ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
DEPARTEMENT OF ANESTHESIA

A COMPARISON OF AWAKE VERSUS DEEP REMOVAL OF LARYNGEAL MASK AIRWAY IN CHILDREN AGED 2 TO 8 YEARS WHO UNDERWENT OPHTHALMIC PROCEDURES AT MENILIK II HOSPITAL: COHORT STUDY

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CERTIFICATION

The undersigned certify that the research entitled A comparison of awake versus deep removal of laryngeal mask airway in children aged 2 to 8 years who underwent ophthalmic procedures at Menelik-II hospital: a prospective cohort observational study is my original work and any literature and/or data cited in this article were listed in the reference section and any assist done during this period has been given an acknowledgement.

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Acronyms and Abbreviations

ASA PS	American Society of Anesthesiologist Physical Status
IV	Intravenous
Kg	Kilogram
LMA	Laryngeal Mask Airway
Mcg	Microgram
Mg	Milligram
Oxygen	O_2
SGA	Supraglotic Airway
Spo_2	Arterial oxygen saturation
SPSS	Statistical Package for Social Sciences
TCI	Target Controlled Infusion
vs	Versus

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Summary

Background: Laryngeal mask airway is a useful airway device which provides an alternative to ventilation through a face mask or endotracheal tube. It can be removed either when a child awakens or deeply anesthetized. However, there is no objective evidence to choose one over the other. It has been studied by various investigators but with conflicting results and conclusions.

Objective: The aim of the study was to compare awake removal of laryngeal mask airway with deep removal regarding to airway related adverse events.

Methodology: A prospective observational cohort study was conducted at Menelik-II hospital from January to April 2018. Sixty two American Society of Anesthesiologists physical status I and II pediatric (aged 2-8 years) patients who underwent ophthalmic procedures under laryngeal mask airway with halothane as maintenance anesthesia were recruited by systematic random sampling technique. Airway related adverse events following deep condition of laryngeal mask airway removal (deep group) versus awake condition removal (awake group) were recorded by trained data collectors. Fisher's exact test were used to analyze breath holding, coughing, and biting. The remaining upper airway obstruction, excessive salivation, and desaturation were analyzed using Chi-square test. Demographic data (age, and weight) were analyzed by independent t test except gender (analyzed by Chi-square test).

Results: The incidence of coughing (12.9% versus 6.5%), upper airway obstruction (41.9% versus 35.5%), breath holding (9.7% versus 3.2%), desaturation (16.1% versus 22.6%), excessive salivation (19.4% versus 12.9%), and biting (6.5% versus 0%) between awake and deep group was not different ($p > 0.05$). Laryngospasm, vomiting, and retching did not occur in either group.

Conclusion: There was no significant difference in the incidence of airway related adverse events whether the laryngeal mask airway was removed in deep or awake condition.

1. Introduction

One of the responsibilities of anesthetists is establishing, securing and maintaining a patent airway which is referred to as airway management. Mask ventilation and endotracheal intubation has been the foundation of airway management before laryngeal mask airway (LMA) has emerged as one of the most important developments in airway devices (1). LMA is a supraglotic airway (SGA) or extraglottic airway devices that was designed by a British anesthesiologist Doctor Archie Brain in 1981 (2). He conceived the LMA to provide the bridge between the face mask and the endotracheal tube. (3)

Indeed, the LMA has proved to be one of the single most important developments in airway management. Furthermore, it is a pivotal component of the American Society of Anesthesiologist (ASA) Difficult Airway Algorithm. (1) It has also been shown that the LMA provides a safe and effective form of airway management in children (4). In the contrary, the use of LMA may be associated with complication such as postoperative sore throat, pain on swallowing, and hoarseness. However, these are relatively rare and most of them are not life threatening. Actually, aspiration remains a serious and even fatal consequences of its use. (4)

LMA is simply and blindly inserted into the pharynx so that it avoids the invasive instrumentation of laryngoscope for endotracheal intubation, and also provides a definitive airway compared to facemask. Taking out airway devices from patient's airway tract is associated with higher incidence of respiratory complications than the time of insertion (5). LMA routinely removed in two conditions at the end of surgery once a patient possesses adequate respiratory rate and depth. It is removed when the patient regains consciousness and is in the awake state or when he is still under anesthesia. However, as there is no clear indication, anesthetist choose either of one based on their experience. Some studies are conducted to show the superiority of one over another, but their results and conclusions are conflicting.

2. Statement of Problem

As takeoff and landing are challenging for pilots, induction (including intubation) and emergence (including extubation) are the challenging anesthetic management part to anesthetists. More importantly, emergence and removal of laryngeal mask airway (LMA) are times of increased risk during anesthesia. It is at this time more complications occur than at induction. Though LMA is a better alternative to endotracheal tube in reducing the incidence of pharyngolaryngeal morbidity(7), its removal can be associated with adverse respiratory events such as cough and straining, laryngospasm, bronchospasm, vomiting, and etc. These unwanted adverse effect of LMA represent a significant source of patient injury and financial liability in anesthesia practice (8). Furthermore, laryngeal function is depressed after LMA use (9). So, the anesthetist should always be ready to perform advanced airway management such as intubation before removing the LMA (10).

Up to date, the optimal or appropriate time to remove LMA is not known exactly. Nevertheless, it can be removed either when the patient awakens or deeply anesthetized. However, there is no objective evidence to choose one over the other. These two ways of LMA removal have been studied by various investigators but with conflicting results and conclusions. The designer of the LMA, Brain, and some investigators suggest that LMA should be removed when a patient's protective airway reflexes returned or after the patient regained consciousness (3,11,12). In spite of these, some researchers concluded LMA is better removed when a patient is deeply anesthetized (13-17). There are also investigators who found that LMA removal either in awake or anesthetized state has similar respiratory adverse effects. And they stated neither of them is superior (18-21). The evidences provided by earlier studies are controversial to show the superiority of either condition of LMA removal (22).

Therefore, in order to find the optimal time to remove the LMA, it is better to compare the airway related adverse events after removal of LMA when the patient is fully awake or deeply anesthetized. This study measured the incidence of laryngospasm, breath holding, coughing, desaturation ($SpO2 < 95\%$), upper airway obstruction, LMA biting, excessive salivation, vomiting, and retching following LMA removal.

3. Significance of the Study

Laryngeal mask airway (LMA) is a mainstay for difficult airway management in addition to providing patent airway. In Ethiopia, its clinical use has been advocated in conferences, and trainings by governmental and nongovernmental health organization. As the result, LMA is becoming a choice of airway device for the country's anesthetists to secure airway particularly in pediatric patient. For example, pediatric ophthalmic procedures are almost always performed under LMA at Menelik-II hospital.

