Isoflurane alone versus small dose propofol with isoflurane for removal of laryngeal mask airway in children-a randomized controlled trial

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Abstract

Objective: To compare the safety of laryngeal mask airway removal using two different deep anaesthesia techniques in paediatric patients.

Methods: The Randomized Control Trial was conducted at Aga Khan University Hospital, Karachi, from April 2012 to November 2013, and comprised patients aged 2-10 years scheduled for infra-umbilical surgeries. Anaesthesia was induced with sevoflurane and later it was maintained by isoflurane, oxygen and nitrous oxide. The laryngeal mask airway was removed in the intervention group-I at 0.4 minimum alveolar concentration of isoflurane with propofol 1mg/kg. In the control group-II, it was removed at 1.2 minimum alveolar concentration of isoflurane alone. SPSS 19 was used for data analysis.

Results: Of the 50 patients, there were 25(50%) in each of the two groups. Overall, there were 46(92%) males and 4(8%) females. Incidence of airway obstruction and teeth clenching was significantly higher in group-II ($p < 0.05$ each). Emergence duration was also significantly increased in group-II compared to group-I ($p = 0.001$). The Post-Anaesthesia Care Unit stay timing was not significantly different between the groups ($p = 0.74$).

Conclusion: Laryngeal mask airway removal under deep anaesthetic technique of low-dose propofol with isoflurane was found to be associated with minimal adverse airway events than isoflurane alone in paediatric patients.

Keywords: Laryngeal mask airway, General anaesthesia, Propofol, Isoflurane, Airway obstruction, Emergence, Paediatric. (JPMA 69: 1596; 2019). doi: 10.5455/JPMA.296240.

Introduction

In anaesthetic practice from its invention till this modern era, the process of laryngeal mask airway (LMA) has a significant role. It is widely used for controlling the airway in paediatric surgical patients.¹ The inventor and manufacturer formerly recommended LMA removal when the patient is fully awake and protective airway reflexes are regained.² However, these recommendations were made and practised for adults because LMA was not in practice for paediatric patients in those days.³ Paediatric airway management is more challenging than adults due to anatomical and physiological variations.⁴ In paediatric patients, LMA has great acceptance. However, the complication rate was remarkable with awake LMA removal in paediatrics.^{4,5} There has been extensive research work done in the last decade which concludes that the process of LMA removal is completely

safe under anaesthetic protocols. Some studies reported awake LMA removal is a better option, causing minimal risk of airway obstruction and negligible risk of aspiration^{5,6} whereas a few other studies have reported no difference in awake or deep LMA removal.^{7,8} However, the majority of studies tend to agree that deep LMA removal is safer for the paediatric population due to nominal risk for coughing, breath-holding, laryngospasm and bronchospasm.⁹⁻¹¹ Intact airway reflexes, unobstructed airway, smooth emergence and faster recovery timing after LMA removal are still challenges for paediatric patients. A combination of a small dose of propofol with isoflurane minimum alveolar concentration (MAC) awake would provide an ideal condition for safe LMA removal in paediatric patients.

The current study was planned to compare safe LMA removal under deep isoflurane anaesthesia versus a combination of small dose of propofol with isoflurane awake paediatric patients.

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Patients and Methods

The Randomized Control Trial was conducted at Aga Khan University Hospital (AKUH), Karachi, from April 2012 to November 2013. After obtaining approval from the institutional review board, the protocol was registered at ClinicalTrials.gov NCT01958138. with due parental consent, children with American Society of Anaesthesiologists (ASA) grade I and II aged 2-10 years planned for elective infra-umbilical surgery were enrolled using consecutive sampling method. Patients with known asthma, recent upper airway infection, facial abnormalities, and gastro-oesophageal disorder were excluded.

The sample size was calculated at the power of 80% and level of significance 5% to discover the difference of 40% among the groups. The calculation was based on clinical experience and it was assumed that the incidence of adverse airway events will be decreased by 70% in the intervention group and 30% in the control group. All the subjects were pre-medicated with oral midazolam 0.3mg/kg, about 45-60 minutes prior to the induction of anaesthesia. Once the standard monitors were applied, the baseline vitals were recorded. General anaesthesia was induced by an inhaled technique using sevoflurane 8% dial volume in oxygen via Mapleson F circuit. Once the child was asleep, the sevoflurane dial was dropped down up to 4% and an intravenous (IV) line was started and LMA was placed after confirming adequate jaw relaxation. LMA (Ambu® AuraOnce™) sizes were determined as per the manufacturer's recommendation (1.5 LMA size for 5-10kg; size 2 for 10-20kg; and size 2.5 for 20-30kg). Sevoflurane was replaced by isoflurane in 60% nitrous oxide and 40% oxygen for the maintenance of anaesthesia. The end-tidal carbon dioxide at 35-45mmHg and isoflurane MAC at 1.2 (Primus® Dräger anaesthesia machine, Germany) in expiratory gases were maintained to standardise the anaesthetic depth. Spontaneous breathing was maintained in all children; 2L gas flow was kept in circle system for the maintenance phase and 8L flow via maples F circuit were kept for induction and emergence phase of anaesthesia. Caudal analgesia was administered in both the groups. Bupivacaine 2mg/kg was diluted in normal saline and total injected caudal volume was calculated by 1ml/kg of body weight. Once the surgery finished, patients were assigned into the study groups according to computer-generated random number table (Figure 1).

