ADDIS ABABA UNIVERSITY

COLLAGE OF HEALTH SCIENCE

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

The effectiveness of a subhypnotic dose of propofol in preventing laryngospasm following tonsillectomy and adenoidectomy in children: A prospective, cohort study

Investigators: BetelhemAyele (B.Sc.)

A research thesis submitted to be Addis Ababa university department of anesthesia as partial fulfillment of requirements for the master of sciences degree in Anesthesia.

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Full title of the research project	The effectiveness of a subhypnotic dose of propofol in preventing laryngospasm following tonsillectomy and adenoidectomy in children
Duration of project	December 2019- March 2020
Study area	Tikureanbessa, Yekatit 12 and Menelik II hospitals
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Declaration

The undersigned certify that the research entitled The effectiveness of a subhypnotic dose of propofol in preventing laryngospasm following tonsillectomy and adenoidectomy in children at Menelik II referral , Yekatit 12 and Tikur Anbssa hospital, Addis Ababa, Ethiopia, 2020: institutional based Prospective Cohort Study, is my original work in partial fulfillment of the requirement of master's science degree in anesthesia. i understand that plagiarism will not be tolerated and all directly quoted material has been appropriately referenced

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Abstract

Background : *Laryngospasm is defined as the sustained closure of the vocal cords, well-known problem typically occurring immediately following tracheal extubation. This blockage can lead to hypoxemia, negative-pressure pulmonary edema, pulmonary aspiration, and cardiac arrest. Incidence of laryngospasm is as high as 25% in patients undergoing tonsillectomy and adenoidectomy. Propofol is an intravenous drug use for the induction of general anesthesia and for moderate to deep sedation, which is also known to strongly suppress airway responses. At a lower concentration than the anesthetic dose, propofol may help to reduce or prevent laryngospasm after extubation in pediatric patients*

Objective: *To determine the effectiveness of propofol to prevent laryngospasm during adenoid and tonsillectomy cases under general anesthesia.*

Methods: *In this institutional based prospective cohort study 66 pediatric patients age up to 9 years were included. It was conducted from December 2019-March 2020 at Tikur Anbessa specialized hospital, Yekatit 12 hospital and Menilke hospital, pediatric patients who scheduled to undergo elective tonsillectomy with or without adenoidectomy under standard general anesthesia who fulfilled the inclusion criteria were included in the study. The data was recorded as group P if anesthesia providers gave suphypnotic dose of propofol(0.5mg/kg) one minute before extubation as well the data were recorded as group C if the anesthesia provider just extubate without giving propofol. Normality of the data was checked using Shapiro-Wilk test and analyzed using student t test for normal distributed data and chi-square test for categorical data. Non- parametric data was analyzed using Mann –Whitney U test with 95% CI and p- value less than 0.05 is considered as statistically significant.*

Result*: Comparison of data from Propfol group and Control group using chi square showed that occurrence of laryngospasm was significantly lower in P group then group C (9.1 Vs. 42.4) with p-value less than 0.05. With no significant difference in the severity of laryngospasm and vital sign changes between groups.*

Conclusions and Recommendation: *Subhypnotic dose of propofol (0.5 mgÆkg)1) decreases the occurrence of laryngospasm upon tracheal extubation in children undergoing tonsillectomy with or with out adenoidectomy. We recommend anesthetists to use 0.5mg/kg of propofol one minute before extubation to prevent postextubation laryngospasm. And we also recommend further randomized control trial in order to avoid bias.*

LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologist
AAU	Addis Ababa University
BP	Blood Pressure
BSC	Bachelor of Science
HR	Heart Rate
IV	Intravenous
IQR	Inter quartile range
MAP	Mean arterial pressure
PI	Principal Investigator
SD	Standard deviation
SPSS	Statistical package for social science
SPO2	Oxygen Saturation

Table of Contents

List of Tables

List of Figure

Chapter One

1. Introduction

1.1 Background

Respiratory events are one of the most common causes of mortality and morbidity during anesthetic-surgical procedures, especially in pediatric anesthesia due to greater tendency to develop collapse of the airways and the smaller residual functional capacity children are more susceptible to hypoxemia (1). In addition, children have a high vagal tonus and can rapidly change to laryngospasm and apnea after vagal stimulation due to irritation of receptors in the airways by tracheal intubation or secretion. Laryngospasm and Hypoxia represent approximately 30% of respiratory events during pediatric anesthesia, difficult intubation represents 13%, and bronchospasm 7% (2)

Laryngospasm is stated as the sustained closure of the vocal cords. It is a primitive protective airway reflex, which occurs to safeguard the integrity of the airway by protecting it from tracheobronchial aspiration. Laryngospasm is also stated as an exaggerated response of the closure reflex or glottic muscle spasm. Even though laryngospasm is essentially a protective reflex, the presence of this reflex results in an impairment to adequate breathing, under these conditions it becomes a sudden obstruction of upper airway. laryngospasm has a feature that the airway closure is maintained even after the initial causal stimulus disappears. (3)This blockage can lead to hypoxemia, pulmonary aspiration, negative-pressure pulmonary edema, and even cardiac arrest.(4)

Some surgical procedures are more suitable to trigger laryngospasm. Oral procedures who promote an increase in secretions with blood in the airways, like laryngeal surgery and tonsillectomy, are associated with a higher risk. Some studies have reported a 21% to 26% incidence of laryngospasm after adenoidectomy and tonsillectomy, Which are the most common surgical procedures performed in children.(2).

Tonsillectomy and adenoidectomy were developed hundreds of years ago, but they become widely popular in the beginning of the early 20th century. It is a surgical procedure to remove the

tonsils as a preventive treatment of Group A beta-hemolytic streptococcal (GABHS) pharyngotonsillitis and its feared complication - rheumatic heart disease.(5)

Approach of airways complications demand fast decisions, especially in children. Primarily giving attention on the duration of surgery, preoperative evaluation, and drugs available for immediate use may help. Since laryngospasm has severe and fatal consequences it demands prompt treatment when it is diagnosed, many investigators have concentrated their efforts on preventing this reflex. (6)

Propofol is an intravenous drug used for the induction of general anesthesia for moderate to deep sedation. (7) Propofol is known to strongly suppress airway responses at the anesthetic dose (8,9). It might help to prevent laryngospasm during extubation in pediatric patients (10) it depresses the laryngeal reflex, producing a low incidence of obstructive problems. (3)Using small dose of propofol may also help us to avoid, the side effects of propofol, including hypotension and bradicardia.

Treatment of perioperative laryngospasm should be initiated by the removal of the stimulus, including: administering CPAP with 100% O2, stopping the surgical procedure , deepening the plane of anesthesia , if it is caused by a painful stimulus, short-acting opioids should be administered; and we have to consider the use of succinylcholine if the stated measures so far not effective.(2) Succinylcholine, because of its rapid onset and short duration of action has long been a preferred pharmacologic agent for treating laryngospasm although its very effective at treating laryngospasm, but comes with potential serious side effects such as arrhythmia and bradycardia. (4)

But it known that prevention is better than treatment, we can prevent or decrease the incidence by using physical interventions to prevent laryngospasm following tonsillectomy and adenoidectomy including emphasizing hemostasis at the time of surgery, gentle suctioning of the oropharynx just before extubation to remove any retained blood and secretions, tracheal extubation in either a very deep plane of anesthesia.

