ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

ASSESSMENT OF PROPHYLACTIC ADMINISTRATION OF PROPOFOL ON INCIDENCE AND SEVERITY OF EMERGENCE AGITATION IN PEDIATRICS ENT AND OPHTHALMIC SURGERY AT SAINT PAUL HOSPITAL MILLENIUM MEDICAL COLLEGE. ADDIS ABABA, ETHIOPIA.NOVEMBER 2018-MAY 2019 G.C. COHORT STUDY.

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ABSTRACT

Introduction: Emergence agitation is a common problem that can occur after administration of general anesthesia and during recovery time especially in pediatric patients, which can result in life threatening events if not managed adequately and timely. The use of modern inhalational anesthetic agents like sevoflurane, isoflurane and also halothane is also another cause for emergence agitation. Currently use of propofol is gaining acceptance largely on decreasing emergence agitation and also post-operative nausea and vomiting. As smooth recovery is mandatory for the well-being of patients addressing such issues will be valuable.

Objective: The objective of this study is to assess the effect of prophylactic administration of Propofol on incidence and severity of emergence agitation in pediatrics ENT and Ophthalmic surgery at saint Paul hospital Millennium medical college. Addis Ababa.

Method: An institutional based prospective cohort study design was conducted at Saint Paul hospital millennium medical college located Addis Ababa, Ethiopia from November 2018 to May 2019. Elective ASA one and two, age 2-12 years old ninty pediatric patients who Underwent General anesthesia for ENT and ophthalmic surgery were studied. Data were collected from selected study Participants using anesthesia record sheet and observed throughout their recovery room stay. By using systematic random sampling method, the study participants allocated into two groups. Group P (n=45), who took propofol 1mg/kg at the end of surgery and group NP (n=45), who did not take propofol at the end. SPSS version 20.0 was used for data entry and analysis. Comparison of variables between study groups were done using Man Whitney u test, after normality is tested by shapiro wilk test. Categorical variables statistical difference between groups were tested using chi square. Significance was determined at p value <0.05. the result is presented by texts, tables and graphs.

Result: post-operative emergence agitation occurred in 64% of patients in non-prophylactic group and 31% in prophylactic group with a p value of 0.02. prophylactic group had lower severity of post-operative emergence agitation at all times. At 5minute,15 minute and 30 minutes with a p value of 0.009 ,0.013 and 0.011 respectively.

Conclusion: we conclude that administering propofol 1mg/kg at the end of surgical procedure in children undergoing general anesthesia for ENT and ophthalmic surgery is important for reducing emergence agitation and severity for providing smooth recovery postoperatively.

Recommendation: we recommend the use of 1mg/kg iv propofol at the end of surgical Procedure for reducing post-operative emergence agitation and severity in pediatric patients undergoing general anesthesia for ENT and ophthalmic surgery.

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Contents

ABSTRACT i

Acknowledgment iii

List of Tables vi

List of Figures vii

Abbreviations viii

CHAPTER ONE 1

1. Introduction 1

1.1 Background 1

1.2 Statement of the problem 2

1.3 Justification of the study 3

Chapter Two 5

2. Literature Review 5

Chapter Three 9

3. Objective of The Study 9

3.1 General objective: 9

3.2 Specific objective 9

Research hypothesis 10

Chapter Four 11

4. Methods and Material 11

4.1 study area 11

4.2 study design and study period 11

4.2.1 source population 11

4.2.2 study population 11

4.3 Eligibility criteria 11

4.3.1 Inclusion criteria 11

4.3.2 Exclusion criteria 11

4.4 sample size and sampling procedure 12

4.4.1 Sample size calculation 12

4.4.2 Sampling technique 13

4.5 study variables 13

4.5.1 Dependent variables 13

4.5.2 Independent variables 14

4.6 Data collection tool and procedure 14
4.6.1 Data source, data collection tools, procedure and personnel 14
4.7 Data quality assurance 15
4.8 Operational defination 15
4.9 Data processing and analysis 16
4.10 Ethical consideration 16
4.11 Result dissemination and plan 17
Chapter Five 18
5. Result 18
5.1 Socio demographic and intraoperative characteristics of study participants 18
5.2 Emergence agitation incidence between the groups 19
5.3 Postoperative emergence agitation severity using PAED scale 20
Chapter SIX 22
6. Discussion 22
6.2 Limitation of the study 24
6.3 Strength of the study 24
Chapter Seven 25
7. Conclusion and Recommendation 25
7.1 Conclusion 25
7.2 Recommendation 25
References 26
Annexes 28
Annex I: Information Sheet 28
Annex II: Study subjects consent Form 30
Annex III: የጥናቱ ተሳታፊ ለመሆን የስምምነት ቅፅ 31
Annex IV: Questionnaire for Data Collection 32
Annex V: Agitation Assessment Tool 36
Certification 37

List of Tables

Table 1. sociodemographic and perioperative data of propofol and non propofol group of pediatrics patients who underwent general anesthesia for ENT and ophthalmic surgeries at saint pauls hospital millennium medical college from November 2018-May 2019. 18
Table 2.Data on type of analgesia and inhalational agent used during maintenance of anesthesia between propofol and non propofol group of pediatrics patients who underwent general anesthesia for ENT and ophthalmic surgeries at saint pauls hospital millennium medical college from November 2018-May 2019 19
Table 3. Incidence of emergence agitation between propofol and non propofol group who underwent general anesthesia for ENT and ophthalmic surgery at saint paul hospital millenium medical college from November 2018 - May 2019 19
Table 4. Postoperative emergence agitation severity between propofol and non propofol group of pediatrics patients who underwent general anesthesia for ENT and ophthalmic surgeries at saint pauls hospital millennium medical college from November 2018-May 2019 21

List of Figures

Figure 1.Incidence of emergence agitation between propofol and non propofol group who underwent general anesthesia for ENT and ophthalmic surgery at saint Paul hospital millennium medical college from November 2018- May 2019. 20
Figure 2. Comparison of severity of emergence agitation between propofol and non propofol group of pediatric patients who underwent general anesthesia for ENT and ophthalmic surgery at saint Paul hospital millennium medical college from November 2018- May 2019. 21

Abbreviations

ASA- American society of Anesthesiologists physical state classification

EA- Emergence agitation

ED- Emergence delirium

ENT- Ear, nose and throat

GA- General anesthesia

PACU-Post anesthesia care unit

PAED-Pediatric anesthesia emergence delirium

RCT-Randomized control trial

SPHMMC-Saint Paul hospital millennium medical college

WHO-World health organization

CHAPTER ONE

1. Introduction

1.1 Background

The word Anesthesia comes from Greek word which means "with- out sensation". It is a temporary induced loss of sensation or awareness. Which can be achieved by administering drugs intravenously or inhalational anesthetic agents and includes a state of Amnesia (loss of memory), unconsciousness, muscle relaxation (paralysis) and analgesia (no pain) as General Anesthesia or administering local anesthetic drugs at desired area as Regional Anesthesia.(1)

Anesthesia practice in Ethiopia was least addressed compared with other health disciplines. Lack of equipment's, drugs and a problem with professional recognition added with inability to gain continuous support for developing professional knowledge is an obstacle for providing quality service. But currently different attempts are being made to improve quality and providing safe anesthesia.