Though its applicability is increasing, the device has basically some unanswered issues. No known optimal time to remove the device out of the patient's airway is one of them. Many anesthetists routinely remove the LMA when patients awake whereas there are others who prefer to remove it when patients are under anesthesia. However, both are doing it based on their preferences. This arbitrary decision is due to absence of objective evidence to rely on. These two choice of LMA removal conditions remain a debating issue among anesthetists. Some anesthetists even adhered only to one condition and neglect the other. Furthermore, there is no clear understanding of the untoward events that follows the removal of LMA among the anesthetists. So, we found conducting the study on the issue was important to clear the cloud judgment of anesthetists in using the device, and to make the anesthetic practice evidence based.

By comparing awake LMA removal with deep removal, the study investigated what these two conditions of LMA removal did to patients, particularly to the patient's airway. It presented each condition's (awake versus deep) airway related adverse events. Hence, the study can serve as a reliable evidence to choose one condition over the other. As far as the author knowledge goes, no similar study was done here in Ethiopia. So, this study can also serve as a baseline information for future valuable researches that will undergone on the subject of interest.

4. Literature Review

The state in which a patient has to be during removal of the LMA is not clear. There are two states at the time of the removal. If the LMA is removed after the patient's natural airway protective reflexes returned or when the patient regains his/her consciousness, it is referred to as awake state, and the removal is called awake removal of LMA. If it is removed when the patient is deeply anesthetized or when he/she is receiving anesthetics, it is referred to as deep or anesthetized state, and the removal is called deep removal. Though they were conflicting, studies were conducted to find the optimal state for LMA removal by making a comparison between the awake and deep removal of the LMA. (11-21)

Gataure et al. compared the incidence of complications such as coughing, biting, retching, vomiting, excessive salivation, airway obstruction and regurgitation in adult patients. Though none of the participants had any evidence of aspiration, the incidence of complications were higher in the awake group than in the anaesthetized group. They concluded that removing LMA in deeply anesthetized patient is safer than in awakened patient. (13)

Kitching et al. studied about the removal of LMA in 59 boys and one girl aged 12 months to 8 years who had urogenital or lower limb plastic surgery. They compared airway complications (laryngospasm, coughing, desaturation, and airway obstruction) which were recorded for 60 minutes after LMA removal. This randomized, prospective, single blinded study only found one significant complication which is coughing. The incidence of coughing was increased in awake group than deep group. Kitching et al advocated the removal of LMA when patients are in deep anesthesia. (14)

Lee et al. found significantly reduced postoperative emergence agitation in a group in which LMA was used and removed deeply compared to a group where endotracheal tube was used and extubated in awake state. (23)

Park et al. conducted a randomized controlled trial comparing laryngeal mask airway removal during adequate anesthesia and after awakening in children aged 2 to 6 years. They found that the frequency of airway-related complications including cough, desaturation, excessive secretion, and LMA biting were significantly less in the anesthesia group than the awake group. (17)

Lee et al. compared the incidence of respiratory adverse events (upper airway obstruction, cough, vomiting, teeth clenching, hypersalivation, desaturation < 90%, and laryngospasm) after the removal of laryngeal tube, either under anaesthesia or on awakening. They followed seventy children (aged 1-12 years) for maximum of one minute after removal of the tube. Their study showed a significant lower incidence of airway complications in anesthetized state of laryngeal tube removal. (16)

Yoo et al. found remifentanil target controlled infusion (TCI) at an established effect-site concentration is a reliable technique for achieving safe removal of LMA without delayed awakening, and without coughing, laryngospasm, or other airway reflexes. (24) In randomized controlled trial, Huang et al. found higher incidence of adverse airway events in awake removal of LMA than deep removal. The investigators concluded deep removal of LMA under TCI with a propofol concentration of 2.0μg/mL is better than awake removal. (15)

Nunez et al. studied complications associated with removal of laryngeal mask airway between anesthetized and awake states of patients. Their study group were 18 to 80 years old and scheduled for urologic, orthopedic or minor breast surgery. After they randomly allocated the patient into the two groups, they compared the complications such as laryngospasm, airway obstruction, desaturation, and regurgitation. According to their findings, the incidence of complications during or after removal of LMA was significantly greater in anesthetized group than awake group. When they concluded, they stated that the LMA can be safely left in place until the patient has regained consciousness after emergence from anesthesia. (11)

Dolling et al. made a comparison between deep versus awake removal of the laryngeal mask airway in pediatric dental day case surgery. In their randomized controlled trial study, they used 2 to 15 years old patients. Their primary comparative parameter was the patients' peripheral arterial oxygen saturations during recovery phase. They found statistically significant dropping of peripheral oxygen saturation (SpO2) in deep group. They also observed secondary outcomes such as coughing, laryngospasm, retching and vomiting. However, only coughing was statistically significant, and it was more frequent in the deep group than awake group. Having these, Dolling et al. concluded that LMA should be taken out when patients are awaken. (12)

Splinter et al. studied airway problems occurring within 15 minutes after awake and deep removal of LMA in children who were 1.5 to 15 years old. The problems included were airway obstruction

(laryngeal spasm and biting of the LMA), peripheral hemoglobin oxygen saturation less than 90%, and strider requiring manipulation of the airway, vomiting, retching, and excessive salivation. They found similar incidence of airway problems in both awake and deep removal of LMA. (18)

Samarkandi compared the incidence of complications such as laryngeal spasm, bronchospasm, coughing, retching, excessive salivation and oxygen desaturation in two groups of pediatric patients (2 months to 13 years) who had lower limb or perineal surgery. However, this randomized prospective study found no difference in the incidence of airway complications whether the LMA was removed in the anaesthetized or in the awake children. (19)

Pappas et al. studied the influence of anesthetic depth and choice of volatile anesthetic drug on the incidence and severity of airway hyperreactivity associated with laryngeal mask airway in children aged 4 months to 7 years. They measured severity of airway hyperreactivity and adverse airway events associated with LMA removal. They found trying to remove LMA in awaken patient during isoflurane anesthesia results in a higher incidence of adverse airway events and carries the risk of severe airway hyperreactivity. They also stated that depth of anesthesia during LMA removal does not appear to affect the incidence or severity of airway hyperreactivity when sevoflurane is the maintenance anesthetic. (20)

