Prevalence of emergence delirium in children recovering from general anaesthesia, its associated risk factors and outcome At Muhimbili National Hospital

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PREVALENCE OF EMERGENCE DELIRIUM IN CHILDREN RECOVERING FROM GENERAL ANAESTHESIA, ITS ASSOCIATED RISK FACTORS AND OUTCOME AT MUHIMBILI NATIONAL HOSPITAL

By

Peter Frank Saria

A Dissertation Submitted in (Partial) Fulfillment of the Requirement for the Degree of Master of Medicine (Anaesthesiology) of

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CERTIFICATION

The undersigned certify that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled, **"Prevalence of emergence delirium in children recovering from general anaesthesia, its associated risk factors and outcome at Muhimbili National Hospital",** in (partial) fulfillment of the requirement for the degree of Master of Medicine (Anaesthesiology) of Muhimbili University of Health and Allied Sciences.

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Dr. Respicious Boniface

Supervisor

_____

Date

DECLARATION AND COPYRIGHT

I, **Peter Frank Saria,** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature: …… **Date:** ……..

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DEDICATIONS

I dedicate this study firstly to all children who participated in this study, secondly to my lovely wife and my daughter Abigail. I would like to dedicate this study to my fellow classmates to their time and committed they have shown during the entire period of the study.

Thank you.

ABSTRACT

Introduction

Emergence delirium is an observed characteristic occurring commonly in children who undergo surgery under general anaesthesia. This condition is associated with the type of surgery, preoperative anxiety, age and type/technique of anaesthesia used.

Broad Objective

The aim of this study was to find out the prevalence of emergence delirium in children recovering from general anaesthesia and its associated risk factors at Muhimbili National Hospital.

Methodology

A hospital-based cross-sectional study conducted in 240 children aged 2-12 years ASA I and II, planned for elective general or ENT surgeries under general anaesthesia. Data were collected and analyzed using SPSS statistical computer software version 20. Categorical variables were summarised as frequency and percentages while continuous variables were summarised by median and inter quartile range. Chi-square has been used as statistical test and Multivariate Logistic Regression was used to test for association between dependent and non dependent variables.

Results

The prevalence of ED was found to 38.3% of the children. Boys were 61(66.3%) and girls were 31(33.7%). Median age was 4(IQR: 3-6) years. Sex, pre-operative anxiety and inhalational maintenance of anaesthesia were significantly associated with the occurrence of ED.

Conclusion

Factors associated with ED were, sex, preoperative anxiety and maintenance with inhalational anaesthetic agents.

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LIST OF ABBREVIATION

AOR	Adjusted Odds Ratio
ASA	American Society of Anaesthesiologists
CI	Confidence Interval
CNS	Central Nervous System
EA	Emergence Agitation
ED	Emergence Delirium
ENT	Ear Nose and Throat
GA	General Anaesthesia
GABA	Gamma Aminobutyric Acid
ICU	Intensive Care Unit
IRB	Institutional Review Board
IV	Intra-Venous
MMED	Master's of Medicine
MNH	Muhimbili National Hospital
MYPAS	Modified-Yale Preoperative Anxiety Scale
NS	Normal Saline
PACU	Post Anaesthesia Care Unit
PAED	Pediatric Anaesthesia Emergence Delirium
SPSS	Statistical Package for Social Scientists
SSEA	Scoring System for Emergence Agitation

DEFINITIONS OF TERMS

Anaesthesia is the pharmacologically reversible induction of loss of pain sensation with or without loss of consciousness.

General anaesthesia is a reversible induction of loss of sensation with loss of consciousness.

Emergence delirium in this study is defined as clinical presentations of agitation with signs and symptoms together with a score of more or equal to 10 as obtained from Paediatric Anaesthesia Emergence Delirium (PAED) scale within the first ten minutes of admission to the recovery room.

Adjunct medications are medications which can be given before or during induction of anaesthesia for the purpose of minimizing the use of sole anaesthetics drugs or to prevent the adverse effects of anesthetics drugs.

CHAPTER ONE

1.1 Background

Emergence delirium(ED) or sometimes used interchangeably with Emergence Agitation is a transient state characterized by abnormal behavior such as irritability and dissociation from the environment once general anaesthesia has been stopped and a patient is an on awake state. At this point the patient cannot be compromised, excessively crying, kicking or thrashing on the bed and this occurs mostly in the recovery room. Currently, there is no clear definition of ED and different authors have come up with different definitions because of a variety of signs and symptoms which overlap with other psychiatric disorders(1).

ED is one of the complications related to anaesthesia and occurs more commonly in children as compared to adults. It occurs following general anaesthesia for various surgical procedures, but is common in head and neck surgeries. It has been found to relate to the type of anaesthetic agents used(2).

Eckenholft et al in 1960's were the first persons to report signs of hyperexcitation in patients emerging from ether, ketamine, cyclopropane especially when circumcision, tonsillectomy or thyroidectomy was performed(3).

Among patients who received general anaesthesia, the pediatric group has been found to have a large number of cases as compared to adults. And within the pediatric group, preschool children aged 1-5 years have a higher prevalence than those with age above 5 years(4).

Apart from age other risk factors which have been associated with emergence delirium include; anaesthetic technique, rapid emergence from general anaesthesia especially when newer inhalational agents such as sevoflurane or desflurane are used, type of surgery, preoperative anxiety, pain and if premedication with drugs like midazolam, alpha agonist or opioids were not used(5).

To assess the prevalence of emergence delirium, someone must use a standard and validated diagnostic tools so as to avoid under or overestimate of the prevalence. Several assessment tools are available for ED or Pain related restlessness. The most commonly used ED diagnostic scales are the Watcha and Cravero scales. The problem of these two scales is that are not yet tested or validated and they have been shown to assess the emotional and psychomotor distress rather than the true features of delirium. Because of the above-aforementioned limitations of the diagnostic scale, Sikichi and Lerman developed the so-called Pediatric Anaesthesia Emergence Delirium(PAED) scale which is mostly used by researchers due to its usefulness and being validated(6).

CRAVERO SCALE(7).

Behavior	Score
Obtunded with no response to stimuli	1
Asleep but responsive to movement or stimulation	2
Awake and responsive	3
Crying >3minutes	4
Thrashing behavior that requires restraint	5

WATCHA SCALE(8)

Behavior	Scale
Asleep	0
Calm	1
Crying but can be consoled	2
Crying but cannot be consoled	3
Agitated and thrashing around	4

PAED scale(9)

Behavior	Not at all	Just little	Quite a bit	Very much	Extremely
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

One of the challenges in the diagnosis of emergence delirium is to distinguish characteristics that are typical for ED and those for other psychiatric conditions.

This is due to the overlapping of the signs and symptoms of ED and other psychiatric conditions. Also, there is a challenge of obtaining a scale that can distinguish those signs and symptoms. These clinical manifestations can occur immediately after switching off the anesthetics but commonly occurs at PACU. In a study of 198 children, 79(39.9%) had a restless recovery, 16(8.1%) in pain, 6(3%) had a tantrum, 8(4%) were “maybe ED” and 4(2%) were “yes ED”. After analyzing for individual behavior of those regarded as Yes for ED, the common behaviors found were: eyes everted, staring or closed, no purposefulness and non-responding(6).

The management of Emergence Delirium depends on the causes, adequate pain management with the use of opioids; Pre-medications with benzodiazepines, alpha agonists have been shown to decrease the incidence of delirium.

1.2 Literature Review

1.2.1 Overview

Many studies have been conducted trying to evaluate the occurrence of emergence delirium in children recovering from general anaesthesia. But with all effort and the known predisposing factors to ED it is still difficult to predict who will be at greatest risk. Due to the overlapping with other psychiatric symptoms makes the definition of ED more challenging. However most of the authors include into their definition; irritability, uncooperative, incoherent, kicking, thrashing and inconsolable crying(10).

The prevalence of emergence delirium is found to be more common in children than the adults(11). And it decreases with age, though there are some other factors which determine the prevalence which will be discussed in the following sections.