Emergence from General Anesthesia is a transition from deep sleep to recovering consciousness and it should be smooth recovery. During emergence from anesthesia Delirium (Agitation) may arise which can be life threatening. Emergence agitation is described first by Eckenoff, in 1961 and it is a common phenomenon that occurs after the administration of general anesthesia.(2)

Emergence agitation can occur in all age groups but more prevalent in pediatrics the incidence ranges from 20-80%. It occurs mostly within thirty minutes after the end of surgery and administration of Anesthesia during recovery time. The child becomes uncooperative, restless, irritable, inconsolable, typical thrashing, crying and moaning during recovery from anesthesia. (3)

There are different causes which contributes for the occurrence of emergence agitation like type of surgery that is Ear, nose, throat (ENT) and ophthalmic surgeries are among the main ones. Type of anesthesia mainly inhalational agents, pain and pediatric age group are also other factors. (4)

Short acting, insoluble volatile inhalational agents play a role in development of emergence agitation like halothane, isoflurane, desflurane and sevoflurane. (5)

Many tools have been developed to diagnose and treat emergence agitation in children. About 16 different scales and 2 visual analog scales, watcha scale is simplest to use in clinical practice and has better sensitivity and specificity. The watcha scales defines emergence agitation at a level of 3 or 4. (6)

The pediatric Anesthesia delirium scale (PAED), is reported to have the advantage of being validated and reflects better the presence of severity of emergence agitation. The scale has described a sensitivity of 64% and specificity of 86% with a PAED score of ≥12. It is used to measure severity of emergence agitation. (7)

As there are different methods to decrease emergence agitation in pediatrics patients one of the safe method is a prophylactic use of sub hypnotic dose of propofol at the end of surgery to decrease emergence agitation and making recovery from General Anesthesia smooth. (8, 9)

Propofol is a short acting Intravenous medication used for induction and maintenance during general anesthesia and for short or prolonged procedural sedation. Has a characteristic of rapid onset and recovery with amnestic effect and is not associated with nausea and vomiting, Propofol is on the list of essential medications by WHO as safest and effective medicine needed in health systems. (5)

1.2 Statement of the problem

Smooth emergence from anesthesia is mandatory for the well-being of patients. But in a patient who is agitated during emergence has an increased risk of falling during struggling and bleeding from pulling out the intravenous lines, disrupting surgical site dressings, drains and catheters. The other problem is pulling out the endotracheal tube and self extubation are among the severe consequences and the patient may even end up in death. (10, 11)

Harming the caregiver and disrupting monitoring equipment's such as pulseoxymetry and Noninvasive blood pressure apparatus is also another concern. (12). Agitated child in the post anesthesia care unit (PACU) is distressing for the caregiver to manage and also for the parents to observe and it decreases satisfaction of the service. (11, 13). According to researches 49%

of children who develop post-operative emergence agitation requires extra PACU personnel to take care of them and this unnecessarily wastes human power. (14).

The other consequence of a child who develop Emergence agitation is seven times more prone for the development of postoperative maladaptive behavior such as general anxiety, bed wetting, night terrors and loss of appetite. (15).

To manage and control agitated child mostly analgesics and sedative drugs are administered but this also prolongs the duration of patient stay in the PACU (4, 16). As there are many factors for the development of emergence agitation adequately identifying the cause and treating accordingly is mandatory (13, 17) professionals misdiagnose and mistreat emergence agitation and it's becoming a common problem. (Mostly miss diagnose emergence agitation as pain and administering unimportant drug to the child which also increases expense and unnecessary drug exposure. (18)

To manage emergence agitation different pharmacologic and non-pharmacologic methods can be used. Administering drugs like fentanyl, clonidine, dexamedithomedine and propofol have been used and parental presence during recovery in PACU is also known to decrease emergence agitation. (8)

Based on current evidence use of subhypnotic dose of propofol at the end of surgery is being safe and gaining acceptance largely to decrease emergence agitation in pediatric age groups.

1.3 Justification of the study

As we are observing daily in our clinical practice more attention is given for inducing (starting) anesthesia than emergence (recovery). This practice should be corrected by giving equal attention for both. Recovery from GA should be smooth, restless recovery may end up in death if not managed adequately and timely. Emergence agitation is a disturbing complication that can occur after general anesthesia. Therefore, such types of researches should be encouraged and practiced in order to reach conclusions regarding in our setup will be valid.

Preventing emergency agitation by administering subhypnotic dose of propofol at the end of surgery. We can decrease morbidity and mortality related with emergence agitation including self-harm, extra human power caring for the patients, other pharmacological drugs exposure

and expenses. And we can increase patient satisfaction by making recovery smooth and decreasing patient stay in PACU.

Pediatrics patient post-operative emergence agitation needs special consideration because they can deteriorate easily and life threatening events can happen so prevention is better than cure. No research is done in Ethiopia regarding emergence agitation in pediatrics so it can be used as a tool for further research to raise staff awareness and based on current evidence how prevention of emergence agitation makes recovery smooth and avoid unwanted complications.

Chapter Two

2. Literature Review

Emergence delirium also referred to as emergence agitation is a well documented phenomena occurring in children and adults in the immediate postoperative period. Emergence agitation is one of the most common complication after general anesthesia. (10, 19)

Mostly inhalational agents like isoflurane,halothane,sevoflurane and desflurane have all been recognized as contributors to emergence agitation. The introduction of this short acting volatile agents into clinical practice contributed to emergence agitation currently we are faced with "many questions and few answers" as described by Vlajkovic.(4)

It was found that sevoflurane is mostly associated with anesthetic implicated in agitation. A study done by Cole et.al showed that desflurane and isoflurane have been shown to have a comparable incidence ranging b/n 50% and 80%. Mohkamer found that among the inhaled anesthetic agents isoflurane was associated with 9.8% of EA compared with sevoflurane 2.5%. (19, 20)

studies question pain and rapid emergence as a cause of EA, since in this studies pain was well controlled and patients still exhibited signs of EA. Almost all 98% of patients who had EA received intraoperative analgesics as compared with 86% of non- agitated children. (21). The presence of pain is thought to be one of the major causes of EA, but painless procedures like MRI 48% of pediatric patients develop EA. (5)