1.2 Statement of problem

A tonsillectomy is a preventive treatment of Group A beta-hemolytic streptococcal (GABHS) pharyngotonsillitis and its feared complication - rheumatic heart disease by removing the tonsils.(5)While tonsillectomy and adenoidectomy have become much safer in the past fifty years, postoperative complications still exist but can be minimized by careful history-taking, good surgical technique and excellent attention to detail postoperatively.(5) One of the complication of tonsillectomy is laryngospasm , Gulhas N et al. has been reported in the literature in patients undergoing tonsillectomy and adenoidectomy the incidence of laryngospasm is as high as 25%. (11) Hobika et al. have also reported incidence of laryngospasm is 21% to 26% after adenoidectomy and tonsillectomy, which are the most common surgical procedures performed in children.(2)

Laryngospasm is a sustained closure of vocal cord which is characterized by severe hypoxia (61%), bradycardia (6%), obstructive pulmonary edema (4%), cardiac arrest (0.5), pulmonary aspiration (3%), arrhythmias and death. It is important to know that of the complications related to anesthesia, 43% are of respiratory origin. Laryngospasm is seen mainly in the child; the most frequent cause is upper airway manipulation. (3)

Different Preventive modalities like magnesium sulfate, lidocaine, intermediate muscle relaxants(3) have been attempted to reduce the incidence and severity of post-extubation laryngospasm but the efficacy of each is variable with their own side effect and some of the modalities are not available in our setup.

Recently, low-dose propofol which produce laryngeal reflex depression was shown to relieve laryngeal spasm in most children following tonsillectomy.(12)

1.3 Justification

The high incidence of laryngospasm despite the use of pharmacological and non-pharmacological methods suggests the need for multimodal prevention. Laryngospasm in tonsillectomy and especially in pediatrics patients is very common, these problems causes a prolonged hospital stay with additional drugs used to treat the consequences.

Thus research should focus on simple and rapid protocol that can be easily applied by anesthetist with low or moderate experience with minimal need to complex device or costly drugs. Propofol is mostly available drug in our setups because it's an inductional agent.

In spite of this there is still different view among researchers on the effectiveness of dose of propofol on postextubation laryngospasm in terms of the occurrence and hemodynamic changes.

There has been considerable research conducted on methods and drugs to prevent the incidence and severity of post-extubation laryngospasm during emergence but the efficacy of each is variable with their own side effect and some of the modalities are not available in our setup.

As far as our knowledge goes, there is no previous study done in our country Ethiopia to assess the efficacy of propofol in preventing laryngospasm in pediatric tonsilectomy, even though it has been studied in other countries.

Therefore conducting such a research which intends to find the effectiveness of subhypnotic dose of propofol in larynospasm will help:

Anesthesia professionals

- To provide Safe and effective alternative for laryngospasm prevention
- To clarify controversies and enhance evidence based practice.

Researchers

- Used as a back ground for future researches on related topic

Chapter Two

2. Literature Review

Laryngospasm is stated as the sustained closure of the vocal cords. It's a primitive protective airway reflex, which is caused by multiple things; the presence of local, thermal, mechanical, or chemical stimuli, which ascend through the superior laryngeal nerve via sensory fibres of the vagus nerve. That is, superior laryngeal nerve gives sensitivity to the supraglottic region, while the sensory innervation below the vocal cords is supply by the inferior or recurrent laryngeal nerve. The motor response is essentially due to the presence of three laryngeal muscles; the lateral cricoaritenoids, the thyroarytenenoids (abductors of the glottis) and also the cricoaritenoids (vocal cord tensor). All innervated by the inferior or recurrent laryngeal nerve, which is a branch of the upper laryngeal.(3)

The presence of this reflex leads to an impairment to adequate breathing, under these conditions it becomes a sudden obstruction of upper airway. Forty percent of the airway obstructions are secondary to laryngospasm, and this might lead to a life-threatening complication, and is a major reason of cardiac arrest within the pediatric patient.(3)

In the child between one and three months old the incidence is that the highest. Within the first nine years of age, the incidence of laryngospasm is 1.74%.(3) Airway manipulation and oral or pharyngeal surgeries are common of the causes of laryngospasm. Gulhas N et al has been reported within the literature in patients undergoing tonsillectomy and adenoidectomy the incidence of laryngospasm is as high as 25%. (11)

A randomized control trial research done by Lee c et al study the incidence of laryngospasm among inhalational anesthetic agents, when used desflurane and isoflurane for induction have an unacceptable rate of laryngospasm, around 50%(13), another randomized control trial research done by Hsu YW et al which is one amongst motives that sevoflurane and halothane are used for inhalational anesthetic induction. But the threat is not abolished and laryngospasm can be triggered by those two agents during anesthetic induction with an incidence of roughly 3% (14) Among intravenous anesthetic agents, Study done in USA by Cohen et al suggested that ketamine is often mentioned as a cause of laryngospasm, explained by the increase in salivation

it causes, resulting in ventilator obstruction (15).This risk can be decreased by the administration of anticholinergic agents that reduce intraoral secretions (16). Though, opposing to what would be expected, a study with 130 children with upper airways infection who underwent elective surgeries and received 0.01 mg.kg-1 of glycopyrrolate to decrease the incidence of laryngospasm didn't to demonstrate a reduction in respiratory events with the use of the anticholinergic agent (17).

A randomized control trial study's Baijal et al. and von Ungern-Sternberg et al, done in USA and Australia respectively suggested that there was no statistically significant difference within the incidence of any perioperative respiratory complication in children undergoing an awake vs deep extubation (18.5% and 18.9% for awake and deep extubation, respectively (P = 0.93)) or had any advantage in preventing laryngospasm (18,19)

Since laryngospasm has severe and fatal consequences. It demands prompt treatment when it's diagnosed, many investigators have concentrated their efforts on preventing this reflex.(6)

Meanwhile tonsillectomy is the procedure with the highest incidence of laryngospasm, it's been the main focus of such studies.

One study done in cats by Nishino T et al reported that inhalation of 5% CO2 at the time of extubation reduces the incidence of laryngospasm; however, this method isn't easily reproducible (20).Theories states that, excess CO2 stimulates upper respiratory centers overriding the laryngospasm stimulus and inhibiting it. Practically, it's known that both severe hypercapnia and hypoxia can cause the adductor muscles of the vocal cords to relax and diminish the laryngospasm (21)

A systemic review done in Lebanon by Alalami et al suggested that Lidocaine has been a highly studied and controversial pharmacologic agent within the prevention of pediatric laryngospasm. A systematic literature review and meta-analysis conducted on the efficacy of lidocaine to prevent laryngospasm in children in 2014 by Mihara et al because of the uncertainty concerning the benefit of lidocaine(22),. The meta-analysis done combined 9 different studies with 787 patients. Studies examining both topical lidocaine and IV routes of administration were included. The results for both the IV and topical lidocaine routes demonstrated a statistically significant

reduction in the incidence of laryngospasm. The authors postulated that the foremost efficacious time to administer IV lidocaine is within 5 minutes of tracheal extubation.(23)

Another randomized control trial was done in turkey by Koç et al 2% lidocaine (1 mg.kg-1) at the time of tracheal extubation lidocaine groups revealed less stridor and laryngospasm than the control groups, and there was no difference found between these groups except the higher sedation scores in the early postoperative period for the intravenous lidocaine group.(24,25) Gharaei et al also specifically compared IV Vs Topical lidocaine and found the difference in the prevention of pediatric laryngospasm to not be statistically significant.(26)

A study done in turkey by Gulhas et al was performed in patients undergoing adenotonsillectomy on the efficacy of magnesium in the prevention of pediatric laryngospasm. This was a double-blind experiment which concludes there was no incidence of laryngospasm observed within the group that received 15 mg/kg magnesium. They believe that the mechanism of action of breaking laryngospasm is by deepening the anesthetic and enhancing muscle relaxation. This study had a small sample population and that they used intravenous (IV) lidocaine (1 mg/kg) on induction, which can be a confounding factor.(22)

