Incidence and associated factors of emergence delirium in pediatric patients undergoing ENT surgery at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia 2024 G.C

A Research thesis submitted to Addis Ababa university, College of Health Sciences; department of Anesthesiology Critical Care and Pain Medicine in Partial Fulfillment for the Requirement of the Specialty certificate of Anesthesiology Critical Care and Pain Medicine.

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Incidence and associated factors of emergence delirium in pediatric patients undergoing ENT surgery at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia 2024 G.C

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STATEMENT OF DECLARATION

I hereby declare and affirm that this thesis is my own original work as a partial fulfillment of the requirement for the specialty certificate training in Anesthesiology. I have followed all the ethical considerations in the preparation, data collection, data analysis and completion of this research. I affirm that I have cited and referenced all the sources used in this document.

RESIDENT

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Name: _____ Signature _____ Date _____

Name: _____ Signature _____ Date _____

Acknowledgement

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Abbreviations

ACCPM _ _ _ _ _ _ _ _ _ _ Anesthesiology, Critical care & Pain medicine

ASA _ _ _ _ _ _ _ _ _ _ _ _ American Society of Anesthesiologists

ED _ _ _ _ _ _ _ _ _ _ _ _ _ Emergence delirium

EENT _ _ _ _ _ _ _ _ _ _ _ Eyes, Ear, Nose and throat

ENT _ _ _ _ _ _ _ _ _ _ _ _ Ear Nose and Throat

FLACC _ _ _ _ _ _ _ _ _ _ _Face, legs, activity, cry and consolability

GA _ _ _ _ _ _ _ _ _ _ _ _ _General anesthesia

IV _ _ _ _ _ _ _ _ _ _ _ _ _ Intravenous

OR _ _ _ _ _ _ _ _ _ _ _ _ _Operating room

ORL-HNS _ _ _ _ _ _ _ Otorhinolaryngology – head and neck surgery

OSA_ _ _ _ _ _ _ _ _ _ _ _ Obstructive sleep apnea

PACU _ _ _ _ _ _ _ _ _ _ _ Post anesthesia care unit

PAED _ _ _ _ _ _ _ _ _ _ _ Pediatric anesthesia emergence delirium

PED _ _ _ _ _ _ _ _ _ _ _ _ Pediatric emergence delirium

TASH _ _ _ _ _ _ _ _ _ _ _ Tikur Anbessa Specialized Hospital

Abstract

Background

Pediatric emergence delirium is a common phenomenon that occurs in children undergoing surgery under GA and is characterized by a brief period of disorientation, agitation and confusion upon waking up from anesthesia. Its duration is variable but is often self-limiting and typically resolves quickly but it can be distressing for both the child and their parents or caregivers as ED might be associated with severe adverse events, which might end up in the unintentional physical injury to the patient or personnel leading to prolongation of hospital stay and increased parental anxiety and dissatisfaction with perioperative care.

This study aims to contribute to the current knowledge on ED in pediatrics undergoing ENT surgery, address knowledge gaps in its incidence and assess risk factors associated with it.

Objective

To assess the incidence and associated factors of emergence delirium in pediatric patients undergoing ENT surgery under general anesthesia in TASH, Addis Abeba, Ethiopia.

Method

An institutional-based prospective cross-sectional study was conducted from September 2023 to April 2024 G.C at TASH. During the study period 88 pediatric patients between the ages of 2 and 12 years, who have undergone elective ENT surgical procedures in the major OR were included in the study. Data was collected using a structured questionnaire by anesthetists and anesthesiology residents in the major OR and PACU. PAED scale was used to assess for ED and a PAED scale of 12 or more was taken as PED. Binary logistic regression analysis was performed to determine predictors of postoperative delirium in pediatric patients undergoing ENT surgery under general anesthesia.

Results

The incidence of Pediatric emergence delirium in this study was 21.6%. Age (toddlers and preschoolers) (p-value 0.039, AOR=4.831; 95% CI:1.08,21.62), maladaptive behavior (p-value 0.003, AOR=12.16; 95% CI:2.278,64.91), premedication (p-value 0.043, AOR=0.11; 95%

CI:0.013,0.928) and moderate to severe postoperative pain (p-value 0.005, AOR=11.05; 95% CI:2.058,59.34) were significantly associated with postoperative ED following ENT surgery.

Conclusion

The incidence of ED in pediatric patients undergoing ENT surgery in TASH was found to be 21.6%. This study also highlights several factors emerging as significant predictors of ED with toddler and preschooler age group, preoperative maladaptive behaviors, lack of premedication and moderate to severe postoperative pain being highly associated with developing postoperative PED.