1.2.2 Epidemiology

The prevalence of emergence delirium as may range from as lower as 8% to 80%. This also depends on the definition used in the study and their objectives, as well as the tool used, in any case, the prevalence is still high. In one randomized study involving 32 children, American Society of Anaesthesiologists(ASA) I or II found the prevalence of 33% when a high threshold for delirium was defined and 80% when the lower threshold for delirium was applied(7).

In another prospective cohort study done in 2003 included children aged 3-7years who had undergone anaesthesia for elective procedures found the incidence of 18% after obtaining data using a validated tool(12).

Another cross-sectional descriptive study done in Iran in 2014 involved 747 paediatric children aged 3-7 years ASA I or II came up with a prevalence of 17.9%(13).

In a prospective randomized study done in Egypt in 520 children aged 4-12 years planned for strabismus correction, found the prevalence of 18.8%(14).

1.2.3 Risk factors

The risk factors for the development of emergence delirium can be grouped into four main categories:

Patient factors
Surgery-related factors
Anaesthetic-related factors
Adjunct medications

1.2.3.1 Patients factors

a) Age

Age has been mentioned as one of the risk factors for the development of emergence delirium in children. Preschool children were found to have a higher incidence/prevalence as compared to the school children.

In a study done in 116 healthy boys aged 3-10 years who underwent different surgeries, whereby 63(3-5 years) undergone circumcision, and 53(6-10) for an inguinal hernia, both receiving either sevoflurane or halothane. All received 0.2mg/kg of diazepam orally one hour before induction, and both received caudal block and standard monitors. The overall incidence was found to be 22/116(25.2%) and when age was compared among the groups, in halothane there was no difference but in sevoflurane group incidence was 12/30(40%) as compared to 3/26(11.5%)(15)**.**

It is speculated that subgroup age 2-5years are most vulnerable to ED as compared to the older group as shown by abnormal behavior as demonstrated in the study(11).

The reasons for the incidence of ED being higher in younger children are thought to be their poorly developed brain with a decline in neurotransmitters such as nor-epinephrine, Gamma Amino-Butyric Acid (GABA), dopamine, and acetylcholine (12).

In a prospective observational study done in Singapore which enrolled 316 children aged 2-12 years ASA I or II, planned for outpatient surgery following a routine anaesthesia practice, the mean age for those who developed ED(n=28) was 5.4±2.2 as compared to a mean of 6.8±2.8 for those who did not develop ED(n=288) p=0.002(13).

The effect of age on the development of ED was also demonstrated in another cross-sectional descriptive and analytical study involved 747 ASA I or II pediatric patients aged 3-7 years. In this study, the mean age was 4.2(13).

b) Anxiety/emotion

Preoperative anxiety/emotion has been associated with an increase in the incidence of emergence delirium in children. This anxiety can be attributed to the separation from the parents, the fear of the operation itself and as well other factors. There are many existing scales for measuring the level of anxiety in children who are undergoing surgery, but the commonly used one is the modified Yale Preoperative Anxiety Scale (mYPAS). In a study of 791 children who underwent surgery without premedication for relieving anxiety the odds of having ED was increased by 10%, though the study failed to demonstrate a causal-effect relationship(14).

c) Temperament

The ability of the children to react to external stimuli and been able to adapt to a new and uncomfortable environment differs. Children who have too much emotion and are less adaptable to the new environment have a higher risk of developing ED as compared to those who can easily adapt to the new unfamiliar environment. The reaction to the external stimuli is the one which can be manifested as excitability, responsivity or arousability(13).

In a prospective cohort study done in the USA in 2003 at Michigan children's hospitals, 521 children planned for different paediatric surgeries were included in the study. Among the observed risk factor was temperament. After scoring the children for temperament the results showed that those who were less adaptable to the environment had a higher incidence of ED(8,13).

1.2.3.2 Anesthetic-related factors

a) Rapid emergency

With the availability of newer inhalational drugs for induction of general anaesthesia, the incidence of emergence delirium has also increased. Studies have shown the association between the use of these drugs and ED. The characteristics of these drugs associated with the risk are their solubility; being less soluble in the blood means they have rapid emergence properties upon completion of surgery. In a study comparing sevoflurane and propofol, the incidence of emergence delirium in the sevoflurane group was high as compared to the propofol group,46%(n=25) vs. 9%(n=25) respectively with *p=0.008*(15).

Another study done in Japan tried to test the hypothesis that "maintenance anaesthesia with propofol after sevoflurane induction would reduce the incidence of ED as compared with continuing sevoflurane for maintenance". This study involved 16 patients 26±15 months of whom 38%(6/16) develop ED after maintenance with sevoflurane as compared to none in the propofol group(16).

This drug effect was also seen in another study done in 53 children aged between 2-36 months who were randomly assigned to maintenance with either propofol or sevoflurane. Those who received sevoflurane demonstrated a high incidence of ED 23.1% against 3.7% of propofol, p=0.05(17).

b) Intrinsic characteristics of anesthetics

Although limited data and evidence are available for the relationship between the intrinsic activity of the drugs and the incidence of ED, sevoflurane has been associated with ED as compared to other drugs like halothane. The reasons thought to be the ability of sevoflurane to exert an irritative effect to the Central Nervous System(CNS) and epileptiform which has been reported during the use of it in volunteers with no history of seizures(18).

1.2.3.3 Surgery-related factors

a) Pain

It is still controversial as to whether pain is the cause of emergence delirium or is just a confounding variable when assessing the child's behavior during emergence from general anesthesia. However inadequate pain management, especially for short procedures, can be one of the causes of restlessness in children recovering from General Anaesthesia (GA). In a study involving 200 children undergoing bilateral myringotomy with pressure equalizing tubes under either sevoflurane or halothane randomly assigned into four group: halothane –ketorolac group, halothane no ketorolac, sevoflurane-ketorolac and sevoflurane with no ketorolac. The incidence was high in those two groups who didn't receive ketorolac,19/50(38%) in sevoflurane-placebo v/s 7/50(14%) in sevoflurane –ketorolac and 21/50(42%) in halothane-placebo v/s 6/50(12%) in halothane-ketorolac $p<0.05$ in both group(19).

The same effect of analgesics on decreasing the incidence of ED was demonstrated in a study in children undergoing adenoidectomy with either sevoflurane or desflurane with or without fentanyl. In this study 100 ASA I or II children were assigned randomly to receive either sevoflurane or desflurane for maintenance after an induction with sevoflurane. Both of them received intravenously 2.5mcg/kg of fentanyl. In both groups, the incidence was low with 18% for sevoflurane and 24% for desflurane(20).

To demonstrate the effect of pain on the prevalence or incidence of EA in children, a double-blind randomized study which included 90 children aged 3-7 years ASA I or II was conducted in Western China. Children were assigned into three groups each containing 30 children planned for ophthalmology surgery. Each group was randomly assigned to receive either sufentanil 0.1mcg/kg, fentanyl 1mcg/kg or N/S. Induction was done by sevoflurane 6-8% and maintenance was 2-4%. At the end of the operation, children were scored for EA by the use of SSEA. The incidence of EA was 30% in sufentanil group,36.67% in fentanyl group and 63.3% in control group hence he concluded that single dose of sufentanil can decrease the incidence of ED(21).

Another study was done in Egypt in 2013 in children undergoing strabismus surgery which aimed to assess the influence of pain on EA. It included 520 children aged 4-12 years who were grouped into four; S/S group (sevoflurane/saline), S/L group (Sevoflurane/Lidocaine), H/S group (Halothane/Saline) and H/L group (Halothane/Saline). Maintenance of anaesthesia was with sevoflurane for SS and SL group while halothane was used for HL and HS group. At the end of surgery SL and HL received 0.5% or 2% subtenons lidocaine injection whereas SS and HS group received a saline injection. The lidocaine injected group showed a low occurrence of EA of 10.4% as compared to 27.7% in the saline group, *P=0.002*(14).

b) Type of surgery

The type of surgery is thought to contribute to the rise of incidence of emergence delirium. Surgeries involving head and neck are higher on the list. Ear, Nose and Throat (ENT) procedures such as adenotonsillectomy, eye surgeries, and dental procedures show a higher incidence.

