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การศึกษาเปรียบเทียบระยะเวลาฟื้นตัวเพื่อเข้าเกณฑ์กลับบ้านสำหรับการผ่าตัดตาในผู้ป่วยเด็ก ด้วยวิธีระงับความรู้สึกแบบทั่วตัวโดยใช้ Flexible Laryngeal Mask Airway เทียบกับการใช้ท่อช่วยหายใจ

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Comparison of Recovery Time to Discharge Criteria following Ophthalmic Surgery in Pediatric Patients under General Anesthesia with Flexible Laryngeal Mask Airway versus Endotracheal Tube: A Prospective, Randomized Controlled Trial

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วัตถุประสงค์ของการศึกษา: การใช้ flexible laryngeal mask airway (fLMA) ช่วยลดอุบัติการณ์ภาวะแทรกซ้อนจากการใส่ท่อช่วยหายใจเพื่อการระงับความรู้สึกในผู้ป่วยเด็ก การศึกษานี้มีวัตถุประสงค์หลักคือ เปรียบเทียบระยะเวลาฟื้นตัวจนเข้าเกณฑ์จำหน่ายผู้ป่วยกลับบ้าน หลังการระงับความรู้สึกแบบทั่วตัว โดยใช้ fLMA เทียบกับการใช้ท่อช่วยหายใจ สำหรับผ่าตัดตาในผู้ป่วยเด็ก และวัตถุประสงค์รองคือเปรียบเทียบการเกิดภาวะแทรกซ้อนจากการระงับความรู้สึก
วิธีการศึกษา: การศึกษาเปรียบเทียบกับกลุ่มควบคุม ในผู้ป่วยเด็กอายุ 1-10 ปี ที่มาผ่าตัดตาและได้รับการระงับความรู้สึกแบบทั่วตัว ในโรงพยาบาลจุฬาลงกรณ์ โดยสุ่มเป็น 2 กลุ่ม คือ กลุ่มทดลอง (fLMA) ได้รับการระงับความรู้สึกโดยใช้ fLMA ส่วนกลุ่มควบคุม (ETT) ใช้ท่อช่วยหายใจ ประเมินคะแนน Pediatric Post anesthesia Discharge Scoring System (Ped-PADSS) ทันทีที่ถึงห้องพักฟื้น และประเมินทุก 10 นาที จนเข้าเกณฑ์จำหน่ายกลับบ้าน (Ped-PADSS ≤ 9 คะแนน)

Background: The flexible laryngeal mask airway is an alternative airway device used for providing general anesthesia in pediatric ophthalmic surgery besides the endotracheal tube. Recent studies demonstrated the better outcome of using flexible laryngeal mask airway over endotracheal tube in reducing incidence of hypoxemia, bronchospasm, postoperative cough and sore throat.
Objectives: The objective of study was to determine the recovery time to discharge criteria in pediatric patients following ophthalmic surgery under general anesthesia with flexible laryngeal mask airway compared with endotracheal tube.
Material and Method: Pediatric patients aged 1-10 years old who scheduled for elective ophthalmic surgery under general anesthesia in King Chulalongkorn Memorial Hospital were randomized into 2 groups. Flexible laryngeal mask airway was used as airway device during anesthesia in fLMA group, while patients in ETT group were intubated with endotracheal tube. Primary outcome was the recovery time to discharge criteria which was evaluated using the

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Received 7 Dec 2018, Revised 2 Jan 2019, Accepted 3 Jan 2019

ผลการศึกษา: ผู้ป่วยเด็กทั้งหมด 40 คน อยู่ในกลุ่มควบคุม (ETT) 21 คน และกลุ่มทดลอง (fLMA) 19 คน การวิเคราะห์ข้อมูลทางสถิติ ไม่พบความแตกต่างของระยะเวลาเฉลี่ยการฟื้นตัวจนเข้าเกณฑ์จำหน่ายกลับบ้านในระหว่างสองกลุ่มอย่างมีนัยสำคัญ (p-value=0.233) ที่ 10 นาทีหลังผ่าตัด มีจำนวนผู้ป่วยเด็กในกลุ่ม ETT เข้าเกณฑ์จำหน่ายกลับบ้านมากกว่ากลุ่ม fLMA แต่ไม่มีนัยสำคัญทางสถติ (95.24% vs 73.68%; p=0.085) อุบัติการณ์ของภาวะแทรกซ้อนจากการระงับความรู้สึกไม่แตกต่างกันในผู้ป่วยทั้งสองกลุ่ม

