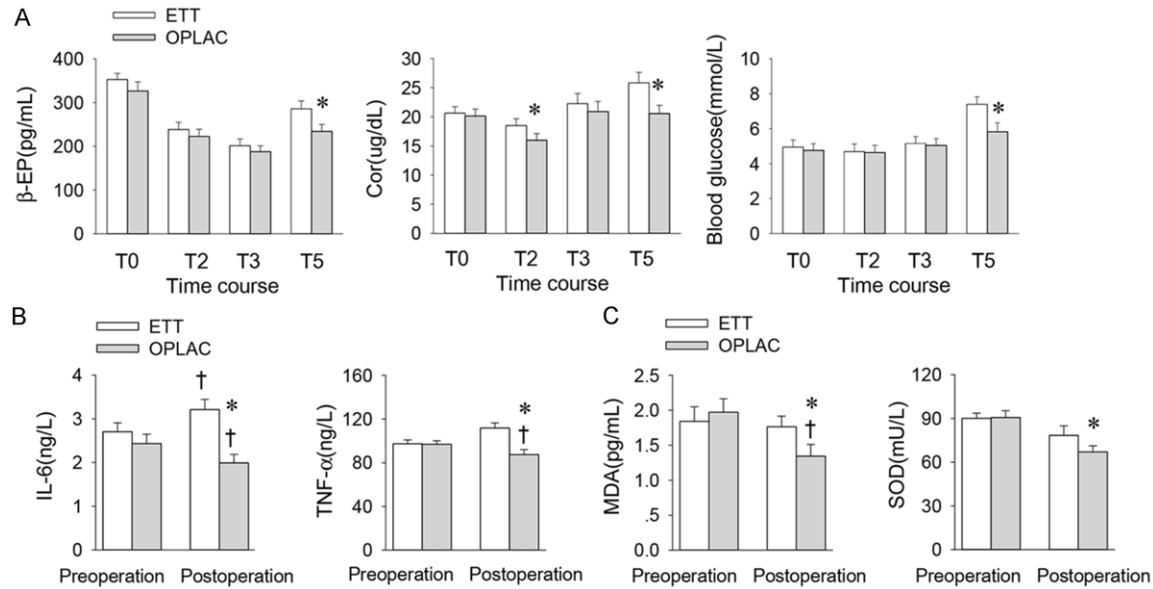


Figure 3. Changes of systemic stress-related variables in patients of two groups. After anesthesia induction (before airway instrument) (T0); 5 min after intubation (T2); before tube removal (T3); 1 min after extubation or OPLA removal (T5). A: Plasma β -E, Cor and blood glucose levels. B: Plasma IL-6, TNF- α . C: MDA and SOD levels. Values are mean (SD). * $P < 0.05$ vs. ETT. † $P < 0.05$ vs. preoperation. $n = 43$ for each group.

Table 2. Anesthesia recovery parameters

Characteristics	Treatment groups		<i>P</i>
	Group ETT ($n = 43$)	Group OPLAC ($n = 43$)	
Spontaneous breathing recovery time (min)	9.5 \pm 1.4	8.4 \pm 1.3	0.078
Eye opening time (min)	13.3 \pm 1.4	10.2 \pm 2.3	0.325

Table 3. Postoperative complications related to the airway instrument

Adverse events	Treatment groups		<i>P</i>
	Group ETT ($n = 43$)	Group OPLAC ($n = 43$)	
No choke to cough	21 (48.8%)	36 (83.7%)	0.001
Mild to moderate choking cough	19 (44.2%)	6 (14.0%)	0.002
Severe choking cough	3 (6.98%)	1 (2.33%)	0.616
Laryngospasm	5 (11.6%)	1 (2.33%)	0.202
Serious hypoxemia	2 (4.65%)	0	0.494

Values are given as number of subjects (%).

In general, laryngeal mask airway has been used as an alternative to endotracheal intubation [13-15]. In recent years, mounting evidence identifies laryngeal mask airway as a safe and effective airway device in children, especially for pediatric patients [16-19]. The application of OPLAC in adult has been documented [12]. However limited evidence is avail-

able on the application of OPLAC in pediatric laparoscopic procedures [20, 21]. As far as we know, our study is one of the first studies to directly compare OPLAC and tracheal intubation for pedi-

atric patients undergoing laparoscopic surgery, who are particularly susceptible to hemodynamic changes and physical stress.