Factors like elevated postop pain, preoperative anxiety and physiologic causes like hypoxia urinary retention, hypoglycemia also contributes for the occurrence of emergence agitation. Age is also one factor more common in preschool age groups plus rapid awakening in unfamiliar environment after surgery, introduction of short acting inhalational agents and site of surgery like ENT and ophthalmic surgery been described as increased risk due to the possibility of the surgery affecting head and neck induces emergence agitation. (15, 22)

A comparison of emergence delirium scales follwing general anesthesia in children as compared by Samira et.al in Australia assessed different scales and concluded that watcha scale is a simpler tool to use in clinical practice and may have a higher overall sensitivity and specificity than the other scales. (7)

Research done by Pieters, et.al on Emergence delirium scales states that it is more practical to use a simple scale to detect delirium and then use the PAED scale to measure its degree.(23)

A research done by Anachanok,et.al in Thailand, on incidence and risk factors of emergence agitation in pediartic patients after general anesthesia indicates that the incidence was high in post anesthesia care unit. Therefore anesthesia personnel who are responsible for pediatric anesthesia should have essential skills and knowledge to effectively care for children before,during and after an operation including implementig the methodes that minimize incidence of emergence agitation.(24)

Prevention is important as the experience of emergence agitation may increase the incidence of new onset postoperative maladaptive behaviour changes such as General anxiety, night time crying ,separation anxiety for upto fourteen days after surgery. (15)

A study of Emergence agitation in pediatric patients undergoing General Anesthesia in India by Dr. Trupti et.al found that 17.9% of patients undergoing General Anesthesia develop emergence agitation most frequent ones were ENT 42.2% ,abdominal surgery 23.7%, orthopedic surgery 18.3% , urology 13% and ophthalmic 3.2%. (25)

A national survey conducted in Germany on prevention and therapy of emergence delirium by Huett et.al shows that propofol is the most important option for prevention and treatment of emergence agitation by most of the anesthesia prviders.(9)

A study done by Abu-shawn in canada showed that doses of propofol 1mg/kg just prior to emergence from General Anesthesia dramatically reduced the incidence of emergence agitation and was not shown to delay recovery or discharge time. Emergence agitation was observed in 11 (26.8%) in control group where as 2 (4.8%) in propofol group ($p < 0.05$). PAED score was significantly lower in the propofol group. (26)

In another research done in korea by Lee.et al patients who undergo adenotonsilectomy propofol was administered at the end of surgery. The incidence of Emergence agitation is assessed using PAED scale at 5 (T5), 15 (T15) and 30 (T30) minute interval and the mean score was 12.6+/- 4.6, 8.2 +/-3.8 and 5.0+/-3.1 respectively in propofol group where as 13.8+/-4.7,8.0+/-3.9 and 4.5+3.1 in the saline group. So the authors didnt recommend the administration of propofol decreases emergence agitation. (27)

Another study done in korea by Kim et al. Compared propofol and fentanyl administered at the end of General Anesthesia for prevention of emergence agitation and found that small doses of propofol 1mg/kg and fentanyl 1microgram/kg reduces emergence agitation but propofol was better than fentanyl due to a lower incidence of nausea and vomiting. (10)

Meta analysis done in china by S.jang proved that propofol can reduce the incidence of emergence agitation in children after sevoflurane and desflurane anesthesia with out extending the length of stay in the post anesthesia care unit. (28)

Study done in singapore ,compared single dose of propofol and dexomeditomedine on the incidence of emergence agitation in children undergoing general anesthesia for MRI and concluded that neither propofol nor dexomeditomedine decreases emergence agitation. (29)

A comparison of nalbuphine and propofol on prevention of Emergence agitation in children under going cochlear implant was done in india by Dr. Sameer and colleagues found that incidence and severity of emergence agitation is lower in both groups although statistically not significant nalbuphine was better than propofol. (30)

A comparative study done by administration of ketamine , fentanyl or propofol at the end of procedure by Batarash in Jordan found out that emergence agitation was 4.4% in propofol group, 5-6% in fentanyl group and 13.97% in ketamin group and concluded that administration of propofol or fentanyl at the end of surgery in children undergoing tonsilectomy could decrease the frequency and severity of postoperative emergence agitation. (31)

A study done by Aoud et al in Lebanon, showed that administration of propofol 1mg/kg at the end of strabismus surgery under general anesthesia, prevents emergence agitation. The incidence of propofol group was lower than control group 19.5% versus 47.2%,;($p < 0.005$) and concluded that administration of propofol at the end decreases incidence of agitation and improves parent satisfaction with out delaying discharge from the PACU. (8)

A study done in Egypt by Ali and abdelatiff compared the effectiveness of propofol versus dexamedithomedine in preventing emergence agitation in children undergoing adenotonsilectomy. The PAED score was assessed and at 5 (T5), 10 (T10) .and 15 (T15) minute interval. The incidence of Emergence agitation with control group was 8.4+/-4.5 and

propofol 6.6+/-3.2 and dexamedithomedine 5.2+/- 2.9. This trial demonstrate propofol reduces the overall PAED score when compared to saline but not lower than dexamedithomedine. (32)

A recent study done by Dr.Elisha in kenya found that the incidence of Emergence agitation is higher in patients who recieve halothane and isoflurane and showed that it can be decreased by administration of fentanyl at the end. And concluded that the incidence of Emergence agitation is significantly lower in fentanyl (14.6%), compared to normal saline (47.3%) . The fact that fentanyl significantly reduces the incidence of emergence agitation by 81% confirmed that there is a high incidence of Emergence agitation in use of halothane and isoflurane. And recommends further studies to be carried out on this topic to compare fentanyl with other drugs like propofol or clonidine in prevention of EA. (33)

Chapter Three

3. Objective of The Study

3.1 General objective:

The General objective of this study is to assess the effect of prophylactic administration of propofol on incidence and severity of emergence agitation in pediatrics ENT and ophthalmic surgery at saint Paul hospital millennium medical college. Addis Ababa from November,2018 – May 2019.

3.2 Specific objective

►To assess the effect of propofol on emergence agitation

►To determine severity of emergence agitation

Research hypothesis

HO1: - there is no difference in incidence of emergence agitation between propofol and non propofol group.

HA1: - there is difference in incidence of emergence agitation between propofol and non propofol group.

HO2: - there is no difference in severity of emergence agitation between propofol and non propofol group.

HO2: - there is difference in severity of emergence agitation between propofol and non propofol group.

Chapter Four

4. Methods and Material

4.1 study area

The study was conducted at saint paul hospital millenium medical college (SPHMMC) Which is one of teaching and referral hospital in the country located in Addis ababa the capital city of Ethiopia around swaziland street. It was established in 1969 G.C. by emperor Haileselassie with the help of German evangelical church, it was aimed at serving the poor. SPHMMC becomes a medical college in 2007G.C. It has 13 departments and in ENT and ophthalmic operation theatre daily surgeries are done.