สรุป: ไม่พบความแตกต่างที่มีนัยสำคัญทางคลินิกและทางสถิติของระยะเวลาฟื้นตัวจนเข้าเกณฑ์จำหน่ายกลับบ้านระหว่างการใช้ fLMA และท่อช่วยหายใจ เพื่อระงับความรู้สึกสำหรับผ่าตัดตาในผู้ป่วยเด็ก

คำสำคัญ: วิสัญญีวิทยาสำหรับเด็ก, การผ่าตัดตัดตาในเด็ก, flexible laryngeal mask airway, pediatric post anesthesia discharge scoring system

Ped-PADSS. Secondary outcomes were perioperative complications related to anesthesia.

Results: A total of 40 pediatric patients (21 in ETT group and 19 in fLMA group) completed the study analysis. There were no statistically significant difference between two groups in median time to discharge criteria, defined as Ped-PADSS score ≥ 9 (p-value=0.233). Although there were more patients in ETT group reached the discharge score than patients in fLMA group at 10 minutes after PACU arrival, the difference was not statistically significant (95.24%vs73.68%; p=0.085). The incidence of postoperative complications related to anesthesia was not statistically different between two groups of patients.

Conclusion: There was no statistical and clinical superiority of using flexible laryngeal mask airway to endotracheal tube in recovery time with home readiness discharge criteria after general anesthesia for pediatric ophthalmic surgery.

Keywords: pediatric anesthesia; pediatric ophthalmic surgery; flexible laryngeal mask airway; pediatric post anesthesia discharge scoring system

วิสัญญีสาร 2562; 45(2): 51-8. • Thai J Anesthesiol 2019; 45(2): 51-8.

Introduction

Generally, endotracheal tube (ETT) has been widely used as classic airway device for general anesthesia in pediatric ophthalmic surgery, however, tracheal intubation is associated with breath holding[1, 2], cough and postoperative sore throat[3].The laryngeal mask airway (LMA) is an alternative airway device introduced for airway management. Recent studies showed the better outcome of using LMA than ETT in reducing incidence of intraoperative hypoxemia, bronchospasm, postoperative cough and sore throat in various types of operations[4, 5] including ophthalmic surgery[6]. Meta-analysis[7] revealed that the incidence of postoperative cough and PONV in which using LMA was less than in which using ETT as an airway device. Previous study in ocular muscle surgery also showed that incidence of PONV in LMA group was 12% less than in ETT group[8]. In addition, Ates Y. et al.[5] showed that general anesthesia with LMA in pediatric ophthalmic surgery had minimal hemodynamic changes during period of induction and extubation, moreover, the incidence of hypoxemia, bronchospasm and postoperative cough were lower than general anesthesia with ETT.

Most previous studies focused on superiority of LMA over ETT in the improvement of hemodynamic disturbance, intraoperative and postoperative adverse outcome. The reduction in the incidence of perioperative cardio-respiratory complications including incidence of PONV improved the patients' outcome from anesthesia and might decreased the recovery time after operation and anesthesia. According to these evidences[1-8], the use of LMA in pediatric patients undergoing general anesthesia presumed to have shorter recovery time than general anesthesia with ETT. One of the few studies, conducted by Zhao N.et al.[9], showed the shorter recovery time in LMA group than in ETT group in children underwent general anesthesia for dental procedure. Nevertheless, there are no studies directly investigate the advantage of LMA on the recovery time in children undergoing general anesthesia for ophthalmic surgery. It's important that the expected

smooth post-anesthetic recovery should reduce risk of adverse anesthetic events and length of hospital stay which may be integrated to development of ambulatory surgery in the future. Because the standard practice in our institute is to perform the pediatric ophthalmic surgery under general anesthesia in inpatient setting, the research team decided to evaluate the readiness for home discharge by using the pediatric post-anesthetic discharge scoring system (Ped-PADSS)[6, 12], which was developed to assess home readiness for pediatric patients undergoing ambulatory surgery, instead of discharging patients as outpatient setting. We decided to use Ped-PADSS as the measurement for the outcome in this study because this score had been developed to use specifically in pediatric population which was adapted from the PADSS that was the gold standard to assess home readiness after ambulatory surgery in adults[6, 12].