Endotracheal intubation, however, is an invasive procedure performed at induction of anesthesia which may be challenges by enhanced hemodynamic and systemic stress [22]. Kovac *et al* showed that laryngoscopy has the maximal increase of blood pressure, and endotracheal intubation

has the maximal increase of heart rate [23]. A recent study conducted by Hashem *et al* has shown that laryngeal mask airway insertion had better hemodynamic profile as compared with tracheal intubation [1]. This is also verified in our study, the MAP and HR were lower in Group OPLAC during intubation. The highest mean intergroup difference of 8.64 mmHg in

MAP and 18.37 beats/min in HR during emergence from anesthesia.

The insertion time was defined as the time needed from insertion to the time of ready to ventilate. The engagement of OPLAC was signaled by loss of resistance against the tongue base as OPLAC is specially designed to seal without a cuff, therefore it's easier for OPLAC insertion [12]. Duration of laryngoscopy can also have significant impact on the hemodynamic responses. Recent studies have established that the increased duration of laryngoscopy causes longer sympathetic stimulation [24-26]. Consistent with these observations, our study showed that the duration of insertion for Group ETT and OPLAC were 15.3 s and 9.42 s. As more time was needed for ETT insertion, the mean MAP and HR in Group ETT changes got more prominent compared to the Group OPLAC.

Our present study showed that there was no significant difference of ETCO_2 , PAP before or after extubation between the groups. The changes in respiratory parameters in our study were similar to those observed in previous published studies. More recent studies have reported that peak airway pressure, SPO_2 and ETCO_2 changes between endotracheal intubation and laryngeal mask airway were similar [3, 27]. Moreover, Tobias *et al* reported a statistically insignificant rise in ETCO_2 levels concerning laryngeal mask usage and tracheal intubation in children undergoing laparoscopic procedures [28].

According to our data, plasma β -EP concentration was lower during intraoperative period than at baseline in both groups. Plasma β -EP concentration and blood glucose levels began to rise during emergence from anesthesia. Plasma Cor levels began to rise right before extubation or OPLAC removal. The increase rate of plasma β -EP, Cor and blood glucose in Group ETT tended to be higher than in Group OPLAC. It showed that the stress reaction reached its maximum value at 1 min after extubation.

It is evidenced that pro-inflammatory cytokines interleukin-6 (IL-6) and $\text{TNF-}\alpha$ have important role in the physical stress [29]. MAD and SOD are known to be the central mediators of oxidation stress [30]. According to our results, Group

ETT had a higher IL-6, $\text{TNF-}\alpha$ and MDA levels associated with a significant increase in hemodynamic during post-operative period. There was a significant drop of plasma IL-6, $\text{TNF-}\alpha$ and MDA levels during emergence from anesthesia in Group OPLAC, which may be due to a slight increase of hemodynamic variables after extubation. Furthermore, we found a decrease in SOD in both groups during post-operative period, which may be explained by the decrease in antioxidant status.

Tang CL *et al* state that the tracheal intubation had higher cough incidence than I-gel laryngeal mask airway for posterior fossa surgery patients during emergence from anesthesia [22]. In our study, mild to moderate cough incidence was significantly increased in Group ETT in contrast with Group OPLAC for laparoscopic surgery pediatric patients during emergence from anesthesia. However, no difference of postoperative laryngospasm or serious hypoxemia incidence was found between the groups.

There were certain limitations of our study. First, ASA I-II pediatric patients were recruited in our study, our findings may not applicable to those who are medically complex with a higher ASA status. Second, we did not measure SPO_2 and arteriolar CO_2 , which are also important indexes for respiration. Third, we did not have a systematic study and follow-up study. However, according to our observation, there were no serious complications in Group OPLAC. Fourth, the blinding was not possible for the anesthesiologist inserting the airway device.

In conclusion, our data suggest that OPLAC is effective in preventing the cardiovascular response, attenuating inflammatory and oxidative response, reducing adverse events risk, and improving anesthesia quality in laparoscopic surgery pediatric patients.

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Disclosure of conflict of interest

None.

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