A study done in Egypt by Ali M. et al compared the efficacy of propofol(0.5 mg.kg-1) vs. lidocaine (1.5 mg.kg-1) within the obstetric patients for treatment of resistant post-extubation laryngospasm after failure of the standard measures. They found that small dose of propofol (0.5 mg.kg-1) is marginally more effective than lidocaine (1.5 mg.kg-1) for the treatment of post-extubation laryngospasm.(27)

A prospective randomized controlled trial study was done in cairo by Dina et al compare between propofol and midazolam in 40 peoples, Within the midazolam group, 17 of 20 patients responded well to the dose of midazolam, whereas 15 of 20 patients responded to treatment. The remaining patients in the two groups, who weren't relieved by either midazolam or propofol, were intubated after administration of succinylcholine. There was a notable decrease in the heart rate and mean arterial blood pressure in both groups after administration of the study drugs, and this decrease was comparable and similar in both groups.(28)

A randomized, double-blinded control trial study done in Kuwait by Batra et al. with 120 children undergoing tonsillectomy who received subhypnotic doses of propofol (0.5 mg.kg-1)

before extubation to prevent laryngospasm concluded that the incidence of laryngospasm in children who received propofol was 6.6% while in patient who received placebo was approximately 20%,. In their study, they found low dose propofol is effective in lowering the incidence of laryngospasm after tonsillectomy ± adenoidectomy. Although none in the propofol treated group required suxamethonium to break the spasm, they recommend a larger number of patients will need to be studied to confirm that observation is statistically significant. (12)Other studies have also suggested the use of propofol with the same objective.(29,30)

In contrary a randomized, double-blinded control trial study done in Thailand by Yanipan et al. with 120 patients scheduled surgery under general anaesthesia were assigned into three groups;Patients within the propofol group (P-group)obtained intravenous 0.25mg/kg propofol, while patients within the propofol combined with ketamine group (PK-group) obtained intravenous 0.25mg/kg of propofol plus 0.15mg/kg of ketamine and patients within the control group (C-group) obtained intravenous 0.9% NaCl. Drugs were administered one minute before extubation who found no significant difference in the incidence and severity of laryngospasm between comparison groups.(31)

Research hypothesis

1.HO: There is no difference between the propofol and control groups in the incidence of post-extubation laryngospasm in children undergoing tonsillectomy.

HA: There is a difference between the propofol and control groups in the incidence of post-extubation laryngospasm in children undergoing tonsillectomy.

2. HO: There is no difference in severity of laryngospasm between the control and propofol groups

HA: There is a difference in severity of laryngospasm between the control and propofol groups

3 HO: There is no difference in change in vital signs of the patients after extubation between the control and propofol groups

HA: There is a difference in change in vital signs of the patients after extubation between the control and propofol groups

Chapter Three

3. Objectives

3.1 General Objective

- To evaluate the effectiveness of a sub hypnotic dose of propofol to prevent laryngospasm following tonsillectomy at Tikur Anbesa, Menilik II and Yekatit 12 hospital from December 2019 – March 2020

3.2 Specific Objective

- To compare the incidence of laryngospasm between the control and propofol groups
- To compare severity of laryngospasm between the control and propofol groups
- To compare the change in vital signs of the patients after extubation in each group

Chapter Four

4. Methodology

4.1 Study Area

This study was conducted at Tikur Anbesa specialized hospitals which is the larger referral hospital in the country, was transferred to AAU by the federal ministry of health, and it has since become a university teaching hospital. Its now the main teaching hospital for both clinical and preclinical training of most disciplines ,Yekatit 12 a specialized hospital found in Addis Ababa around 6 kilo and Menelik II hospital it was the first Ethiopian hospital in Addis Ababa which was established in 1910 by the order of Emperor menelik II and in the compound of this hospital there is a statue of the emperor himself. It has been serving as referral hospital and giving service in both outpatient and inpatient basis for different department in Ethiopia. Today the hospital is operated by Addis Ababa health bureau.

4.2 Study Design and Period

An institutional based prospective cohort study was employed from December – March 2019/20

4.3 Source Population

All pediatric patients who were undergo elective tonsillectomy with or without adenoidectomy surgery under general anesthesia.

4.4 Study Population

All pediatric patients who were undergo elective tonsillectomy with or without adenoidectomy surgery under general anesthesia during the data collection period (December 2019-March 2020) and who fulfill the inclusion criteria.

4.5 Study Variables

4.5.1 Dependent Variable

- The occurrence of laryngospasm
- Severity of laryngospasm
- Vital signs (BP, SPO2 and HR)

4.5.2 Independent Variables

- Socio demographic variables (Age, weight and ASA),
- Induction drugs
- Inhalational drug used for maintenance
- Duration of surgery
- Estimated intraoperative blood loss
- Presence of OSA

4.6 Eligibility Criteria

4.6.1 Inclusion Criteria

All ASA I and ASA II pediatric patents up to 9 years of age scheduled to undergo tonsillectomy with or without adenoidectomy under general anesthesia done from December 2019-March 2020.

4.6.2 Exclusive Criteria

- Children with a history of recent upper respiratory infection,
- Children with a history of asthma
- Those in whom tracheal intubation and extubation were predicted difficult.
- Unexpected difficulty of intubation
- Those who took other than 0.5 mg/kg propofol 1 minute before extubation,
- Those who took propofol induction and
- Those who took any other drug used to prevent laryngospasm

4.7 Operational Definition

ASA status: is a surgical risk stratifications validated by American Society of Anesthesiologist; described as follows:

ASA I: A healthy patient with no organic/physiological/pyschtric problems

ASA II: Controlled medical conditions with mild systemic effect and no limitation of functional ability

Bradycardia: when an individual has heart rate less than 60 bpm.

Hypotention :when an individual has blood pressure less than 90/50 or MAP less than 62

Laryngospasm(32)

- **Stridor***:* an abnormal, high pitched sound produced by turbulent airflow through a partially obstruct airway.
- **Total occlusion:** identified by absence of sound in the presence of spontaneous respiratory efforts.
- **Cyanosis**: is bluish discoloration of the skin or mucosal membrane due to tissue low oxygen saturation with evidence for airway obstruction at the level of vocal cords.

Hypoxia:an absence of enough oxygen in the tissues to sustain bodily functions.

4.8 Sample Size and Sampling Technique

4.8.1 Sample size determination

Sample size for 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 80%. In one study done in Kuwait by Batara et al. which shows the incidence of laryngospasm within control group is 20% and in sub hypnotic dose of propofol group is 6.6%(12) .Taking this into consideration , the calculation of sample size has been.

(P1.q1+p2.q2)f(a.B)/(p1-p2)2=n

n=(0.2x0.8 +0.06x0.94)(1.96.0.84)2/(0.06-0.2)2=30 in each group .adding of 10% of total sample size as a contingency the sample size in each group will be 33. Where:

n = Sample size in each group

α =significance level (1.96)

1-β=power of study at 80% (0.84)

q1= 1-p1

q2=1-p2

P1= incidence of laryngospasm in control group

P2= incidence of laryngospasm in sup hypnotic propofol group

4.8.2 Sampling Technique:

Systematic random sampling technique was used from daily scheduled surgeries depending on the average number of tonsillectomy surgeries in Menelik referral Hospital, Yekatit 12 and Tikur Anbesa hospital per week that we got from surgery log book record.