The aim of this study was to determine the recovery time to discharge criteria following ophthalmic surgery in pediatric patients under general anesthesia, using the flexible laryngeal mask airway compared with the endotracheal tube, measured by Ped-PADSS. The secondary outcomes were to compare the perioperative complications between both groups, which consisted of hypoxemia, equipment dislodgement, laryngospasm, bronchospasm, cough, sore throat, nausea and vomiting. We hypothesized that the use of flexible LMA in pediatric patient undergoing general anesthesia for ophthalmic surgery would have shorter recovery time to discharge than the use of endotracheal tube.

Materials and Methods

Study Design and Setting

We conducted a prospective randomized controlled trial study at King Chulalongkorn Memorial Hospital, Thailand. This study was approved by the institutional review board of Faculty of Medicine, Chulalongkorn University (IRB number 018/59).

Methods

We enrolled the pediatric patients aged 1-10 years old with body weight at least 10 kg and ASA physical status classification I-II who were scheduled for ophthalmic surgery under general anesthesia at King Chulalongkorn Memorial Hospital from October 2015 to October 2016. The exclusion criteria were patients who had upper respiratory tract infection within 2 weeks or lower respiratory tract infection within 4 weeks prior to surgery, neurological problems, airway anomalies, risk of pulmonary aspiration, severe systemic diseases and body weight greater than 3SD of the standard median weight-for-height for Thai children[10]. Patients who underwent retinal surgery, nasolacrimal duct surgery and emergency surgeries were also excluded. Enrolled patients were randomly allocated to the flexible laryngeal mask airway (fLMA) group or the endotracheal tube (ETT) group.

Preoperative preparation was done to every patient according to American Society of Anesthesiologist (ASA) practice guidelines for preoperative fasting[11]. All patients were provided general anesthesia by an at least 3-year-experienced anesthesiologist. In the operating theater, inhalational induction using 2-8% sevoflurane in oxygen with nitrous oxide was applied to all patients then 1 mcg/kg of intravenous fentanyl was administered after successful IV access. The oxygen saturation, pulse rate, non-invasive blood pressure (NIBP), EKG and capnography were monitored after anesthetic induction and cycled at 5-minute intervals until the end of operation. Patients in ETT group were given intravenous cisatracurium in dose of 0.15-0.2 mg/kg for facilitating endotracheal intubation and additional dose of 0.05 mg/kg was administered during the operation according to the attending anesthesiologist's judgment. Oral Ring-Adair-Elwyn (RAE) endotracheal tube was used for every patient in ETT group. Uncuffed endotracheal tube was used in patient aged younger than 8 years old while cuffed endotracheal tube was used if patient is 8 years old or older. The size of endotracheal tube was determined by the formula, (age in years/4) + 4. We accepted the minimal leakage around endotracheal tube at airway pressure 20-25 cmH_2O. In fLMA group, the flexible laryngeal mask airway was placed when patient was at adequate depth of anesthesia without muscle relaxant administration. Spontaneous ventilation or occasional assisted ventilation was applied to patients in this group depended on capnography monitoring.

The size of fLMA was based on patients' body weight as shown in Table 1. If fLMA insertion was failed for 3 times, we would switch to endotracheal intubation.

Table 1 Recommended size and cuff volume of flexible laryngeal mask airway

Body Weight (Kg)	Size of flexible laryngeal mask airway	Cuff volume (ml)
10.0-19.9	2.0	10
20.0-29.9	2.5	14
30.0-49.9	3.0	20

All airway devices were secured at the center of patients' chins. After successful placement of airway devices, the patients' mouths and ventilators were covered with cloths in order to blind the surgeons and assessor. However, the attending anesthesiologists could not be blinded in this study because they have to insert the airway devices according to patients' group

Ventilation methods:

• Patients in ETT group received positive pressure ventilation with tidal volume 7-10 ml/kg and respiratory rate 12-25 times per minute in order to keep end-tidal CO_2 ($ETCO_2$) 30-40 mmHg.