4.2 study design and study period

An institutional based Prospective observational cohort study design was conducted from November to May 2018/2019 GC.

4.2.1 source population

All pediatric patients who were scheduled for ENT and ophthalmic surgeries at Saint Pauls Hospital Millennium Medical college. Addis Ababa, Ethiopia.

4.2.2 study population

The study population comprises all elective pediatric patients undergoing General Anesthesia for ENT and ophthalmic surgery and meeting the inclusion criteria during the study period.

4.3 Eligibility criteria

4.3.1 Inclusion criteria

- ASA 1 and 2 children undergoing General anesthesia
- Children aged 2-12 years old.

4.3.2 Exclusion criteria

- Children with psychiatric disorder
- Incomplete data or loss to follow up
- Emergency cases
- Children induced with propofol
- Children induced with ketamine
- Children who took fentanyl at the end of the procedure
- Children on propofol infusion

4.4 sample size and sampling procedure

4.4.1 Sample size calculation

Sample size was determined by using Epi info version 7 stat calculator program and re checked by manual calculation. By considering A power of 80%, confidence interval 95% and ratio of unexposed to exposed 1:1, and incidence of agitation in unexposed =47.2% and incidence of agitation in exposed = 19.5%, which is estimated from previous study done in western Asia, Lebanon. (8) A sample size of 45 patients per group will be necessary.

$$n_1 = \frac{(Z_{\alpha/2} + Z_{1-\beta})^2 \ \bar{p}\,\bar{q}\,(r+1)}{r\,(P_1-P_2)^2} \qquad n_2 = r\,n_1$$

$$\bar{p} = \frac{p_1 + r p_2}{r+1} \qquad \bar{q} = 1 - \bar{p}$$

n_1 = number of exposed

n_2 =number of unexposed

$Z_{\alpha/2}$=1.96 = value of the standard normal distribution corresponding to a significance level of α (1.96 for a 2-sided test at the 0.05 level)

Z_{β}=0.84 = value of the standard normal distribution corresponding to the desired level of power (0.84 for a power of 80%)

P_1= proportion of exposed with disease and $q_1 = 1-p_1$

P_2=proportion of unexposed with disease and $q_2 = 1-p_2$

r = ratio of unexposed to exposed

$p_1 = 0.47$ and $p2 = 0.19$ r=1

$$\bar{p} = \frac{0.47 + (1 \times 0.195)}{1 + 1} = 0.333$$

$\bar{q} = 1-0.333 = 0.667$

$n_1 = \frac{(1.96+0.84)^2 \times 0.333 \times 0.667(1+1)}{1(0.472-0.195)^2} = \frac{3.4827}{0.0767}$

$n_1 = 45.4 = 45$

$n_2 = 45$

By adding 10% contingency sample size become 99.

4.4.2 Sampling technique

Children were selected by systematic random sampling method until the required sample size was reached during the study period. The daily operation schedule list was used as a sampling frame. The situational analysis showed that 10 patients per week underwent surgery, during the data collection period we have 200 elective cases performed. The calculated sample size is 99 and Therefore, K=N/n= 200/99 = 2.02 so 2 (skip interval). This will yield a value of two (k=2) and every k^{th} unit was selected. The first study participant or random start was selected using a lottery method from daily operation schedule list by taking the first two cases and then every 2^{nd} interval, selected participant after then were placed to either group whether they received propofol prophylaxis or not based on the anesthesia providers plan. This information is gained from anesthesia recording sheet.

4.5 study variables

4.5.1 Dependent variables

- Postoperative incidence of emergence agitation
- Severity of emergence agitation

4.5.2 Independent variables

Socio-demographic variables:

- Age
- sex
- ASA status

Procedure related variables:

- Duration of surgery
- Type of surgery

Anesthesia related variables:

- Type of analgesics drug used
- Type of inhalation agents
- Exposure variables; prophylaxis propofol given or not.

4.6 Data collection tool and procedure

4.6.1 Data source, data collection tools, procedure and personnel

All Pediatric patients who were scheduled for elective general anesthesia for ENT and Ophtalmic surgery and which fulfills the inclusion criteria and parents or guardians who gave written informed consent were included in the data collection process from November 2018 to March 2019 G.C.

Anesthesia plan and management for ENT and Ophthalmic elective general anesthesia cases in Saint Paul hospital starts from preoperative evaluation and visit the night before surgery. Evaluation of patients according to standards and patients who are fit for anesthesia and surgery will be informed about any complication and outcomes of anesthesia and surgery and if they give informed consent for surgery they undergo surgery.

To prevent emergence agitation some of the anesthesia providers use propofol 1mg/kg as propylaxis at the end of surgery to make smooth recovery and some do not use. This information can be gained on anesthesia sheet which was filled by anesthesia provider as every drug that is administered to the patients and other informations from starting or induction of anesthesia to emergence or recovery were documented well.

By systematic random sampling method from daily operation list by using the lottery method,the first random start was selcetd then every 2nd interval the patient were selected and placed to propofol and non propofol group.

After training by the principal investigator on collection of data ,the pretested questionnaire were filled by one Msc, and one recovery nurse who were trained on data collection. After the patient was transferred to PACU, the trained data collector nurse fills the WATCHA and PAED scale which determines the presence of Emergence Agitation and severity respectively at the time interval of 5 ,15 and 30 minutes and other parameters on the questionnaire were filled.

A score of 3 or 4 on Watcha scale was considerd as emergence agitation by observing the child behaviour that is if the child becomes inconsolable and thrashing around. Severity was assessed using PAED score and a score greater or equal to 12 was considerd as severily agitated this is also measured by observing the child behaviour.

4.7 Data quality assurance

To assure the quality of data, training on the objectives and relevance of the study and brief orientations on the assessment tools were provided for data collectors. During data collection, each questioner was revised by the investigator for being complete and appropriate. Supervision were done during data collection by principal investigator and the questioner was collected every day and cross checked if incomplete. Pretesting on 5% of total sample size was done at Tikur anbesa specialized hospital. The questionnaire was also used to see the effectiveness of the data collecting tool.

4.8 Operational defination

- **American Society of Anesthesiologists (ASA) physical status classification**: developed by the ASA taskforce which classify patients according to their physical status (systemic well-being)
    - **ASA class I**: normal healthy patient except the surgical compliant he had
    - **ASA class II**: a patient with a mild systemic disease without substantive functional limitation
    - **ASA class III**: a patient with severe systemic disease with substantive functional limitation

- **ASA class IV**: a patient with severe systemic disease that is a constant threat to life
- **ASA class V**: moribund patient who is not expected to survive without the operation

❖ **Anxiety**: a feeling of worry, nervousness or unease about something with an uncertain outcome.

❖ **Calm**: patient not showing nervousness, anger, emotions, violence or confrontation activity.