1. INTRODUCTION

1.1. Background

During emergence from general anesthesia, a brief period of agitation is usually common. Patients may exhibit features of disinhibition, agitation, crying, restlessness, hyperexcitability and mental confusion as they transition through a stage of delirium during initial emergence. This intraoperative stage of emergence is usually very brief and typically lasts only for a few minutes, and following removal of a noxious stimulus, such as the endotracheal tube, it often resolves fast. In children notably, it's not uncommon to observe a brief period of emergence delirium in the OR but, some patients may experience postoperative delirium that persists or recurs after the initial emergence from the anesthesia, or only manifests itself in the PACU.(1)
In the postoperative period following initial emergence from general anesthesia, postoperative delirium may present as agitation (hyperactive subtype) or somnolence with altered mental status (hypoactive subtype). Compared to adult patients, pediatric patients have a higher prevalence of delirium during and soon after awakening from general anesthesia.(1)
Emergence delirium in children is defined as a dissociated state of consciousness in which the child is irritable, uncompromising, uncooperative, incoherent, and inconsolably crying, moaning, kicking or thrashing(2).
Although the terms "emergence agitation" and "emergence delirium" are frequently used interchangeably, emergence agitation is more typically understood as a mild to moderate state of restlessness and distress that, unlike delirium, is not always accompanied by a noticeable alteration in behavior or cognition.(3) A variety of factors, such as discomfort, pain, a compromised physiological state, or anxiety, can cause agitation.
Delirium can also take place in the absence of agitation, restlessness or non-purposeful movement. This type of delirium is referred to as a hypoactive or quiet delirium. It's a state of an altered consciousness where a child is unable to focus, is unaware of his or her surrounding and appears to be quiet or withdrawn. It starts with emergence from anesthesia and lasts through the initial stages of recovery period.(1)
In children undergoing GA, ED is a common PACU event. Children with ED may move around in a non-purposeful, aimless manner and avoid or fail to establish eye contact or interact with their parents or caregivers or otherwise behave abnormally. They might stare or avert their gaze, seem lost, confused and disorientated and pull at IV lines, monitors and dressings.

Several rating scales have been created for the diagnosis of ED, despite the fact that it's mainly a clinical diagnosis. This rating scales include the Watcha scale, the Cravero scale and the Pediatric Anesthesia Emergence Delirium (PAED) scale. However, the Pediatric Anesthesia Emergence Delirium (PAED) scale which was introduced in 2004 incorporates a combination of cognitive and agitation assessment items and is widely regarded as the most valid and reliable tool to for diagnosing ED. It's the accepted standard for the diagnosis of ED.(4) A score of 12 or above has the highest diagnostic sensitivity and specificity.

1.2. Statement of the problem

Pediatric emergence delirium is a well-known occurrence in children, but managing it still continues to be a challenge in pediatric anesthesia management. Due to their excessive movement, children with ED run the risk of disrupting surgical repairs and dislodging surgical drains or tubes as well as intravenous (IV) catheters. These children present a danger to not only themselves but also the PACU care staff. Additionally, caring for these children frequently necessitates the burden of hiring more nursing staff, which may affect the PACU's capacity for staffing. (5)

Parental satisfaction is a crucial indicator of the quality of anesthetic care. Concern, worry, and dissatisfaction are regularly expressed by parents of children who experience ED. For up to two weeks after surgery, children with ED are 1.4 times more likely to develop maladaptive behavioral changes like separation anxiety, sleep disturbance, and eating disturbance. (5)

Different literatures list different risk factors as probable cause of emergence delirium. One of the commonly mentioned risk factors for ED is the type of surgery that is undergone, with ENT procedures being on top of the list. But there is lack of research specifically on the incidence of ED in children undergoing ENT surgeries in many African countries including Ethiopia, so there is an important knowledge gap to fill. Even in worldwide studies that were conducted, its incidence varies greatly, so it's important to conduct further research to better understand its frequency and severity in our pediatric population in order to help us improve our understanding of this condition and the factors that contribute to its development, which could ultimately lead to better prevention and treatment strategies.

1.3. Significance of the study

Pediatric emergence delirium is a common phenomenon that occurs in children undergoing surgery under GA. ENT surgeries are among the surgeries that are routinely performed in our set up here in TASH.

ED can cause distress and anxiety for both the child and caregiver. The potential consequences of ED include increased postop pain, injury to the child, delayed recovery, longer hospital stay and increased healthcare costs. Therefore, its important have a better understanding of this condition in order to develop strategies for prevention and management of patients in this population. This research can help raise awareness about ED and its potential impact on children undergoing ENT surgery, which could ultimately help improve the quality of care and support provided to these patients.

The findings in this study can be used to

- Suggest means to reduce the incidence of PED
- Predict the likelihood of developing PED following ENT surgery
- Identify at risk patients, leading to earlier interventions and better outcomes
- Formulate a strategy or standardized guideline for postop management and care for these pts in the PACU
- Provide data for further study in this topic

2.Literature review

The incidence of emergence delirium in the pediatric population has been widely reported, with estimates ranging from 2% to 80% worldwide. Some of the variation is explained by variations in study design and methodology, particularly the use of various ED rating systems and the variety of surgical and anesthetic contexts being studied. (2)

The increased incidence of ED has been linked in literatures to the use of short-acting volatile anesthetics like sevoflurane. The risk is increased by anesthetic methods that cause a rapid emergence from anesthesia in an unfamiliar environment. (2)

Younger patients, in particular those between the ages of 2 and 5, are more likely to develop ED. The most significant risk factors for the onset of ED were found to be preexisting anxiety or maladaptive behaviors, such as agitated, uncooperative behavior, exaggerated displays of anger, and poor adaptability abilities. (5)

The site of the surgery has also been suggested as a risk factor. Compared to urological and general surgery procedures, otorhinolaryngological and ophthalmological procedures have been shown to increase the risk for ED. (2)

In research published on September 2022 by physicians from the department of Anesthesiology and pain management and department of ORL- HNS at a tertiary children's hospital in the United States, the charts of 4974 patients were retrospectively reviewed to identify children who develop ED. The incidence of ED in children who underwent tonsillectomy and Adenoidectomy was reported to be 1.3%. And out of this, toddlers and male children had a significantly higher prevalence for ED.(6)