The patients were grouped based on the three hospital schedule lists and proportion allocation in to the three hospitals. The situational analysis showed at 4 month a total 136 tonsilectomy cases who fulfill our inclusion criteria were operated in Menelik II referral Hospital=32, Yekatit 12 hospital =88 and Tikur Ambesa =16.based on this total population it should be required population allocation to each hospitals. In yekatit 12 hospital =(88/136)*100=64% of patients are operated for the last 4 months and then 0.64*66=42 patents needed from Yekatit similarly by using same equation 15 patent from Menelik and 7 patents from Tikur Anbesa hospital. Taking individuals every Kth unit based on sampling, we got approximately k =2 for the three hospitals. The first participant was selected randomly using lottery method. Then every second patients were included in this study until the required sample size was met.

n=total sample population

N=total study population

K=skip interval

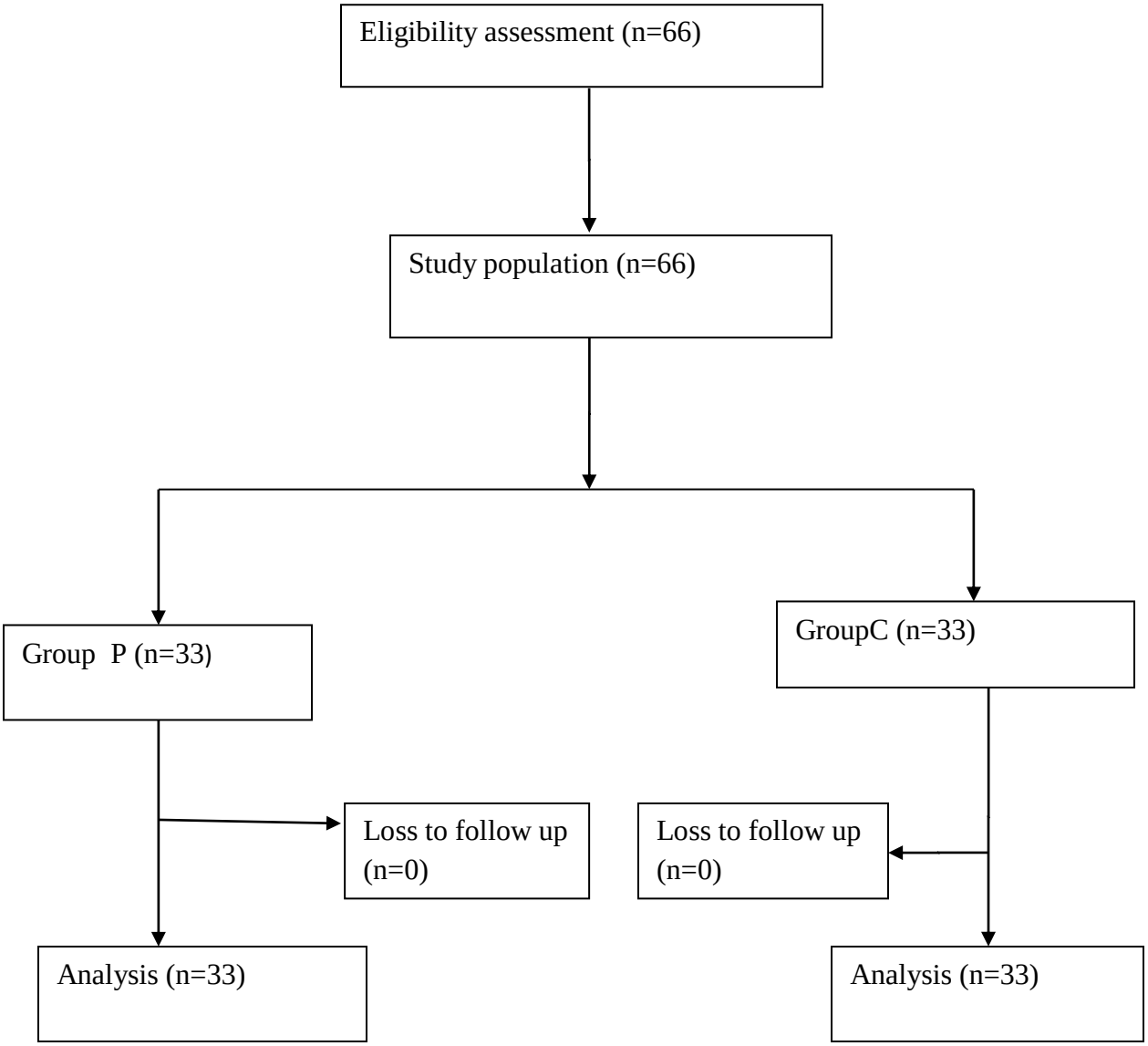


Figure 1: A study flow chart for enrolment of patients who underwent tonsilictomy with or without adenectomy at Menelik II referral Hospital ,Yekatit 12 and Tikuranbssa hospitals

4.9 Implementation of Observation and Measurment Variable

Anesthesia management for adenotonsilictomy patients in study hospitals are usually carried out by BSc and Msc anesthesia professional. Per practice all patents were preoxygenated with 100% oxygen via face mask before induction of anesthesia under standard monitors applied and after baseline vital signs is recorded. They induce anesthesia with IV inductional agent in children who preferred IV induction. After induction of anesthesia, suxamethonium 1-2 mgÆkg) IV is given to facilitate tracheal intubation. The anesthesia maintained with isoflurane or halothane in oxygen. After recovery from suxamethonium some anesthetists administer non-depolarizing muscle relaxant and the others continue with the suxametonium. All patients receive intravenous fluids per protocol using preexisting guidelines to replace preoperative deficits and provide standard maintenance fluids. As routinely practiced patients took intraoperative analgesia fentanyl 1-2 mcg/kg or petidine 0.5-1 mg/kg. At the end of the procedure, blood and secretions is carefully suctioned, inhalational anesthesia is discontinued and the child is allowed to breathe 100% oxygen. When the child started to react to the tracheal tube (swallowing, grimacing and making purposeful movements),Some anesthetists prefer to give small dose of propofol (0.5 mgÆkg)1 Sixty seconds before they perform tracheal

Laryngospasm was graded as a condition occurring within 2 min after extubation, characterized by the following findings (32) as evaluated by the data collector

(i) Stridor;

(ii) Total occlusion of the cords (respiratory efforts with no air movement);

(iii) Cyanosis with evidence for airway obstruction at the level of vocal cords.

If laryngospasm happen treatments were given in the standard way:

1) Positive pressure ventilation with 100% oxygen with facemask

2) Administration of suxamethonium 3) Intubation.

The data collector also record the pulse, mean arterial blood pressure and oxygen saturation at different time interval at the end of surgery, after extubation, 1 min after propofol, 5 min, 10 min, 15 min, 20 min and 30 min post operatively.

4.10 Data Collectors

Two BSC anesthetists were selected to collect data and One MSc anesthetist was assigned to assist and supervise data collectors at each study area. One day training was given regarding how to collect data, appropriate use of the data collection instruments and the confidentiality of the collected data.

Data was collected from December 2019 to March 2020 in selected areas using pretested questionnaires which have been performed with 5% of total sample size in Yekatit 12 hospital 2 weeks before data collection started which were not included in the study. Questioner was prepared in English; it includes demographic data, patients ASA class, types of diagnosis, types of procedure, type and dose of induction agent used, type of inhalational anesthesia for maintenance. The questioner also includes incidence, severity and treatment of laryngospasm and post-operative hemodynamic and respiratory parameter.