• Patients in fLMA group received spontaneous ventilation or occasional assisted ventilation (peak airway pressure < 20 cmH_2O) to keep $ETCO_2$ below 50 mmHg[8]

After induction and insertion of airway devices, 0.15 mg/kg of dexamethasone (maximum 10 mg) was administered intravenously. Anesthetic depth was maintained using 2-3% Sevoflurane in O_2 mixed with N_2O (FiO_2 0.5). During the operation, 0.5 mcg/kg fentanyl could be administered as indicated with the maximal total dose 1 mcg/kg/case. Ondansetron 0.1 mg/kg (maximum 8 mg) was given at 30 minute before the end of operation. Oculocardiac reflex during the operation was treated by intermittently discontinuing the operation. If bradycardia existed, 0.02 mg/kg of atropine would be administered after excluding other causes of bradycardia. At the end of operation, 0.05 mg/kg of neostigmine and 0.02 mg/kg of atropine were given to patients in ETT group for reversal of neuromuscular blocking agent. When criteria of extubation were completely fulfilled, patients in ETT group were extubated. Patients in fLMA group were removed fLMA at the end of operation when patients were fully awake. At the recovery room, all patients were given oxygen (FiO_2 0.4) with O_2 nebulizer flow 8 LPM for at least 10 minutes in order to keep $SpO_2 \geq 95\%$. The pediatric post-anesthetic discharge scoring system (Ped-PADSS)[6,12] was recorded immediately on arrival in recovery room and every 10 minutes until the patient had score at least 9 (Maximum 10) by a blinded nurse anesthetist. The primary outcome of the study was the time to discharge criteria defined as time (in minutes) from PACU arrival until Ped-PADSS score was 9. (Table 2)

Table 2 The pediatric post-anesthetic discharge scoring system (Ped-PADSS)[6,12]

Criteria	2	1	0
Vital signs: Heart rate and blood pressure according to age	Variation < 20% of preoperative value	Variation between 20 - 40% of preoperative value	Variation > 40% of preoperative value
Level of activity	Steady gait (normal activity)	Able to ambulate with assistance (reduced activity)	Unable to ambulate (hypotonia)
Nausea and/or vomiting	None or minimal	Moderate	Severe (despite treatment)
Pain: level of pain that is acceptable and/or controllable by oral medication	-	Yes	No
Surgical bleeding	None or minimal (no dressing requirement)	Moderate (1 or 2 dressing requirements)	Severe (>2 dressing requirements)

Postoperative pain was controlled by administration of 0.5-1.0 mcg/kg fentanyl every 5-minute-interval by the permission of attending anesthesiologist. Emergence delirium, a common postoperative complications in pediatric patients that might affect recovery time after anesthesia, defined as Pediatric Anesthesia Emergence Delirium (PAED) score ≥10[7, 13] (Table 3) was managed by 0.5-1.0 mcg/kg of intravenous fentanyl. If the PAED score was not less than 10 after fentanyl treatment, administration of 0.5-1.0 mg/kg propofol would be considered.

Table 3 Pediatric Anesthesia Emergence Delirium (PAED)[7, 13]

	Not at all	Just a little	Quite a bit	Very much	Extremely
Makes eye contact with caregiver	4	3	2	1	0
Actions are purposeful	4	3	2	1	0
Aware of surroundings	4	3	2	1	0
Restless	0	1	2	3	4
Inconsolable	0	1	2	3	4

Postoperative nausea and vomiting was treated by administration of 0.2 mg/kg metoclopramide. Complications that occurred in the recovery room and postoperative day 1 (at ward) such as hypoxemia, laryngospasm, bronchospasm, cough, sore throat, nausea and vomiting were recorded.

Statistical Analysis

Continuous variables were presented as mean and standard deviation. To compare continuous variables with normal distribution between the fLMA and ETT groups, the Independent t-test was used. Other skewed variable differences were analyzed using the Mann-Whitney U test and were presented in median with minimum to maximum range. Categorical variables were shown as numbers and percentage. The differences in categorical variables between 2 groups were analyzed using the Chi-square test or Fisher's exact test. To compare time to discharge between 2 groups, the Wilcoxon (Breslow) test and the Kaplan-Meier Curve were performed. SPSS version15.0 software was used for the statistical analysis. The p-value <0.05 was considered statistically significant.

The pilot study was done to calculate the sample size, the mean recovery time to discharge criteria (time to reach 9 Ped-PADSS score) and standard deviation were 47.56 minutes and 9.02, respectively. We expected the difference in time to recovery between two groups at least 10 minutes as clinical significance. In each group, 19 patients were required with a power of 0.9, a risk for 0.05 for a type-I error for a 2-tailed statistical analysis, and a 10% assumed drop-out rate.