❖ **Emergence delirium**: children scoring 3 or 4 after general anesthesia using Watcha scale will be interpreted to have emergence delirium.

❖ **Maladaptive behavior**: is a type of behavior that inhibits a person's ability to adjust to certain situations.

❖ **PAED SCALE**: is used to measure severity of emergence agitation with a score of ≥12.

❖ **Ophthalmic surgery**: is eye surgery or known as ocular surgery.

❖ **Sleep**: altered state of consciousness easily aroused by external stimuli.

❖ **Watcha scale**: this is a simple scale for determining the presence of ED in clinical practice, it has a better specificity and sensitivity. It defines emergence delirium at a score of 3 and 4.

4.9 Data processing and analysis

Data was checked manually for completeness and, edited and then entered to Statistical package for Social Sciences (SPSS) software version 20.0 data was entered and analyzed. Normality was checked by Shapiro wilk test and histogram. Comparison of numerical variables between study groups was done with Manny Whitney U test. Frequency and percentage were used to describe categorical variable and statistical difference between groups tested using Chi square. Significance was determined at P value <0.05. Results are presented by using text, table's and graphs.

4.10 Ethical consideration

The study was conducted after approval by Addis Ababa University, college of health science and medicine, department of Anesthesia ethical review board to conduct the study. A legal letter was also submitted to SPHMMC Verbal and written informed consent were obtained from all

parents and guardians after full explanations of the goals and procedures of the study. After taking permission from the hospital and study participant the data collection was conducted

4.11 Result dissemination and plan

The result of the study will be submitted to the Collage of medical and health science of Addis Ababa University, SPHMMC, Addis Ababa city health bureau, Ethiopian Association of anesthetists and other responsible bodies. The result will be presented at different seminars and workshops and efforts will be done to publish the findings of the study and disseminated through different journals and scientific publications.

Chapter Five

5. Result

5.1 Socio demographic and intraoperative characteristics of study participants

A total of ninty participants were enrolled in this study, 45 in each group. Sociodemographic data duration and type of surgery, ASA physical status, type of maintenance of inhalational agents and analgesia used there were no significant difference between the groups. Results are presented in median(IQR), and as number(percentage) and chi square test was used, p value <0.05 was considered statistically significant. With inter age difference between the groups has a p value of 0.11 which is not statistically significant.

Table 1. sociodemographic and perioperative data of propofol and non propofol group of pediatrics patients who underwent general anesthesia for ENT and ophthalmic surgeries at saint pauls hospital millennium medical college from November 2018-May 2019.

variables	Propofol group(n=45)	Non propofol group(n=45)	p-value
Age in year	4(2-12)*	5(2-12)*	0.11
Sex Female	23(51.1%)	21(46.7%)	0.67
Male	22(48.9%)	24(53.3%)	
Duration of surgery	1(1-3)*	1(1-3)*	0.5
ASA I	44(97.8%)	45(100%)	0.31
ASA II	1(2.2%)	0(0%)	
Type of surgery ENT Ophthalmic	 27(60%) 18(40%)	 22(48.9%) 23(51.1%)	0.29

Key; values are presented as*=median(IQR), and number (%) chi-square test and p value <0.05 is statistically significant.

Table 2.Data on type of analgesia and inhalational agent used during maintenance of anesthesia between propofol and non propofol group of pediatrics patients who underwent general anesthesia for ENT and ophthalmic surgeries at saint pauls hospital millennium medical college from November 2018-May 2019

Types of analgesia	Propofol group	Non propofol group	P-value
opioid	6(13.3)	10(22.2)	0.18
Non opioid	4(8.9)	8(17.8)	
both	35(77.8)	27(60)	
Types of inhalational agent			
Halothane	13(28.9)	11(24.4)	0.63
Isoflurane	32(71.1)	34(75.6)	

Key; values are presented as number (%) chi-square test and p value <0.05 is statistically significant.

5.2 Emergence agitation incidence between the groups

Chi square test was used to analyze the presence of emergence agitation between propofol and non propofol group and there was statistically significant difference between the groups with p value of 0.002. Incidence of emergence agitation was 31% on propofol group and 64% from non propofol group.

Table 3. Incidence of emergence agitation between propofol and non propofol group who underwent general anesthesia for ENT and ophthalmic surgery at saint paul hospital millenium medical college from November 2018 - May 2019

Incidence of emergence agitation	Propofol group	Non propofol group	P value
Agitated	31.1%	64.40%	0.002
Not agitated	68.90%	35.60%	

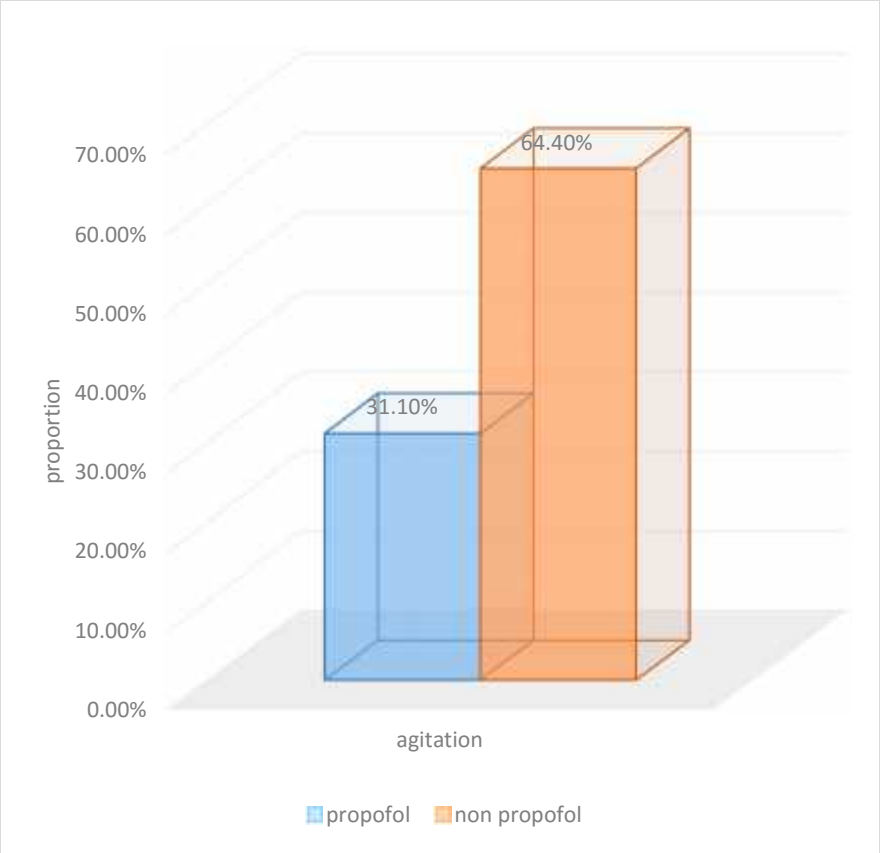

Figure 1.Incidence of emergence agitation between propofol and non propofol group who underwent general anesthesia for ENT and ophthalmic surgery at saint Paul hospital millennium medical college from November 2018- May 2019.