4.11 Data Quality Control

To assure quality of data, training on the objectives of the study and brief orientations on the assessment tools was provided for data collectors and supervisors. During data collection, regular supervision and follow up were undertaken. The principal investigator checked completeness of data every day.

4.12 Data entry and analysis

After finishing data collection process in Tikur Anbessa, Yekatite 12 and Menilk II hospital, the questionnaire paper was checked manually for its completeness. The data was entered, cleaned and analyzed using SPSS version 20 numeric data was described in terms of mean and SD, median(IQR) or frequencies when appropriate. Comparison of numerical variable between study groups using independent t test for normally distributed data and Mann-Whitney u test for non-normally distribution. Chi square test was employed to compare for categorical variables. Fishers exact test or pearsans chi square depending cell value. Paired t test was used to compare the before and after propofol vital signs. A statistical Significance was determined at p value less than 0.05.

4.13 Ethical Consideration

The research was conducted after approval by the Institutional Review board of medical faculty, AAU. Official support letter was written to the hospitals and Addis Ababa Health Bureau and permission to for data collection was sought from the responsible authorities. The purpose and the importance of the study were explained and verbal informed consent was obtained from each participant's family. Confidentiality was maintained at all levels of the study by avoiding identifiers and using code to identify patients.

4.14 Dissemination plan

The result of the study will be submitted to the collage of medical and health science of Addis Ababa University, to the Hospital medical administration office, Addis Ababa city health bureau, Ethiopian Anesthetist Association and other responsible bodies. Moreover, efforts will be done to publish the findings of the study and send to different reputable journals and scientific publications.

Chapter Five

5 Results

5.1. Socio-demographic characteristics of the participants

A total of 66 patients (33 patients in each group) were finally involved for data analysis and interpretation of the study. There was no statistically significant difference among the groups in demographic data and perioperative characteristics such as age, sex, ASA status, weight, duration of surgery, estimated blood loss and presence of OSA as shown in **[Table1].**

Table1: Demographic and operative characteristics between group p & group c of patients who undergone Tonsillectomy at Tikur Anbessa specialized, Menilk II referal and yekatit 12 Hospital , Addis Ababa, Ethiopia, from December 2019 to March, 2020 G.C

	Group p	**Group c**	**p-value**
Age(mean±SD)	5.64 ±2.572	5.94 ±2.499	0.629
Sex n:-M/F	17/16	17/16	
Weight (mean±SD)	21.1 ± 5.46	21.18 ± 5.37	1.000
ASA n(%) I	32(96.6%)	31(93.9%)	0.555
II	1(3%)	2(6%)	
Duration of surgery(mean±SD)	44.39 ± 8.54	45.15 ± 7.23	0.699
Blood loss	63.67 ±16.89	64.24 ±16.25	0.889
Presence of OSA	24(72%)	19(57.6%)	0.301

NB. Group P propofol group, group C control group, SD= Standard deviation, ASA= American society of anesthesiologist, n: Independent T test and X2 test was used, p-value < 0.05 considered statistically significant.

Similarly, there were no differences between groups in the number that received drugs for induction and maintanace anesthesia.

Table2.Operative characteristics between group p& group c of patients who undergone Tonsilictomy at Tikur Anbessa specialized, Menilik II referal and Yekatit 12 Hospital , Addis Ababa, Ethiopia, from December 2019 to March, 2020 G.C

INDUCTION	group p	group c	p value
Thiopental	17(51%)	18(54%)	0.52
Ketamine	16(48%)	15(45%)	
MANTAINANCE			
Halotane	13(39%)	13(39.3%)	0.59
Isoflurane	20(60%)	20(60%)	

5.2 Incidence and severity of laryngospasm

Fourteen patients in the control group developed laryngospasm(42.4%),in the propofol group, three children suffered laryngospasm (9.1) (Figure 2). The overall incidence of laryngospasm was significantly lower in the propofol group versus control group (P =0.002).

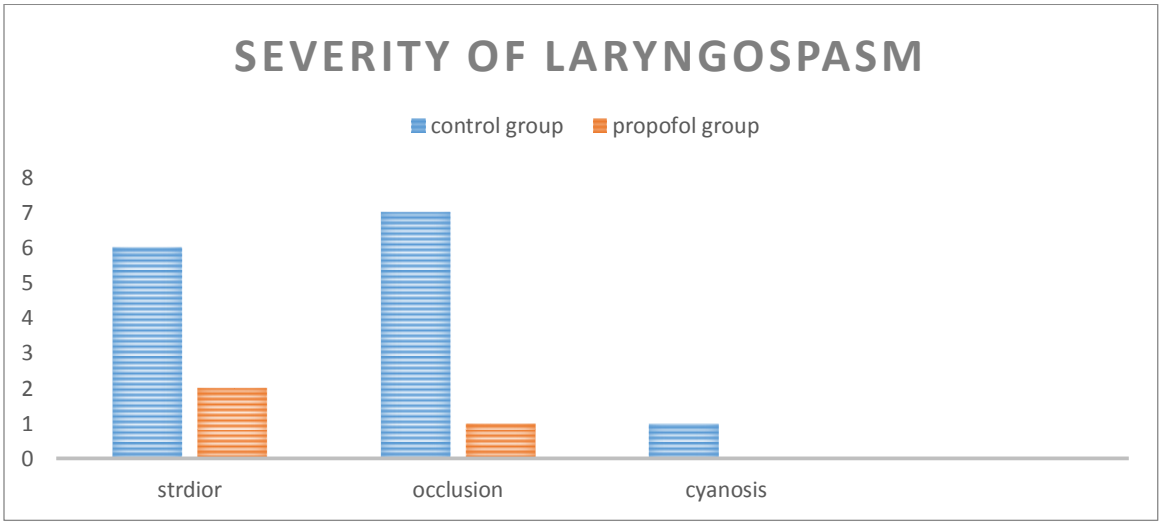


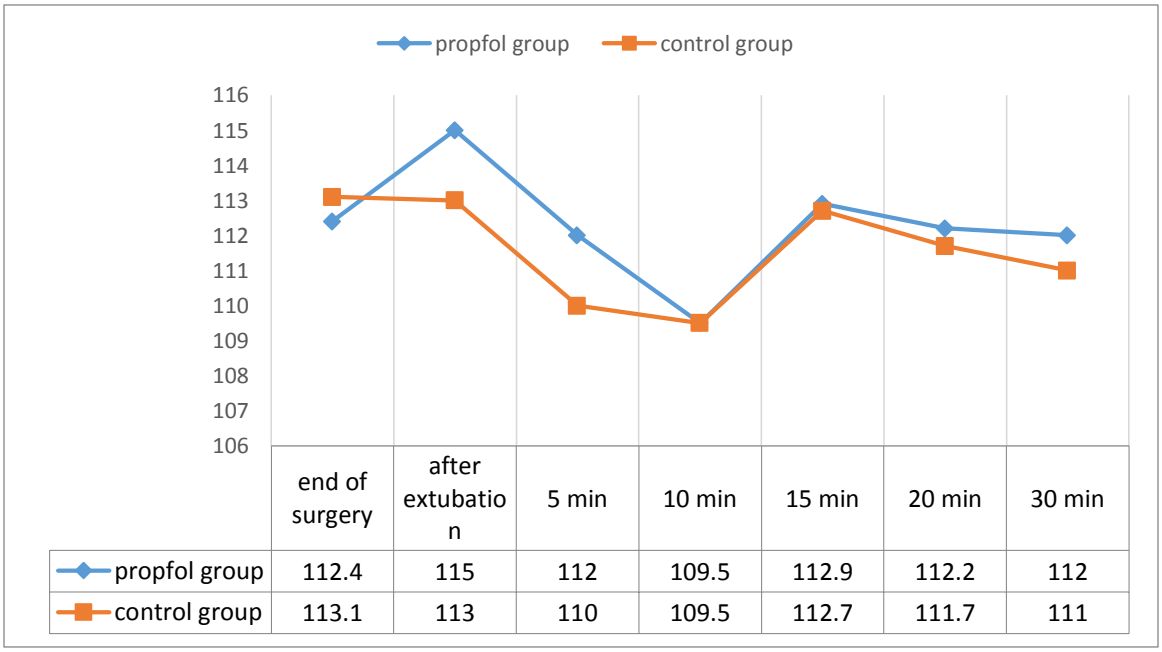
Fig 2. Incidence and severity of laryngospasm in patents between group P & group C patients who had adenotonsilectomy surgery

Of these 14 children with laryngospasm in the control group, 7 responded to positive pressure ventilation with 100% oxygen, Six children's required suxamethonium to break the spasm and one child required reintubation for laryngospasm. In the propofol treated group, 2 children's were successfully relieved with positive pressure ventilation with oxygen; one required suxamethonium. None of propofol group patient required intubation.