In a prospective cohort study of emergence delirium in pediatric post-anaesthesia care unit involving 521 children, an overall of 18% showed ED,based on the nature of surgery 42(26%) were ENT cases, 23(28%) was ophthalmologic procedures, 15% was for both urologic and orthopedic surgeries, 12% for general surgery and 6% for others, p=0.02(12).

Another prospective study done in India in 2015 involving 246 ASA I and II children aged 3-12 years who were planned for ENT surgeries, found an incidence of 23.6%. This shows that ENT surgeries are associated with ED(1).

The reason why the incidence of emergence delirium is very high in the head and neck surgeries is thought to be a “sense of suffocation” though there is no supporting evidence for this. Another cross-sectional study which was done in Iran, involved 747 pediatric cases ASA I or II under GA, and found that the incidence was higher in ENT surgeries as compared to others. For instance, out of 315 ENT surgeries, 85(26.9%) were having ED as compared to 16(16.4%) n=97 in urology surgeries and 17(9.6%) n=177 in abdominal surgeries*,P≤0.001*(13).

Many authors also demonstrate the influence of the type of surgery on the incidence/prevalence of ED(4),(18),(2).

1.2.3.4 Adjunct medications

Some of the medications given to the children undergoing surgery as pre-induction have shown to decrease the incidence of post-operative emergence delirium. These drugs include:

Benzodiazepines

Alpha agonists

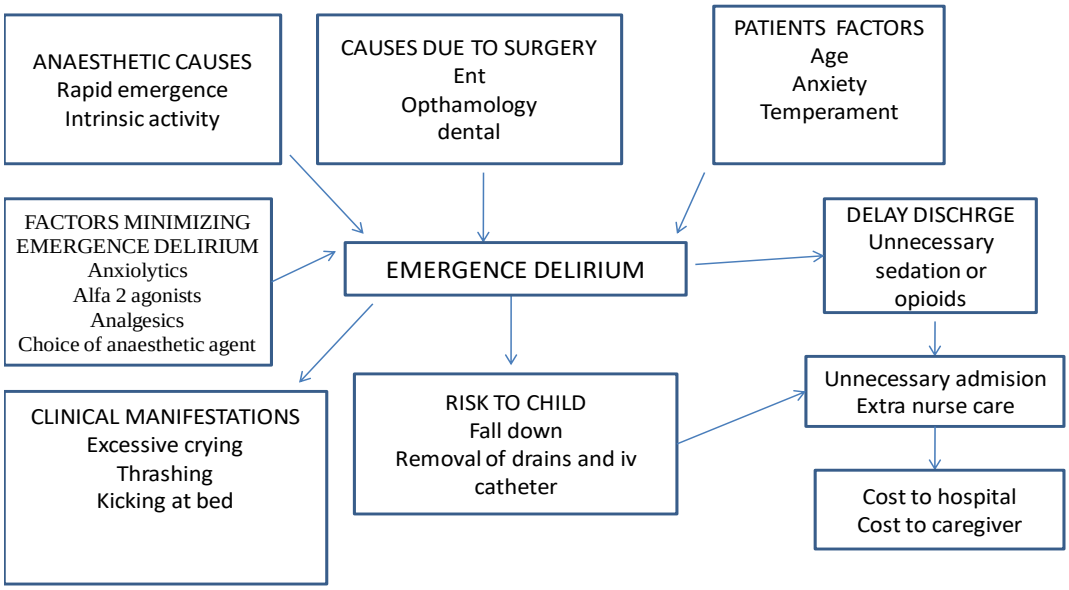
Opioids

In a blinded randomized study done in Perugia Italy which included 169 children in which one group received 2mcg/kg of clonidine (alpha agonist) and the other group received normal saline. Induction was done using sevoflurane, ED was 13/91(14.2%) in clonidine group as compared to 26/78(33.3%) in the normal saline group(22).

A similar study was done in Chile, randomized in nature, assessing the effectiveness of the alpha agonist dexmedetomidine in 90 children aged 1-10 years who were randomized into three groups of no dexmedetomidine, 0.15mcg/kg, and 0.3mcg/kg. The incidence of ED was 37% in placebo group, 17% in 0.15mcg/kg and 10% in 0.3mcg/kg (n=30 for each group with $p<0.05$). This led to the conclusion that an alpha agonist given before induction decrease the incidence of ED(23).

Another study tried to assess whether premedication with midazolam would decrease the incidence of emergence delirium. A total of 115 children were divided into two groups randomly, one group received 0.5mg/kg and the other received 1mg/kg. Anaesthesia was induced with either propofol or sevoflurane and maintained with 1.5% sevoflurane. The ncidence was 42.1% in the 1mg/kg group as compared to36.2% in the 0.5mg/kg group. Therefore midazolam was not shown to decrease the incidence(24).

1.3 Conceptual Framework



Description of Conceptual Framework

This study intends to assess the occurrence of emergence delirium in children undergoing surgery under general anaesthesia at Muhimbili National Hospital. Also one of the objectives of the study is to look at the associated factors which can influence the occurrence of the outcome.

The associated risk factors for the development of emergence delirium which will be studied in this research can be grouped into three main categories, namely:

- Anaesthetic cause
- Nature of surgery
- Patient risk factors

All these either alone or in combination with others can increase the likelihood of developing emergence delirium.

The primary outcome variable in this study will be the development of emergence delirium when the score from PAED is found to be equal to or more than 10. The secondary outcome variable is the occurrence of any of the following; any injury at recovery room not surgical related, need for re-catheterization or re-insertion of IV cannula, or delayed discharge from the recovery room.

1.4 Statement of a Problem

With the increased use of newer inhalational agents such as sevoflurane, there is a possibility of an increasing prevalence of ED.

General anaesthesia in children for long time has been associated with the development of neurocognitive disorders. Children with cognitive and intellectual disturbance may have the history of developing emergence delirium following general anaesthesia. The strong opioids given to children with ED cause sedation to the child and may results in delayed discharge from PACU and hospital in general. And for the daycare surgery may result in unnecessary admission.

1.5 Study Rationale

The study aimed at identifying the prevalence and risk factors of emergence delirium in children receiving general anaesthesia at Muhimbili National Hospital since there is no published data showing the magnitude of this problem at MNH.

This post anesthesia event(ED) may point out the quality of anaesthesia we are providing, staffs as well as patients/caregivers satisfaction.

Due to the overlapping of the clinical presentations with other conditions, diagnosis of emergence delirium is not always apparent and this study may lead to the development of checklist for easier identification of the condition.

Lastly as part of partial fulfillment for an award of MMED of anaesthesiology.

1.6 Research Question

- What is the prevalence of emergence delirium among children undergoing surgery under general anaesthesia at Muhimbili national hospital and what are the associated risk factors?

1.7 Objectives

1.7.1 Broad Objectives

To determine the prevalence of Emergence Delirium in children undergoing surgery with general anaesthesia at Muhimbili National Hospital.

1.7.2 Specific Objectives

1. To find out the prevalence of Emergence Delirium among children undergoing surgery under General Anaesthesia at Muhimbili National Hospital between July 2017 and May 2018.

2. To determine factors associated with Emergence Delirium among children undergoing surgery under General Anaesthesia at Muhimbili National Hospital between July2017 and May 2018.

3. To find out the clinical manifestations of the children developing emergence delirium at recovery at Muhimbili National Hospital between July 2017 and May 2018

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study Design

A Hospital based quantitative cross-sectional study.

2.2 Study Area

The study was conducted at Muhimbili National Hospital operating theaters. Muhimbili National Hospital is a super specialty teaching hospital with the bed capacity of 1500 with an approximately 3000 person workforce. It offers both medical and surgical services and patients come within the country and outside the country. About 1000-1200 patients attend the hospital as outpatients each day, with 1000-1200 admission per week. The hospital offers both endoscopic and non-endoscopic surgeries ranging from urological, gynecological, herniorrhaphies and general surgery such as Thoracotomies. The hospital has seven operating rooms located in the main theater and two operating obstetric rooms situated along the maternity wards and isinprocess of expanding its operating rooms and establishing renal transplant operating rooms in the main theater. Subjects will come from ENT operating room and pediatric general surgery operating room.