In a prospective cohort study over a one-year period, 521 healthy children (3 to 7 years old) undergoing GA were included for an outpatient surgical procedure. A nonprobability, consecutive-sampling technique was used to include all children with an ASA physical status of I–II who were cognitively intact. 96 (18%) of these children exhibited ED. Children who experienced EA were significantly younger and less likely to have had previous surgery compared with those who awakened without agitation. Forty-two (26%) and 23 (28%) children who underwent otorhinolaryngologic and ophthalmologic procedures, respectively, experienced

EA, compared with urologic (15%), orthopedic (15%), general surgical (12%), and other (6%) procedures.(7)

A prospective multicenter observational study was undergone in Germany to measure the incidence of postoperative pediatric emergence delirium and to investigate the occurrence of early postoperative negative behavior within two weeks after outpatient adenoidectomy in preschool children. The study compromised of 222 children age 1 – 7 years where all received multimodal anesthesia with TIVA. The incidence of emergence delirium following this anesthetic regime was 23%. The incidence of early postoperative negative behavior was significantly higher among patients with emergence delirium (24%).(10)

A cross - sectional descriptive and analytic study was performed on 747 pediatric patients aged 3- 7 years that underwent general anesthesia for various elective surgeries at Bou-Ali Sina Hospital in Sari, Iran between January 2010 and January 2011. A non-probability quota sampling technique was used. This study was done to determine the prevalence of emergence agitation and associated risk factors in pediatric patients who underwent general anesthesia. One hundred thirty-four (17.9%) children had emergence agitation. Otorhinolaryngological surgical procedures, pain and induction behavior of children were associated with higher rates of post anesthetic emergence agitation(8).

Between March and August 2018, a retrospective cohort study was conducted based on a review of 413 medical charts of children (<14 years) who underwent an elective/nonemergency surgery and then were admitted to a Post Anesthesia Care Unit. The aim of this study was to determine the prevalence of ED and its associated factors among children who underwent surgeries at a major tertiary healthcare facility in Saudi Arabia. The prevalence of ED among children who underwent surgeries during the 6-month period was 23 (6.6%). The leading surgery category was ear, nose, and throat surgeries (44.6%) and dental surgeries (26.4%).(9)

In a prospective observational study conducted at selected governmental hospitals in Addis Abeba to assess the incidence and associated factors of emergence agitation in pediatric patients aged 2 – 12 years, the incidence of post operative emergence agitation was 49%. Young age, EENT surgery, uncooperative and restless parental separation behavior, short duration of surgery and pain were significantly associated with post operative emergence agitation after GA.(11)

In a study conducted in Turkey, Dicle university hospital to determine whether oral ketamine premedication affected the incidence of emergence agitation in children, 80 children who were undergoing adenotonsillectomy with or without bilateral myringotomy and insertion of tubes received either ketamine 6 mg/kg per oral in group K or sour cherry juice alone in group C. The incidence of emergence agitation was 56% in group C, and 18% in group K.(12)

An observational study including 250 children between the ages of 2 and 8 was done in a tertiary care institution in South Asia to determine the incidence of emergence delirium and its association with preoperative anxiety using the PAED scale and the modified Yale preoperative anxiety scale. 22.4% of the children experienced emergence delirium and a significant association was observed between preoperative anxiety and ED.(13)

In a multicenter, prospective follow up study done at Amhara regional state Tertiary hospitals in Ethiopia which included 404 pediatric patients between the ages of 0 and 16 to identify predictors of postoperative delirium in pediatric patients having GA, the study found that 160 (39.6%) patients experienced ED and ophthalmic surgery, corticosteroid use, anticholinergic use, severe postoperative pain and preoperative anxiety were found to be predictors of postoperative ED.(14)

In 336 children between the ages of 2 and 13, a prospective observational trial was undergone to assess for the incidence and risk factors of children undergoing surgery under GA and the incidence of ED was 3.87% and male gender, severe preoperative anxiety and pain were significantly associated with postoperative ED.(15)

A study was conducted to estimate the incidence of postoperative pediatric delirium in low surgical risk procedures and to analyze risk factors in 340 children between the ages of 2 and 10 using a prospective analytical observational methodology, and an incidence of ED of 13.2% was found with a strong relationship between the presence of sever acute postoperative pain and ED.(16)

3. OBJECTIVES

3.1. General objectives

To assess the incidence and associated factors of emergence delirium in pediatric patients undergoing ENT surgery under general anesthesia in TASH.

3.2. Specific objectives

To state the incidence of ED following ENT surgery

To identify factors associated with the development of ED in pediatrics post ENT surgery

4. METHODS

4.1. Study area and period

The study will be conducted at Addis Ababa university, college of health science, Tikur Anbessa Hospital. It is the largest referral hospital in the country and an institution where specialized clinical services that are not available in other public or private institutions are rendered to the whole nation.

The study period will be from September 1 2023 to April 30 2024.

4.2. Study design

An institutional based prospective cross-sectional study

4.3. Population

4.3.1. Source population

All pediatric patients who underwent surgery under general anesthesia in Tikur Anbessa specialized hospital

4.3.2. Study population

All pediatric patients 2 – 12 years of age who underwent ENT surgery under GA in TASH during the study period that meet the inclusion criteria.

4.4. Eligibility criteria

4.4.1. Inclusion criteria

ASA I, II and III pediatric patients between the ages of 2 and 12 who are scheduled to undergo an ENT surgery under GA.