5.3 Hemodynamic parameters and respiratory parameter

5.3.1 Mean heart rate

There was no statistically significant difference in mean heart rate at end of surgery, after extubation, 5min, 10min, 15min, 20min,and 30min.(p= 0.656,0.370,0.572,0.991,0.967, 0.847 and 0.814 respectively) in both groups as shown in [Fig.].

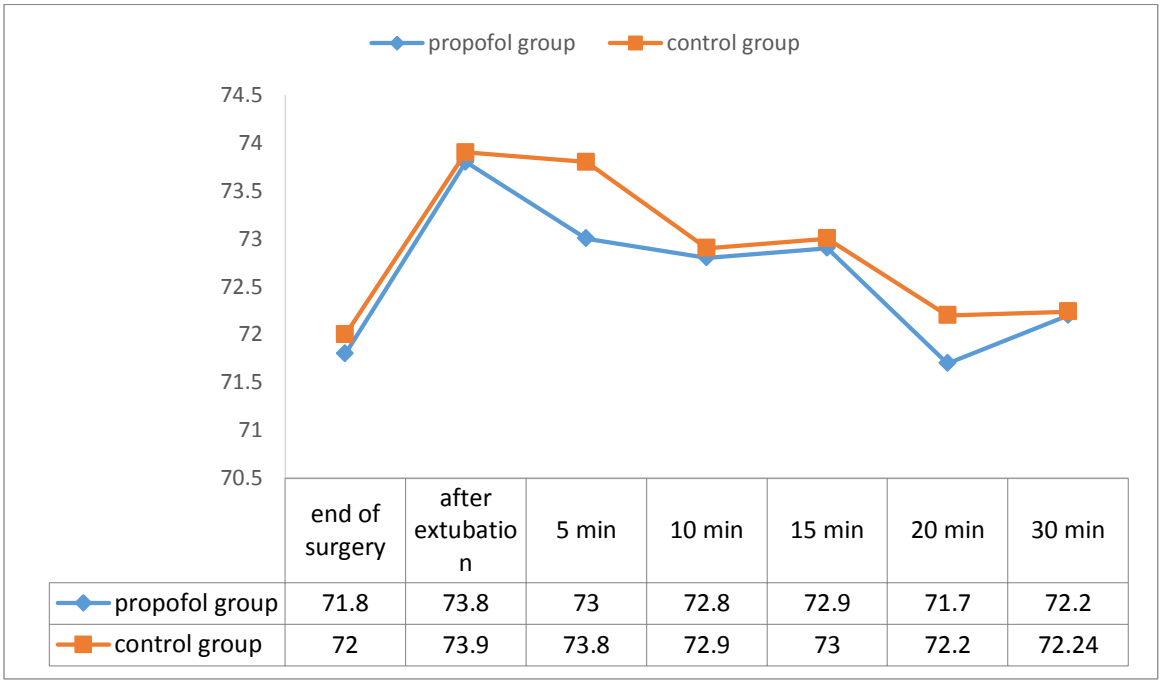


	end of surgery	after extubation	5 min	10 min	15 min	20 min	30 min
propfol group	112.4	115	112	109.5	112.9	112.2	112
control group	113.1	113	110	109.5	112.7	111.7	111

Fig.3: A graph showing the mean heart rate at various time interval between group P & group C patients who had adenotonsilectomy at Tikur Anbessa specialized, Menilik II referal and Yekatit 12 Hospital , Addis Ababa, Ethiopia, from December 2019 to March, 2020 G.C

5.3.2 Blood pressure parameter

Mean arterial blood pressure was not statically difference end of surgery, after extubation, 5min, 10min, 15min, 20min,and 30min.(p= 0.857, 0.950, 0.561, 0.929, 0.929, 0.706 and 0.980 respectively) in both groups as shown in [Fig.3].



	end of surgery	after extubation	5 min	10 min	15 min	20 min	30 min
propofol group	71.8	73.8	73	72.8	72.9	71.7	72.2
control group	72	73.9	73.8	72.9	73	72.2	72.24

Fig.4: A graph showing the mean arterial blood pressure at various time interval between group P & group C patients who had adenotonsilectomyat TikurAnbessa specialized, Menilik II referal and Yekatit 12 Hospital , Addis Ababa, Ethiopia, from December 2019 to March, 2020 G.C

5.3.3 Comparison of respiratory parameter

The Mann Whitney U test showed that the median spo2 score was comparable in the 15 min, 20 min and 30 minute after extubation between the control and propofol groups. But the median spo2 score were lower in control group at the end of surgery, immediately after extubation, 10 min and 15 min after extubation hours and there was statistical significant difference at the end of surgery, immediately after extubation and 10 min after extubation postoperatively between propofol and control groups ($p<0.005$) .

Table 3: Comparison of respiratory parameter between group P & group C group analyzed by Mann Whitney U test at Tikur Anbessa specialized, Menilik II referal and Yekatit 12 Hospital , Addis Ababa, Ethiopia, from December 2019 to March, 2020 G.C

SPO2 in (Median and IQR)	GROUP P Median (IQR)	GROUP C Median (IQR)	P-value
End of surgery	100(99-100)	99(99-100)	0.004
After extubation spo2	98(97-99)	95(90-99)	0.005
5 min spo2	98(97-99)	96(93-99)	0.001
10 min spo2	99(98-99)	97(95-98)	0.001
15 min spo2	98(98-99)	97(97-99)	0.071
20 min spo2	99(98-99)	98(97-99)	0.123
30 min spo2	99(98-99)	99(97-100)	0.473

NB.Group p=propfol group group c=control group IQR= Interquartile Range, p-value < 0.05 considered statistically significant

5.4 Hemodynamic parameters and respiratory parameter with in propofol group

A paired T test was conducted to compare before and after administering propofol HR. there was no significant difference in the score of before propofol(M=112.7, SD=10.466) and after propofol (M=111.4, SD=9.17)t(32)=1.590 P=0.122

We also conducted paired t test for the before and after administration propofol blood pressure. There was no significant difference in the score before (M=70.2, SD=6.848) and after (M=70, SD=7.119) t(32)=0.852 p=0.401

We compare before and after administration oxygen saturation by Wilcoxon sign rank test because SPO2 was not normally distributed. The median of before and after administration SPO2 were both 99. An Wilcoxon signed rank test shows that there is no significant effect of these two ($z = -0.247$, $p > 0.05$)

Chapter Six

6 Discussion

Upper airway surgeries especially adenotonsilictomy is associated with high incidence of laryngospasm and the reported incidence of laryngospasm during emergence in patients undergoing tonsillectomy and adenoidectomy under general anesthesia anesthesia ranges from 21% to 26% when no prophylactic is given. Laryngospasm also represent approximately 30% of respiratory events during pediatric anesthesia.(2,11)

The main purpose of this study was to test the hypothesis that intravenous administration of small dose of propofol before extubation would reduce the incidence of postextubation laryngospasm without hemodynamic and respiratory side effects.