Figure-1: Study flow diagram.

Prior to LMA removal in group-I, isoflurane MAC awake (MAC less than or at 0.4) was achieved in end-expiratory gases with 60% nitrous oxide and 40% oxygen. Thereafter, propofol 1mg/kg was administered to maintain deep anaesthesia state for LMA removal. In group-II, the deep anaesthesia state was maintained by an end-expiratory isoflurane 1.2 MAC with 60% nitrous oxide and 40% oxygen. In both the groups, LMA was removed with inflated cuff, throat was suctioned and patients were turned into the lateral recovery position. Isoflurane and nitrous oxide were turned off and 100% oxygen was supplemented till the patient had regained consciousness. All patients were transported to the Post-Anaesthesia Care Unit (PACU), once airway patency and peripheral oxygen saturation (SpO₂) >95% was ensured on room air. Children were allowed to wake up on their own in PACU at 5L/minute of oxygen via Hudson mask. A self generated proforma was used to record demographics, type of surgeries, surgical and anaesthesia duration, LMA insertion attempts and primary outcome, airway obstruction (noisy or stridor breathing) requiring jaw support, laryngospasm, bronchospasm, retching and vomiting. Primary outcome elements noted were adverse airway events, such as coughing, bucking, hyper-salivation, and oxygen desaturation (SpO₂<90%). The adverse airway events were observed for 15 minutes after LMA removal. The secondary outcome was the emergence time duration and PACU stay duration. SPSS 19 was used for data analysis. Relevant descriptive statistics, frequencies and percentages were computed for categorical variables, including gender, ASA status, number of LMA insertion attempts, mode of analgesia and type of surgery. Mean $\pm$ standard deviation (SD) was

computed for normally distributed quantitative variables and analysed by independent sample t-test. The median (interquartile range [IQR]) were reported for non-normal distribution and analysed by Mann Whitney U test. Chi-Square test and Fisher exact test were used to compare the difference between the groups for adverse airway events, teeth clenching, airway obstruction, laryngospasm, bronchospasm, retching, and vomiting. $P < 0.05$ was considered statistically significant.

Results

Of the 50 patients, there were 25(50%) in each of the two groups. Overall, there were 46(92%) males and 4(8%) females. There was no significant difference in demographic and baseline vitals between the groups (Table 1).

LMA insertion on first attempt was 25(100%) in group-I and 24(96%) in group-II. There were no differences in the type of surgeries, surgical duration and anaesthesia duration between the groups (Table 2).

The incidence of coughing and bucking was 4(16%) in group-II and 1(4%) in group-I. Hyper-salivation was observed in 3(12%) patients in group-II and 4(16%) in group-I. Hypoxia 2(8%) and laryngospasm 1(4%) were seen in group-II only. Teeth clenching in group-II was 7(28%) versus 1(4%) in group-I, and airway obstruction in group-II was 9(36%) versus 3(12%) in group-I. Both values were statistically significant in group-II (Table 3).

Emergence timing was significantly shorter in group-I

Table-1: Comparison of demographics and baseline vital parameters between groups.

Variables	Group-I n=25	Group-II n=25	p-values
Age (Years)†	4.2(3.5)	3.1(3)	0.31
Weight (kg)†	15.5(6.8)	13.7(5.3)	0.28
Height (cm)†	106(20)	94.5(15)	0.05
Gender			
Male	24(96%)	22(88%)	0.61
Female	1(4%)	3(12%)	
ASA Status			
I	17(68%)	22(88%)	0.08
II	8(32%)	3(12%)	
Heart Rate (bpm)	115.7±13.9	117.36±19.9	0.73
Systolic Blood Pressure (mmHg)	92.1±11.2	91.2±8.8	0.74
Diastolic Blood Pressure (mmHg)	47.7±9.0	46.6±9.4	0.65
Respiratory Rate	21.2±3.3	22.6±3.5	0.16

Results are presented as †median (interquartile range [IQR]), compared with the Mann Whitney U test; mean ± standard deviation, compared with t-test and n (%), compared with chi-square or Fisher exact test. ASA: American Society of Anaesthesiologists.

Figure-2: Comparison of mean emergence time duration between the groups.

Table-2: Comparison of LMA insertion attempts, surgery duration, anesthesia duration and type of surgeries between study groups.

Variables	Group-I n=25	Group-II n=25	p-values
LMA Insertion attempts			
1	25(100%)	24(96%)	0.99
2	0(0%)	1(4%)	
Duration of surgery (min)†	35.5(16)	28.5(23)	0.21
Duration of anaesthesia (min) †	59(23)	59(21)	0.37
Type of surgery			0.43
Circumcision	12(48%)	10(40%)	
Inguinal Hernia	6(24%)	7(28%)	
PPV Ligation	3(12%)	3(12%)	
Hypospadias Repair	1(4%)	5(20%)	
Circumcision and Inguinal Hernia	1(4%)	0(0%)	
Inguinal Hernia and Meatotomy	1(4%)	0(0%)	
Urethro cutaneous fistula repair	1(4%)	0(0%)	

Results are presented as †median (interquartile range [IQR]), Mann Whitney U test; mean ± standard deviation t-test; n (%), chi-square or Fisher exact test. * $p < 0.05$.