Usually, when surgery is over the anaesthesia provider switches off the anesthetic agent and gives the reversal drugs. Extubation is done once routine criteria such as eye opening, conjugate gaze, spontaneous breathing and clinician experience are met. The child will then be transferred to the recovery room for observation before discharged to the ward. A recovery room is a place designed to receive all patients coming from theatres for observation before sent back to their wards. It is under the care of a trained nurse in anaesthesia or critical care and is equipped with an oxygen supply, suction machines, and basic monitors and close to operating room. When the patient reaches the recovery room the handover of the patient to the recovery nurse is done by escorting anaesthetist. The procedure, medicines which have been

given and any significant events during the procedure as well as post-operative orders are given to the recovery nurse.

While at recovery the child will be observed, his/her vital signs monitored, IV fluid will be given and urine monitored. Any abnormal condition will be noticed and rectified including emergence delirium. Once the patient is stable and meets the discharging criteria he/she will be released to the initial ward.

2.3 Study Population

The study population was all children between 2-12 years who were planned for surgery at any of the operating theaters at MNH within the period of study.

2.4 Study Subjects

2.4.1 Inclusion criteria

All children aged between 2-12 years who were planned for elective ENT and general surgery procedures with general anaesthesia technique.

ASA I and II physical status were included

2.4.2 Exclusion criteria

Those with mental problems

Those who were to be admitted to ICU soon after the operation.

2.5 Sample Size

A sample size was calculated using the current existing prevalence from the literature by using a formula for cross-sectional studies. The power of the study and 95% confidence was considered.

$n = z^2p(1-p)/\varepsilon^2$

P = 17%, which was the prevalence found in the studies conducted in Egypt and Iran (9,10).

Z = 1.96 (assuming 95% confidence interval)

ε = 5% (maximum error allowed).

n=216.8

To adjust for non-response rate and assuming the non-response rate (f %) to be10%, then

n= n x Adjusted factor

Adjusted factor= (100%/100%-f %)

n=n x (100%/100%-f %)

n=217x (100%/100%-10) = 241.11

Hence sample size found to be 242

2.6 Sampling Procedure

The operating list was obtained a day before surgery and all children planned for surgery under general anaesthesia were identified. Children who met inclusion criteria were selected by convenience every day until a sample size was reached.

2.7 Data Collection

Two research assistants were used in the collection of the data. One assistant was a senior and experienced nurse working at recovery unit and the other assistant was an anaesthetic nurse. The first assistant who is an anaesthetic nurse was responsible for the filling of the mYPAS which was used to record the level of anxiety a night before surgery (Appendix 3.5.3) and also was responsible for filling the questionnaire in all parts before handling the patient to a recovery nurse. The second assistant who is a recovery nurse was responsible for completing the form up to the time the patient was discharged to the ward. They were not allowed, to sum

up, the scores. They were trained on how to fill up the questionnaire both theoretically and practically but were not allowed to sum up the scores

Data on the occurrence of emergence delirium as defined by the score of equal to or more than 10 was collected by using PAED scale (Appendix 3.5.1 for English and 3.5.2 for Swahili).This two tool (mYPAS and PAED) were used in this study because these are commonly used tools in many studies including some African country (Egypt).These available tools have been modified in some parts to fit for local use.

2.8 Data Analysis

Data collected were entered and analyzed using Statistical Package for Social Scientists (SPSS)-version 20 computer program.Categorical variables are summarized using frequency distributions while continuous variables are summarised using measures of central tendency and variability. Chi square will be used as statistical test and the association between the dependent variable (emergence delirium) and independent variables is assessed using an odds ratio and 95% Confidence interval. Any variable with a *p*-value less than 0.05 are considered statistically significant. All predictors with *p*-value < 0.05 in the chi square analysis are entered into multivariate logistic regression model to identify the independent predictors of emergence delirium while controlling for potential confounders. All the predictor's variables with a *p*-value less than 0.05 at the multivariate level are considered as independently associated with the occurrence of emergence delirium.

2.9 Quality Control Measures

The quality of the data is a priority in this research and this is achieved by having assistants who are trained, testing of the tools before the starting of research and close supervision.

2.10 Study Variables

2.10.1 Dependent

The primary dependent variable is the occurrence of Emergence Delirium measured as the number of those scored equal to or more than10 on PAED scale over a total number of study participants.

2.10.2 Independent

The independent variables are:

- Age
- Sex
- Preoperative anxiety
- Type of surgery
- Anaesthetics used
- Adjunct medications

2.11 Ethical Consideration

Ethical clearance was obtained from the IRB after submission of the proposal draft.

All ethical issues including patient's autonomy, confidentiality, not to cause harm to the patient were considered, i.e. parents or caretaker could refuse to allow their children to participate at anytime during the study, and all information obtained from the study will be used for academic purposes. Patient care was not compromised by refusing to participate in the study.

Participants were free to withdraw from the study at anytime.

This proposal was taken to the Institute Review Board for ethical clearance.

2.12 Study limitations and mitigation

Since we don't know the current prevalence of ED in Tanzania, it makes it difficult to compare the results with what is happening in other hospitals in our country but the obtained data can be compared with another part of Africa where similar studies were done.

Information bias due to failure to observe the behavior of the child at the recovery room can occur and this may lead to either underscore or overscore the child when assessing the occurrence of delirium and ending up underestimating or overestimating the prevalence respectively. To mitigate this all questionnaires were reviewed on a daily basis or weekly together with the research assistants.

Improper filling of the checklists and questionnaire was corrected by going over the questionnaires every often with the research assistants while the research was still in progress.

CHAPTER THREE

3.0 RESULTS

Table 1: Characteristics of the study population

Variables		Total N (%)
Sex	Male	134(55.8)
	Female	106(44.2)
Age	2-5	172(71.7)
	6-12	68(28.3)
	Median age (IQR)	4(3-6)

Table 1 above shows the characteristics of the study population. 134 (55.8%) were males and 106 (44.2%) were females. In case of age group, the majority of the participants 172 (71.9%), were aged between 2-5 years, the remaining 68(28.1%) were aged 6-12 years, with the median age of 4 years (IOR; 3-6).

Table 2a: Prevalence of emergence delirium

Time at recovery unit	Males(n)	Females(n)	Total(n)	Prevalence (%)
1st ten minutes	61	31	92	38.3%
2nd ten minutes	45	21	66	27.5%
Soon before discharge	18	7	25	10.4%

The overall prevalence of emergence delirium was 38.3% within the first ten minutes of recovery admission. This study shows the decrease in prevalence with the length of recovery stays. The prevalence of 27.5% and 10.4% during the next ten minutes and soon before recovery discharge respectively.