5.3 Postoperative emergence agitation severity using PAED scale

A Man Whitney u test revealed significant difference in the severity of emergence agitation in post anesthesia care unit propofol group at 5 minute (MD=10, n=90) and without propofol (MD=12, n=90), with a p value of 0.009. At 15 minute also significant difference with severity propofol group (MD=8, n=90) and without propofol (MD=9, n=90), with p value of 0.013, At 30 minutes there is significant difference between the groups propofol group (MD=5, n=90) and without propofol (MD= 6, n=90), with p value of 0.011,

Table 4. Postoperative emergence agitation severity between propofol and non propofol group of pediatrics patients who underwent general anesthesia for ENT and ophthalmic surgeries at saint pauls hospital millennium medical college from November 2018-May 2019

Time interval	Propofol group	Non propofol group	p-value
5 minutes	10(5-17)*	12(6-17)*	0.009
15 minutes	8(1-12)*	9(5-13)*	0.013
30 minutes	5(3-8)*	6(4-9)*	0.011

Key; Data are expressed using median (IQR); *

Severity of emergence agitation is expressed by figure 2.

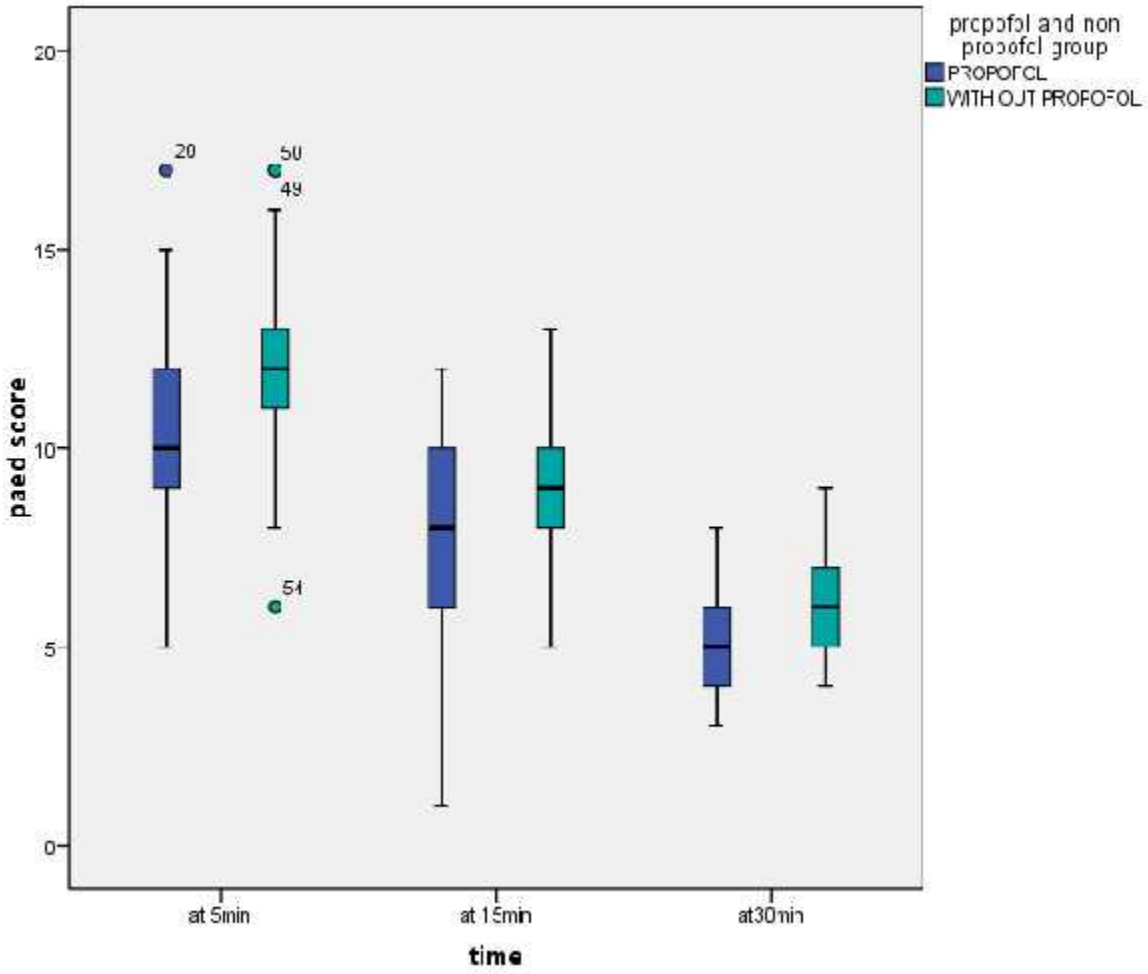

Figure 2*. Comparison of severity of emergence agitation between propofol and non propofol group of pediatric patients who underwent general anesthesia for ENT and ophthalmic surgery at saint Paul hospital millennium medical college from November 2018- May 2019.*

Chapter SIX

6. Discussion

In our study there was a high incidence of agitation (64%) in patients who did not took propofol at the end of surgery than propofol group (31%). Patients who took prophylactic propofol at the end of surgery there is a significant reduction in agitation compared to non-prophylactic group with a p value of 0.002.

Post-operative emergence agitation is the most common encountered problem in post anesthesia care unit especially in pediatric patients who are recovering from general anesthesia. (14)

Agitated child in the recovery room is distressing for the care giver to manage and also can result in life threatening events like self-harm, disrupting intravenous lines surgical dressings and as a result bleeding and even falling down accidents can happen and may even result in death. (15)

There are different approaches for management of postoperative agitation in pediatric patients. The aim of this study was to assess the effectiveness of prophylactic administration of propofol 1mg/kg at the end of surgery for ENT and ophthalmic surgeries.