Heidari et al. studied the influence of depth of anesthesia (awake or deep anesthesia) and choice of anesthetic drug (halothane or propofol) on the incidence and severity of airway hyperreactivity associated with LMA removal. They found significant differences only in cough and straining, breath holding, and vomiting. Their incidence were highest in group with halothane maintenance anesthesia and in which awake LMA removal occur, and lowest in group with propofol anesthesia maintenance, and in which deep LMA removal takes place. Finally, Heidari et al. recommend use of propofol for maintenance of anesthesia in procedures that airway device is LMA. (21)

Mathew et al. did a systematic review on deep versus awake removal of LMA for general anaesthesia. They primarily measured the outcome of laryngospasm, coughing, desaturation, and airway obstruction. In the review, they found no evidence that demonstrate the superiority of deep over awake or vice versa. (22)

Neither awake nor deep removal of LMA are perfect. There are investigators who got the designer of the LMA, Brain, suggestion is right and advocated awake removal. On the other hand, other

researchers found awake removal with higher incidence of airway related complications and concluded deep removal is better. Additionally, some researchers found no difference of airway related adverse events, and concluded both can be used equally. Taken as whole, it appears that it is not clear whether in awake or deep (anesthetized) state should LMA be removed.

5. Conceptual Framework

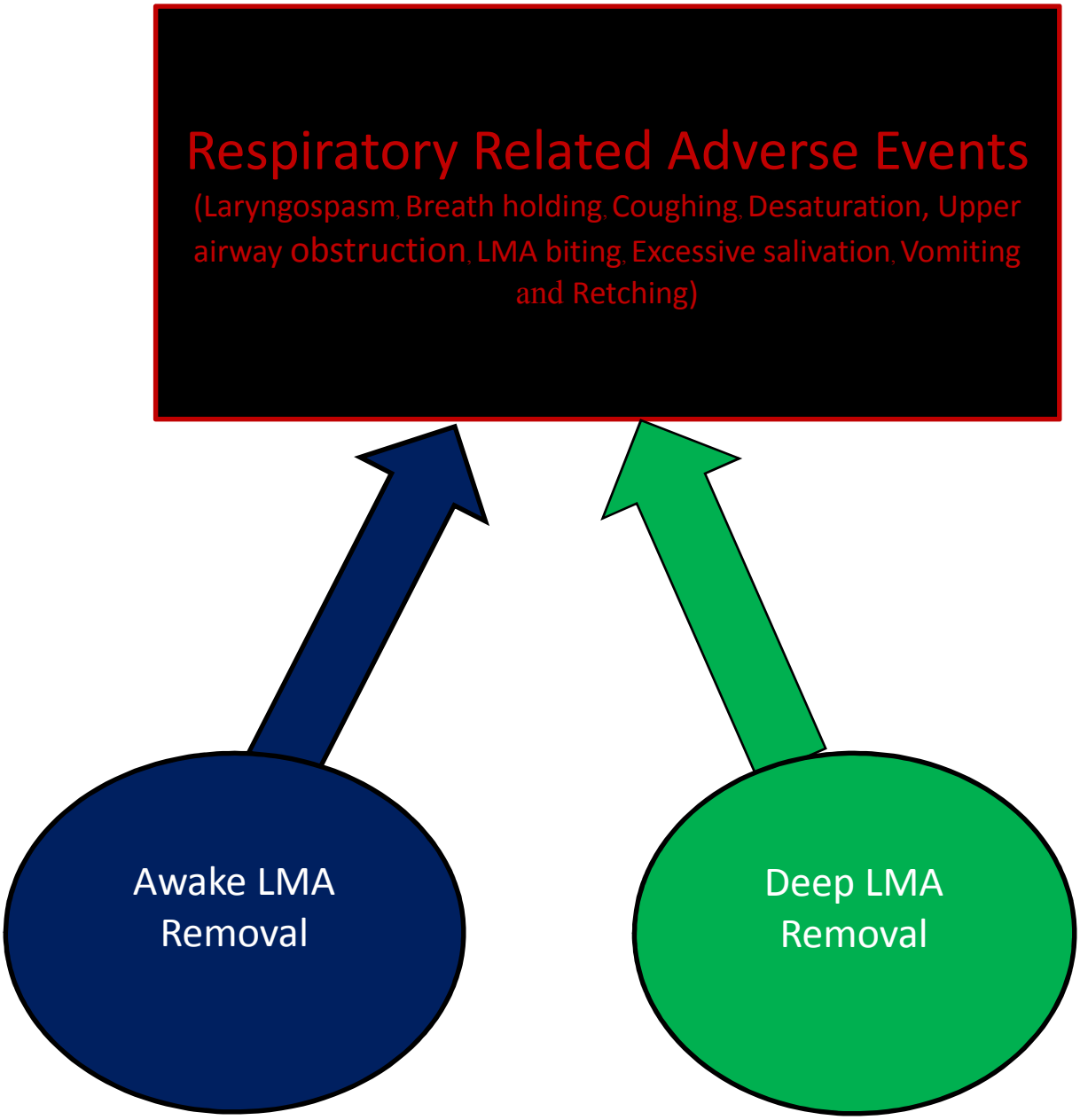

Figure 1. Conceptual frame work of the study

6. Objectives

6.1. General objective

The general objective of the study was to compare awake removal of laryngeal mask airway with deep removal regarding to airway related adverse events.

6.2. Specific objectives

- To assess the incidence of airway related adverse events in awake removal of laryngeal mask airway
- To assess the incidence of airway related adverse events in deep removal of laryngeal mask airway

7. Methodology

7.1. Study Area

The study was conducted at Menelik-II Hospital. The hospital is one of largest hospital in Ethiopia. It is now the main health provider center that offers high quality comprehensive health services to patient from all over the region of the country with affordable cost. The hospital is well known by ophthalmic surgery. There are six operation tables in the ophthalmic operation department. One of the table is reserved for pediatric ophthalmic procedure.

7.2. Study Design and Period

A prospective observational cohort study was conducted from January 15 to April 05/ 2018.

7.3. Population

7.3.1. Source Population

All pediatric patients who underwent ophthalmic surgery under LMA at Menelik-II hospital.

7.3.2. Study Population

All pediatric patients scheduled for ophthalmic surgery at Menelik-II hospital from January 15 to April 05/ 2018.

7.4. Eligibility Criteria

7.4.1. Inclusion Criteria

All pediatrics, American Society of Anesthesiologists physical status (ASA PS) I and II, aged 2 to 8 years, underwent ophthalmic surgery under LMA with halothane as maintenance anesthesia.