4.4.2. Exclusion criteria

Patients who are mechanically ventilated after the surgery

Patients who are transferred to the ICU following the surgery

Patients with cognitive developmental delay

4.5. Sample size and sampling technique

n = Z2 x P(1-P) / D2

n = required sample size

Z = confidence level at 95% (standard value of 1.96)

P = estimated incidence of ED in pediatric patients who underwent ENT surgery which is put at 50%

D = margin of error at 5% (standard value 0.05)

n = (1.96)2 x 0.5(1 – 0.5) / (0.05)2

n = 384

In a time frame of twelve months (01/07/14 – 30/06/15), 114 pediatric patients underwent ENT surgery in the major OR of TASH, so I took the population to be studied to be114.

The population to be studied is less than 10,000 (114 in our case) so we will apply this next formula

nf = n / (1 +n / N)

n = required sample size (384 in our case)

N = the estimated population size (100 in our case)

nf = desired sample size when the population studied is under 10000

nf = 384 / (1 + 384 / 114) = 87.9

Hence the estimated number of patients required to achieve the desired sample size is 88.

Sampling technique

Consecutive sampling technique will be used where every voluntary patient fulfilling the criteria of inclusion will be selected until the required sample size is achieved.

4.6. Data collection procedures

After receiving an informed oral consent, the data was collected using a standardized questionnaire. The data was gathered starting from the immediate post - extubation period in the OR and then in the PACU by anesthesiology residents and anesthetists assigned to the ENT OR table. PAED scale was used to assess for ED and a PAED scale of 12 or more was taken as PED.

4.7. Study variables

4.7.1. Dependent variable

Emergence delirium

4.7.2. Independent variables

Age

Sex

ASA classification

Comorbidity/Coexisting disease

Preoperative behavior

Premedication

Type of anesthesia

Anesthesia duration

Postoperative pain

4.8. Operational definition

Maladaptive behaviors – behavior that prevents an individual from adjusting well to certain situations. This behavior includes anxiety, withdrawal, agitation, uncooperative behavior, temper tantrums or aggressions.

Premedication – administration of medications to patients before induction of general anesthesia for a surgical procedure in order to reduce their anxiety, induce sedation or prevent pain.

Cognitive developmental delay – condition in which children lag in intellectual functioning and whose behavior and communication are significantly below expectations.

Pediatric emergence delirium – patients with a PAED score of 12 or more were taken as having emergence delirium.

FLACC pain scale – is a behavioral pain assessment scale scored 0-10 where 0- relaxed and comfortable, 1-3: mild discomfort, 4-6: moderate pain, 7-10: severe pain or discomfort.

4.9. Data analysis procedures

The data collected was reviewed by the main investigator and checked for quality and any missing documents prior to data input and manually analyzed using SPSS version 26 software. Bivariant logistic regression analysis was carried out to examine the predictors of the outcome variable. Variables with a p-value of < 0.25 on bivariant logistic analysis were taken to multivariable logistic regression analysis and a p value of less than 0.05 was taken as statistically significant predictor of postoperative delirium. The goodness of fit test was evaluated using Hosmer-Lemeshow goodness of fit test where $p > 0.05$ indicates appropriateness of the model. Descriptive statistics was done for all variables and the results are presented in tables, graphs and pie charts.

4.10. Data quality management

The data collectors were briefly trained before data collection on pediatric emergence delirium and there was a daily meeting during the data collection to clear up any ambiguity. The data collected from the questionnaire was reviewed by the main investigator and checked for completeness every day.

4.11. Ethical consideration

The study participants and their attendants were informed about the aim of the study before the data collection begun and that they were able to withdraw from the study at any point during the research, then oral consent was obtained from each patient's parents or legal guardians. Specific patient identifiers were not used in the data collection instead code numbers were assigned to each data. Ethical clearance and support letter was obtained from Addis Ababa University College of Health Science department of Anesthesiology, Critical Care and Pain Medicine and submitted to Tikur Anbessa Comprehensive Specialized Hospital Chief Clinical and Academic Director Offices

4.12. Dissemination plan

The study will be presented to Addis Ababa university, School of Medicine, department of Anesthesiology Critical care and Pain medicine.

5. Result

5.1. Sociodemographic and preoperative data

A total of 88 pediatric patients who have undergone elective ENT surgery between the period of September 2023 and April 2024 in TASH were included in the study. 31(35.2%) were toddlers and preschoolers while 57(64.8%) were school aged children.42(47.7%) were female and 46(52.3%) were male.59(67%) had no coexisting disease compared to 29(33%) patients who had other coexisting diseases. 19(21.6%) were premedicated with ketamine and 51(58%) were calm compared to 37(42%) who had maladaptive behavior during separation from their parents in the waiting room area.

Table 1: Sociodemographic characteristics and preoperative data of pediatric patients who underwent ENT surgery in TASH, A.A

Variables		Frequency	Percentage
Age	Toddler & preschool	31	35.2
	School age	57	64.8
Sex	Female	42	47.7
	Male	46	52.3
ASA	I	58	65.9
	II	28	31.8
	III	2	2.3
Coexisting disease	Yes	29	33
	No	59	67
Premedication	Yes	19	21.6
	No	69	78.4
Premedication type	Ketamine	19	21.6
	Midazolam / Diazepam	-	-
	Other	-	-
	None	69	78.4
Behavior during parental separation	Calm	51	58
	Maladaptive behavior	37	42

5.2. Intraoperative data

During induction in the OR 29 (33%) were calm, 44 (50%) had maladaptive behavior and 15 (17%) were previously sedated in the waiting room area. All 88 patients were given inhalational anesthesia as maintenance of anesthesia and 69 (78.4%) of the patients had surgery duration of less than 45 minutes and anesthesia duration of less than 1 hour compared to 19 (21.6%) patients whose surgery and anesthesia duration was greater than 45 minutes and 1 hour respectively.