Our result is comparable with research done by aoud.et.al, in Jordan as there is a high incidence of agitation (47.2%) of non propofol group versus (19.5%) of propofol group with a p value of 0.01. So the authors recommend administration of propofol at the end of surgery. (8)

Another study done by Abushawan et.al in Canada uses 1mg/kg propofol at the end of surgery and the incidence of agitation decreased 26.8% non propofol group versus (4.8%) propofol group with a p value of <0.05 which is also comparable with our study. In comparison to our study the above result incidence is low may be they used different scale to assess agitation. (26)

A study done by costi.et.al the group who receive propofol 3mg/kg at the end of surgery has a decreased incidence of agitation 7% versus 29% in non propofol group with a p value of 0.001. Compared to our study the incidence is low but they use different dose than our study. (34)

In contrast to our study a Randomized control trial study done by Jin Lee et.al in Korea administered 1mg/kg propofol at the end of surgery and the incidence and severity was assessed at T5, T15 and T30 was 61.4% ,27.3%, and 4.5% in the propofol group and in saline group was 68.2%,29.5% and 9.1% respectively. The incidence and severity were not found to be significantly different between the groups. (27)

The severity of emergence agitation is also assessed in our study by using PAED scale and our study showed that there is a reduction of emergence agitation severity by using propofol at the end of surgery. In our study the PAED score was low in propofol group compared to non propofol group at all-time intervals with at 5 ,15 and d30 minutes was 0.009,0.013 and0.011 respectively. This finding was supported by research done in Jordan by Aoud.et.al. the mean score of propofol group was 8.6 ±3.9 compared to saline 11.5±4.5 with a p value of 0.004. (8)

Randomized control trial done by Kim et.al compared propofol, fentanyl and placebo and the patients have a mean PAED score of 4.3 in group P, 4.9 in group F with p value of 0.682 and 9 for group S with $p< 0.001$ and concluded that both propofol and fentanyl decreases emergence agitation but propofol is better than fentanyl due to low incidence of nausea and vomiting. This study is also comparable to our study that propofol has decreased incidence of emergence agitation. (10)

Another RCT by chen et.al compared propofol, ketamine and midazolam on incidence and severity of emergence agitation and ketamine has incidence of 45% and severely agitated were 15%, in propofol group the incidence is 20% and severely agitated were 7.5%, midazolam group with incidence of 15% and severely agitated were 2.5%. compared to our study propofol has reduction effect on both incidence and severity of emergence agitation. In contrast to our study they didn't compare propofol with placebo. (35)

A study done in Egypt by Ali abdelatif et.al found that PAED at arrival ,5,15 and 30 minutes was assessed and severity of emergence agitation was lower in propofol group at arrival, 5 and 15 minutes but not at 30 minutes. Our study was comparable with this RCT except the difference which is observed at 30 minutes. The authors recommend administration of propofol at the end of surgery decreases severity of emergence agitation. (32)

6.2 Limitation of the study

- ✓ Lack of prior study on this and related title in our country.
- ✓ Postoperative environment is not to the standard.
- ✓ Most of the studies we compared with our study were RCT

6.3 Strength of the study

- ✓ During data collection there was strict follow up

Chapter Seven

7. Conclusion and Recommendation

7.1 Conclusion

We can conclude that giving 1mg/kg iv propofol at the end of surgical procedure for ENT and Ophthalmic procedures in pediatric patients decreases post-operative emergence agitation and severity.

7.2 Recommendation

For anesthetists: we recommend that to administer 1mg/kg iv propofol at the end of surgical procedure to decrease emergence agitation and severity for pediatric ENT and Ophthalmic patients.

For researchers: we recommend RCT to be done on propofol so as to be used as a base line in our country.

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Annexes

Annex I: Information Sheet

TITLE OF THE RESEARCH PROJECT: ASSESSMENT OF PROPHYLACTIC ADMINISTRATION OF PROPOFOL ON INCIDENCE AND SEVERITY OF EMERGENCE AGITATION IN PEDIATRICS ENT AND OPHTHALMIC SURGERY AT SPHMMC HOSPITAL. ADDIS ABABA, ETHIOPIA. COHORT STUDY. 2018/2019.

Name of Principal Investigator: Samrawit Haile

Name of the Organization: Addis Ababa University, College of Medicine and health science. Department of Anesthesia

Name of the sponsor: Addis Ababa university

Introduction: The main concern of this information was prepared with the aim of assessing the effect of prophylactic administration of propofol at the end of surgical procedures for ENT and Ophthalmic surgery on incidence and severity of emergence agitation at saint Paul hospital millennium medical college. The research group includes the principal investigator, two data collectors, and one advisor from Addis Ababa university.

Purpose of the Research Project: The main concern of this study is to assess the effect of prophylactic administration of propofol on incidence of emergence agitation and to determine severity in pediatrics patients undergoing general anesthesia for ENT and Ophthalmic surgery at SPHMMC. The finding of this study is expected to be used by Decision makers, Federal Ministry of Health, Ethiopian Association of Anesthetists', Department of Anesthesia and Health Practitioners.

Procedure: This study will include all elective pediatric patients coming for ENT and Ophthalmic surgical procedures during the study period. They will be selected as part of the study participants whose parents are willing to participate in the study and willing to have consent. Any one (child parents) can have autonomy to refuse participating in this study.

Benefits: There will be no direct benefit to study participants but they will be monitored and followed till post-operative recovery unit stay. The information gained from this research will be used to make clinical recommendations and increases safety during recovery of pediatric

patients undergoing general anesthesia for ENT and Ophthalmic surgical procedures and it also increases satisfaction of the service.

Risk and /or Discomfort: it will not impose any harm on patients due to participating in this study.

Confidentiality: The information collected from the study participants will be kept confidential and stored in the file by assigning code number.

Right to Refusal or Withdraw: Study subjects' family will have full right to refuse participation of their child in this study**.**

Person to contact: If you have any further questions or would like to receive further information about the study, please contact:

Samrawit Haile (Principal investigator):

Phone: +251-911-02-45-43

Email: nslgfg@ gmail.com

Thank you for reading the Information Sheet and asking any questions that you might have had.

Annex II: Study subjects consent Form

Addis Ababa University School of Medicine, College of Health Sciences, Department of Anesthesia

Dear participant:

Hello, my name is **Samrawit Haile** and I am one of the member of the research team in Addis Ababa university. The purpose of this questionnaire is to gather information on to assessing the effect of prophylactic administration of propofol on incidence of emergence agitation and to determine severity in pediatric patients undergoing General Anesthesia for ear, nose, throat, eye surgery at Saint Paul hospital millennium medical college, Addis Ababa, Ethiopia, November – May,2019.

The study is aimed at to improve on health planning on safe emergence during recovery from general anesthesia since the study is not linked with any financial aid there is no direct incentives paid as a result of your child taking part in the study.

I would like to assure you, that your child name will not be written on this form and all the information gathered will be kept strictly confidential. You can decide whether your child to take part in this study or not.

Are you volunteer to participate in this study?

A. Yes B. No

If you are volunteer the observation will be started.

Date of data collection .....

Name of data collector..... signature.....

Name of supervisor..... signature .....