7.4.2. Exclusion Criteria

- Children who had:
  - airway disease such as asthma
  - airway surgery

- a history of upper respiratory tract infection in the 2 weeks preceding surgery
- an anticipated difficult airway
- more than three attempts of LMA insertion
- taken drugs that affects the airway during anesthesia such as opioids, and local anesthetics

7.5. Sample Size and Sampling Techniques

7.5.1. Sample Size

Sample size for the study was calculated using double population proportion formula for comparison of two proportions based on the following assumptions: significance level 5% (α= 0.05), power of study (1 – β) of 90%. According to a study published in 2012, and conducted at Yonsei University College of Medicine, Seoul, Korea, on children aged 2 to 6 years, the incidence of airway related adverse events in awake and deep removal were 37.2% and 4.8% respectively (21). Taking 37.2% as P1 and 4.8% as P2, the calculation of sample size became:

$$n \text{ (in each group)} = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \times ((p_1q_1) + (p_2q_2))}{(p_1 - p_2)^2}$$

$$n = \frac{(1.96 + 10.4976)^2 \times ((0.372 \times 0.628) + (0.048 \times 0.952))}{(0.372 - 0.048)^2}$$

$$n = 28$$

Adding 10 % for accidental withdrawal from the study, n became 31.

So, total sample size become 31 x 2 = 62

7.5.2. Sampling Technique

The study participants were selected using systematic random sampling technique from daily operation schedule list until the required sample size was obtained.

From situational analysis, the size of population in three months was 165. Every 3rd (165/62= 2.7) scheduled patient was selected as a study unit. The first sample was selected by lottery method from scheduled patients listed on display board in the first day of the study period.

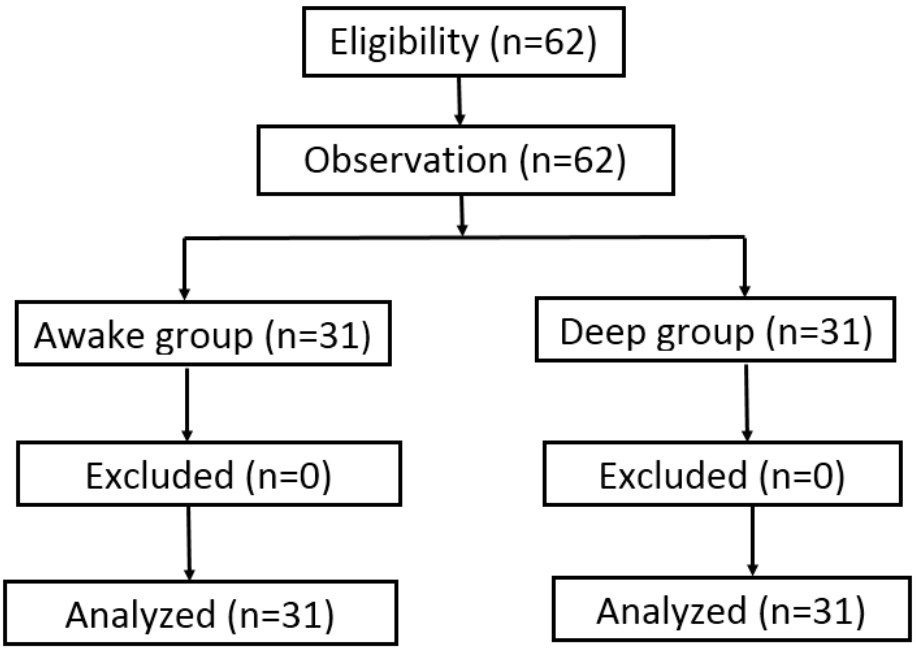

Figure 2. Flow diagram showing patient flow according to the study protocol.

7.6. Methods of Data Collection

7.6.1. Data Collection Tool

A pretested questioner were prepared to collect demographic data, and perioperative anesthetic management. The observed airway related adverse events were recorded on checklist developed for this purpose.

An aeonmed pulseoxymetry with finger probe was used to record arterial oxygen saturation after the removal of LMA.

7.6.2. Data Collection Procedure

A trained two BSc. anesthetists were assigned for data collection process. The data collectors were supervised by the investigator.

The data collectors were observing the following routine perioperative anesthetic management of Menelik-II hospital anesthetists. Preoperatively, the anesthetists starved the patients by forbidding eating solid or semisolid food by mouth after mid night till the day of surgery.

The hospital anesthetists always applied the common standard monitoring such as pulseoximeter, electrocardiograph, and noninvasive blood pressure monitoring in all patients before anesthetizing them. After premedicating the children with atropine (0.02mg/kg I.V), they induced them with ketofol (mixture of 0.5mg/kg of ketamine plus 3.0mg/kg of propofol). The hospital anesthetists chose the appropriate LMA size based on the patient weight. They did not use any muscle relaxant for the insertion of the LMA, and let patients to breathe spontaneously throughout the procedure. They maintained anesthesia with appropriate concentration of oxygen, and inhalants (either halothane or isoflurane). The anesthetists also provided the patients with corticosteroid (dexamethasone or hydrocortisone) when clinically indicated. However, the data collectors observed only those under halothane anesthesia, and not provided with corticosteroids.

At the end of surgery, the hospital anesthetists, after suctioning, removed the LMA when the patients were either in awake or deep condition based on their preferences. In awake condition, they closed the halothane, and administered 100% oxygen. Then, they waited the patients to satisfy the criteria for being awake: adequate ventilation (symmetric chest expansion without retraction or tidal volume > 6 ml/kg on the monitor), facial grimace, spontaneous eye opening, purposeful movement of the extremities without any physical stimulation, and responding to verbal commands in older patients. When the patients met the criteria, they removed the LMA. In deep condition, they first maintained the anesthesia with halothane 1%. Once adequate spontaneous ventilation was assured, they removed the LMA while the patient was deeply anesthetized. In both conditions, they removed the LMA with the cuff remained inflated. After the removal, they immediately administer 100% O2 via a facemask.

A close observation, by assigned data collectors, was started at the time of halothane discontinuation, and continued until the children were fully awake or up until 30 minutes after anesthetic discontinuation. In the observation, the data collectors were identifying airway related adverse events (laryngospasm, breath holding, coughing, desaturation (Spo2 < 95%), upper airway obstruction, LMA biting, excessive salivation, vomiting, and retching). These study variables were recorded at 5 minute intervals. They observed 31 patients in whom the LMA removed in awake condition, and other 31 patients in whom the LMA removed in deep condition.

7.7. Variables

7.7.1. Dependent Variables

- Airway related adverse events

7.7.2. Independent Variables

- Age
- Sex
- Weight
- Awake removal of LMA
- Deep removal of LMA

7.8. Data Quality Assurance

To assure the quality of the data, data collectors were trained, and the investigator made a regular supervision and follow up. In addition, regular checkup for completeness and consistency of the data was made on daily basis. Once the data was collected and checked for completeness, consistency and accuracy, it was sorted, categorized and summarized.