In the current study the incidence of laryngospasm ,severity of laryngospasm, hemodynamic and respiratory profile were compared between sub hypnotic dose of propofol and control group, in pediatrics undergoing adenotonsilictomy under general anesthesia.

From short review above, key patient data's like the demographic characteristics (age, sex, weight, ASA status), agents used for induction and maintenance, duration of surgery, blood loss and presence of OSA were not statistically significant between the groups, $p>0.05$.As it has different magnitude on the incidence and severity of laryngospasm. (3,12,33)

This study showed that low dose propofol is effective in lowering the rate of post extubation laryngospasm. The overall incidence of laryngospasm was 9.1% in propofol and 42.4% control which was significantly lower in the propofol group versus control group ($P < 0.05$).This result coincides with randomized double blind study done in Egypt by Amira et al on comparison of the effectiveness of midazolam and small dose of propofol in preventing laryngospasm following extubation they conclude that intravenous administration of both midazolam or small dose of propofol before tracheal extubation decreases the incidence and severity of laryngospasm in adult patients undergoing oropharyngeal surgeries(33)

In another randomized, double blind study done in Kuwait by Batara et al. on the efficacy of a sub hypnotic dose of propofol in preventing post extubation laryngospasm who got 20% control group and 6.6% in propofol which is significantly lower incidence of laryngospasm.(12)

The precise mechanism by which propofol is effective in preventing laryngospasm is not known. propofol is considered to effectively suppress N-methyl-D-aspartate (NMDA) receptors and block the ascending pathway from the trachea . Also there has been a report that it might be due to the diminishing effect of propofol on laryngeal responses.(34)

In contrast to the present study, a randomized, double-blinded control trial study done in Thailand by Yanipan et al. who compare the effects of intravenous propofol and propofol with low-dose ketamine on preventing postextubation cough and laryngospasm among patients awakening from general anesthesia. Their patients were classified in three groups, the control group (C-group) obtained intravenous 0.9% NaCl, while patients in the propofol group (P-group) obtained intravenous 0.25mg/kg propofol and patients in the propofol combined with ketamine group (PK-group) obtained intravenous 0.25mg/kg of propofol plus 0.15mg/kg of ketamine. Drugs were administered before extubation. They found no significant difference in the incidence and severity of laryngospasm between comparison groups.(31).The use of very small dose of propofol might be the reason of the result.

Eventhough we got insignificant result on the severity of laryngospasm, which was 14 children with laryngospasm in the control group, 7 responded to positive pressure ventilation with 100% oxygen, Six children's required suxamethonium to break the spasm and one child required reintubation for laryngospasm. In the propofol treated group, 2 children's were successfully relieved with positive pressure ventilation with oxygen; one required suxamethonium. None of propofol group patient required intubation, the results were comparable with the results found by a randomized, double blind study done in Kuwait by Batara et al. on the efficacy of a sub hypnotic dose of propofol in preventing post extubation laryngospasm.

This study describe the result of oxygen saturation ,which show statistical significant difference at the end of surgery, immediately after extubation and 10 min after extubation SPO2 between propofol and control groups ($p<0.005$). Spo2 score were lower in the control group. We speculate that this sign difference might be due to laryngospasm associated with a decrease of oxygen saturation.Because the incidence of laryngospasm happened mostly in the control group.

Contrary to the finding of Amira et al research done in Egypt who got significant decrease in mean arterial pressure and significant increase pulse rate after administration up to 5 min after

extubation this study didn't find significant difference in mean arterial pressure and pulse rate P>0.005. However, the reason for significant result in their study might have been due to the use of slightly increased dose of propofol 0.8mg/kg. (33)

Consistent to our result a randomized, double blind study done Korea by Jung et al., on The effect of a sub hypnotic dose of propofol(0.3mg/kg) for the prevention of coughing in adults during emergence who got no significant difference between the two groups.Compared to the control group, the propofol group showed a slightly high MAP from the discontinuation of anesthetic drugs to 10 minutes in PACU, but no significant difference was found between the two groups. Additionally, the change in HR was not significantly different between the two groups. These results are considered to be because only a small dose of propofol was used in this study, and it did not have a significant effect on the change in MAP and HR during emergence. (35)

The present study also tried to study the vital sign difference with in the propofol group before administering and after administering. And there was no significant difference (p-value> 0.05) in pulse rate, blood pressure and oxygen saturation.

None of side effects of propofol occurred using the subhypnotic dose of propofol. This lack was likely because of the use small dose of propofol.(35)

The most appropriate dose of propofol to prevent postextubation laryngospasm has not been determined. Many related studies reported that sub hypnotic doses from 0.25 to 0.8mg/kg of propofol could treat laryngospasm during the emergence period and have proven effective(36) In this study we choose medium sub hypnotic dose of propofol 0.5 mg /kg as supported with many researches (12,27,28 and 33) to avoid the side effect and gain the wanted effect.

Chapter Seven

7 Strength and Limitations of the study

Strength

- The strength of this is the fact that the study participants were homogenous between the two groups and the study subjects were representative.

Limitation

- The main limitation in this study is inability to conduct double blind control study.
- Lack of prior cohort studies on this and related title most studies we used for comparison were randomized control trial.

Chapter Eight

8 Conclusion and Recommendations

8.1 Conclusion

Based on the result of this finding we conclude that use of subhypnotic dose of propofol(0.5 mgÆkg)1) minimizes the risk of post-extubation laryngospasm without affecting the hemodynamic and respiratory parameters in children undergoing tonsillectomy with or without adenoidectomy.

8.2 Recommendation

Based on the finding of this studythe following recommendation was drawn.

- We recommend to use subhypnotic dose(0.5mg/kg) of propofol one minute before extubation to prevent post extubation laryngospasm.
- Further randomized control trial in order to avoid bias in the use of subhypnotic dose(0.5mg/kg) of propofol before extubation to prevent post extubation laryngospasm.

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Annex 1

Verbal consent form before conducting interview

Addis Ababa University

College of Health Sciences

School of Medicine department of anesthesia

Data abstraction tool

Greeting

English Version Consent Form

This questionnaire is to be used as a guide to collect information for the data collectors!

Hello! My name is ----------I'm a data collector for the study entitled "To assess effectiveness of small dose of propofol on preventing laryngospasm in patients undergoing tonsillectomy .The purpose of this questionnaire is to gather information on the effect of in TikurAnbesa ,Yekatit 12 and MenilkeII referral hospital. I have identified your child (family member) as a study participant hoping that you would be willing to give your assent during this observational study. Your participation on this study is definitely important to assess whether the use of a sub hypnotic dose of propofol prior to emergence will decrease the occurrence of laryngospasm following extubation in children undergoing tonsillectomy at Tikur Anbesa ,Yekatit 12 and MenilkeII referral hospital.Your child is selected randomly to participate in the study just because your child undergo a surgery in this hospital no other special criteria. You are free to withdraw from the study and you can stop answering to any questions that are forwarded to you at any time you want. In the study any answer you gave will be confidential and in addition your child name, address or any information that identifies your child will not be used. All information gathered will be kept confidential. I will not include any identifiers, such as your name or exact address. For your participation there is no specific benefit and if you find it not good you can quite the participation in between without any punishment.

