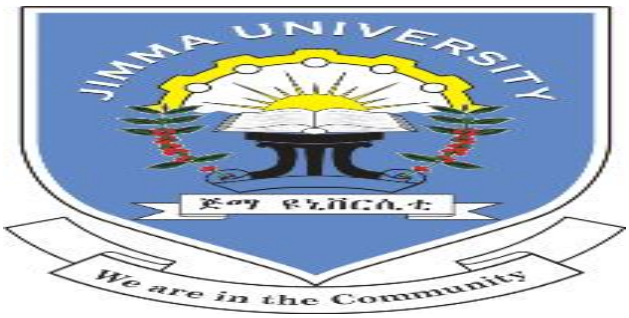

COLLEGE OF PUBLIC HEALTH AND MEDICAL SCIENCE

DEPARTMENT OF ANESTHESIOLOGY AND CRITICAL CARE

INCIDENCE AND ASSOCIATED FACTORS OF PERIOPERATIVE SERIOUS ADVERSE EVENTS IN PEDIATRIC PATIENTS UNDERGOING SURGERY IN JIMMA UNIVERSITY SPECIALIZED HOSPITAL

By: Efrem Hailu

THESIS SUBMITTED TO DEPARTMENT OF ANESTHESIOLOGY, CRITICAL CARE AND PAIN MEDICINE JIMMA UNIVERSITY MEDICAL CENTER IN PARTIAL FULFILLMENT OF THE REQUIREMENTS OF SPECIALTY CERTIFICATE IN ANESTHESIOLOGY, CRITICAL CARE AND PAIN MEDICINE.

January 2022

Jimma Ethiopia

JIMMA UNIVERSITY

COLLEGE OF PUBLIC HEALTH AND MEDICAL SCIENCE

DEPARTMENT OF ANESTHESIOLOGY AND CRITICAL CARE

INCIDENCE AND ASSOCIATED FACTORS OF PERIOPERATIVE SERIOUS ADVERSE EVENTS IN PEDIATRIC PATIENTS UNDERGOING SURGERY IN JIMMA UNIVERSITY SPECIALIZED HOSPITAL

By: Efrem Hailu (MD)

Advisor: Teshome Assefa (MD, Ass. professor of anesthesiology)

January 2022

Jimma, Ethiopia

Abstract

Background: Serious adverse events are the leading causes of morbidity and mortality of pediatric patients undergoing procedures in perioperative period. Perioperative serious adverse events related to anesthesia involve multiple factors. Patient characteristics and comorbidities play a role in many of these events, highlighting the importance of preoperative screening. There is a limited resource on perioperative serious adverse events in pediatric patients undergoing surgery in Jimma University specialized hospital.

Objective: To assess the incidence and associated factors of perioperative serious adverse events in pediatric patients undergoing surgery in Jimma University Specialized Hospital.

Methods: Hospital-based cross-sectional study was done, data was collected from August to November 2021 by anesthesiology residents and anesthetists after taking orientation on the questionnaire by the principal investigator and they were supervised daily throughout data collection time. Data was edited, coded and entered, and cleaned by Epidata manager version 4.6.0.6. First descriptive analysis was made, and bivariate analysis and multivariate logistic regression model was used by SPSS (version 25) to identify risk factors associated with perioperative Serious adverse events. Variables with p-value<0.25; candidates for MLR and P-Value <0.05 was considered statistically significant.

Result: A total of 135 study subjects were included. The overall incidence of perioperative serious adverse events was 3.7%. Pediatric patients who had emergency surgery (AOR:1.42,95% CI:1.33,4.61), ASA classification III (AOR: 3.14,95% CI:1.3,5.32) and IV (AOR:3.31,95% CI:1.3,6.71) and airway event (AOR: 1.52, 95% CI: 1.46, 12.57) were more likely to have perioperative serious adverse events than their counter parts.

Conclusion: Perioperative serious adverse events were common under pediatrics age during anesthesia. Independently positively associated factors were having emergency surgery, higher ASA classification and air way event. Most of the cases were recognized and managed early. On the basis of the findings, it is advisable that preoperative screening should be done, patients undergoing emergency surgery should be stabilized before the surgery and close monitoring and follow-up should be given for patients with higher ASA classification and also, avoid repetitive air way manipulation.

Keywords: Airway event, Incidence, perioperative, serious adverse events, pediatrics.

ACKNOWLEDGMENT

First of all, I would like to thank Jimma University department of anesthesiology, critical care and pain medicine for allowing me to conduct this research.

I am grateful to my advisor Dr. Teshome Assefa for his valuable support, guidance, and prompt replay to my preparation of this research. I wish to express my appreciation to anesthesiology, Critical Care and pain medicine residents and anesthetists, operation theatre staffs for their cooperation during data collection.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS AND ACRONYM

ANs Anesthetic Events

ASA American Society of anesthesiologist

CPAP Continuous Positive Pressure Ventilation

CHOP Children's Hospital of Philadelphia

ETT Endotracheal tube

JMUC Jimma university medical center

JUSH Jimma University specialized hospital

LMA Laryngeal mask airway

μg/kg Micro gram per kilogram

Mg/kg Milligram per kilogram

PACU post-operative care unit

PPV Positive Pressure Ventilation

SAEs Serious Adverse Events

SAJAA South Africa Journal of analgesia and anesthesia

SPSS Statistical Package for Social Science

TASH Tikur Anebessa specialized hospital

URTI Upper respiratory tract infection

LISTS OF TABLES

LIST OF FIGURES

LIST OF ANNEXES

1. INTRODUCTION

1.1. Background

Safe anesthesia practice is by default the ultimate target for every anesthesiologist. The comprehensive study of pediatric perioperative adverse events has been complicated by non-uniform definitions, reporting failure and/or incomplete data collection, and the overall rarity of serious events(1).

An adverse event is defined as an unexpected and undesirable response to medication and medical intervention used to facilitate anesthesia and analgesia that threaten or cause patient injury or discomfort (2).

Serious Adverse Events (SAEs) are defined as untoward occurrences during anesthesia care or within 24 h of the end anesthesia care that results in life-threatening injury, requiring unplanned hospitalization or prolongation of hospitalization, result in disability, incapacity, or death (3).

The perioperative mortality rate is regarded as a credible quality and safety indicator of perioperative care, but its documentation in low- and middle-income countries is poor (4).

Perioperative morbidity and mortality related to anesthesia involve multiple factors. Patient characteristics and comorbidities play a role in many of these events, highlighting the importance of preoperative screening. While optimization of patient comorbidities is not always possible, having data regarding those comorbidities can prove life-saving. Equipment and medication considerations also enter into untoward outcomes such as anesthetic interventions outside of the traditional operating room where resources are sometimes lacking and haste creates errors (5).

1.2. Statement of the Problem

Globally, surgical volumes are large. An estimated 312.9 million operations took place in 2012 (6). Children comprise more than 50% of the overall population in many low- and middle-income countries. Perhaps 85% of these children will require a surgical operation before their fifteenth birthday. Surgical admissions account for 6 to 12% of all pediatric hospitalizations in Sub-Saharan

Africa, although this may be even higher in urban settings or areas of conflict. Surgical capacity in Sub-Saharan Africa is well below current goals.(7)

However, there are little data on perioperative morbidity and mortality in the pediatric surgical population in Ethiopia. Additionally, information is not known on the number of children undergoing surgery, who provides their anesthesia (specialist anesthesiologists versus nonspecialist anesthesiologists), and the quality outcomes of their perioperative care.

Cronje's review of anesthesia-related mortality and morbidity in this edition of SAJAA highlights the potentially large discrepancy in anesthesia-related mortality rates between developed and developing countries. Anesthesia in children is considered to be safe in developed countries, with anesthesia-related deaths reported to be from 0.1–1.2/10 000.6–8 The data are limited in developing countries but suggest that the number of anesthesia-related deaths is between two and 100 times higher than that in developed countries (6).

Anesthesia provided in a traditional operating room has become remarkably safe, with the incidence of significant perioperative events such as cardiac arrest or anesthesia-related mortality in children reported to be 5.3-8.5 per 10,000 and 0.18-0.36 per 10,000 anesthetics respectively. Studies of adverse events (AEs) in off-site locations have typically been retrospective in nature and involve mainly non-anesthesia sedation providers (8).

It is well described that the rates of perioperative mortality and adverse perioperative respiratory events in children are highest among neonates and infants and additional risk factors for perioperative pediatric mortality include complex congenital heart disease, an American Association of Anesthesia (ASA) status greater than three, emergency surgery, and general vs neuraxial anesthesia (9).

Three high-risk categories for serious adverse events and mortality have emerged, and are consistent across developed and developing countries. These are age, i.e. neonates and infants aged ≤ 1 year, American Society of Anesthesiologists (ASA) status III-V, and emergency surgery. The last two are the only factors that are predictive of death after a cardiac arrest (10).

Large pediatric datasets have been provided by some middle and low-middle-income countries. Anesthetic-related mortality is still 2–3 times that of the developed world. As these countries

develop, the perioperative risk may initially increase because of increased surgical penetration rates and case complexity (10).

In a study which was done on perioperative respiratory adverse events in general anesthesia among pediatric surgical patients in Comprehensive Specialized Hospitals in Northwest Ethiopia, the incidence of perioperative respiratory adverse events among 210 (93.3% response rate) pediatrics surgical patients was 26.2% (95% CI: 20.5, 30.9). Most of the adverse events (89 (69.0%)) were occurred postoperatively (2).