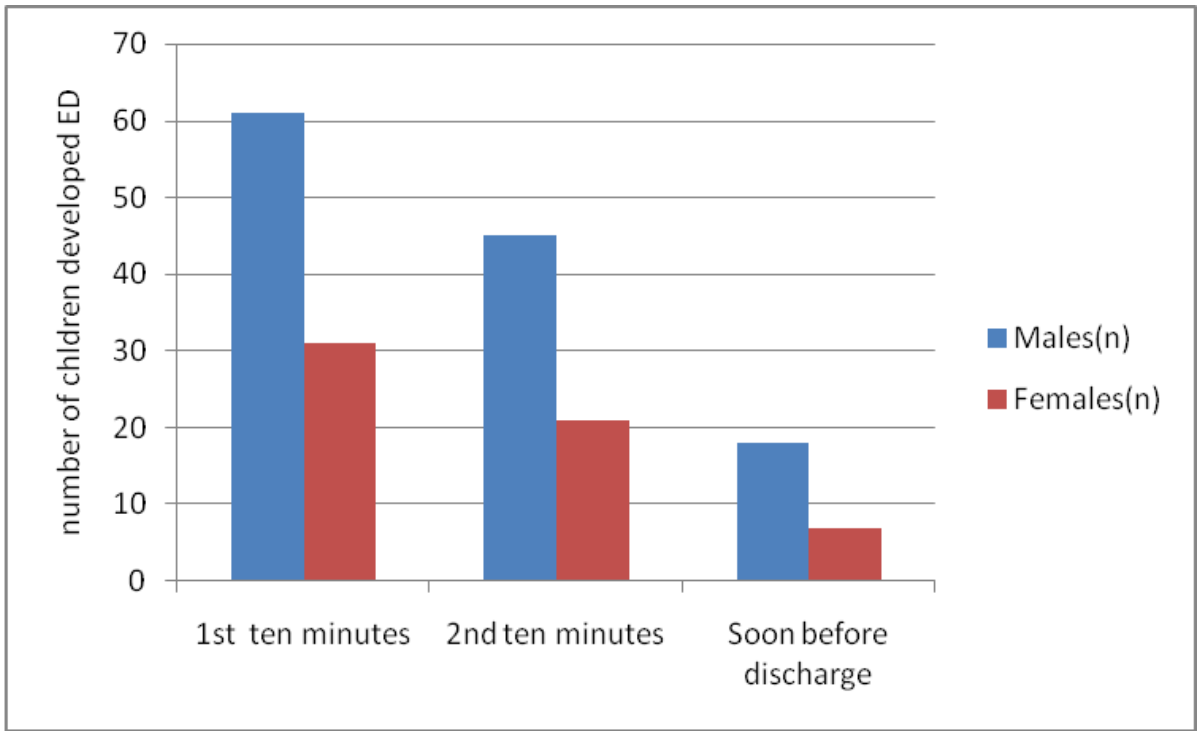


Figure 1: Showing trend of decrease of ED with time at recovery unit

Table 2b:Factors associated with ED in the first ten minutes of recovery admission

Variables		**Emergence Delirium**		**P value**
		Yes (N %)	**No (N %)**	
Sex	Male	61 (45.5%)	73 (55.5%)	0.01
	Female	31 (29.2%)	75 (70.8%)	
	2-5	68 (39.5%)	104 (60.5%)	
Age (years)	6-12	24 (35.3%)	44 (64.7%)	0.543
Nature of surgery	ENT	55 (39.6%)	84 (60.4%)	
	General surgery	37 (36.6%)	64 (63.4%)	0.644
Preoperative anxiety	5-9	39 (23.4%)	128 (76.6%)	
(mYPAS) scores	10-15	53 (45.3%)	64 (54.7%)	0.0001
Maintenance with	Sevoflurane	14 (42.4%)	19 (57.6%)	
inhalational agents	Isoflurane	72(41%)	104 (59%)	
	Halothane	5 (16.7%)	25 (83.3%)	0.033
Previous surgery	Yes	16 (40%)	24 (60%)	
	No	76 (38%)	124 (62%)	0.812
Premedication	Yes	3 (33.3%)	6 (66.6%)	
	No	89 (38.5%)	142 (61.5%)	0.753

Table 2c: Multivariate Logistic Regression for ED associated factors

Variables	AOR	95% Confidence Interval	p-value
Sex			
Female	1	.	.
Male	2.3	1.2-4.2	0.009
Inhalational maintenance			
Halothane	1	.	.
Isoflurane	2.9	0.97-9.2	0.056
Sevoflurane	3.8	1.03-14	0.045
Pre operative anxiety			
mYPAS 10-15	1	.	.
mYPAS 5-9	0.12	0.06-0.23	0.0001

3.1Sex

From table 2a and 2b above a total of 92(38.3%) of children in this study developed emergence delirium within the first ten minutes of recovery admission, 61(66.3%) were boys and 31 (33.7%) were girls. This shows that boys were more likely to develop emergence delirium as compared to girls, with boys having an OR of 2.3 (95% CI 1.2-4.2, *P*=0.008) as shown on table 2c above.

3.2 Age

The majority of the participants in this study 172 (71.7%) were children aged 2-5 years as depicted in Table 2b above. The number of children who developed emergence delirium within this age group was 68 (39.5%) as compared to other age group. There was a trend

towards younger children having a high risk of getting emergence delirium but it did not reach statistical significance (*P*= 0.543).

3.3 Nature of surgery

Among 240 children who underwent surgery 139(57.9%) were ENT surgeries and 101 (42.1%) were general surgeries. Among children who underwent ENT surgery 55(39.6%) were found to have developed emergence delirium upon admission to recovery unit while 37(36.6%) undergone general surgery procedures as shown in the table 2b above. This study shows more children in ENT group developed emergence delirium as compared to general surgery group but was not statistically significant.(*P*= 0.644)

3.4 Pre-operative Anxiety

Preoperative anxiety was found to associate with the developing the emergence delirium after surgery. Among children who developed emergence delirium while at the recovery unit, 39(23.4%) scored 5-9 and the remaining 53 (45.3%) scored 10-15, neither scored above 15.Table 2b above summarize the relationship between the preoperative anxiety and emergence delirium. The association between preoperative anxiety and development of emergence delirium was done by the use of multivariate logistic regression, it was found that those who scored between 5-9 were 0.12 times less to develop ED as compared to those scored 10-15(95% CI;0.06-0.23,*P*= 0.0001) as seen in table 2c above.

3.5 Inhalational maintenance

For the majority of the surgeries done, induction of anaesthesia was done by inhalational agents and fewer surgery inductions were done by intravenous drugs. A total of 215(89.6%) of cases were done by inhalational agents 139(57.9%) with sevoflurane,71 (29.6%) with halothane and 1(0.4%) with Isoflurane. The remaining 25(10.4%) of cases were induced by intravenous drugs mainly propofol. For maintenance of anaesthesia 176(73.3%) of cases were done with Isoflurane, 33(13.8%) by sevoflurane and 30(12.5%) was done by halothane. Among those maintained with Isoflurane 72(41%) developed emergence delirium and

14(42.2%) of those maintained with sevoflurane developed also emergence delirium. Only 5(16.7%) of those maintained with halothane. As shown in table 2b above there is a significant relationship between ED and inhalational maintenance (*P*= 0.033). As seen in table 2c above of multivariate analysis, those maintained with sevoflurane were 3.8 times more likely to develop ED as compared to those maintained with halothane(95% CI;1.O3-14,*P*=0.045) and those maintained with isoflurane were 2.9 times more likely to develop ED as compared to those maintained with halothane(95%CI;0.97-9.2, *P*=0.056).

3.6 Previous Surgeries

Among children who participated in the study only 40(16.7%) had a history of previous surgery and the rest of children 200(83.3%) this was the first exposure to surgery. Of those who developed emergence delirium, 16(40%) had a history of previous surgery while 76(38%) did not have a history of previous surgery. Previous exposure to surgery was not significantly associated with occurrence of emergence delirium in this study (*P*= 0.812).

3.7 Pre-medication

Table 2b above shows that out of 240 participants included in the study, only 9(3.8%) were given premedication with either analgesia or anxiolytics a day or few hours before induction of anaesthesia. Those who received pre-medications were less likely to develop emergence delirium. Of those who developed emergence delirium 89(38.5%) had not received pre-medication (*P*= 0.753).

Table 3a: Clinical manifestations of Children with ED at recovery unit

Variables	Yes N(%)	No N(%)	Total N(%)
Excessive crying	65(29.3)	27(29.3)	92(100%)
Thrashing on bed	62(67.4)	30(32.6)	92(100%)
Staring at caregiver	62(67.4)	30(32.6)	92(100%)
Others	1(1.1)	91(98.9)	92(100%)

Table 3b: Chi-square analysis for clinical manifestations and occurrence of ED

Variables		Emergence delirium		X^2	df	p-value
		Yes (n)	No (n)			
Excessive crying	Yes	65	93			
	No	27	54	1.4	1	0.24
Thrashing in bed	Yes	62	65			
	No	30	83	3	1	0.082
Staring at a caregiver	Yes	62	76			
	No	30	72	6	1	0.015
Others	Yes	1	3			
	No	91	145	0.3	1	0.58

3.8 Clinical manifestations

The clinical manifestations of the children who developed emergence delirium while in recovery are summarized in table 3a and 3b above. The majority of the children presented with excessive crying, thrashing in the bed or staring at a caregiver. Among the three clinical manifestations, staring at a caregiver is strongly suggestive clinical manifestation of emergence delirium as shown in table 3b above *(P= 0.015*).