Annex III: የጥናቱ ተሳታፊ ለመሆን የስምምነት ቅፅ

አዲስ አበባ ዩኒቨርስቲ፣ጤና ሳይንስ ኮሌጅ አንስቴዝያ ት/ት ክፍል

የተከበራችሁ የጥናቱ ተካፋይ ዎላጆች/የቅርብ ዘመዶች ጤና ይስጥልን፡ ስሜ **ሳምራዊት ሀይሌ** ይባላል በአዲስ አበባ ዩኒቨርስቲ ምርምር ስር ተሳታፊ ስሆን ለምናደርገው ምርምር ልጆትን ተሳታፊ ልናደርገው የፈለግን ሲሆን ይሄን ለማድረግ የርሶን ፍቃደኝነት እንጠይቃለን። የማንኛውም ግለሰብ ስምና ማንኛውም ሚስጥር ይፋ ማይደረግና ማይማዘገብ መሆኑን አረጋግጥሎታለው። ይህ ጥናት ከአንገት በላይ እና የዐይን ቀዶ ህክምና ለሚደረግላቸዉ ህፃናት ከጠቅላላ አነስቴዝያ በኋላ ለሚከሰት መረበሽና አለመረጋጋት እንዲሁም ያለመረጋጋት ደረጃ (emergence agitation and severity) ላይ የምንሰራ ሲሆን ለቅድመ መከላከያ የሚሆን መድሃኒት (prophylactic administration of propofol) ቀዶ ህክምው ባለቀበት ሰዓት በመስጠት ምን ያህል ችግሩን መቀነስ እንደምንችል ለማወቅ ሲሆን ምረምሩ በቅዱስ ጳውሎስ ሆስፒል ሚሊኒየም ሜዲካል ኮሌጅ ካንገት በላይና የዓይን ህክምና ክፍል ከህዳር እስከ ግንቦት 2011 ዓ/ም ይደረጋል። ይህ ጥናት ዕድሜያቸው ከ2 እስከ 12 ዓመት ያሉ ህፃናትን የሚያካትት ሲሆን ቀዶ ጥገናው ካለቀ በኃላ በማገገሚያ ክፍል ውስጥ የሚከሰተውን ያለመረጋጋት ችግር መከታተል ይሆናል። ልጅዎን ለማሳተፍ የእርስዎ ፍቃደኝነት አስፈላጊ ሲሆን ያለማንም አስገዳጅነት በርሶ ፍላጎት ብቻ ይሆናል። ስለዚህ ስምምነትዎን በአክብሮት እንጠይቃለን። ይህ ጥናት ከማኛውም የገንዘብ ድጋፍ ውጪ ስለሆነ እዚህ ጥናት ላይ ልጅዎን በማሳተፍዎ ምንም አይነት የገንዘብ ጥቅም እንደሌለው ከወዲሁ ማሳወቅ እወዳለሁ።

የጥናቱን አላማ እንዲሁም የኔን ሃለፊነት ተረድቻለሁ ሰለዚህ ልጄ እንዲሳተፍ

ሀ) ፈቅጀለሁ ለ) አልፈቅድም

- ከፈቀዱ ክትትሉ ይጀመራል።

መጠይቁ የተሞላበት ቀን ----------

የአጥኝው ስምና አድራሻ፡ ሳምራዊት ሀይሌ

ስልክ ቁጥር፡ +251911024543

Annex IV: Questionnaire for Data Collection

ADDIS ABABA UNIVERSITY SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCE DEPARTMENT OF ANESTHESIA

Questioner developed for collection of data for the study "To assess the effect of prophylactic administration of propofol on incidence of emergence agitation and to determine severity in pediatric patients undergoing General Anesthesia for ear, nose, throat and eye surgery at Saint Pauls Hospital Millennium Medical College in Addis Ababa, Ethiopia."

Part One: Socio -Demographic

Serial number	Question	Response	Code
101	Age		
102	Sex	M... F.....	
103	ASA classification	A.ASA(l) B.ASA(ll)	
104	If Any coexisting disease		
105	Current medication	A. Yes B. No	
106	If yes for above question Type and dose		

Part Two: Preoperative and Intraoperative Data

201	Diagnosis		
202	Type of surgery Specify		
203	Premedication used (type and dose)		
204	Type of induction agent	A.IV B. Inhalational	
205	Specify drug and dose		
206	Analgesics used (dose and type)	A. Paracetamol ..... B. Fentanyl..... C. Tramadol..... D. Diclofenac ..... E. Other specify.....	
207	Maintenance of anesthesia	A. Halothane B. Isoflurane C. Propofol infusion D. Other agent	
208	Prophylactic propofol given before z end of procedure	A.YES dose..... B.NO	
209	Fentanyl at the end of the procedure	A. Yes dose..... B. No	
210	Duration of surgery		

Part Three: Emergence Characteristics

Level of Emergence agitation observed in recovery room as per Watcha scale. At 05, 15 and 30 minutes.

301	Behavior	Score	At05 min	At15 min	At 30 min	code
	Asleep	0				
	Calm	1				
	Crying, but can be consoled	2				
	Crying, but cannot be consoled	3				
	Agitated and thrashing around	4				

302. Measure of severity of emergence agitation PAED scale. At 5, 15 and 30 minutes.

Behavior	Not at all	Just a little	Quite a bit	Very much	Extremely	At 5 min	At 15 min	At 30 min	code
Makes eye contact with caregiver	4	3	2	1	0				
Actions are purposeful	4	3	2	1	0				
Aware of surrounding	4	3	2	1	0				
Restless	0	1	2	3	4				
Inconsolable	0	1	2	3	4				
Total score									

303. Does the patient have nausea and vomiting during recovery room stay? A. Yes B. No

304. Any adverse effect self-harm? A. Yes B. No

305. Duration of PACU stay …….

Annex V: Agitation Assessment Tool

WATCHA behavior scale for emergence agitation

How to score incidence of emergence agitation in pediatrics patients per WATCHA scale observe for the first 30 minutes of PACU stay. Score of 3 or 4 is considered as agitated.

Level	Description
1	Calm
2	Crying, but can be consoled
3	Crying, cannot be consoled
4	Agitated and Thrashing around

Pediatrics anesthesia emergence delirium(PAED) scale

PAED scale used to measure severity of emergence agitation. Score of greater than or equal to 12 is considered as severely agitated

	Description	Not at all	Just a little	Quite a bit	Very much	Extremely
1	The child makes eye contact with the caregiver	4	3	2	1	0
2	The child's actions are purposeful	4	3	2	1	0
3	The child is aware of his/her surroundings	4	3	2	1	0
4	The child is restless	0	1	2	3	4
5	The child is inconsolable	0	1	2	3	4

Certification

The under signed certify that the research entitled A prospective cohort study on the assessment of prophylactic administration of propofol on the incidence of emergence agitation and to determine severity in pediatric patients undergoing general anesthesia for ENT and ophthalmic surgery at saint Paul hospital millennium medical college, Addis Ababa, Ethiopia Institutional based prospective cohort 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.

Name of the student: Samrawit Haile

Signature _____ Date _____

Approval of the primary advisor

Name Assistant professor Leulayehu Akalu_____ Signature Date _____