This study assessed the incidence and associated factors of perioperative serious adverse events in pediatrics patients undergoing Emergency and Elective surgery.

1.3. Significance of the Study

This study determined the frequency of perioperative serious adverse events in children undergoing surgery in both elective and emergency pediatrics surgery, and identify those perioperative risk factors which are associated with the incidence of the SAEs.

There is limited resource generally about pediatric perioperative adverse events in Jimma University specialized hospital and in Ethiopia as a whole therefore this study added new knowledge on incidence, risk factors, prevention of perioperative serious adverse events.

This study also suggested preparation and use prospective electronic datasets which is being applied in other low and middle income countries for clean collection of critical incidents and mortality

Also, this research will be used as baseline data and a footstep for next studies to be done on similar problems.

2. LITERATURE REVIEW

2.1. Incidence of Perioperative Serious Adverse Events in Pediatrics

Despite the methodological limitations, large volumes of pediatric data are available from high-income countries. A retrospective case-control study conducted from 2010 to 2012 at the Children's Hospital of Philadelphia (CHOP), the prevalence of perioperative adverse events requiring rapid response assistance are termed Anesthesia Now (AN!) events was 0.0043 (1:234) with a 95% confidence interval (CI) (0.0037, 0.0049). Respiratory events, primarily laryngospasm, were most common followed by events of cardiovascular etiology. Median age was lower in the AN! group than in controls, 2.86 years (interquartile range 0.94, 10.1) vs 6.20 (2.85, 13.1), $P < 0.0001$. Odds ratios (with 95% CI) for age, 0.969 (0.941, 0.997); American Society of Anesthesiologists physical status, 1.67 (1.32, 2.12); multiple (≥2) services, 2.27 (1.13, 4.55); nonoperating room vs operating room location, 0.240 (0.133, 0.431); and attending anesthesiologist's experience, 0.976 (0.959, 0.992) were all significant (1).

A prospective descriptive study was conducted in 22 hospitals across Thailand for any perianesthetic adverse incident during 12 months (between January 1 and December 31, 2015), The incidence of adverse events included cardiac arrest within 24 h (15.5: 10,000), death (13.0: 10,000), reintubation (11.1: 10,000), esophageal intubation (8.5: 10,000), difficult intubation (8.0: 10,000), and malignant hyperthermia (1: 200,000) (11).

Cardiac arrest from all causes during anesthesia is approximately 20–30 per 10 000 anesthetics, while anesthetic-related cardiac arrest ranges from 1–5 per 10 000 anesthetics. Mortality following anesthetic-related cardiac arrest is 30% in high-income countries, but far higher in low-income countries. Anesthetic-related serious adverse event rates are 1.4 per 1 000 to 1.4 per 10 000 anesthetics. Anesthetic-related critical incidents are three times more common in children and occur in 3–8% of all anesthetics, revealing high nonfatal event rates, even in high-income countries(10).

In a retrospective cohort study done at the Wilhelmina Children's Hospital, Utrecht, The Netherland, the all-cause 24-hour hospital mortality was 13.1 per 10 000 anesthetics (95% CI: 9.9–16.8) and the all-cause 30-day in-hospital mortality was 41.6 per 10 000 anesthetics (95% CI:

35.9–48.0). In total five patients were partially contributable to anesthesia (30-day mortality: 1.1/10 000, 95% CI: 0.4 2.6) and four patients were partially contributable to surgery (30-day mortality: 0.9/10 000, 95% CI: 0.2–2.3). Mortality was higher in neonates and infants, children with ASA physical status III and IV, and emergency- and cardiothoracic surgery (12).

There are relatively little pediatric data from developing countries, compared to those from high-income countries. Anesthetic-related mortality in middle-income countries is 2–3 times higher than that in developed countries. Anesthetic-related mortality increases by a factor of 50–100 in low-income countries but maybe 1 000-fold higher in certain poor countries (10).

An observational study conducted a tertiary teaching hospital in Brazil between January 1, 2005, and December 31, 2010, from 10,649 anesthetics performed during the study period, with 22 perioperative cardiac arrests and 11 deaths (20.65 and 10.32 per 10,000 anesthetics, respectively). A high incidence of perioperative cardiac arrest occurred in the ASA IV–V neonates and infants who underwent emergency surgery(13).

According to a study done by Ain Shams University, Cairo, Egypt, a total of 56 mortality and morbidity reports from July 2009 to August 2012 were reviewed and showed equal distribution of the three main categories of contributing factors (preoperative, intraoperative, and postoperative) was noticed, although 62% of the incidents could be easily gathered under a specific scenario of inappropriate preoperative management (20%) that led to improper choice of anesthesia (22%) (6).

2.2. Risk Factors

Risk factors can be classified into three categories: anesthesia-related factors, patient-related factors, and surgery-related factors identified as contributing to high perioperative serious adverse events include a paucity of trained anesthesia providers (particularly physician anesthetists), staff working in isolation without medical supervision, equipment problems, system factors, and patient factors (9).

2.2.1. Patient-related factors

Studies published over the last 50 years have established that infants younger than 1 year and children with complex comorbidities have a higher risk of perioperative morbidity and mortality (12).

Mortality was higher in neonates and infants, children with ASA physical status III and IV (14).

On average, in comparison to older children, 24-hour perioperative mortality is 50-fold greater in neonates, and approximately 20-fold greater in infants, and may be higher depending on ASA status and surgical complexity. Anesthetic-related mortality is conversely low in high-risk age groups, indicating causes of cardiac arrest that predominantly relate to the patient's condition.

The relationship between heart disease and mortality is complex. Despite under-representation in studies, children with heart disease account for 80–100% of cardiac arrests and deaths, most during cardiac surgery or interventions (10).

2.2.2. Surgery-related factors

Access to elective surgery is limited. Thus, patients present predominately for emergency or very basic surgery. Important differences in patient demographics and disease patterns exist.

Mortality was higher and emergency- and cardiothoracic surgery(9).

There is a difference in mortality between patients having procedures on the weekend compared to weekdays, in particular, those admitted electively (15).

2.2.3. Anesthesia-related factors

Hypoxemia from hypoventilation and laryngospasm and bronchospasm are frequent anesthetic-related events with good outcomes in high- and middle-income countries. Data from parts of Africa show that respiratory monitoring by pulse oximetry or capnography, even when available, is not routinely used, delaying the detection of hypoxemia, hypoventilation, or hypercapnia. Outcomes from such arrests are poor. The majority die or have a permanent disability. Contributing factors are Lack of medication, or the use of inappropriate medication, such as ketamine-only anesthesia, cardiac depressants, arryhthmogenic volatile agents, and long-acting, outdated neuromuscular blockers. manual ventilation only, as ventilator equipment and oxygen are lacking in certain hospitals. Limited airway devices and airway skills training. Poor cardiopulmonary resuscitation (CPR) technique. Inexperienced or untrained practitioners (10).

A retrospective population-based cohort study (April 1, 2009-March 31, 2015 set in the Canadian province of Ontario) of adult patients showed among adults undergoing major surgery, complete handover of intraoperative anesthesia care compared with no handover was associated with a higher risk of adverse postoperative outcomes (16).