7.9. Operational Definitions

ASA PS I - A normal healthy patient

ASA PS II - A patient with mild systemic disease

ASA PS III – A patient with a severe systemic disease that limits activity

ASA PS IV - A patient with an incapacitating disease that is a constant threat to life

Awake removal of LMA- removal of LMA after discontinuation of halothane but when patient satisfy the criteria for being awake; adequate ventilation (symmetric chest expansion without retraction or tidal volume > 6 ml/kg on the monitor), facial grimace, spontaneous eye opening, purposeful movement of the extremities without any physical stimulation, and responding to verbal commands in older children.

Breathe holding – cessation of breathing longer than 5 sec

Coughing - to expel air from the lungs suddenly with a harsh noise, often involuntarily.

Deep removal of LMA- immediate removal of LMA after discontinuation of halothane but after 5 or more minutes of maintenance of anesthesia with 1% halothane and assuring adequate ventilation.

Desaturation - A peripheral oxygen saturation reading below 95% with 100% O_2 administration via facemask.

Excessive salivation – salivation requires suctioning after LMA removal

Laryngospasm- A closure of the larynx that blocks the passage of air into the lungs and which necessitates intervention such as positive pressure of ventilation or propofol or suxamethonium injection.

LMA biting – strong bite of LMA during recovery from general anesthesia

Retching - a strong involuntary effort to vomit.

Upper airway obstruction - an obstruction to air entry that can be relieved by jaw thrust or chin lift maneuver or that require the use of guedel airway.

Vomiting - the ejection of matter from the stomach in retrograde fashion through the esophagus and mouth.

7.10. Data Processing and Analysis

The collected data were entered into epi info version 7, and exported to Statistical Package for the Social Sciences (SPSS) version 20 computer program for analysis. Descriptive statistics were used to summarize data, tables and figures to display results.

Patient characteristics were analyzed using independent t test and Chi-square test, where appropriate. The airway related adverse events such as breath holding, coughing, and LMA biting were analyzed using Fisher's exact test as there were more than one cell with expected count less than 5, while upper airway obstruction, excessive salivation, and desaturation were analyzed using Chi-square test.

P value less than 0.05 ($p < 0.05$) was considered as significant.

7.11. Ethical Considerations

Ethical clearance and approval was obtained from the ethical review committee, anesthesia department, Addis Ababa University.

Permission was obtained from Menelik-II hospital to conduct the research. The study was undertaken on the basis of the parent's wish by obtaining informed oral consent. There was no coercion, and or no incentives to be involved in the study. At last, the confidentiality of information obtained was secured or assured.

7.12. Dissemination plan

The result will be presented for the fulfillment of master degree in science of anesthesia. It will be submitted to anesthesia department in soft and hard copy. It will also be given to Menelik-II hospital, and presented in conferences. Finally, it will be published on journals, and on the official website of Addis Ababa university.

8. Results

8.1. Socio-demographic Characteristics

Patients' characteristics of age, sex, weight, and anesthesia duration were comparable in both groups, as shown in **Table 1**. The induction technique was similar between the groups. Forty five LMA size # 2.0 (23 in awake, and 22 in deep group), and 17 LMA size # 2.5 (8 in awake, and 9 in deep group) were used in both group. The LMA was correctly inserted at the first attempt in 57 patients, at the second attempt in 4 and in one patients at the third attempt.

Table 1. Patient characteristics of the pediatric patients at Menelik-II Hospital, Addis Ababa, Ethiopia, from January 15-April 05/2018.

	Awake Group (n=31)	**Deep Group (n= 31)**	**P Value**
Age (yrs)	4.9 ± 1.7	4.7 ± 1.8	0.660
Gender (M/F)	19/12	22/9	0.421
Weight (kg)	20.5 ± 5.8	18.8 ± 5.9	0.346
Anesthesia duration (min)	34.6 ± 20.0	38.1 ± 13.8	0.434

Values are means ± standard deviation (SD) except for gender (n). Variables analyzed by independent t-test, chi-square. Awake group, removal of LMA in awake condition; Deep group, removal of LMA in deep condition.

8.2. Airway Related Adverse Events

The number of patients with airway related adverse events in each group is shown in **Table 2**. The adverse events associated with LMA removal were totally noted in 37 patients. Airway related adverse events occurred in 22 patients in whom the LMA were removed in awake condition, while 15 patients in whom the LMA were removed in deep condition. However, there is no significance difference in the incidence of airway complications between the groups ($p > 0.05$). Laryngospasm, vomiting, and retching did not occur in either group. The percent incidence of the adverse events is also depicted by **Figure 3**.

Table 2. Number of patients with airway related adverse events at Menelik-II Hospital, Addis Ababa, Ethiopia, from January 15-April 05/2018.

	Awake group	Deep group	P Value
Upper airway obstruction	13	11	0.602
Coughing	4	2	0.671
Laryngospasm	0	0	-
Breath holding	3	1	0.612
Excessive Salivation	6	4	0.490
LMA biting	2	0	0.492
Desaturation	5	7	0.520
Vomiting	0	0	-
Retching	0	0	-

Data are numbers. Awake group, removal of LMA in awake condition; Deep group, removal of LMA in deep condition. Variables analyzed by chi-square, fisher's exact test