Table 2: Intraoperative data of pediatric patients who underwent ENT surgery in TASH, A.A

Variables		Frequency	Percentage
Induction behavior in the OR	Calm Maladaptive behavior Previously sedated	29 44 15	33 50 17
Anesthesia type	Inhalational TIVA	88 -	100 -
Surgery duration	< 45 minutes >45 minutes	69 19	78.4 21.6
Anesthesia duration	< 1 hour > 1 hour	69 19	78.4 21.6

5.3. Postoperative data

None of the 88 patients who underwent surgery had vital sign derangement in the PACU. 58 (65.9%) had mild or no pain in contrast to the 30 (34.1%) who experienced moderate to severe pain. Out of the 88 patients, 19 (21.6%) had ED.

Table 3: Postoperative data of pediatric patients who underwent ENT surgery in TASH, A.A

Variables		Frequency	Percentage
Vital sign derangement in the PACU	Yes NO	- 88	- 100
Post operative pain score	None – Mild pain Moderate to Severe pain	58 30	65.9 34.1
Pediatric anesthesia emergence delirium score	PAED score </=12 PAED score >12	69 19	78.4 21.6

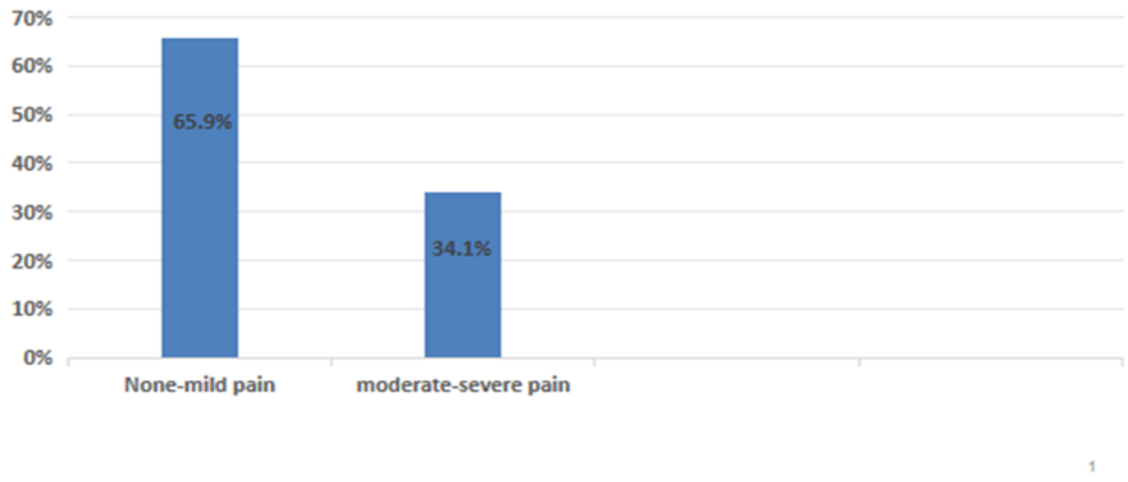

Figure 1: Postoperative pain score of pediatric patients who underwent ENT surgery

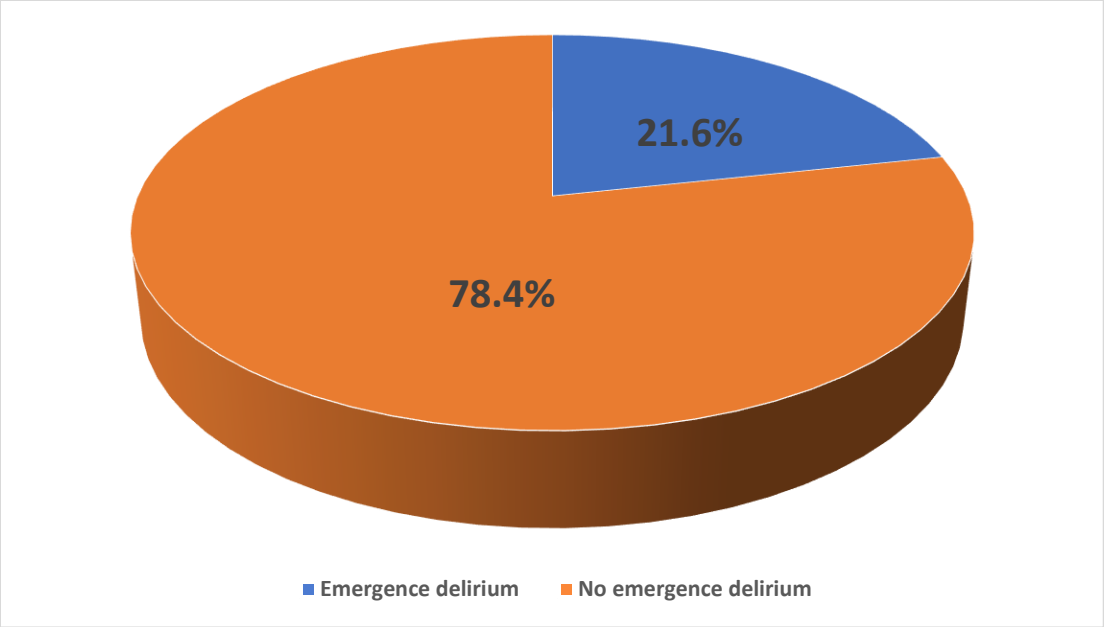

Figure 2: Incidence of pediatric emergence delirium following ENT surgery

5.4. Factors associated with pediatric emergence delirium following ENT surgery

To test the relationship between pediatric emergence delirium and the independent variables, bivariate binary logistic regression analysis was performed on selected independent variables with the dependent variable. Variables having a p-value of < 0.25 were selected and then included in the multivariable logistic regression analysis. These variables were age, sex, behavior of patient during parental separation, premedication, anesthesia duration & post operative pain scale in the PACU.