CHAPTER FOUR

4.0 DISCUSSION

4.1 Prevalence

Emergence delirium has been shown to occur in children recovery from general anaesthesia especially when they underwent ENT surgeries as compared to general surgery. Several studies have been conducted to establish the prevalence of this condition and its associated risk factors. In this study the prevalence of emergence delirium was found to be 38.3% in children who were admitted at recovery unit after either ENT or general surgeries under general anaesthesia. The same high prevalence of 32% was obtained by Cyna et al (8) though in this study they include children up to the age of 18 years in contrary to my study which include up to age of 12 years. There are some studies which report low prevalence of emergence delirium, examples includes the study done by choon et al (17) who reported a prevalence of 10% in 316 children aged 2-12 years and another study done by Nagula (1) who obtained a prevalence of 23.57% on his study including children aged 3-12 years. This difference of prevalence between this study and other studies can be due to several factors such as the scales used to measure the occurrence of ED, even in the case of same scale might be due to the cutoff points used by the researchers. Also these variations can be due to limitations of observer during scoring of the child at recovery.

4.2 Associated risk factors

This study included both male and female children who underwent either ENT of general surgery. It has been noted that there is association between the occurrence of emergence delirium and the gender of the child. Males were more prone to developed ED as compared to females. In contrast Nagula et al (1) found no difference between male and female when it comes to the development of emergence delirium. Same findings were reported also by Rachel et al (29) who noted no difference between male and female

The prevalence of emergence delirium was found to be higher in younger children than the older ones. In this study those aged 2-5 years developed emergence delirium much than those aged above five years though was not statistically significance(p=0.543). This is different from the results of a study done by Aono and another study done by Choon both of whom found the relationship between the occurrence of emergence delirium and young age (11,13). This difference between the findings of this study and their results could be that the sample size was not big enough to show a difference.

Preoperative anxiety was found to have a significant association with the development of emergence delirium. Those who the scored high on the preoperative anxiety scale also developed ED much as compared to those who scored low. This result shows that preoperative anxiety was significantly associated with the development of emergence delirium. Several studies also demonstrate the association between preoperative anxiety and the development of emergence delirium. For example, a study done by Kain Z. in 2004 which included a total number of 333 participants found that preoperative anxiety was statistically associated with the occurrence of emergence delirium(18)

This study demonstrated that maintenance of anaesthesia with inhalational agents were associated with emergence delirium. The same findings were also reported by V. Picard in his study comparing sevoflurane with propofol(19). This difference can be explained by the short time it takes to emerge from anaesthesia based on the chemical property of the two agents and their solubility in blood.

Though the majority of studies demonstrate the association of sevoflurane with the occurrence of emergence delirium, the results shows there were no difference between the inhalational agents in this study. Roland Meyer in his study of children maintained with either sevoflurane or Isoflurane obtained the same findings of no statistical difference between the two inhalational agents(30). The difference seen in this study can be due to the fact that majority of the children were maintained with Isoflurane and halothane.

The nature of the surgery was not found to have an influence in the occurrence of emergence delirium in this study ie there was no statistical significance between ENT surgeries and general surgeries. This is different from the study done by Voepel who had found a significant increase in emergence delirium with the type of surgery especially ENT surgeries(12).

Children who were recovering from general anaesthesia in the recovering unit presented with excessive crying, thrashing in the bed, staring at the health care provider and some were trying to remove catheters and IV giving set (The canula and giving set were re-inserted). Staring at the caregiver was strongly associated with ED. These findings were also seen in a study done by S. Malarbi of children 1.5-6 years planned for surgical or non surgical procedures(6) Therefore children who are recovering from general anaesthesia and developed these clinical manifestations should be suspected to have emergence delirium.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATION

5.1 Conclusion

There was no statistical significant between the type of surgery and age on the occurrence of emergence delirium though preoperative anxiety, sex and anaesthetic technique especially the use of the inhalational agents during maintenance of anaesthesia was shown to have an association with the development of emergence delirium. The majority of children present with emergence delirium within the first ten minutes of Post Anaesthesia Care Unit (recovery). And it usually manifests as thrashing in the bed, excessive crying and staring at the care providers.

5.2 Recommendations

1. Another study should be conducted to compare the length of time of stays in the recovery unit between those who develop emergence delirium and those who do not develop emergence delirium.
2. Knowledge, attitude, behavior and level of satisfaction toward management of children developed emergence delirium should be assessed in staffs working in the recovery unit.
3. In the future studies focusing on the occurrence of emergence delirium in our settings, if PAED scale is planned to be used it should be modified to fit to our local environment.

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APPENDICES

Appendix I: Research Questionnaire (English Version)

PART ONE

Age ……..

Sex ……

Weight……...

Residency ……..

Any history of previous surgery……YES/NO

Any history of mental illness…….……YES/NO

PART TWO (Put V when applicable)

1: Type of surgery

ENT……. ☐

OPTHALMOLOGY…… ☐

DENTAL…… ☐

HERNIA……. ☐

OTHERS……. ☐

Specify…….

2:0 Type of general anaesthesia used

2:1 Induction technique

2:1:1 inhalational…… ☐

Sevoflurane ☐

Halothane ☐

Isoflurane ☐

Others……

2:1:2 intravenous …….. ☐

Ketamine ☐

Propofol ☐

Thiopental ☐

Others…….

2:2 Maintenance techniques

2:2:1 inhalation……. ☐

Sevoflurane ☐

Isoflurane ☐

Halothane ☐

Others …….

2:2:2 intravenous…….. ☐

Ketamine ☐

Propofol ☐

Thiopental ☐

Others ……

3: Any other pre-medicationsis given? Yes/ No

4: If yes, mention them……..

PART THREE

5: Time of starting induction…….

6: Time of starting surgery……

7: Time for finishing surgery/switching off anesthetics……

8: Time of arrival at PACU…….

Table 3: PAED scale

Behavior	Not at all	Just little	Quite a bit	Very much	Extremely
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

- Excessive crying…… ☐
- Thrashing on bed…… ☐
- Starring to the caregiver……..… ☐
- Others …….. ☐

  Specify……..

10: Any medication is given after a diagnosis of ED……

11: Time at discharge from PACU……Duration of stay…….minutes

Appendix II: Research Questionnaire (Swahili Version)

DODOSO LA TAFITI

SEHEMU YA KWANZA

Umri ……..

Jinsia ……..

Uzito ……

Makazi …….

Historia ya upasuaji kabla……NDIO/HAPANA

Historia ya ugonjwa wa akili……....NDIO/HAPANA

SEHEMU YA PILI (weka alama ya V panapo husika)

1:0 Aina ya upasuaji

PUA, KOO NA MASIKIO…… ☐

MACHO…… ☐

KINYWA……... ☐

NGIRI…….. ☐

NYINGINEZO…….. ☐

Zitaje…….

2:0 Aina ya njia ya nusu kaputi iliyotumika

2:1 Kumlaza mgonjwa

2:1:1 Dawa ya kuvuta kwa njia ya hewa…… ☐

Sevoflurane ☐

Halothane ☐

Isoflurane ☐

Ingine **……...**

2:1:2 Dawa za mishipa za nusu kaputi…… ☐

Ketamine ☐

Propofol ☐

Thiopental ☐

Ingine……..

2:2 Dawa za muendelezo wa nusu kaputi

2:2:1 Dawa za kuvuta kwa hewa. ☐

Sevoflurane ☐

Halothane ☐

Isoflurane ☐

Ingine ……...

2:2:2 Dawa za mishipa za nusu kaputi…… ☐

Ketamine ☐

Propofol ☐

Thiopental ☐

Ingine ……..

3: Kuna dawa zozote amepewa kabla ya kulazwa? Ndio /Hapana

4: Kama ndiyo,zitaje……

SEHEMU YA TATU

5: Muda wa kuanza kumlaza mgonjwa…….

6: Muda wa kuanza upasuaji……

7: Muda wa kumaliza upasuaji/kufunga dawa…….