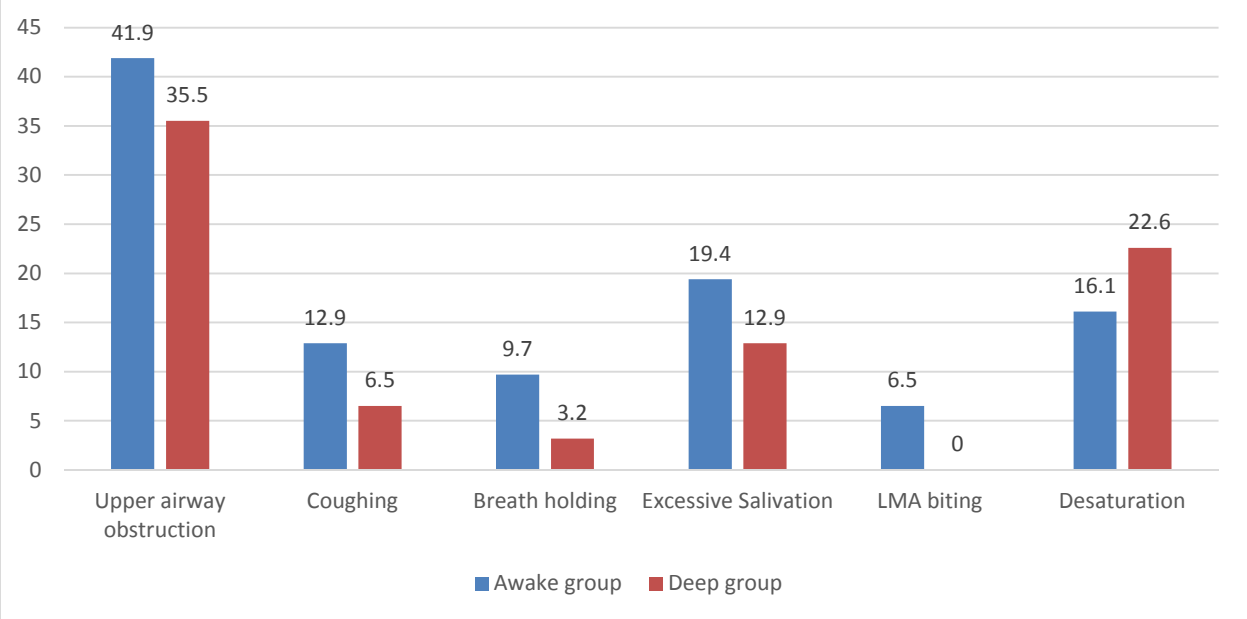

Figure 3. Percent incidence of airway related adverse events following removal of laryngeal mask airway in awake and deep condition at Menelik-II Hospital, Addis Ababa, Ethiopia, from January 15-April 05/2018.

9. Discussion

In the presented study, we found no statistically significant difference in the incidence of airway related adverse events between awake and deep removal of LMA ($p > 0.05$). The incidence of complications on removal of the LMA in this study was 71% in the awake group and 48.4% in the deep group. This high incidence of complications could be attributed to the involvement of many anesthetists with different year of experience. A serious complication, breath holding, occurred not frequently. In the study, four patients in both groups with this complication developed desaturation ($SPO_2 < 90\%$). They were managed by applying jaw thrust, and administering manual positive pressure ventilation with 100% oxygen. The most common adverse event noted in the study was upper airway obstruction (41.9% vs 35.5%) were managed by applying jaw thrust or inserting oral airway. LMA biting was the least occurred event. It occurred only in two patients (both were from awake group).

Several studies have been conducted to examine the incidence of airway related adverse events between awake versus deep removal of LMA. Similar to our findings, there are studies did not found statistical difference between awake and deep group (14, 18-21). In accordance to our study, Splinter et al. found no statistically significant difference in the incidence of airway complications (desaturation, breath holding, and excessive salivation) between the awake and deep group. (18) Similarly, in the study of children who underwent lower limb or perineal surgery, Samarkandi found no statistically significant difference in the incidence of airway complications (desaturation, vomiting and retching, coughing, and excessive salivation) between deep and awake group (19).

In consistence with our study, Kitching et al. found no difference in incidence of desaturation, and excessive salivation ($p > 0.05$). However, they reported coughing was significantly higher in awake group. In the study of 60 children (aged 1-8 year), Kitching et al. noted coughing occurred in seventeen (51.5%) children of awake group, whereas two (7.4%) of deep group. This was not similar to our results of incidence of coughing (12.9% versus 6.5%). The higher incidence of coughing in their study may be attributed to removal of the LMA when the child began to swallow and this represents an inadequate or "light" depth of anaesthesia. Furthermore, Kitching et al. administered morphine. This may produce bias and reduced the incidence of coughing in deep

group because of morphine effect on the upper airway reflex. (14) These drug was not administered to the participants in our study.

There are studies reported removal of LMA in deep condition better than in awake condition (13, 15-17). In the study of 70 children (aged 1 - 12 year), Lee et al. noted a significant higher incidence of cough (37.1% vs 2.9%), hypersalivation (28.6% vs 5.7%), and desaturation (20% vs 0%) in awake group compared to deep group (16). In our study, the incidence of excessive salivation in awake group (19.4%) was lower compared to Lee et al. This may be since the children in our study were premedicated with atropine. Similarly, we found lower incidence of coughing (12.9%) in awake group compared to Lee et al. They found the higher incidence of coughing since they classified several patients who faced accidental dislodgement, who did not satisfying all of the awake criteria, into the awake group. The coughing event may also be attributed to their finding of higher incidence of desaturation in awake group compared to our result (16.4%). However, in consistence with our findings, Lee et al. found no statistical difference in LMA biting between the groups. Similar to our findings, a randomized controlled trial conducted by Park et al. found no difference between awake and deep group regarding to upper airway obstruction, and breath holding incidence. However, they noted more patients with coughing, desaturation, excessive secretion, and LMA biting ($p < 0.05$) in awake group. (17)

Studies have also denoted removal of LMA in awake condition better than in deep condition (11,12). Not in line with our findings, Dolling et al. showed the removal of LMA in awake condition to be associated with a significant lesser airway complications (coughing, and desaturation) than in deep condition. However, they conducted their study in dental surgery, and this would irritated the upper airway or increased secretions, and attributed to the difference observed between the groups (12). Incomparably, Nunez et al. found higher incidence of airway complications in deep group compared to awake group ($p < 0.05$). However, in the study of 60 patients, Nunez et al. did not consider, coughing as complication instead they considered it as a sign of return of physiological response (11). However, coughing increases oxygen demand and inhibits the inability to take an adequate tidal breath, leading to desaturation, especially in younger children (25). Our result showed there was difference in coughing incidence between awake versus deep group (12.9% vs 6.5%) though the difference did not reach statistical significance ($p > 0.05$).

The strength of the study is the study participants were homogenous between the two groups. There are some limitations in this study. Since the study was observational, the anesthetists removed the LMA were not fixed. This was because one anesthetist scheduled only one day in a week at ophthalmology operating room. So, anesthetists with different year of experience were involved. It is obvious experience of anesthetist matter despite the anesthetic management is similar. The other limitation was observer bias. Since the condition of LMA removal (awake versus deep) could be clearly distinguished from one another, the observer could not be blinded to group allocation. Therefore, further large scale randomized controlled trial is needed.

10. Conclusion

In conclusion, the study showed the difference of incidence of airway related adverse events between awake and deep removal of LMA did not reach statistical significance in pediatric patients.

11. Recommendation

We would like to recommend anesthetists to adopt deep removal of LMA over awake removal as the higher incidence of airway related adverse events observed in the awake group of the study is practically significant.