Indeed, your role in the success of the research is important and I appreciate your contribution to the research.

Would this be okay with you?

I understood about the advantage of the research and the roles I will have in the research. I have agreed to participate in the research.

A. Agree B. disagree

If Respondent agrees to be interviewed, the interview will be started

Questionnaire Code _____

Date of data collection _____Starting time _____finishing time _____

Name of data collector _____signature _____

Name of supervisor _____signature_____

Name and contact address of investigator

Betelhem Ayele

phone+251-910-02-50-74Email betelhemayele1@gmail.com

Annex II:

Amharic Version Consent Form

<u>በአዱስአበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ፣ህክምናትምህርትቤት፣በድህረ-ምረቃ ፕሮግራም አንስቴዝያ ትምህርት ክፍል የመጠይቅ ፈቃዯኛነት ቅጽ</u>

እንደምንነዎት! ስሜ_____እባላለሁ፡፡ በአዱስ አበባ ዩኒቨርሲቲ በአንስቴዝያ ትምህርትክፍል የምርምር ቡዴን ውስጥ አንዴ አባል ነኝ፡፡ የዚህ መጠይቅ አላማ በመጠኑ አነስተኛ የሆነ ፕሮፖፎል ከኦፕራሲዮን በኃላ የሚፈጠርን የአየር ባንባ መዘጋት ሊይ ያለውን ውጤታማነት ፕሮፖፎል ካልወሰዯ ጋር ጥናታዊ ምልከታ በማካሄዴ መረጃ ሇመሰብሰብ የሚያገሇግሌ ነው፡፡ ጥናቱን የሚያካሂዯት በአዱስ አበባ ዩኒቨርስቲ አንስቴዝያት /ክፍል የሁሇተኛ ዴግሪ ተማሪ የሆኑት ቤተሌሄም አየሇ ናቸው፡፡

የእርስዎን ሌጅ(የቤተሰብአባል) አንዴ የጥናቱ ክፍል አዴርጌ ስመርጥ አስፈሊጊ የሆኑ መረጃዎችን እንዯማገኝ በማሰብ ነዉ፡፡ ሇጥናቱ ፍቃዯዎን ስሇሰጡኝ ከወዱሁ አመሰግናሇሁ፡፡ ከምልከታው የሚገኝ ማንኛውም መረጃ በሚስጥር ይጠበቃሌ፡፡ ሇዚህም ሲባሌ የእርስዎም ሆነ በጥናቱ ሊይ የተሳተፈ የቤተሰብዎ አባሌ ሥምም ሆነ አዴራሻ አይገሇጽም፡፡ እርስዎ ያሌፈቀዱትን ማንኛውንም ምሌከታ አናካሂዴም፡፡ በማንኛውም ሰዓት ከጥናቱ ሂዯት እራስዎን ማግሇሌ ይችሊለ፡፡ በጥናቱ በመሳተፍዎ የሚዯረግ የተሇየ ክፍያም ሆነ ጥናቱን በማቋረጥዎ የሚጣሌብዎት ቅጣት አይኖርም፡፡ነገር ግን ቀዯም ሲሌ እንዯተገሇጸው እርስዎ የተሳተፉበት ጥናት በኦፕራሲዮን ጊዜ የሚሰጡ መዴሃኒቶች ውጤታማነት ሇማወዲዯር የሚዯረገውን ምርምር/ጥናት/ በከፍተኛ ሁኔታ ያግዛሌ፡፡ እንዯሁም ከጥናቱ በኋሊ ኦፕራሲዎን ሇሚዯረግሊቸዉ ታካሚዎች ውጤታማ የሆነውን መዴሃኒት በተገቢዉ ጊዜ በመስጠት ተገቢ የሆነዉን እርምጃ ሇመዉሰዴ ይረዲሌ፡፡

የቃሌሥምምነትየዚህጥናትዓሊማውንብቶኝበጥናቱለመሣተፍ

ሀ. ፈቃዯኛሆኛሇሁ ሇ. ፈቃዯኛአይዯሁም

በጥናቱ ሇመሳተፍ ፈቃዯኛ ከሆኑ መቀጠሌ ይቻሊሌ፡፡

የጥያቄውመሆያቁጥር----------መጠይቁየተካሄዯበትቀን----------

የተጀመረበትሰአት----------ያለቀበትስዓት----------

የጠያቂው ስምና ፊርማ

የሱፐርቫይዘር ስምና ፊርማ

ጥናቱን በተመለከተ ማንኛዉም አይነት ጥያቄ ካላችሁ የሚከተለዉን አድራሻ ተጠቀሙ::

በዋናነት ምርምሩን የሚያካሂዉ ሰዉ

ስም፡ቤተልሄም አየለ

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Questioner

Date _____

Card no _____

Section I: Socio Demographic Data (chart review)

S.no	**Question**	**Response**	
101	Age		
102	ASA (I/II)	A. ASA I B. ASA II	
103	Sex (M/F)	A. Male B. Female	
104	Weight	_____kg	

Section 2: Data during preoperative period

No	**Question**	**Response**	**Code**
201	Base line Heart rate	___bpm	
202	Base line Blood pressure(MAP)	____/____(____)mm hg	
203	Base line RR & spo2	_____br/min &_____%	
204	Diagnosis	_____	
205	Surgery Procedure:	_____	

206	Does the patient have any Coexisting disease?	1.yes 2.no If ,yes specify_____	
207	Does the patient have obstructive sleep apnea	YES NO	

Section III. Question related to anesthetic and surgical interventions

No.	**Question**	**Response**	**Code**
301	Does the patient received any premedication	1. YES 2. NO	
	If YES specify type and dose	1.atropine 2.fentanyl _____(____mg)	
302	Type of Induction agent	1.IV 2. Inhalational 3. Awake	
303	Induction agent type and dose	1.Thiopental _____mg 2.Propofol _____mg 3.Ketamine_____mg 4.Halothane _____MAC 5.Isoflurane _____MAC 6.Sevoflurane _____MAC	

		7.Others_____	
304	Maintenance of inhalational Anesthesia	1.Halothane _____MAC 2.Isoflurane_____MAC 3.Sevoflurane_____MAC	
	Maintenance of muscle relaxant	1.Pancronium_____mg 2.Suxamethonium_____mg 3.Vecoronium_____mg 4.Others_____	
305	Does the patient extubated in the OR?	1.YES 2.NO	
306	If yes Type of extubation	1.Deep 2.Awake	
307	Duration of surgery	_____min	
308	Duration of anesthesia	_____min	
309	Blood loss	_____ml	
310	Does the patient take small dose propofol before extubation	1.YES 2.NO	
311	If yes	Dose_____mg/kg Time_____	
312	Extubation time /minute		
313	Does the patient take steroid perioperatively	1.YES 2.NO	

Section IV: vital sign changes in HR , MAP and spo2

TIME(min)	**Hemodynamic change**		
	HR(beats/min)	**MAP(mm hg)**	**Spo2**
At the end of surgery			
Before inducing propofol			

After inducing propofol			
After extubation			
5 min after extubation			
10 min after extubation			
15 min after extubation			
20 min after extubation			
30 min after extubation			

Section v: severity of laryngospasm

501	Does laryngospasm occur after extubation	1.yes 2.no If ,yes encircle	1.Stridor 2.Occlusion 3.Cyanosis
502	Is there any treatment given to the patient for treating laryngospasm	1.yes 2.no If ,yes encircle/specify	1.postive pressure ventilation 2.suxametonium 3.intubation Other specify_____