2.3. Conceptual Framework

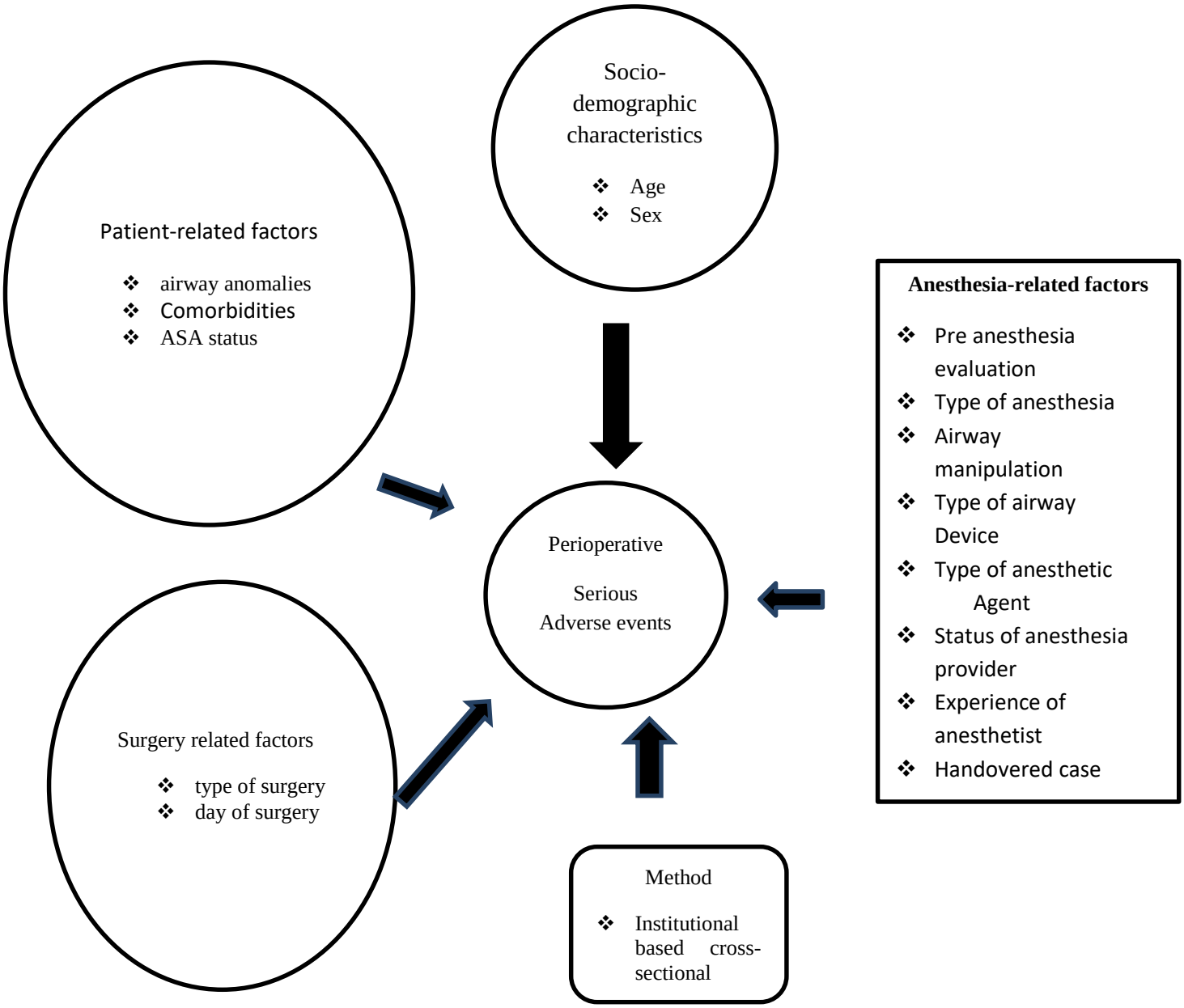

Figure 1 Conceptual framework of the study

3. OBJECTIVE

3.1. General Objective

To assess the incidence and associated factors of perioperative serious adverse events of pediatric patients who undergo surgery in Jimma University Medical Center from August 1 to November 1, 2021.

3.2. Specific Objectives

- To determine the incidence of pediatrics perioperative serious adverse events in JUMC.
- To identify associated factors of perioperative serious adverse events among pediatrics patients in JUMC.

4. METHOD AND MATERIALS

4.1. Study Area and study period

Jimma University Teaching Hospital is one of the oldest public hospitals in the country. It was established in 1930 E.C (1922 G.C) Geographically it is located in Jimma town 352 km southwest of the capital Addis Ababa and above sea level 1780m and it has a latitude and longitude of 7°40´N 36°50´E. Previously, it has been governed under the Ethiopian government by the name of "Ras Desta Damtew Hospital" and later "Jimma Hospital" during the dergue regime and currently named as Jimma university medical center. The hospital with 800 beds is expected to provide health services for more than 20 million people living in southwestern Ethiopia and also give services for South Sudan and neighboring countries. Pediatrics general operation started as a separate unit in September 2020 in JUMC, monthly estimated pediatrics operation in the unit is 60 to 70 patients. The study was conducted from August 1 to November 1, 2021.

4.2. Study Design

An Institutional based cross-sectional study was employed.

4.3. Source Population

All pediatric patients who undergo surgery in JUMC were the source population of the study.

4.4. Study Population

All pediatric patients who undergo surgery in JUMC during the study period were the study population of the study.

4.5. Eligibility Criteria

4.5.1. Inclusion criteria’s

- Pediatrics patients age less than or equal to 14 years.
- Pediatrics patients undergoing elective surgery under sedation or general anesthesia.
- Pediatrics patients undergoing emergency surgery under sedation or general anesthesia

- Pediatrics patients undergoing elective surgery under regional and neuraxial anesthesia.
- Pediatrics patients undergoing emergency surgery under regional and neuraxial anesthesia.

4.5.2. Exclusion criteria's

- Pediatric patients who undergo procedures outside the operation theatre.
- Pediatric patients who had surgeries in other institutions before coming to JUMC
- Pediatric patients who had known congenital heart disease.

4.6. Sample Size Determination

The sample size was determined using single population proportion formula by assuming the prevalence as 0.5 (since no previous study of the same setup is done) and 5% margin of error at 95% confidence interval using the following formulas:

Sample size $n = \frac{\left(Z\frac{\alpha}{2}\right)^2 P(1-P)}{d^2}$

Where: Z= Standard normal distribution value at 95% CI= (1.96)2

p= proportion of perioperative adverse events; P= 50% (0.5)

d= margin of error (0.05)

n= sample size

Therefore = $\frac{(1.9620)2\times0,5\times(1-0.5)}{(0.05)2} = \frac{3.8494\times0.5\times\mathbf{0.5}}{0.0025}$

= 384.9≈ 385

But, the sample is to be taken from a relatively small population (estimated N in study setting is 180 to 210 over 3 months) the required minimum sample was taken from the above estimate by using finite population correction formula.

$$n = \frac{\text{no}}{1 + {}^{\text{no}}/_{\text{N}}}$$

$$Final\ sample\ size = \frac{385}{1 + \frac{385}{180}} = 122.6896 \approx 123$$

Considering non respondent rate 5 % = 103×.05= 6.15 $\approx$ 129

4.7. Sampling Technique

Consecutively all eligible pediatric patients who underwent surgery in Jimma university specialized hospital during the study period were included in the study.

4.8. Variables

4.8.1. Dependent Variable

- Perioperative serious adverse events (SAEs)

4.8.2. Independent variables

Age, Sex, Type of surgery, Airway manipulation, Status and experience of the anesthesia provider, Airway device, Anesthetic agents, Underlying pathology, and Comorbidity.

4.9. Operational Definitions

Perioperative: - can be defined as the period extending from when the patient goes into the hospital, clinic, or doctor's office for surgery until the 24 hours after surgery.

Intraoperative: defined as the period when patient goes to operation room until time patient transferred to PACU

Serious Adverse Events (SAEs): defined as untoward occurrences of aspiration, death, cardiac arrest, or unplanned hospital admission during anesthesia care or within 24 h of the end anesthesia care.

Anesthesia-related mortality: defined as patients dying under, or following, the care of an anesthetist.

Airway event: defined as severe hypoxemia or hypercapnia while receiving intubation and medication during anesthesia, or within 24 hours of anesthesia.

Cardiac arrest: defined as heart rate below 60 beats/min) and requiring chest massage or administration of epinephrine).

Desaturation or hypoxemia: peripheral arterial oxyhemoglobin saturation (SpO2) < 95% more than 30 seconds measured by pulse oximetry regardless of administrations of 100% Oxygen or SpO2 <90% in atmospheric air. The Oxygen saturation was recorded when the pulse oximetry showed consistent readings with no artifacts (2).

Laryngospasm: complete airway obstruction associated with muscle rigidity of the abdominal and chest walls and it need requirement of positive pressure ventilation or administration of succinylcholine

Induction time: the time between starting of anesthesia and the starting of an incision.

Maintenance period: the time between starting of incision and finishing the operation.

Emergence time: the time between finishing the operation and the airway device being removed.

4.10. Data Collection Tool and Procedure

After reviewing different works of literature, a written structured questionnaire in the English language was prepared to assess the incidence and associated factors of pediatrics perioperative serious adverse events in JUMC. The data was collected by interviewing parents, legal guardians, or children above 12years on a question related to Sociodemographic data, comorbidities, and by reviewing the chart of the patient about preoperative diagnosis and physical status of the patient written by the treating physician. Question related to drugs used during premedication, induction, and maintenance was taken from the intraoperative anesthesia follow-up sheet. The overall intraoperative condition of the patient was asked from anesthesia provider at end of the procedure. And the 24-hour postoperative course was followed by the data collectors. The principal investigator oriented ten anesthesiology residents and two anesthetists for 2 days before starting data collection. All collectors can speak Amharic and five of them additionally speak Afan Oromo. The orientation was on the objectives of the study, the contents of the questionnaire, clinical

diagnosis of perioperative serious adverse events, on matters related to confidentiality, and about the transmission of covid-19 since the data collection was during the pandemic. Data was collected after taking consent from the parents or legal guardians and assent children above 12 years in the waiting area preoperatively. The data was carried out in pediatrics emergency and elective OR, ophthalmology OR, orthopedics, plastic, and maxillo facial OR during the intraoperative period.

4.11. Data Quality Control

To maintain the quality of data pretest was conducted by the principal investigator in Jimma University specialized hospital on 5% of the sample size to know whether the questions are understandable or not one week before moving to study. The modification was done on the questionnaire that is found with any ambiguity and affect the consistency of the questionnaire. During data collection principal investigator gave onsite technical support and close supervision. Data was checked daily for completeness, consistency and then errors were corrected accordingly before data processing and analysis.

4.12. Data Processing and Analysis

Data was edited, coded and entered, and cleaned by Epidata manager version 4.6.0.6. and was exported to SPSS (version 25) for analysis. The data analysis started from basic description to identification of potential associated factors of SAEs. Bivariate analysis and multivariate logistic regression was used to show the relationship between SAEs and various associated factors. The descriptive summaries of the cases' characteristics outcomes of interest were computed as simple frequencies, the measure of central tendencies, and the measure of dispersions. All explanatory variables which resulted in $p < 0.25$ with the outcome variable in the bi-variate variable were entered into a multivariate logistic regression model using the backward likelihood ratio method to identify independent predictors of SAEs. P-Value <0.05 is considered as statistically significant and the odds ratio are used at a 95% confidence interval to estimate the precision and strength of association.