11. References

1. Carin Hagberg, Carlos Artime. Airway Management in the Adult. In: Ronald Miller, Neal Cohen, Lars Eriksson et al, 8th ed. Miller's Anesthesia. Philadelphia: Elsevier Saunders, 2015: 1647-1683.
2. Van Zundert TC, Brimacombe JR, Ferson DZ, Bacon DR, Wilkinson DJ. Archie Brain: celebrating 30 years of development in laryngeal mask airways. Anaesthesia. 2012 Dec 1;67(12):1375-85.
3. BRAIN A. The laryngeal mask—a new concept in airway management. BJA: British Journal of Anaesthesia. 1983 Aug 1; 55(8):801-6.
4. Lopez-Gil M, Brimacombe J, Alvarez M. Safety and efficacy of the laryngeal mask airway A prospective survey of 1400 children. Anaesthesia. 1996 Oct 1; 51(10):969-72.
5. Asai T, Koga K, Vaughan RS. Respiratory complications associated with tracheal intubation and extubation. British Journal of Anaesthesia. 1998 Jun 1; 80(6):767-75.
6. Michalek P, Donaldson W, Vobrubova E, Hakl M. Complications associated with the use of supraglottic airway devices in perioperative medicine. BioMed research international. 2015 Dec 13; 2015.
7. Venugopal A, Jacob RM, Koshy RC. A randomized control study comparing the pharyngolaryngeal morbidity of laryngeal mask airway versus endotracheal tube. Anesthesia, essays and researches. 2016 May; 10(2):189.
8. Caplan RA, Posner KL, Ward RJ, Cheney FW. Adverse respiratory events in anesthesia: a closed claims analysis. Anesthesiology. 1990 May; 72(5):828-33.
9. Tanaka A, Isono S, Ishikawa T, Nishino T: Laryngeal reflex before and after placement of airway interventions: Endotracheal tube and laryngeal mask airway. *Anesthesiology*. 2005 Jan; 102(1):20-25.
10. John Henderson. Airway Management in the adult. In: Ronald Miller, Lars Eriksson, Lee Fleisher et al, eds. 7th. Miller's Anesthesia. Philadelphia: Elsevier Saunders, 2015.
11. Nunez J, Hughes J, Wareham K, Asai T. Timing of removal of the laryngeal mask airway. Anaesthesia. 1998 Feb 1; 53(2):126-30.
12. Dolling S, Anders NR, Rolfe SE. A comparison of deep vs. awake removal of the laryngeal mask airway in paediatric dental daycase surgery. A randomised controlled trial. Anaesthesia. 2003 Dec 1; 58(12):1224-8.

13. Gataure PS, Latto IP, Rust S. Complications associated with removal of the laryngeal mask airway: a comparison of removal in deeply anaesthetised versus awake patients. Canadian Journal of Anesthesia/Journal canadien d'anesthésie. 1995 Dec 1; 42(12):1113-6.
14. Kitching AJ, Walpole AR, Blogg CE. Removal of the laryngeal mask airway in children: anaesthetized compared with awake. British journal of anaesthesia. 1996 Jun 1; 76(6):874-6.
15. Huang RC, Hung NK, Lu CH, Wu ZF. Removal of Laryngeal Mask Airway in Adults Under Target-Controlled, Propofol–Fentanyl Infusion Anesthesia: Awake or Deep Anesthesia?. Medicine. 2016 Apr; 95(17).
16. Lee J, Kim J, Kim S, Kim C, Yoon T, Kim H. Removal of the laryngeal tube in children: anaesthetized compared with awake. British journal of anaesthesia. 2007 Apr 7;98(6):802-5.
17. Park JS, Kim KJ, Oh JT, Choi EK, Lee JR. A randomized controlled trial comparing Laryngeal Mask Airway removal during adequate anesthesia and after awakening in children aged 2 to 6 years. Journal of clinical anesthesia. 2012 Nov 30;24(7):537-41.
18. Splinter WM, Reid CW. Removal of the laryngeal mask airway in children: deep anesthesia versus awake. Journal of clinical anesthesia. 1997 Feb 1; 9(1):4-7.
19. Samarkandi AH. Awake removal of the laryngeal mask airway is safe in paediatric patients. Canadian Journal of Anesthesia/Journal canadien d'anesthésie. 1998 Feb 1; 45(2):150-2.
20. Pappas AL, Sukhani R, Lurie J, Pawlowski J, Sawicki K, Corsino A. Severity of airway hyperreactivity associated with laryngeal mask airway removal: correlation with volatile anesthetic choice and depth of anesthesia. Journal of clinical anesthesia. 2001 Nov 30; 13(7):498-503.
21. Heidari SM, Abbasi S, Rahimi M. Removal of Laryngeal Mask Airway: Awake or deep anesthesia?. Journal of Research in Medical Sciences. 2005; 10(2):59–62.
22. Mathew PJ, Mathew JL. Early versus late removal of the laryngeal mask airway (LMA) for general anesthesia. Cochrane Database Systemic Review. 2015; 8:CD007082.
23. Lee YC, Kim JM, Ko HB, Lee SR. Use of laryngeal mask airway and its removal in a deeply anaesthetized state reduces emergence agitation after sevoflurane anaesthesia in children. Journal of International Medical Research. 2011 Dec; 39(6):2385-92.

24. Yoo JY, Kwak HJ, Lee KC, Kim GW, Kim JY. Predicted EC50 and EC95 of remifentanil for smooth removal of a laryngeal mask airway under propofol anesthesia. Yonsei medical journal. 2015 Jul 1; 56(4):1128-33.
25. Patel B, Bingham R. Laryngeal mask airway and other supraglottic airway devices in paediatric practice. Continuing Education in Anaesthesia, Critical Care & Pain. 2009 Feb 1;9(1):6-9.

12. Annexes

12.1. Annex I: English Version Oral Consent

Hello my name is_____. I am master's student in anesthesia from Addis Ababa University. We are doing study on the airway device called laryngeal mask airway (LMA). I am going to give you information and invite your child to be part of this research. You do not have to decide today whether or not your child will be involved in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain.

LMA is an ordinary device that is used to open airway. It is inserted into a patient's airway after he/she took anesthesia. It provides as a channel through which the patient breaths oxygen and inhalational anesthetics. The optimal time to remove it once the surgery finished is not clearly known. Thought they are usually managed at ease, its removal is also associated with unwanted airway related events. Anesthesia provider remove it when the patient regain his consciousness or he/she is still under anesthesia. There is no good evidence that show which removal is better. The reason we are doing this study is to know which condition of LMA removal is superior by comparing the unwanted airway related adverse events.