Results

From October 2016 to October 2017, there were 42 pediatric patients were enrolled in the study and randomly allocated into two groups which were the fLMA group and ETT group. Two patients were excluded from the study. Finally, there were 19 patients in fLMA group and 21 patients in ETT group. (Figure 1)

Baseline characteristics of patients in both groups were similar in age, sex, weight, height and underlying disease as listed in table 4. There were no significant differences in number of attempt and duration of airway device insertion including incidence of intraoperative patients' movement and duration of anesthesia. The total dosage of perioperative fentanyl was slightly higher in fLMA group than in ETT group but there was no statistical significance.

Upon arriving in the recovery room, more than 70% of patients in both groups had Ped-PADSS score 9 from 10 as shown in Table 5 (76.19% in ETT group and 73.68% in fLMA group). At 10 minutes after returning from operating theater, the Ped-PADSS score of 20 patients (95.24%) in ETT group was 9 while there were only 14 patients (73.68%) in the fLMA group met the Ped-PADSS discharge criteria (score ≥9). However, this difference was not statistically significant (p-value = 0.085). There was no significant difference in median time to reach 9 Ped-PADSS score between ETT and fLMA group (p-value = 0.233) as demonstrated in Figure 2.

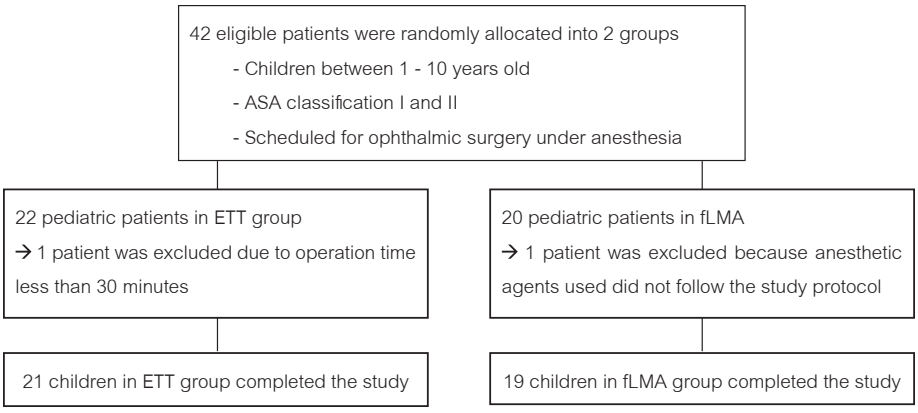


Figure 1 Flowchart of the study

Table 4 Characteristics of patients, anesthesia and perioperative pain management

		ETT group (n=21)	fLMA group (n=19)
Age (years)		4.29±2.47	4.05±2.66
Sex	Male	11 (52.38%)	11 (57.89%)
	Female	10 (47.62%)	8 (42.11%)
Weight (kg)		17.21±5.79	18.27±7.77
Height (cm)		101.24±17.32	99.48±19.81
Underlying diseases	No	15 (71.43%)	17 (89.47%)
	Yes	6 (28.57%)	2 (10.53%)
Number of airway device insertion	1 time	17 (80.95%)	18 (94.74%)
	2 times	3 (14.29%)	1 (5.26%)
	3 times	1 (4.76%)	0 (0.00%)
Duration of airway device insertion (minutes)		9.52±1.59	9.49±1.37
Intraoperative movement of patient	No	20 (95.24%)	19 (100.00%)
	Yes	1 (4.76%)	0 (0.00%)
Duration of anesthesia (minutes)		102.38±32.70	85.58±32.84
Total perioperative fentanyl (mcg/kg)		1.47±0.42	1.57±0.50
Time to remove airway devices at end of operation (minutes)		11.23±1.65	10.97±1.55

Continuous variables are shown as mean±standard deviation. Categorical values are expressed as numbers of patients (%)