4.13. Ethical Consideration

An ethical clearance letter was obtained from the institutional ethical review board of Jimma University. The purpose of the data collection and necessary information about the study was explained to respondents to increase their awareness about the study before the start of the interview. A formal written consent was obtained from the parents or legal guardian of the patient and assent from children whose age is above 12 years included in the study. All data obtained in the course of the study was kept confidential and was used solely for the research. The name of respondents was never used by any means throughout the research. A brief explanation was given for parents about the risks and benefits of participation in the study and they were asked for their willingness.

4.14. Dissemination of Results

The result was presented by the principal investigator and was submitted to the Department of Anesthesiology, Critical Care and pain medicine. Furthermore, the paper can be presented at workshops, seminars, and on other professional gatherings and an effort will be made to publish in a peer-reviewed journal.

5. RESULT

5.1. Characteristics of respondents

A total of 135 pediatrics patient underwent surgery under anesthesia were participated in the study giving a response rate of 100%. The majority of participants were male account 102(75.6%). and the mean age of respondents was 2.6 years SD of 2.12 years and 57 (42.2%) of them were in the age range of birth to 1 year and followed by the age group between 1 to 5 years of age which is 44(32.6%) (Table 1).

5.2. Surgical- and Anesthetic-Related Variables

Majority of patients 92 (68.1%) were operated under GA ,20 (14.8%) of patients with sedation. Among all patients 100(74.1%) were done as emergency surgery and 35(25.9%) were elective surgery. Majority of patients 61(45.2%) were ASA class I followed by ASA class II ,36 (26.7%) and ASA class IV, 22 (16.3%). Commonly done procedures in this study were General surgery 75(55.6%), neurosurgery 27 (20%), genitourinary tract 9(6.7%), orthopedic surgery 8(5.9%), plastic surgery 8(5.9%), and ENT 5(3.7%) (Table 1).

5.3. Anesthetic-Related Variables

All the study participants 135 (100%) were induced with intravenous anesthetic agents. 81(60%), induced with ketamine and propofol, 40(29.6%) ketamine and 3(2.2%) propofol and thiopental each and 102 (75.6%) were relaxed with suxamethonium and 2(1.5%) were induced with Vecronium. The majority of them were maintained with isoflurane 89 (65.9%) (Table 1).

Majority of the cases 117 (86.7%) were managed by anesthesiology residents with Anesthesiologists supervision.

Table 1 Socio demographic characteristics of pediatrics who undergo surgery under anesthesia and anesthesia providers for them from, August 1, 2021 to, November 1, 2021 Jimma University Medical Center (n=135)

Variables	Category	Frequency	Percent (%)
Age	birth - 12 months	57	42.2
	1 year+ - 5 years	44	32.6
	5 years+ - 10 years	25	18.5
	10 years+ - 14 years	9	6.7
Sex	Male	102	75.6
	Female	33	24,4
ASA physical status	Class I	61	45,2
	Class II	36	26.7
	Class III	16	11.9
	Class IV	22	16.3
Air way device used	ETT	103	76.3
	LMA	1	.7
	Face mask	19	14.1
Status of the Anesthesia providers	BSC anesthetist	7	5.2
	MSC anesthetists	6	4.4
	Resident	117	86.7
	Anesthesiologist	5	3.7
Induction agent	Ketamine + propofol	81	60
	Ketamine	40	29.6
	Propofol	3	2.2
	Thiopental	3	2.2
Neuromuscular agents used for induction	suxamethonium	102	75.6
	Vecronium	2	1.5
Maintenance agent	Isoflurane	89	65.9
	Halothane	2	1.4
	Ketamine	4	2.8
Premedication	Atropine	12	8.9
	Atropine and dexamethasone	19	14.1
	Atropine, and pcm	26	19.3

	Atropine, dexamethasone and paracetamol	49	36.3
	Others*	29	21.4

Variables	Category	Frequency	Percent (%)
Types of procedures	orthopedic	8	5.9
	neurosurgery	27	20
	GIT	75	55.6
	GUT	9	6.7
	Plastic	8	5.9
	ENT	5	3.7
	Others**	3	2.2

BSC: Bachelor of Science MSC: Masters of Science, GIT (Gastrointestinal tract), GUT (Genitourinary tract), others*(IV lidocaine, diazepam, pethidine), LMA (laryngeal mask airway), ETT (endotracheal tube) others** (Ophthalmology and maxillofacial surgery)

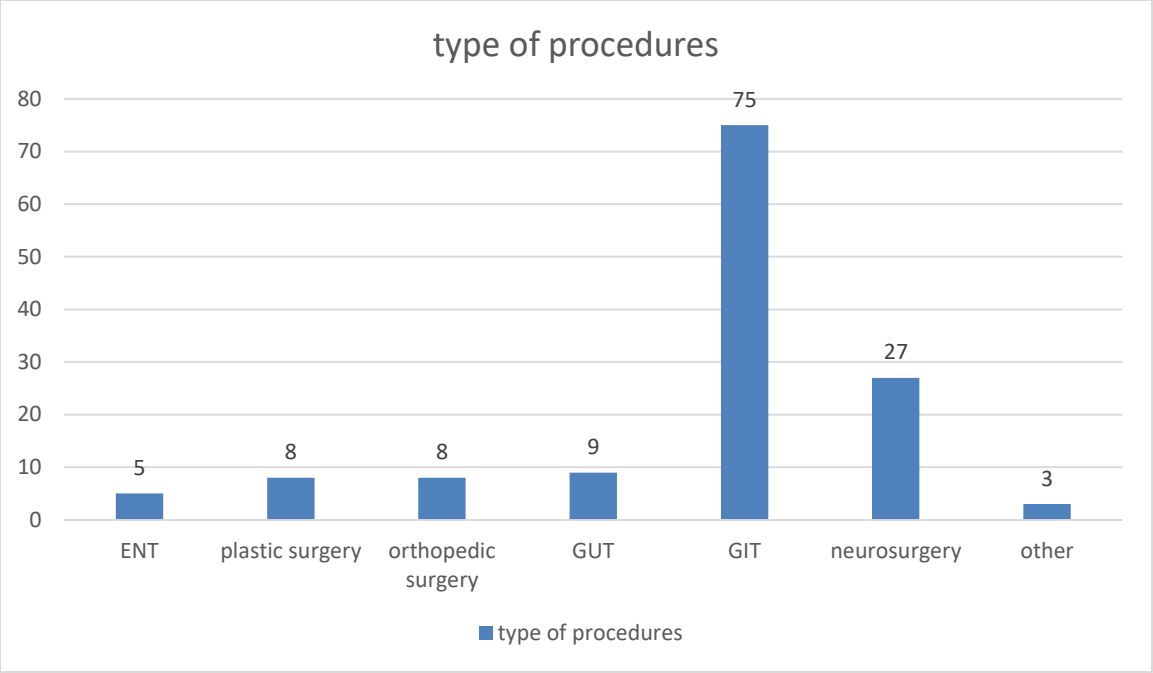

Figure 2 Types of procedures done for pediatrics who undergo surgery under anesthesia from, August 1, 2021 to, November 1,2021 at Jimma University Medical Center (n=135)

5.4. Incidence of adverse events

Of the total of study subjects 50 (37%) identified adverse events. Among them majority 58% are respiratory adverse events followed by cardiovascular events. Of the respiratory adverse events desaturation and laryngospasm account the majority ones; and from the cardiovascular events dysrhythmias and hypotension are the leading causes.

Of the total study subjects, 5 (3.7%) cases of SAEs were identified. From the SAEs majority was cardiac arrest ,2(40%), reintubation 1(20%) aspiration 1(20%) and death 1(20%). Among them, the onset of the events during intraoperative period was 3(60%), and 2(40%) in first 24 hours post operatively.

Of the total study subjects the incidences of individual SAE were cardiac arrest 2(1.48%), reintubation, aspiration and death were each1(0.7%).