The hospital anesthetists will insert the LMA into your child's airway as usual, and provide the regular management. At the end of surgery, they will remove the LMA when your child regain consciousness or when he/she is unconscious with anesthesia. This is the regular management of the hospital. We will not do anything other than observing, and recording airway related adverse events that follow the LMA removal.

Your child's involvement in the study will be voluntary, and you may decide to withdraw him/her from the study at any time without any penalty. The study will be conducted with the approval of Addis Ababa University ethical committee.

Your child identity will be protected with utmost confidentiality during the study. Now I would like to ask you if you agree to let your child involved in this study. Do you agree?

12.2. Annex II: Amharic Version Oral Consent

ጤና ይስጥልኝ ……እባላለው፡፡ በአዲስ አበባ ዩኒቨሪስቲ የሁለተኛ ድግር የአንስቴዝያ ተማሪ ነኝ፡፡ “laryngeal mask airway (LMA)” በሚባል የአየር ቱቦ መክፈቻ ላይ ጥናት እያደረኩ ነው፡፡ አሁን በምነግሮት መረጃ መሰረት ልጆ በጥናቱ አንዲካተት እጋብዛለው፡፡ፍቃደኝነቶን ዛሬ ማሳወቅ አይጠበቅቦትም፡፡ ከመወሰኖ በፊት የፈለጉትን ሰው ስለጥናቱ መጠየቅ ይችላሉ፡፡ አሁን ስለጥናቱ ገለጻ በማደርግሎት ግዜ ያልገባዎት ነገር ካለ አሰቁመዉኝ መጠየቅ ይቸላሉ፡፡

“laryngeal mask airway (LMA)” የአየር ቱቦን ለመክፈት የሚያስፈልግ የተለመደ መሳሪያ ነው፡፡ በታካሚዎች የአየር ቱቦ ውስጥ በመማስገባት አክስጅንና የሚሳቡ የማደንዘዣ አይነቶች ወደሰውነት ውስጥ እንዲገቡ ይደረጋል፡፡ ሆኖም ግን ቀዶ ጥገናው ሲያልቅ መቼ መዉጣት እንዳለበት አይታወቅም፡፡ ምንምእንኳ በቀላሉ የሚቀረፉ ቢሆንም ይህ የአየር ቱቦ በሚወጣበት ግዜ የጎንዮሽ ጉዳትም ያደርሳል፡፡ የማደንዘዣ ባለሙያው ይህን ቱቦ የሚያወጣው ቀዶ ጥገናው እንዳለቀ ታካሚው ሲነቃ ወይም ደግሞ በማደንዘዣ ውስጥ እንዳለ (ሳይነቃ) ነው፡፡ ሆኖም ግን የትኛው እንደሚሻል የሚያሳይ አጥጋቢ ማስረጃ የለም፡፡ እኛም ይህን ጥናት የምናካሂድበት ምክንያት ቱቦው በሚወጣበት ግዜ የሚያደርሰውን ተያያዥ ጉዳት በማነፃፀር የትኛው እንደሚሻል ማሳየት ነው፡፡

የሆስፒታሉ አንስቴቲስቶች ለሁሉም ታካሚዎች እንደሚደርጉት ይህን ቱቦ የልጆት የአየር ቱቦ ውስጥ በማስገባት ለልጆ የሚያስፈልገውን ተገቢውን አገልግሎት ያደርጉለታል፡፡ ቀዶ ጥገናውም ሲያልቅ አንስቴቲስቶች ይህን ቱቦ የሚያወጡት ልጆት ከሰመመን ሲነቃ ወይም ሰመመን ውስጥ እንዳለ ይሆናል፡፡ ይህም የሆስፒታሉ አንስቴቲስቶች ለሁሉም ታካሚዎች የሚያደርጉት መደበኛ አገልግት ነው፡፡ የኛ ሚና ቱቦው በሚወጣበት ግዜ የሚያደርሰውን ተያያዥ ጉዳት መመልከትና መመዝገብ ብቻ ነው፡፡

ልጆት በጥናቱ ውስጥ የሚካተተው በእርሶ ፍቃደኝነት ሲሆን በማንኛውም ሰአት ልጆት በጥናቱ እንዳይካተት ማለት ይችላሉ፡፡ ይህን በማድረጎም የሚደርስቦት ቅጣት ሆነ ከልጆ የሚጓደልበት አገልግሎት አይኖርም፡፡ ይህ ጥናት የሚካሄደው ከአዲስ አበባ ዩኒቨሪስቲ የስነምግባር ኮሚቴ ይሁንታን አግኝቶ ነው፡፡

በጥናቱ ግዜ የልጆት ማንነት በሚስጥር ይያዛል፡፡ አሁን ልጆ በጥናቱ እንዲካተት ፍቃደኝነቶን ጠይቃለው፡፡ ፍቃደኛ ኖት?

12.3. Annex III: Questionnaire

Questionnaire prepared to collect demographic data, and perioperative anesthetic management information.

Date: _____

Demographic Data	
Age (Years)	
Weight (Kg)	
Sex (M/F)	
ASA	
Perioperative Anesthetic Management	
Premedication (drug type, dosage & route)	
Induction (drug type, dosage & route)	
Maintenance (drug type, dosage or MAC & route)	
Additional drugs given intraoperatively other than the maintenance (drug type, dosage & route)	
LMA Size	
Number of Attempts at LMA Insertion	
Associated Problems on LMA Insertion	
LMA Removal (awake or deep)	
Type of procedure	
Anesthesia start time	
Surgery start time	

Surgery end time	
Inhalational discontinued time	
Fully awake time	

12.4. Annex IV: Checklist

Checklist prepared to record the observed airway related adverse events.

Airway Related Adverse Events Following LMA Removal	**Put 'X' on the space provided only when the event occur with respect to the occurrence time (at 5 minute intervals)**					
	5 min	**10 min**	**15 min**	**20 min**	**25 min**	**30 min**
Laryngospasm						
Breath holding						
Coughing						
Jaw thrust/ chin lift applied						
Oral airway used						
LMA biting						
Suction after LMA removal						
Vomiting						
Retching						

Spo_2 After LMA Removal (one minute interval)	1st min	2nd min	3rd min	4th min	5th min	6th min	7thmin	8thmin	9th min	10thmin
	11thmin	12thmin	13thmin	14thmin	15thmin	16thmin	17thmin	18thmin	19thmin	20thmin
	21stmin	22ndmin	23rdmin	24thmin	25thmin	26thmin	27thmin	28thmin	29thmin	30thmin