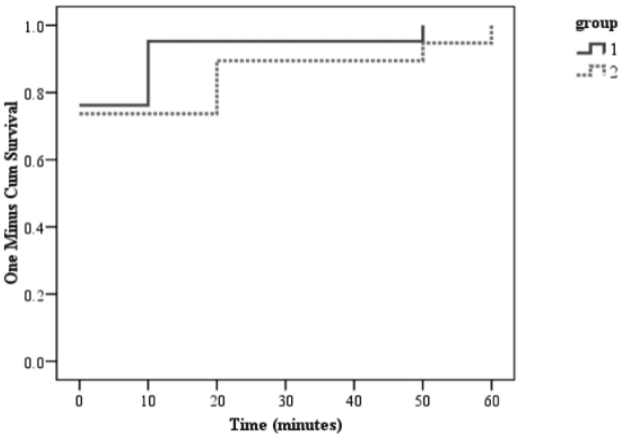


Figure 2 Kaplan-Meier Curve of time to reach 9 Ped-PADSS score

Table 5 Number of patients who had Ped-PADSS score 9 in time interval

Time to reach 9 Ped-PADSS score (minutes)	ETT group (n=21)		fLMA group (n=19)	
	N	%	N	%
0	16	76.19	14	73.68
10	4	19.05	0	0
20	0	0	3	15.79
50	1	4.76	1	5.26
60	0	0	1	5.26

Both groups had similar incidences of postoperative emergence delirium and cough but the incidence of postoperative sore throat in ETT group was higher than fLMA group without statistical significance as shown in Table 6. (23.81% in ETT group versus 5.26% in fLMA group, p-value = 0.186). Nevertheless, there was no incidence of serious postoperative complications such as hoarseness, severe hypoxemia and cardiac arrest in this study.

Table 6 Postoperative complications

		ETT group		fLMA group		p-value
Emergence delirium	No	19	(90.48%)	17	(89.47%)	1.000
	Yes	2	(9.52%)	2	(10.53%)	
Cough	No	21	(100.00%)	18	(94.74%)	0.475
	Yes	0	(.00%)	1	(5.26%)	
Sore throat	No	16	(76.19%)	18	(94.74%)	0.186
	Yes	5	(23.81%)	1	(5.26%)	

Discussion

Using the Ped-PADSS as the discharge criteria after general anesthesia for pediatric ophthalmic surgery, we did not find the flexible laryngeal mask could decrease the recovery time to discharge criteria compared with the use of standard endotracheal tube. The results of this study were different from previous studies which revealed the benefits of using flexible laryngeal mask airway as an airway device for pediatric ophthalmic surgery when compared with the standard endotracheal tube. In additions, study by Zhao N. et al.[9] in pediatric dental procedures showed shorter recovery time in LMA group compared with ETT group. This could be explained by the multi-factors which affected the recovery of pediatric patients after general anesthesia such as the incidence of postoperative airway complications that was higher in ETT group than in LMA group in Zhao's study, while this incidence was not significantly different in our study. Moreover, the method used for measuring the outcome of recovery time in Zhao's study was different from our study. This might be one of the reasons why the results were different.

There were no differences in the incidence of postoperative complications such as emergence delirium, cough and sore throat. Interestingly, there was no report of serious perioperative complications such as interruption of the operation due to intraoperative patients' movement, postoperative hoarseness. Furthermore, all patients had the Ped-PADSS score at least 9 within 1 hour after returning from the operating theater which was the standard time of patients to be observed in the recovery room before discharging in our institution. All of these results promote the further study in larger population and support the opportunity to develop this type of procedure to be an ambulatory surgery in the future.

There were some limitations of this study. Firstly, the anesthesiologists who inserted the airway device could not be blind to the group of the patients. Secondly, the use of different ventilation techniques for each group of patients which were controlled ventilation with muscle relaxation for patients in ETT group and spontaneous ventilation for patients in fLMA group might have some effects on the recovery of pediatric patients after general anesthesia. However, the ventilation techniques used in this study are the standard techniques generally used in our hospital.

Recently, there were no other studies that investigated the recovery time after anesthesia in pediatric ophthalmic surgery comparing the use of LMA and endotracheal tube. In the future, the study in larger population is challenging in order to detect the difference in recovery time between using LMA and endotracheal tube as an airway device for anesthesia in these procedures. The variables associated with the recovery time such as level of preoperative anxiety and time to turn-off the inhalational agent should be controlled and generalized.

Conclusion

There was no statistical and clinical superiority of using flexible laryngeal mask airway to endotracheal tube in recovery time with home readiness discharge criteria (Ped-PADSS) after general anesthesia for ophthalmic surgery in pediatric patients.

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