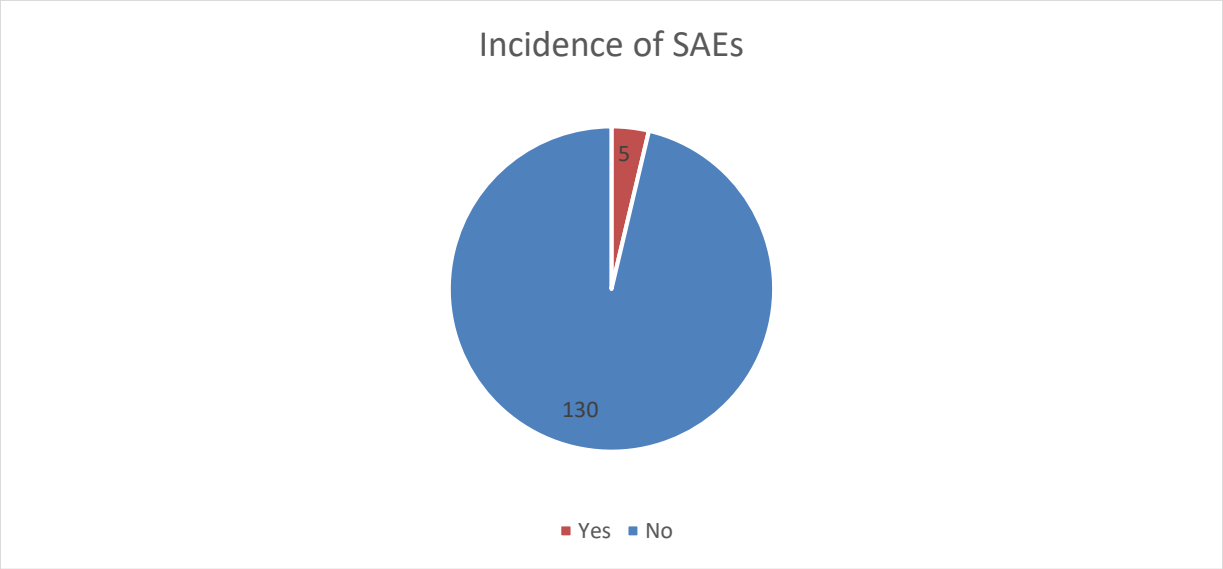

Figure 3 Incidence of SAEs among pediatrics who undergo surgery under anesthesia from August 1, 2021 to, November 1, 2021 at Jimma medical center (n=135)

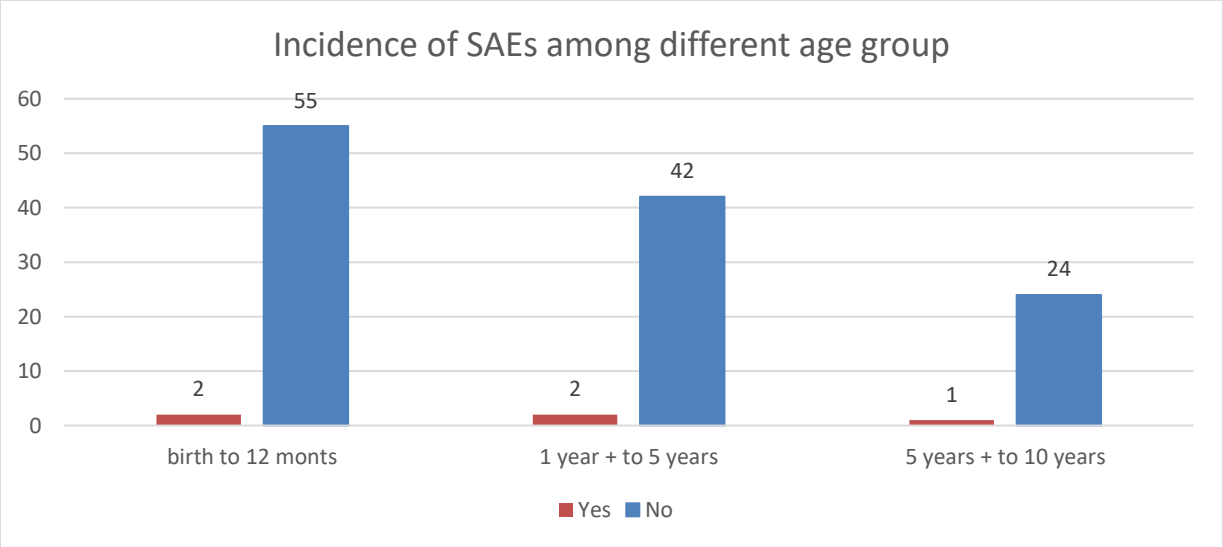

Figure 4 Incidence of SAEs among different age groups of pediatrics who undergo surgery under anesthesia from, August 1,2021 to, November 1,2021 at Jimma University Medical Center (n=5).

5.5. Factors Associated with perioperative SAEs

Before the multi-variable analysis regression diagnostic procedures were carried out under linear regression by collinearity diagnostics and multicollinearity diagnosis was performed using variance inflation factor and none was detected. In addition, variables did not meet the assumption of X2 -tests were not considered for multivariable analysis. These variables were status of anesthesia providers, year of experience, type of anesthesia, duration of surgery, duration of anesthesia, air way device and comorbidities. Variables associated in the bivariate such as age, ASA classification, airway event and type of surgery were entered to multivariable logistic regression model. The multivariable logistic regression analysis confirmed those variables with P value less than 0.05 such as ASA classification, airway event and type of surgery as potential predictors of perioperative SAEs in pediatric patient.

Pediatric patients who undergo emergency surgery were 1.42 times (AOR:1.42,95% CI:1.33,4.61) more likely to develop perioperative SAEs than elective cases. Patients who had ASA status classification of III and IV were 3.14 times (AOR: 3.14,95% CI:1.3,5.32) and 3.31 times (AOR:3.31,95% CI:1.3,6.71) more likely to develop perioperative SAEs respectively. Those who have airway event were 1.52times (AOR: 1.52, 95% CI: 1.46, 12.57), more likely to have perioperative SAEs than those who were not having airway event (Table 2).

Table 2 Binary and Multivariate logistic regression analysis of factors associated to perioperative serious adverse events of pediatrics who undergo surgery under anesthesia, August 1, 2021 to November 1, 2021 at Jimma University Medical Center (n=135)

Variable	Category	Perioperative serious adverse event		Crude OR (95 % CI)	Adjusted OR (95 % CI)	P- value
		Yes: N (%)	No: N (%)			
Age	birth - 12 months	2(3.5)	55(96.5)	0.78(0.19, 3.24)	0.45(0.057, 3.57)	0.45
	1 - 5 years	1(2.3)	43(97.7)	0.58(0.13, 2.5)	0.41(0.049, 3.5)	0.41
	5 - 10 years	1(4)	24(96)	0.83(0.17, 3.88)	1.02(0.1, 10.28)	0.98
	10-14years	1(11.1)	8(88.9)	1	1	
ASA classification	I		61(100)	1	1	
	II	1(2.8)	35(97.2)	0.87(0.39, 1.96)	0.33(0.1, 1.13)	0.29
	III	1(6.3)	15(93.7)	4.1(1.9,6.93)	3.14(1.3,5.32)	0.006
	IV	3(15.6)	19(86.4)	4.1(1.2,8.16)	3.31(1.3,6.71)	0.006
Type of surgery	Emergency	4(4)	96(96)	2.42(1.8, 7.35)	1.42(1.33,4.61)	0.007
	Elective	1(2.9)	34(97.1)	1	1	
Airway event	yes	3(60)	2(40)	2.75(1.6,11.13)	1.52(1.46,12.57)	0.011
	no	2(1.5)	128(98.5)	1	1	

5.6. Outcome of perioperative serious adverse events

Among the patients who developed the SAEs 1 (20%) died ,3 (60%) improved and 1(20%) remain comatose over 24 hours after anesthesia.

6. DISCUSSION

The aim of this study was to determine magnitude perioperative SAEs and its associated factors in pediatrics patients undergoing surgery in Jimma university medical center. Pediatric perioperative management is always challenging and adverse events occur more commonly in Pediatric anesthetic practice than in adults. In this study the highest number of age group was between birth to 12 months 57 (42.2%) and followed by the age group between 1 to 5 years of age 44 (32.6%). the mean age of respondents was 2.6 years with SD of 2.12.

In this study the overall incidence of perioperative SAEs was 5(3.7%) from those 3 (60%) and 2(40%) happened intraoperatively and postoperatively in first 24 hours respectively. Its higher than a prospective descriptive study which was conducted in 22 hospitals across Thailand in 2015 (15.5 in 10000) (11). It is also higher than retrospective case-control study conducted from 2010 to 2012 at the CHOP which was 0.0043 (1:234) (1). The discrepancies of this study and the above studies could be due to difference in sample size, the set up difference by level of services the institutions provide or structure of hospitals or equipment supply or differences of medication.

In this study cardiac arrest from all causes during anesthesia is approximately 1.5% which is significantly higher than data collected from liability claims, incident-reporting systems (registries) and anaesthetic information systems (databases) in south Africa which is 0.2%to 0.3% (10).

A retrospective cohort study done at the Wilhelmina Children's Hospital, Utrecht, The Netherland, the all-cause 24-hour hospital mortality was 0.13% which is significantly lower than this study 0.7% which could be due to the set up difference by level of services the institutions provide or structure of hospitals or equipment supply or differences of medication (12). The study was done retrospectively where there was no pre-stated definition of perioperative SAEs and there were difficulties in interpreting such data. Anesthetic-related mortality in middle-income countries is 2–3 times higher than that in developed countries. Anesthetic-related mortality increases by a factor of 50–100 in low-income countries but maybe 1 000-fold higher in certain poor countries (10). This is also supported by the authors of a prospective cohort study from 24 hospitals in Kenya have established a baseline pediatric perioperative mortality rate that is greater than 100 times higher than in high-income countries (17).

Of the total of study subjects 50 (37%) identified adverse events,58% are respiratory adverse events which is similar with 6-year period study by Jurgen C de Graaff in Netherlands in 2014 which showed most frequently reported incidents (46.5%) (18).

In this study, it was found that the majority of perioperative SAEs occurred in children from birth to 12months of age 2 (40%) and from 1 year to 5 years of age 2(40%). But statistically it was not associated with occurrence of SAE. It is inconsistent with other similar studies which showed the magnitude of SAEs in young children being higher especially in infants less than 1 year of age (17,12).