The odds of developing emergence delirium were 4.8 times higher in toddlers and preschoolers [AOR=4.831 (95%CI):(1.08-21.62)] compared to school age children.

Patients with maladaptive behavior like anxiety, agitation and restlessness were found to be 12 times more at risk of pediatric emergence delirium [AOR=12.16 (95%CI):(2.278-64.91)] compared to those who were calm during their separation from parents in the waiting room area.

Those patients who were premedicated before induction of anesthesia were 89% less likely to develop emergence delirium [AOR=0.11,(95%CI):(0.013-0.928)] than those who did not receive premedication prior to start of surgery.

Patients with moderate to severe pain postoperatively were 11 times more likely to have emergence delirium [AOR=11.05 (95%CI):(2.058-59.34)] compared to the patients with mild to no pain in the PACU.

Table 4: Multivariable binary logistic regression analysis of factors associated with emergence delirium in pediatric patients undergoing ENT surgery in TASH, A.A, 2023-2024

Variables		Pediatric emergence delirium		COR 95% CI	p-value	AOR 95% CI	p-value
		Yes	No				
Age	Toddler & preschool	12(63.16%)	19(27.53%)	4.51(1.545,13.17)	0.006	4.831(1.08,21.62)	0.039
	School age	7 (36.84%)	50 (72.46%)			1	
Sex	Female	4 (21.05%)	38(55.07%)			1	
	Male	15 (78.94%)	31(44.92%)	4.597(1.38,15.27)	0.013	4.24(0.882,20.367)	0.071
Behavior of the patient during parental separation	Calm	5 (26.3%)	46(66.66%)			1	
	Maladaptive behavior /anxious/ /uncooperative/ /restless/ agitated/	14 (73.68%)	23(33.33%)	5.60(1.796,17.46)	0.003	12.16(2.278,64.91)	0.003
Premedication used	Yes	2 (10.5%)	17 (24.63%)	0.36(0.075,1.72)	0.20	0.11(0.013,0.928)	0.043
	No	17 (89.47%)	52 (75.36%)			1	
Duration of anesthesia	Less than one hour	17 (89.47%)	52(75.36%)	2.779(0.58,13.27)	0.20	0.93(0.126,6.875)	0.943
	More than one hour	2 (10.5%)	17(24.63%)			1	
Post operative pain score	None - Mild	4 (21.05%)	54 (78.26%)			1	
	Moderate to Severe	15 (78.94%)	15 (21.73%)	13.5(3.897,46.76)	0.000	11.05(2.058,59.34)	0.005

AOR- Adjusted odds ratio, COR- Crude odds ratio, CI- Confidence interval.

6. Discussion

ED is a very common PACU occurrence in children with an overall incidence of 10% to 80% in children undergoing anesthesia for a variety of procedures. In this study the prevalence of ED was 21.6% which was close to other studies done on the incidence of emergence delirium on pediatric patients undergoing GA for different surgical procedures in Michigan (USA) (18%), Iran (17.9%), Germany (23%) and South Asia (22.4%) (7,8,10,13).

In other studies, conducted specifically in pediatric patient undergoing ENT surgeries, the incidence of PED was 1.3% in one study conducted in the university of Texas (6) and 56% in another study conducted in Turkey (12). Possible explanation for the variance in incidence of ED from our study could be due to differences in demographics, preoperative anxiety level, anesthetic management, methodology and data analysis methods used during the study.

Age emerged as a significant predictor of ED in our study, with toddlers and preschool age children exhibiting a higher propensity for developing delirium upon emergence from anesthesia ($p=0.039$). This aligns with a retrospective study done in the University of Texas Southwestern Medical Center, Dallas, TX, USA (6) where Toddlers had a higher prevalence of ED than preschooler ($p=0.04$), middle age ($p<0.001$), and teenage children ($p=0.01$). Preschoolers had a higher prevalence of ED than middle age children ($p=0.02$) and in a prospective observational study done in selected hospitals in Addis Ababa where younger age between 2-6 years of age ($p=0.042$) had 2 times greater risk when compared with 7–12-year-old patients who underwent surgery (11). The reason for this result could be because children in this age group will usually have limited ability to understand and communicate their feelings, have low adaptability to new environment, have immature cognitive development and have high separation anxiety from their parents therefore leading to increased stress levels and more likelihood of having an ED.

In contrast to the retrospective study conducted in the University of Texas Southwestern Medical Center, Dallas, TX, USA where boys had higher prevalence of ED ($p=0.03$) than girls (6) and also in another prospective observational trial in India ($p=0.04$) with similar result (15), our study did not reveal an association between male gender and ED ($p=0.071$). The reason for this could be that the males included in the above-mentioned study in the US who had ED, had longer anesthesia time compared to the females unlike our study where both genders had comparable anesthesia time. The reason for the difference in result between ours and the second study stated

above, could be attributed to the difference in the demographics of the patients. 82.4% boys and only 17.6% girls were included in the Indian study versus 52.3% boys & 47.7% girls in ours. Similar to our finding, the observational study done in South Asia also did not find correlation between gender and ED.