8: Muda wa kufika sehemu ya uangalizi baada ya upasuaji……..

Table 3: PAED scale

Tabia	**Sio kabisa**	**Kidogo tuu**	Kiasi kidogo	**Kwa sana**	**Kupita kiasi**	**Alama dk kumi za mwanzo**	**Alama dakika kumi zilizofuata**	**Alama wakati wa kuruhusiwa**
Ana mtazama mtoa huduma	4	3	2	1	0			
Anaonyesha matendo ya kueleweka	4	3	2	1	0			
Anatambua mazingira aliyopo	4	3	2	1	0			
Kutokutulia	0	1	2	3	4			
Hali yakuweza kumtuliza	0	1	2	3	4			

9: Mtoto ameonyesha dalili zipi

- Kulia sana kupita kiasi…….. ☐
- Kuji tupa tupa kitandani…… ☐
- Kumshangaa kwa butwaa mtoa huduma…… ☐
- Nyingine ……. ☐

  Zitaje ……

10: Dawa alizopewa baada ya kupata dalili hizo

…….

11: Muda alio ruhusiwa kurudi wodini…….. muda alio kaa chumba cha uangalizi ni dakika…….

Appendix III:Modified Yale Preoperative Anxiety Scale

ITEM	SCORE
A:Activities	
1.The child looks around, is curious, plays with toys, reads(or other behavior appropriate with age group) moving around the pre-anaesthetic/treatment room to get toys or seeking family members; might move towards the equipment in the operating room.	1
2.The child does not explore or play, may look down, plays with own hands or sucks its thumb(blanket);may sit close to family members while playing or may show a manic quality while playing.	2
3. The child moves without concentration to the toys to the family members, movements are not connected to the activity, movement or play is frantic/agitated; twisting, moving on the table, may push the mask or family members.	3
4.Tries to escape, pushes with feet and arms, may move its entire body; in the waiting room runs around without purpose, does not look at the toys, does not want to be apart from family members, clings on desperately	4
B:Vocalization	
1.Reads(vocalization not adequate for the activity),ask questions, makes comments, stutters, laugh, answer questions promptly, but is usually quiet; the child is too young to speak in social situations or too absorbed in the play to answer.	1
2. Answers to adults but whispers “baby talk”, only shake its head	2
3. Quiet,no sound or does not answer to adults	3
4.Weeping,moaning,grunting,silent cry	4
5.The child is crying or might yell “ no”	5
6. Crying. high pitched and sustained cry	6
C: Expressing emotions	
1.Happy,smilingor concentrated on the play	1
2.Neutral,no discernible face expression	2

3.From worried(sad) too frightened, sad,worried,or teary eyes	3
4.Distressed,crying,uncontrolled,eyes might be a wide opening	4
D:State of arousal	
1.Alert,looks around occasionally, notice or follows anesthesiologist's actions(might be relaxed)	1
2.Withdrawn,calm and silent, might suck its thumb, or its face might like an adults' face	2
3.Alternativelooks around quicklymight be startled by noises, eyes wide opened, the body is tense	3
4. Whines in panic, might cry or shun others, urns the body around	4
E:Interaction with family members	
1.It is concentrated while playing, is sitting down inactive or shows behavior appropriate to age and does not need family members might interact with family members in they initiate the interaction	1
2. Seeks interaction with family members (gets close to them and talks to family members that were silent until then),seeks and accepts support, might lean against family members.	2
3. Looks silently to family members, apparently observes their actions, does not seek, contact or consolation but accepts it if it is offered, clings on to family members	3
4. Keeps family members at a distance or might leave the area when parents are present, might push family members away or cling desperately to them, not letting them go away.	4

Appendix IV: Modified Yale Preoperative Anxiety Scale (Swahili version)

KIASHIRIA	**ALAMA**
A: Matendo	
1. Mtoto anayatambua mazingira, anaangalia pande zote huku na huko,anacheza na midoli au vitu vinavyo mzunguka, anakimbia kimbia pande zote, anacheza na kuwakimbilia wana ndugu.	1
2. Mtoto hachezi vizuri,amekaa sehemu moja huku akichezea vidole au akinyonya vidole,anakaa tuu karibu nawana ndugu.	2
3. Mtoto anakimbia kimbia bila muelekeo maalumu au bila kufuata vitu vya kuchezea, hawataki badhi ya watu na anaonekana mwenye shari.	3
4. Anajaribu kurudia alikotoka,anarusha miguu na mikono,katikachumba cha kusubiria upasuaji anakimbia kimbia huku na kule bila malengo,hataki vitu vya kuchezea hataki kukaa mbali na familia	4
B: Uongeaji	
1. Anasoma ,anauliza maswali,anacheka,anajibu maswali vizuri ila huwa mkimyaa,mtoto ni mdogo kuongea kwenye hadhira ya watu au amezidiwa na michezo hawezi kujibu	1
2. Ana wajibu watu wazima kwa sauti ya chini, anatikisa kichwa pekee	2
3. Mkimya,hatoi sauti au hawajibu watu wazima	3
4. Analia kwa sauti ya chini,anagugumia	4
5. Mtoto analia au anapiga kelele ya “sitaki”	5
6. Analia sana kwa sauti ya juu na kwa muda mrefu	6
C: Hali ya emotions	
1. Ana furaha ,anatabasamu,yupo makini na kucheza	1
2. Yupo katika hali ya kawaida	2
3. Ana ogopa sana, ana huzuni,anatokwa machozi	3

4. Analia sana, hawezi kutulizwa, amekazana kufungua macho sana	4
D:Hali yauchangamfu	
1. Anajitambua ,anatizama kila mahali na kufuatilia mambo yanayo fanywa na mtoa huduma. Anaweza kuwa ametulia	1
2. Mkimyanaametulia ,ananyonyakidole	2
3. Anatazama kila mahali kwa haraka,ana shtushwa na kelele, anakodoa macho, mwili unaonyesha wasiwasi.	3
4. Ana hali ya wasiwasi,anaweza kuwa analia,hataki kuguswa	4
E: Kuwasiliana na wana familia	
1. Amekazana kucheza ametulia sehemu moja, hataki kukaa nawana familia, ana wasiliana na wanafamilia kama wataanza kumsemesha	1
2. Anataka kukaa na kuchangamana na wana familia, anawaongelesha wana familia, anakaa nao na kuwaegemea.	2
3. Anaonekana mkimya,anawaangalia wanachofanya, hapendi kuwasogelea.	3
4. Hapendi kabisa kuwana wana familia, anapenda kukaa peke yake muda wote.	4

Appendix V: Consent Form (English Version)

Introduction

I am Dr. Peter Frank Saria a researcher from MUHAS. I am planning to conduct a study involving children undergoing surgery with general anaesthesia MNH with a title "Prevalence of Emergence Delirium in children recovering from general anaesthesia". The aim of this research is to find out how many of these children usually get this condition.

Participation in the study and confidentiality

I would like to request your permission to allow your child to participate in this research. Neither your name nor your child's name will be mentioned in this study. Also, all your particulars and information obtained from you or observed from your child will not be disclosed to anyone. The data obtained will be used for research purpose only. You are kindly requested to participate in this study.

Risk to participant

No anticipated risk or harm that may result from participating in this study. This is an observational study were no any invasive instruments will be used. Data will be obtained mainly by observing the behavior of the child during awakening from general anesthesia and will be recorded to the approved questionnaire. Participating in the study/research is voluntary, and weather accepts or not will not affect your right to get quality health services. And you are allowed to withdraw from the study anytime you wish without compromise your right

Contact Person

The principal Researcher, Dr. Peter Frank Saria contacts are 0759637155 or 0787577825. You may also wish to contact the chairman of the university senate research and publications, Dr Bruno Focus Sunguya, MUHAS P.O.BOX 65001, Dar es Salaam.

The signing of the consent

I (initials)…… have read and understood the contents of this form and I have been given enough information about the aim of these research and therefore I consent without any reinforcement to allow my child to participate in this study.

Signature of interviewee .....……Date.....