In this study patients who had ASA classification III and IV were about three times more likely to develop perioperative SAEs which is in line with a study done at the Wilhelmina Children's Hospital, Utrecht, in Netherland and study conducted from at the CHOP (12) (1). Gonzalez LP et al. also confirmed a high incidence of perioperative SAEs occurred in the ASA IV–V (13).

The study also showed pediatric patients who undergo emergency surgery were about one and half times more likely to develop perioperative SAEs than elective cases which goes together with data collected from liability claims, incident-reporting systems (registries) and anaesthetic information systems (databases) in south Africa odds ratio of 2.8 (10). Barbour R, Deka P also confirmed a high incidence of perioperative SAEs occurred in emergency surgical cases (9). This is also supported the authors of a prospective cohort study from 24 hospitals in Kenya and by the study done at Wilhelmina Children's Hospital, Utrecht, in Netherland in 2015 (18 ,12).

Airway event (Air way manipulation) during intubation was one and half times more likely to have perioperative SAEs than those who were not having airway event which is consistent with data collected from liability claims, incident-reporting systems (registries) and anaesthetic information systems (databases) in south Africa in 2015(10). Lee et al. also confirmed high incidence of SAEs in patients with tracheal tube related events (19).

In a prospective cohort study from 24 hospitals in Kenya not having the Safe Surgery Checklist performed was associated with a statistically significant increase in 7-day mortality however in this study checklist was performed in 91% of cases and didn't show any association (19)

In a retrospective case-control study conducted at CHOP, attending anesthesiologist's experience was significantly associated with SAEs; which is supported by prospective descriptive study conducted in Thailand (1,11). However, this study didn't show any statically significant association with status of anesthesia provider and experience. Possible reason was majority of the procedures were done with anesthesiology residents supervised by anesthesiologist and had similar year of experience.

In this study 60% SAEs happened intraoperatively and 2(40%) postoperatively in first 24 hours and the categories of contributing factors (preoperative, intraoperative, and postoperative) were equal though not statistically significant which is supported by study done by Ain Shams University in Egypt (6).

7. LIMITATION OF THE STUDY

Data collection lack some, consistency during weekend and night time of emergency pediatrics surgery because, trained data collector may not be on duty during whole study period.

There is lack of large, prospective datasets for documentation of perioperative incidents so there may be under reporting or lack of willingness to report extremely poor incidents and outcomes.

The study identified perioperative SAEs from all causes during anesthesia and didn't differentiate whether the SAEs are surgery related or anesthetic related.

Because of the small sample size used in single hospital study may result in over estimation of results plus because of the hospital based differences in facilities and status of providers, it precludes wide generalization of the results so future studies should involve a large sample size and should as well involve multiple hospital centers.

8. CONCLUSION AND RECOMMENDATION

In conclusion, perioperative adverse events were common under pediatrics age group during both intraoperatively and postoperatively.

The independent associated factors were emergency surgery, higher ASA physical status and airway event. It was associated with significant perioperative morbidity and mortality.

On the basis of the findings of the study the followings are recommended.

1, JUMC and Anesthesiology, Critical Care and Pain Medicine department, should prepare prospective electronic dataset which is being applied in other low and middle income countries for clean collection of critical incidents and mortality.

2, Anesthesia providers should do preoperative evaluation and optimization of emergency cases and patients with higher ASA physical status classification.

3, Anesthesia providers should reduce airway events during airway management intraoperatively.

4, Researcher should conduct further researches including larger sample size and multiple hospital centers.

9. REFERENCES

1. Schleelein LE, Vincent AM, Jawad AF, Pruitt EY, Kreher GD, Rehman MA, et al. Pediatric perioperative adverse events requiring rapid response: a retrospective case–control study. Paediatr Anaesth. 2016 Jul 1;26(7):734–41.

2. Wudineh[1] DM, Woldegerima Berhe[2] Y, Chekol[2] WB, Adane[2] H. Perioperative respiratory adverse events in general anesthesia among pediatric surgical patients in Comprehensive Specialized Hospitals in Northwest Ethiopia, 2020; a cross-sectional follow-up.

3. Murat M D P M D P H H D D I, And DD, Le`ne HÉ, Le`ne Maud'huy M D L. Perioperative anaesthetic morbidity in children: a database of 24 165 anaesthetics over a 30-month period.

4. Wake. ANESTHESIA & ANALGESIA [Internet]. 2018. Available from: www.anesthesia-analgesia.org

5. Lee S, Reddington E, Koutsogiannaki S, Hernandez MR, Odegard KC, DiNardo JA, et al. Incidence and risk factors for perioperative cardiovascular and respiratory adverse events in pediatric patients with congenital heart disease undergoing noncardiac procedures. Anesth Analg. 2018;127(3):724–9.

6. References [Internet]. Available from: www.tandfonline.com/ojaa

7. Sileshi B, Newton MW, Kiptanui J, Shotwell MS, Wanderer JP, Mungai M, et al. Monitoring anesthesia care delivery and perioperative mortality in Kenya utilizing a provider-driven novel data collection tool. Anesthesiology. 2017 Aug 1;127(2):250–71.

8. Uffman JC, Tumin D, Beltran RJ, Tobias JD. Severe outcomes of pediatric perioperative adverse events occurring in operating rooms compared to off-site anesthetizing locations in the Wake Up Safe Database. Paediatr Anaesth. 2019 Jan 1;29(1):38–43.

9. Barbour R, Deka P. Paediatric anaesthesia for low-resource settings. BJA Educ. 2017 Nov 1;17(11):351–6.

10. Cronjé L. A review of paediatric anaesthetic-related mortality, serious adverse events and critical incidents. Vol. 21, Southern African Journal of Anaesthesia and Analgesia. Medpharm Publications; 2015. p. 5–11.

11. Charuluxananan S, Sriraj W, Punjasawadwong Y, Pitimana-Aree S, Lekprasert V, Werawatganon T, et al. Perioperative and Anesthetic Adverse events in Thailand (PAAd Thai) incident reporting study: Anesthetic profiles and outcomes. Asian Biomed. 2017 Feb 1;11(1):21–32.

12. Critical elements for the pediatric perioperative anesthesia environment. Pediatrics. 2015 Dec 1;136(6):1200–5.

13. Gonzalez LP, Braz JRC, Módolo MP, De Carvalho LR, Módolo NSP, Braz LG. Pediatric perioperative cardiac arrest and mortality: A study from a tertiary teaching hospital. Pediatr Crit Care Med. 2014 Nov 10;15(9):878–84.

14. De Bruin L, Pasma W, Van Der Werff DBM, Schouten TANJ, Haas F, Van Der Zee DC, et al. Perioperative hospital mortality at a tertiary paediatric institution. Br J Anaesth. 2015 Oct 1;115(4):608–15.

15. Perioperative Mortality in New Zealand: Fifth report of the Perioperative Mortality Review Committee PERIOPERATIVE MORTALITY REVIEW COMMITTEE: FIFTH REPORT [Internet]. 2016. Available from: www.hqsc.govt.nz

16. Jones PM, Cherry RA, Allen BN, Bray Jenkyn KM, Shariff SZ, Flier S, et al. Association between handover of anesthesia care and adverse postoperative outcomes among patients undergoing major surgery. JAMA - J Am Med Assoc. 2018 Jan 9;319(2):143–53.

17. Newton MW, Hurt SE, McEvoy MD, Shi Y, Shotwell MS, Kamau J, et al. Pediatric perioperative mortality in Kenya a prospective cohort study from 24 hospitals. Anesthesiology. 2020;(3):452–60.

18. De Graaff JC, Sarfo MC, Van Wolfswinkel L, Van Der Werff DBM, Schouten ANJ. Anesthesia-related critical incidents in the perioperative period in children; A proposal for an anesthesia-related reporting system for critical incidents in children. Paediatr Anaesth. 2015;25(6):621–9.

19. Lee JH, Kim EK, Song IK, Kim EH, Kim HS, Kim CS, et al. Critical incidents, including cardiac arrest, associated with pediatric anesthesia at a tertiary teaching children's hospital. Paediatr Anaesth. 2016 Apr 1;26(4):409–17.

10. ANNEXES

Annex 1: Information sheet and consent form (English version)

A questionnaire for assessing incidence and associated factors of pediatrics perioperative serious adverse events in Jimma University specialized hospital

Good morning/good afternoon. My name----------; we come from Jimma University. We are working with an investigator, Efrem Hailu, doing his thesis for the partial fulfillment of specialty certificate of Anesthesiology, Critical Care and Pain Medicine. We are interviewing associated factors of pediatric perioperative serious adverse events. We are going to ask you some questions that are not difficult to answer. Your name will not be written in this format and never be used in connection with any of the information you are going to tell me. You are not obliged to answer any question that you do not want to answer and you may end this interview at any time you want to. However, your honest answers to these questions will help us to identify the main risk factors associated with perioperative serious adverse events of pediatric patients and helps to solve the identified problems in the future to control and prevent it. We would like to appreciate your help in responding to these questions, and the interview will not take more than 30 minutes.

Informed consent

I am the individual asked to be a study participant. Based on the information provided by the principal investigator, understand that it is not necessary to write my name, the information I tell to her/him will not to be used for other purpose and the information obtained from me will help to identify the main risk factors associated with perioperative pediatrics laryngospasm under general anesthesia and helps to solve the identified problems in the future to control and prevent it in the future. So I agree to be a study participant.