The behavior of the patient during parental separation in the waiting room area was also identified as a significant factor influencing the incidence of ED. Certain maladaptive behavior trait like agitation, anxiety, restlessness, uncooperativeness & exaggerated displays of anger predisposed pediatric patients to a higher likelihood of experiencing delirium upon emergence from anesthesia (p=0.003). A similar result was found in an observational study done at a tertiary care institution in South Asia (p=0.0005), in a cross sectional descriptive and analytic study Bou-Ali Sina Hospital in Sari, Iran (p=<0.005), in a prospective multicenter observational study in Amhara regions (p=0.02) and in a prospective observational trial in India (p=0.01) (13,8,14,15). An explanation for this outcome could be that maladaptive behaviors in children could increase their stress levels disrupting their ability to regulate emotions and cognitive function during the recovery period potentially leading them to develop delirium.

Premedication use emerged as a key determinant of ED susceptibility in our study (p=0.043), where patients who received premedication were less likely to develop delirium after surgery. Similarly, a study conducted in turkey showed that incidence of emergence agitation in children was lower 18% in those who received premedication with oral ketamine (p=0.001) compared to those who did not receive premedication 56% (12). A study conducted in Amhara region also showed that use of sedative premedication's had a 58% lower risk of developing delirium (p=0.007) compared to those who were not premedicated (14). The reason for this could be that sedative premedication's might help calm and relax the patient prior to the procedure, reducing their anxiety and stress levels.

Pain was identified as another potential factor influencing the occurrence of ED (p=0.005). As shown in this study patients with moderate to severe pain in the PACU were 11 times more likely to have emergence delirium. Similar results were also found in other four studies which include a cross sectional descriptive and analytic study done at Bou-Ali Sina Hospital in Sari, Iran, where pain was associated with higher rate of post anesthetic emergence agitation (p<0.0005), in a prospective multicenter study conducted in Amhara region severe postoperative pain was a

strongly associated with ED ($p<0.001$), in a prospective analytical observational study, pain was taken as perhaps the most important risk factor for postoperative delirium in pediatric patients ($p<0.0001$) and another study in India also showed similar results ($p=0.002$) (8,14,16,15). One possible explanation could be that any condition that's capable of interfering with the brain's conduction, in this instance like pain, would make the brain vulnerable, impair its activity and favor emergence of neurologic manifestations like delirium after surgery.

Some studies have identified that shorter anesthesia time was correlated with increased incidence of pediatric emergence delirium (11) but similar results were not replicated on our multivariate logistic regression ($p=0.943$). The reason for the difference in result could be due to the difference in anesthesia drugs and techniques that were used on these patients.

7. Strength and limitation

7.1. Strength of the study

The study design was a prospective study which increases the ability of this research to establish stronger evidence of causality between factors and emergence delirium.

Even though there are several rating scales for the assessment of PED, this study used the PAED scale, which is the accepted standard for the diagnosis of emergence delirium in children.

The study tried to identify pediatric patients at risk of developing ED, this can help anesthesia providers to work on its prevention.

7.2 Limitation of the study

Even though a valid and reliable tool was used to diagnose emergence delirium in pediatrics, the PAED scale, due to its subjective nature may cause/introduce inter-rater variability due to differences in interpretation among different observers.

Due to the poor standard of the PACU and scarcity of resources, confounding factors of ED like hypoglycemia and hypotension could not be ruled out in patients using objective blood glucose and blood pressure measurements instead pulse rate and capillary refill were used to identify hypotension and other signs and symptoms of hypoglycemia were looked for in order to rule out hypoglycemia.

The study was conducted in a single center with a small sample size so generalizability of the findings to broader pediatric populations may be limited.

8. Conclusion and recommendation

8.1. Conclusion

The incidence of ED in pediatric patients undergoing ENT surgery in TASH was found to be 21.6%. This study also highlights several factors emerging as significant predictors of ED with toddler and preschooler age group, preoperative maladaptive behaviors, lack of premedication and postoperative pain being highly associated with developing postoperative PED.

8.2. Recommendation

Conducting thorough preoperative evaluations to identify patients at increased risk of ED, providing psychosocial support to our patients throughout the perioperative period, administering premedication to patients with high levels of anxiety in the preoperative period, giving multimodal analgesia to minimize perioperative discomfort/pain and developing hospital protocols to promptly identify and manage ED in the PACU is recommended based on this study.

Further multicenter studies should be done in the pediatric population to work towards reducing the incidence of ED, identify any additional risk factors for ED, enhance pre-and postoperative anesthetic management, and improve the overall perioperative experience for pediatric patients.

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ANNEX

Annex 1: Subject information sheet

Addis Ababa University

School of medicine

Subject information sheet

Hello, my name is ----------, I am here in behalf of Dr. Hanna Beshah, a student in Addis Ababa University School of medicine. She is conducting research on "Incidence and associated factors of emergence delirium in pediatric patients undergoing ENT surgery at Tikur Anbesa Specialized Hospital (TASH), Addis Ababa Ethiopia." She has received permission from Addis Ababa University School of medicine and Tikur Anbessa Specialized Hospital officials to conduct the study.

You are selected to participate in this study because you / your child / is currently admitted to the hospital and elective surgery has done for you/ them. Your participation in this study will only be based on your willingness to participate. You have the right to choose not to take part in this study. If you are willing, you have the right to stop at any time or withdraw without giving any reason which you will not be subjected to any ill-treatment. There will be no direct benefit by participating in this study but in future information gathered by this study will help policy makers, programmers and researchers to give appropriate attention on issues of interest and design specific treatment options.