Signature of interviewer .....Date ……

Appendix VI: Child Assent Form

I am Dr Peter Frank Saria from Muhimbili University of Health and Allied Sciences. I am doing a study to find out the prevalence of emergence delirium in children recovering from general anaesthesia and their associated risk factors. I am asking you to take part in the research study because you have been planned for surgery under general anaesthesia.

For this study, I will come to see you a night before surgery and fill some forms by just observing your behavior while in the ward and asking you few questions when necessary. Also soon after surgery, I will also observe how you behave when waking from anesthesia. I will keep all the results secret, and will not show them to anyone. Only those who are helping me from Muhimbili hospital and University will see them and will also not tell anyone.

I am not anticipating any problem happen to you as part of this study

You should know that:

- You have right of not participate in this study
- You may stop being in the study at any time.
- Your parents were asked I can include you in this study. Even if they agree, it is still your choice whether or not to participate.
- You can ask any questions you have at any time.

Declaration:

If have understood what you will be your role in this study, have had all your questions answered, have talked to your parent about this study and agree to take part in this research, please write your name and signature in the space provided below:

_____

Name Signature Date

Appendix VII: Assent form (Swahili Version)

Mimi naitwa daktari peter frank saria, kutoka chuo cha udaktari na sayansi ya tiba Muhimbili,nipo katika kufanya utafiti kuhusiana na hali ya kutokutambua mazingira mara baada ya kuzinduka kutoka kwenye dawa za nusu kaputi ulizopatiwa wakati wakufanyiwa upasuaji. Ninaomba ushiriki wako katika tafiti hii kwani nimeona na wewe ni miongoni mwa watakao patiwa dawa ya nusu kaputi wakati wa upasuaji.

Kwenye tafiti hii, nitakuja kukuona usiku kabla ya upasuaji na kujaza fomu baada ya kuangalia viashiria vya tabia yako wakati uwapo wodini na kukuuliza maswali machache pale itakapo lazimika. Pia punde tuu baada ya upasuaji nitaangalia viashiria mbalimbali ninavyo vichunguza mara baada ya kuzinduka kutoka usingizini. Taarifa zote nitakazo zikusanya zitakua siri na hazitaonyeshwa kwa yeyote asiyehusika katika utafiti huu.

Utafiti huu hauta kuweka katika hatari yeyote kwa kipindi chote cha utafiti.

Pia tambua ya kuwa:

- Una haki ya kukataa kushiriki katika tafiti hii
- Unaweza kujitoa wakati wowote wa utafiti huu
- Wazazi/walezi wako waliombwa uwepo wako katika tafiti hii. Hata kama wamekubali, bado maamuzi ya kushiriki au kuto kushiriki yapo juu yako.
- Unaweza kuuliza swali wakati wowote kwa muda wote wa utafiti.

Tamko:

Kama umeelewa jukumu lako katika utafiti huu,na kama maswali yako yame jibiwa ipasavyo na kueleweshwa kila palipo itajika, umeongea na wazazi/walezi wako kuhusu utafiti huu na kukubali kushiriki,tafadhali andika jina lako na sahihi yako kwenye nafasi iliyo wachwa wazi.

_____

Majina yako Sahihi Tarehe

Appendix VIII: Fomu ya kuridhia kushiriki katika tafiti

Utangulizi

Mimi, Daktari Peter Frank Saria, mtafiti kutoka chuo kikuu cha sayansi ya Tiba Muhimbili. Nipo katika kufanya utafiti wa kiwango cha kutapa tapa kwa watoto wanao amka kutoka kweye dawa za nusu kaputi walizo patiwa wakati wa upasuaji.

Ushiriki na Usiri

Ninaomba utayari wako na wa mtoto wako kushiriki katika tafiti hii. Maelezo yako binafsi,na ya mtoto wako,majina yake hayata tumika popote katika tafiti hii.Viashiria vitakavyo kusanywa katika tafiti hii vitaendelea kuwa siri kati ya watafiti na hakuna mtu yeyote asiye husika ataweza kuona taarifa hizi. Taarifa zitakazo patikana zitatumika kwa malengo ya tafiti yaliyo kusudiwa.

Athari za ushiriki

Hakuna madhara yeyote yatakayo mpata mtoto wako wakati wote wa ushiriki. Tafiti hii inalenga kuangalia viashiria vyote vinavyo takiwa na kujazwa kwenye dodoso la viashiria lililo pitishwa na mamlaka husika. Kushiriki na kutokushiriki kwako hakutaathiri kwa namna yoyote ile upatiwaji wako wa huduma ya afya. Unaruhusiwa kujiondoa kwenye utafiti huu wakati wowote ule pasipo kumtaarifu mtafiti isipokua kama utapenda kwa hiari yako.

Mawasiliano

Mtafiti mkuu, Daktari Peter Frank Saria,simu namba 0759637155 au 0787577825

Pia unaweza kuwasiliana na Mwenyekiti wa Baraza la Utafiti na Uchapishaji wa chuo kikuu cha Sayansi na Tiba Muhimbili Dr Bruno Focus Sunguya kwa SLP 65001, Dar-es-Salaam.

Kukubalikushiriki

Mimi(Majina)…….nimesoma na kuelewa mambo yaliyo andikwa katika fomu hii ya ushiriki,na pia nakiri kupewa taarifa zote muhimu pamoja na malengo ya tafiti hii. Kwa hiari yangu mwenyewe pasipo kulazimishwa na kubali mwanangu ashiriki katika utafiti huu.

Sahihi ya mhojiwa……..... Tarehe…….....……

Appendix IX: Ethical Clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES

P.O. Box 65001
DAR ES SALAAM
TANZANIA
Web: www.muhas.ac.tz

Tel G/Line: +255-22-2150302/6 Ext. 1015
Direct Line: +255-22-2151378
Telefax: +255-22-2150465
E-mail: dpgs@muhas.ac.tz

Ref. No. MU/ PGS/SAEC/Vol. X/

20th July, 2017

Dr. Peter Frank Saria
MMed. Anaesthesiology
MUHAS.

RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED: "PREVALENCE OF EMERGENCY DELIRIUM IN CHILDREN RECOVERING FROM GENERAL ANAESTHESIA, ITS ASSOCIATED RISK FACTORS AND OUTCOME AT MUHIMBILI NATIONAL HOSPITAL"

Reference is made to the above heading.

I am pleased to inform you that, the Chairman has, on behalf of the Senate, approved ethical clearance for the above-mentioned study. Hence you may proceed with the planned study.

The ethical clearance is valid for one year only, from 20th July, 2017 to 19th July, 2018. In case you do not complete data analysis and dissertation report writing by 19th July, 2018, you will have to apply for renewal of ethical clearance prior to the expiry date.

Prof. Andrea B. Pembe
DIRECTOR OF POSTGRADUATE STUDIES

cc: Director of Research and Publications
cc: Dean, School of Medicine

Appendix X: Permision Letter

MUHIMBILI NATIONAL HOSPITAL

Cables: "MUHIMBILI"
Telephones: +255-22-2151367-9
FAX: +255-22-2150534
Web: www.mnh.or.tz

Postal Address:
P.O. Box 65000
DAR ES SALAAM
Tanzania

In reply please quote:

MNH/TRC/Permission/2017/115

25th July, 2017

Dr. Peter Frank Saria,
MUHAS

RE: PERMISSION TO COLLECT DATA AT MNH: 2017

Name of Student	Dr. Peter Frank Saria
Title	**"PREVALENCE OF EMERGENCE DELIRIUM IN CHILDREN RECOVERING FROM GENERAL ANAESTHESIA, ITS ASSOCIATED RISK FACTORS AND OUTCOME AT MUHIMBILI NATIONAL HOSPITAL".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Boniface Respicious
Period	25/07/2017 to 24/01/2018

You have been permitted to collect data in respect to the undertaking of the above mentioned study.

Please ensure that you abide to the ethical principle and other conditions of yours approval.

Sincerely,

HEAD, TEACHING RESEARCH & CONSULTANCY UNIT
MUHIMBILI NATIONAL HOSPITAL
P. O. BOX 65000
DAR ES SALAAM.

Dr. Faraja S. Chiwanga
Head of Teaching, Research and Consultancy Coordination Unit