1. Yes_____ If yes go to next section
2. No_____ If no go to next participant

Name of data collector_____ signature_____

Annex 2: Information sheet and assent form for child age 12 years and above (English version)

Dear participant, my name is _____ I am anesthesiology resident/anesthetist at JUSH, working with investigator, Efrem Hailu conducting his thesis for the partial fulfillment of specialty certificate of Anesthesiology, Critical Care and Pain Medicine. The purpose of this form is to inform you about the study. You are invited to this study because we are doing research on pediatric age group less 14 years old, who undergo surgeries under anesthesia to identify incidence and associated factors of perioperative serious adverse events. If you agree to participate in the study you will explain to the participant the research activities you expect them to engage (e.g. taking a test/questionnaire, participating in interview, observation) I will start asking you here before you will go to operation room and information will be taken from your documents during operation and by observations. I will take your information until your surgery will be completed and until 24 hours after the surgery. You are participating in this study voluntarily and you may decline to participate at any time, even after study has started. If you choose not to participate or to with draw from study, there will be no penalty and you will be able to keep any incentives you have earned up to the point at which you withdraw. Although there may be no direct benefit to you the possible benefit of your participation will help to identify the incidence and major contributing factors of perioperative serious adverse events in children undergoing surgery. This helps to assess the adverse event early and treat before it complicate and avoid identified risk factors. The participant will assign ID number during the study any personal information will not be written in the study. Your information will be kept confidentially and will be used only for the purpose of study. The result of the study may be used in reports, presentation, or publications your name will not be used. There will be minimal risks and inconveniences to participate in this study.

If you have question about the study, please call me at phone No 0912404198

Email address: Efrem.hn@gmail.com

Certificate of Assent

I understand the research is to identify incidence and associated factors of perioperative Serious adverse events and the study may help for children undergoing surgeries under Anesthesia.

I have read this information (had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I don't wish to take part in the research and I have not signed the assent below. _____

Name of child: _____

Signature of child: _____

Date: _____

For illiterate witness

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____ and thumb print of participant_____

For literate witness

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Name of researcher: _____

Signature of researcher: _____

Date: _____

Statement by researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done

1._____

2._____

3._____

I confirm that the child was given an opportunity to ask questions about the study, and all question asked by him/her have been answered correctly and to the best ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form will be provided to the participant.

Name of researcher/ person taking the assent: _____

Signature researcher/person taking the assent: _____

Date: _____

Copy provided to the participant _____ (initiated by researcher/assistant)

Parent/guardian has signed informed consent ____ Yes No_____ (initiated by researcher/ assistant)

Annex 3: Questionnaire (English version)

Questionnaires on incidence and associated factors of perioperative Serious adverse events among pediatric patients undergoing surgery at JUMC

Questioner Code _____

I. Socio-demographic characteristics and observed pre-operative documentations

1. ID_____
2. Age/year____
3. Sex
    a. Male
    b. Female
4. Type of surgery
    a. Elective
    b. Emergency
5. Time of surgery
    a. Weekday
    b. Weekend
6. Unit (department) of the surgical procedure
    a. Otorhinolaryngology
    b. General surgery
    c. Orthopedics
    d. Plastic surgery
    f. Ophthalmology
    g. Neurosurgery
    h. Multiple
    i. Maxillofacial Surgery

e. Urology j. Other (specify_____)

7. ASA classification

a. 1 b. 2 c. 3 d. 4 e. 5 f. 6

8. NPO status observed in elective cases

a. Yes b. No

9. Pre-op interview observed/documented

a. Yes b. No

10. Anesthesia consent found on file

a. Yes b. No

11. Allergies documented

a. Yes b. No

12. Medication history documented

a. Yes b. No

13. Medical history/co-morbidity documented

a. Yes b. No

14. If “yes” to question 13, specify the co morbidity

a. Respiratory d. Endocrine

b. Cardiovascular e. Other(specify)____

c. Neurological

15. Previous history of anesthetics/surgery documented (If any)

a. Yes b. No

16. Pertinent lab results/investigations documented on file

a. Yes b. No

17. Patient identification observed

a. Yes b. No

18. Pre-op airway assessment observed/documented

a. Yes b. No

19. Pre-op v/s done and recorded

a. Yes b. No

20. WHO pre-op team review of anticipated challenges done

a. Yes
b. No

21. Status of anesthesia provider

a. BSc
b. MSc
c. Anesthesia resident
d. Anesthesiologist

22. Year of experience____

II. Intra-op anesthesia procedures/medications and post op disposition

1. Planned anesthetic technique

a. GA
b. SA
c. GA + Caudal
d. GA + PNB
e. Sedation
f. Sedation + PNB
g. Sedation + Caudal
h. Spinal (Epidural)

2. Airway management

a. ETT
b. LMA
c. Face mask
d. None

3. Intubation equipment used

a. Direct laryngoscope
b. Video laryngoscope
c. Other (Specify_____)

4. Airway adjuncts used

a. Yes
b. No

5. Anesthetic /adjunct drugs used

i. Premedication(s)

a. Atropine/Glycopyrrolate
b. Dexamethasone
c. Acetaminophen
d. Iv lidocaine
e. Diazepam
f. Other (Specify_____)

ii. Induction agent(s)

a. Ketamine
b. Thiopental
c. Propofol
d. Halothane
e. Isoflurane
f. Sevoflurane

iii. Muscle relaxants

a. Succinylcholine
b. Vecronium
c. None

iv. Maintenance

a. Halothane
b. Isoflurane
c. Ketamine
d. propofol
e. Halothane + Ketamine
f. Isoflurane + ketamine
g. Halothane + propofol
h. Isoflurane + propofol
i. Ketamine + propofol

v. Reversal

a. Yes
b. No

vi. Opioids

a. Yes
b. No

vii. Anti-emetics

a. Yes
b. No

viii. Others (specify_____)

6. Monitors used intra-operatively (more than one answer)

a. NIBP
b. ETCO2 monitor
c. Pulse oximeter
d. Temperature monitor
e. ECG monitor
f. Anesthesia depth monitor
g. Nerve stimulator
h. Others

7. Duration of surgery (minutes) _____
8. Duration of Anesthesia (minutes)_____
9. Is the case Handovered from another provider

a. Yes
b. No

10. WHO post-op safety checklist done?

a. Yes
b. No

11. Postoperatively the patient was transferred to___

a. PACU
b. ICU
c. Ward
d. Other (specify_____)

12. Monitors available at the postop place

a. NIBP
b. Pulse oximeter
c. ECG
d. Temperature monitor

III. Adverse events and patient outcome

1. Are there any observed(documented) intraoperative/postoperative events?

a. Yes
b. No

2. If yes to Ques.1 what was the event (s)

I. Respiratory

a. Laryngospasm
b. Bronchospasm
c. Difficult airway
d. Airway obstruction
e. Desaturation
f. Aspiration
g. Accidental extubation
h. Other___

II. Cardiac

a. Dysrhythmias
b. Cardiac arrest
e. Other_____
c. Hypotension
d. Myocardial infarction

III. Hemorrhage/bleeding

IV. Others

a. PONV
b. Anaphylaxis
c. Communication/medication error
d. Total spinal blockage
e. High spinal blockade
f. Hypothermia

3. What is the outcome of the patient in 24 hours?

a. Resolved
b. Comatose
c. Death
d. If other, specify__

Annex 4: Information sheet and consent form (Amharic version)

የመጠይቅ ፈቃድ

ጂማ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ ፣ህክምና ትምህርት ቤት፣የአንስቴዥሎጂትምህርት ክፍል

የመጠይቅ ፈቃደኛነት ቅጽ

ስሜ_____ይባላል።እኔ

በጂማ ዩኒቨርሲቲ በአንስቴዥሎጂ ትምህርት ክፍል የምርምር ቡድን ዉስጥ አንድ አባል ነኝ። የዚህ መጠይቅ አላማ ህጻናት ቀዶ ጥገና በሚደርጉ ወቅት የሚያጋጥሙ ከባድ ክስተቶች መጠን እና ተያያዥ ምክንያቶችን ለማዎቅ ለሚደረገው ምርምር/ጥናት /መረጃ ለመሰብሰብ ነው።

የእርስዎ ልጅ አንድ የጥናቱ ክፍል አድርጌ ስመርጥ አስፈላጊ የሆኑ መረጃዎችን እንደሚሰጡኝ በማሰብ ነው፡ ፡ በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ ከእርስዎ የሚገኘው ማንኛውም መረጃ በሚስጥር ይጠበቃል። ለዚህም ሲባል የእርስዎ ምሆነ የልጅዎ ሥም ና አድራሻ አይገለጽም።እንድሁም ከጥናቱ በኋላ ኦፕራሲዎን ለሚደረግላቸዉ ህጻናት ቀዶ ጥገና በሚደርጉ ጊዜ ላሪንጎስፓዝም የሚባል የጉሮሮ ውስ ጥህመም መጠን እና ተያያዥ ምክንያቶችን ለማዎቅ እና ተገቢ የሆኑ እርምጃዎችን ለመዉሰድ ይረዳል።

የቃል ሥምምነት

የዚህ ጥናት ዓላማው ገብቶኝ በጥናቱ ለመሣተፍ

ሀ. ፈቃደኛ ሆኛለሁ ለ. ፈቃደኛ አይደለሁም

በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ ቃለመጠይቁን መቀጠል ይቻላል።

ፈቃደኛ ከሆኑ የመጠይቁ መለያ ቁጥር ____ መጠይቁ የተካሄደበት ቀን _____

የጠያቂው ስም ና ፈርማ _____

የሱፐርቫይዘር ስም ና ፈርማ _____ ጥናቱን በተመለከተ ማንኛዉም አይነት ጥያቄ ካላችሁ የሚከተለዉን አድራሻ ተጠቀሙ::