The information that you provide will be kept confidential by using only code numbers and locking the data. Only the members of the study team will have the access to the non-coded data and the data will not be used for purposes other than the study. Your willingness and active participation is very important for the success of this study.

If you need any further information or explanation regarding to the study, you can have this address to contact.

Name: Dr. Hanna Beshah Tel- +251-913011815 Email- beshahhanna1@icloud.com

Annex II: Informed consent form

My name is Dr. Hanna Beshah, a postgraduate student in anesthesia at Addis Abeba University. I am conducting research on the incidence and associated factors of emergence delirium in pediatric patients undergoing ENT surgery in TASH.

What is emergence delirium?

Emergence delirium in children is a common occurrence that is defined as a dissociated state of consciousness in which the child is irritable, uncompromising, uncooperative, incoherent, and inconsolably crying, moaning, kicking or thrashing.

Reason for the study

The incidence of ED in pediatric patients undergoing ENT surgery in TASH is not known.

So, findings in this study will be used to reduce the incidence of ED in these patients and be aimed at improving safe emergence during recovery from general anesthesia.

Participation in the study

Your child's participation in this study is voluntary and you can decide to withdraw at any stage without penalty. There is no risk in taking part of the study as it is purely observational and non-invasive. Participating in this study will not interfere with the regular management of your child.

Confidentiality

This research is approved by the ethical review board of AAU and college of health science, department of Anesthesiology. Your child's identity will be protected and their name will not be written on this form and all information gathered will be strictly confidential.

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I consent to take part in the research study of "Assessment of the practice of preoperative informed consent in adult hospitalized elective surgical patients at Tikur Anbesa Specialized Hospital, Addis Ababa, Ethiopia"

Participant's Signature _____ Date _____

CONTACT INFORMATION

If you have questions at any time about this study, you may contact the researcher whose contact information is provided below.

Name: Dr. Hanna Beshah

Phone no: 0913011815

Email address: beshahhanna1@icloud.com

Annex III: Questionnaire
Section A: Patient identification

1. MRN-

Section B: Sociodemographic data

1. Age - _____ 2. Sex – A/Male B/Female

Section C: Health state of the patient

1. ASA classification -

2. Presence of any coexisting disease – Yes/ No

3. If your answer is Yes, please specify _____

Section D: Preoperative data

1. What was the patient's behavior during separation from their parents in the waiting area?

A/ Calm B/ maladaptive behavior (Anxious/uncooperative/restless/agitated)

2. Any premedication used – A/Yes B/No

3. If your answer is Yes, please specify which drug – A/ Ketamine B/Midazolam/Diazepam C/Other (specify)……

Section E: Intraoperative data

1. Induction time behavior

A/Calm B/Maladaptive behavior(anxious/uncooperative/restless/agitated)

C/Previously sedated

2. Type of maintenance of anesthesia used

A/Isoflurane B/Sevoflurane C/Halothane D/TIVA

3. Duration of surgery - _____

4. Duration of anesthesia - _____

Section F: Postoperative data

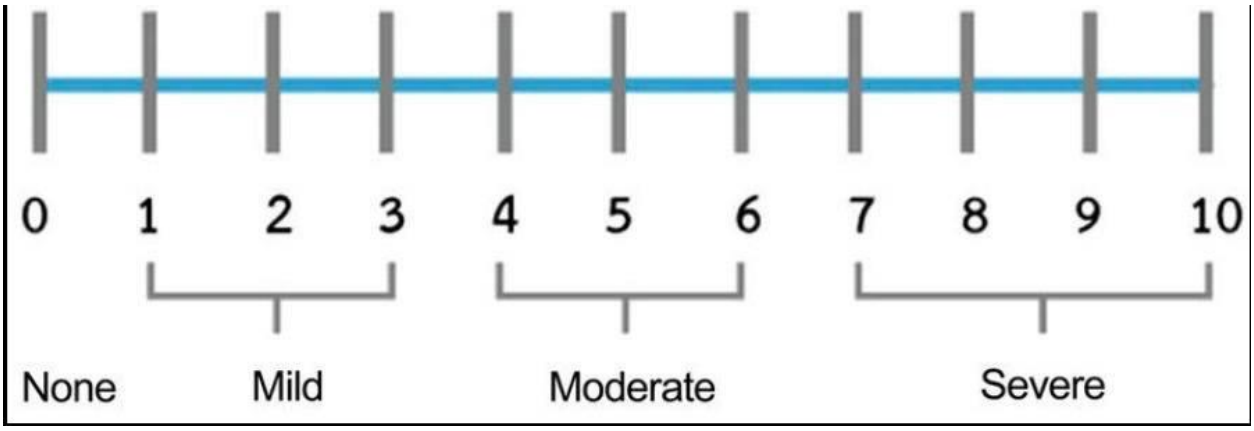
1. Was there any derangement in vital signs in the PACU – Yes / NO

2. If your answer is Yes, please specify

A/Desaturation B/Hypo/hypertension C/Bradycardia D/Bradypnea

3. Postoperative pain score

A/Numeric rating scale (for patients 8 – 12 years of age)



Pain score - _____

B/ FLACC Pain Scale (for patients 2-7 years of age or nonverbal patients of any age)

Category	Scoring			
	0	1	2	Score
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw	
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up	
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking	
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints	
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort	

Pain score - _____

Section G: Emergence delirium assessment

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

1. Total PAED score - _____