LMA: Laryngeal mask airway PPV: Patent processus vaginalis

Table-3: Comparison of adverse airway events between groups.

Adverse Airway Event	Group-I n=25	Group-II n=25	Diff (95%CI) n=25	p-values
Cough	1(4%)	4(16%)	12% [-4.3% to 28.3%]	0.34
Mild	1	3		
Moderate	0	1		
Severe	0	0		
Bucking	0(0%)	4(16%)	16% [-1.6% to 30.4%]	0.11
Oxygen desaturation (<90%)	0(0%)	2(8%)	8% [-2.6 to 18.6%]	0.49
Hyper-salivation	4(16%)	3(12%)	-4% [-23.2% to 15.2%]	0.99
Teeth Clenching	1(4%)	7(28%)	24% [4.8% to 43.2%]	0.05*
Airway Obstruction requiring Jaw support	3(12%)	9(36%)	24% [1.3% to 46.7%]	0.047*
Laryngospasm	0(0%)	1(4%)	4% [-3.7% to 11.7%]	0.99

Results are presented n (%), chi-square or Fisher exact test.

than group-II ($p=0.001$) (Figure 2). Duration of recovery room stay was almost similar in both groups ($p=0.74$). Bronchospasm, retching and vomiting were not reported in either of the two groups.

Discussion

The major finding of the current study is the reduction of coughing, bucking, teeth clenching and airway obstruction in group-I, which had LMA removal at isoflurane 0.4 MAC awake plus propofol 1mg/kg, compared to group-II, which had isoflurane at 1.2 MAC alone. In addition, there was minimal wake-up time in group-I.

The focal point of the study was to explore a safe method for LMA removal by overcoming the existing challenges, like airway obstruction, aspiration risk, emergence and PACU time duration. We compared LMA removal by two different deep anaesthesia techniques; deep isoflurane MAC 1.2¹² versus a combination of propofol 1mg/kg with isoflurane 0.4 MAC awake. Confounding factors, such as induction and maintenance of anaesthesia, were standardised. Analgesia was achieved with caudal block and none of the patients required rescue analgesia. The age groups (3.1 years in group-II and 4.2 years in group-I) were proponents for the development of emergence complications.¹³

In a study,⁵ children developed severe airway hyper-reactivity in which LMA was removed under awake isoflurane anaesthesia. Six out of 30 patients in deep isoflurane LMA removal group required manual jaw support.⁵ In contrast, 3 out of 25 children in our deep propofol isoflurane group required jaw support and 9 out of 25 children needed jaw support in the deep isoflurane group. However, we noticed a significant difference in patient's emergence time duration, the 6.88 minutes in our deep propofol-isoflurane group and 9.76 minutes in deep isoflurane group which is comparably lower than the earlier reported deep isoflurane emergence time duration of 19 minutes and 11 minutes of awake isoflurane group.⁵ A study¹³ on LMA removal under sevoflurane anaesthesia reported that the patients' awakening time was similar in deep and awake sevoflurane anaesthesia. Our study's combined propofol-isoflurane group's awakening time duration was almost similar, but the incidence of adverse airway events was much lesser than the study groups in the earlier study.¹³ The current study failed to detect the time differences

between the groups for the recovery room stay duration, as the departmental policy confined ASA-I and II patients for 45 minutes of PACU stay. We preferred low-dose propofol with isoflurane to obtain the deep anaesthesia state for LMA removal. Propofol is a potent inhibitor of airway reflexes at the hypnotic dosage and it is well-known for the prevention of emergence complications in children at sub-hypnotic concentrations.¹⁴

The current study has its limitations. Isoflurane MAC reduction to a pre-determined level and propofol addition in the study group were impractical for blinding purposes. However, an independent observer in the operating room and in the recovery room was assigned to collect data. Besides, pain score was not recorded that could have interrupted sensorium. Nevertheless the caudal was the sole analgesia and none of the patients requested rescue analgesia. Also, Dixon's method¹⁵ was not applied; fixed isoflurane MAC might have caused variation in anaesthesia depth among the subjects. Moreover, propofol dose of 1mg/kg was administered that is relatively higher than the reported sub-hypnotic dose of 0.5-0.8mg/kg;¹⁶ nevertheless, the propofol group awakening time was shorter in our study. Finally, oral surgery¹⁷ (dental, otolaryngologic) has direct airway involvement and was excluded from the current study.

Further studies could be considered with larger sample size, replacement of isoflurane with sevoflurane and the use of propofol at lower doses.

Conclusion

Deep LMA removal in paediatric patients by a combination of low-dose propofol with isoflurane MAC awake reduced adverse airway events and minimised the emergence time duration in children. This method can be considered as an alternative to deeper plane of isoflurane anaesthesia.

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