በዋናነት ምርምሩን የሚያካሂዉ ሰዉ ስም፡ ኤፍሬም ሀይሉ

ስልክቁጥር 0912404198

Annex 5: Information sheet and assent form for child age 12 years and above (Amharic version)

የመጠይቅ ፈቃድ

ውድ ተሳታፊዬ ስሜ ————————— ይባላል በጅማ ዩኒቨርሲቲ የ አነሰቲዮሎጂ ሬዝደንት/አንስቴቲስት ስሆን ከ ተመራማሪ ኤፍሬም ሀይሉ ጋር እየሰራሁ ነው። የዚህ ቅጽ ዓላማ ስለ ጥናቱ ላንተ/ቺ ለማሳወቅ ነው ። አንተን/ችን ወደዚህ ጥናት የ ጋበዝንበት ምክንያት ከ 14 በታች በሆኑ ህጻናት ቀዶ ጥገና በሚደርጉ ወቅት የሚያጋጥሙ ከባድ ክስተቶች መጠን እና ተያያዥ ምክንያቶችን ለማዎቅ ምርምር /ጥናት /እየደረግን ስለ ስለሆነ ነዉ። በዚ ጥናት ለመሳተፍ ከተስማሙ ለተሳታፊዉ አንዳንድ ለ ምርምሩ የሚረዱ ተግባራትን (መጠይቅ፤ በቃል መጠይቅ መሳተፍ፤ ምልከታ) ይፈጽማሉ ። ወደ ቀዶ ጥገና ክፍል ከመግባትህ በፊት እዚህ አንዳንድ ነገሮች እጠይቅህ እና ወደ ቀዶ ጥገናዉ ክፍል ግበትህ ቀዶ ጥገናዉ ሲጀመር ከሰነዶችህ/ሽ እና በምልከታ ለጥናቱ የሚያስፈልጉ መረጃዎች ቀዶ ጠገናዉ እስኪያልቅ ድረስ ይወሰዳሉ። እንዲሁም ቀዶ ጥገናው ካለቀ በኹላ እስከ 24 ሰዐት ያሉ ለጥናቱ የሚያስፈልጉ መረጃዎች ይወሰዳሉ። በዚህ ጥናት እየተሳተፍክ ያለሀዉ/ሽው በፍቃደኝነት ነዉ። በመንኘውም ጊዜ ተሳትፎህን/ሽ ማቆረጥ ትችላለህ/ሽ። ተሳትፎህን/ሽን በማቆረጥህ/ሽ ምንም አይነት ቅጣት የለዉም፤ ማንኛውም መበረታቻ እስከ ተሳተፉበት ጊዜ ይደረግልሃል/ሻል። ይህ ጥናት በ ቀጥታ በይጠቅምህም/ሽም ሙሉ ሰመመን ወስደው ቀዶ

ጥገና ለሚ ሰራላቸዉ ህፃናት በዚህ ወቅት የሚያጋጥሙ ከባድ ክስተቶች እንዳይጋለጡ እና ተያያዥ ነገሮችን ለመከላከል ይረደል። ከ አንተ የተገዉ መረጃ ለ ጥናቱ አላማ ቢቻ የሚውል ሲሆን ሚስጥረህ የተጠበቀ ነዉ፡ ፡መረጃዉን ተሳታፊው መለያ ቁጥር ሰጥቶ ይመዘግ በወል መንነተህም ሆነ ሰምህ/ሽ አይጠቀስም።የጥነቱ ውጠት ለ ርፖርት፤መማሪያ፤ ህትመት ሊያገለግል ይ ችላል ።

የማረጋገጫ ወረቀት

ህጻናት ቀዶ ጥገና በሚደርጉ ወቅት የሚያጋጥሙ ከባድ ክስተቶች መጠን እና ተያያዥ ምክንያቶችን ለማዎቅ ለሚደረገው ምርምር/ጥናት / እንደሆነ አንብቤ (ተነቦልኝ) ብዙ ጥያቄዎችን መልሻለሁ በሁላ ጥያቄ ቢኖረኝ መጠየቅ እንደምችል ተረድቻለሁ።

ለመሳተፍ ተስማምቻለሁ

የ ልጁ ስም----------

ፊርማ----------

ቀን----------

ማንበብ እና መጻፍ ለ ማይችሉ መመስክር

የ ስምምነቱ ለ ልጁ ሲነበብለት እና በ ነፃነት ጥያቄ መጠየቅ እንደሚችል አየቻለሁ።

የ ምስክሩ ስም---------- የ ጣት አሻራ----------

መንበብ እና መጻፍ ለሚችሉ መመሸር

የ ስምምነት ቅጹ አንብቤ ወይም ስነበብለት እና ልጁ ጥያቄ መጠየቅ እንደሚችል በደንብ አይቻለሁ።

የ መርማሪው ስም----------

ፊርማ----------

ቀን----------

የ ተመራማሪው ቃል

የ መረጃ ወረቀቱን ለተሳታፊው በ ትክክል አንብቤዋለሁ፡ በ ሚቻለኝ አቅም ልጁ ሚከተሉትን ልጁ የከናወናሉ ብሎ መረደቱን አረጋግጣለሁ፡፡

1.----------

2.----------

3.----------

ልጁ/ቱ ስለ ጥናቱ የሚፈልገውን/ትገውን ጥያቄ እና በልጁ/ቱ የተጠቁ ጥያቄዎች በ አግባቡ እንደ ተመለሱለት/ላት አረጋግጣለሁ፡፡

የ ስምምነቱ ቅጽ በ ኮፒ ለ ተሳታፊ ይሰጣል

የተመራማሪው/የ ተሳታፊው ስም----------

የ ተመራማሪው/የ ተሳታፊው ፊርማ----------

ቀን----------

የ ልጁ/ቱ ቤተሰብ/አሳዳጊ የ ፈቃደኝነት ቅጹን ተሸማምተው ፈርመዋል፡፡ አወን---------- ---- አልተስማሙም፡፡

Annex 6: Informed sheet and consent form (Afan Oromo version)

Walii galitee

Ani Obboo/addee/Dr _____ , miseensa garee qorannoo irra

Qoranoo kun kan inni irratti xiyeefatee, waa'ee dhibee daa'imman waggaa 14 gadii muudannaa rakkoowwan hamaa yeroo yaala baqaqsanii hodhuu mul'atan ilaalata.

kanaafuu qorannoo kana irrattii wanta isin irraa eegamu akka nuufgotan kabajaan isin gaafanna. Kuni ammoo fayyaa daimmaniif fayidaa guddaa jijjiirama qabu akka fidu niabdana.

Waliigalitee kessaniin ala iccitii kessan nama tokkoofu yokan ammoo waajira tokkoofuu akka

dabarsinee hinkenineef waadaa isinii galla. Yoo qorannoo kana irratti hirmachuu waliigallee

gaafii waliigalaa irraa isinii jaliqabaa. Deebii kessan kan dhugaa irratti hundahee fayidaa jijjiirama fayyaatif nuqarqaara.

Qorannoon kun karaa univarsitii Jimma irraa fudhatama argatee jira. Kanafuu qorannoo

kanarratti hirmaachuuf fedhii qabduu?

Assurance of principal investigator

The undersigned agrees to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the Institute of health faculty of medical science in effect at the time of grant is forwarded as the result of this application.

Name of the student: _____ Signature _____

Date: _____

Approval of the first advisor

Name of First Advisor: _____Signature_____

Date: _____

Ref.No: IHRPGD/83/21

Date: 28/11/2021

To : Dr. Efrem Hailu

Subject: Ethical Approval of Research Protocol

The IRB of Institute of Health has reviewed your research project " **Incidence and associated factors of perioperative serious adverse events in pediatric patients undergoing surgery in JUSH** "

Thus, this is to notify that this research protocol has presented to the IRB meets the ethical and

Scientific standards outlined in national and international guidelines. Hence, we are pleased to inform you that your research protocol is ethically cleared under the following strict conditions:

1. Any significant deviation from the methodological details indicated in the approved protocol must be communicated to the IRB before it has been implemented.
2. Approval shall be only for a period of twelve months. The principal investigator is required to submit an application for the renewal of the ethical approval.
3. The Committee must be notifi Determinants of delayed care seeking for TB suggestive Symptoms in Siltie Zone, Southern Ethiopia: A community based unmatched case-control study ed, in writing, of any alteration to the project including unforeseen events/circumstances that might affect the acceptability of the approved protocol.
4. The Principal researcher is required to immediately notify the committee in the event of any adverse effects on participants or of any unforeseen events that might affect continued ethical acceptability or amendment to the original consent form.
5. The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project; should be communicated.

IRB, Chairperson

Million Tesfaye, PhD
Tel: +251917063744
E-mail: ethicsjuirb@gmail.com

Tel. +251-47 11 114 57
PBX. +251471111458-60
Fax: +2514711114 50
+251471112040
P.O.Box. 378
JIMMA. ETHIOPIA
e-mail: ero@ju.edu.et
website: http://www.ju.edu.et