



ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
DEPARTMENT OF ANESTHESIA

Magnitude and associated factors of Tracheal Intubation related adverse events in Pediatric Surgery at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia; 2019/20: Cross-sectional Study

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DECLARATION

I, the undersigned, declare that this thesis is my original work in partial fulfillment of the requirements for the Master of Science degree in Anesthesia. I understand that plagiarism will not be tolerated and all directly quoted material has been appropriately referenced.

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Abstract

Background: Tracheal intubation is a rapid, simple, safe and non-surgical technique to achieve airway patency, protects the lungs from aspiration and permits leak free ventilation during ventilation while surgery is undergo. But it may associate with adverse events. Determining its magnitude and associated factors are paramount in making smooth tracheal intubation.

Objective: To assess magnitude and associated factors of tracheal intubation related adverse events in Pediatric surgery at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia

Methods: Institutional based cross sectional study was conducted among 310 pediatric patients who underwent surgery from December 30, 2019 to February 30, 2020 at TASH Addis Ababa, Ethiopia. Systematic random sampling technique was used for selecting the study participants. Prepared questionnaire was used for data collection. Variables that were found to be (p value of < 0.25) on binary logistic regression entered into a multivariable logistic regression analysis to identify independent predictors of tracheal intubation related adverse events. Level of statistical significance was declared at p-value less than 0.05.

Result: During the study period, 310 intubations occurred in pediatric patients who underwent operation room for pediatric surgery intubations were eligible for the study. In our study the overall incidence of trachea intubation related adverse events among pediatrics patients who underwent surgery was 36.5 %. Output of multivariable logistic regression revealed that, being neonate (AOR of 4.134(1.266-13.498), emergency surgery (AOR of 3.392(1.415-8.132), difficult intubation (AOR of 4.083(1.017-7.501)), intubation without using premedication (AOR of 1.759(1.452-10.83)), intubation without using muscle relaxant (AOR of 1.811(1.103-8.142)) and trachea intubation attempted more than three (AOR 3.921(2.164-7.396)) were as independent predictors of trachea intubation related adverse events

Conclusion and recommendations: The incidence of trachea intubation related adverse effect in pediatric surgical patients is high. Being neonate, presence of difficult intubation, intubation without using medication and paralytic drugs, emergency surgery, and multiple attempt of intubation might be the predictors of tracheal intubation related adverse events. Anesthetist should consider these factors during trachea intubation.

Key word: Magnitude, Trachea intubation related adverse events, Tikur Anbessa Specialized Hospital, Addis Ababa, Pediatric, Endotracheal intubation, operation room, and patient factors.

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ABBREVIATIONS/ACRONYMS

AOR	Adjusted Odds Ratio
CI	Confidence Interval
CML	Cormack and Lehane
DI	Difficult Intubation
ED	Emergency Department
ETI	Endotracheal Intubation
ETT	Endotracheal Tube
ICU	Intensive Care Unit
NICU	Neonatal Intensive Care Unit
OR	Operation Room
PICU	Pediatric Intensive Care Unit
QI	Quality Improvement
RSI	Rapid Sequence Induction
SPSS	Statistical Package for Social Science
TASH	Tikur Anbessa Specialized Hospital
TI	Tracheal Intubation
TIAEs	Endotracheal Intubation Associated Events

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1. INTRODUCTION

1.1. Background

Airway management in children is a major challenge for anesthetists at operation theatre. Compared with adults, the airway anatomy in children is unique. A more cephalad larynx, a relatively larger tongue, and a more limited mouth opening in a child's airway present difficulty for laryngoscopy and intubation. Furthermore, the oxygen consumption of children is much higher than that of adults. Therefore, the duration allowed for an intubation is limited if oxygen delivery is not available during the procedure(1).

Tracheal intubation is a common intervention in the operating room. It is a rapid, simple, safe and non-surgical technique that achieves all the goals of airway management. It maintains airway patency, protects the lungs from aspiration and permits leak free ventilation during mechanical or manual ventilation while surgery is undergo(2).

Endotracheal intubation is associated with different complications, some of them life threatening. There were different determinants to cause complication during tracheal intubation at operation. From those factors; patient factors, anesthetist factors, and environmental factors most common of it. It was essential for anesthetist to be aware of these complications, and to have an effective strategy to prevent and manage these complications when they arise(3).

The overall incidence of difficult intubation was high during surgery. In patients younger than one year, the incidence of CML (Cormack and Lehane) III or IV was significantly higher than in the older patients. Pediatric patients intubated at ICU, the incidence of trachea intubation related complication was high with difficult intubation. The common etiology of trachea intubation related adverse effects due to the presence of anatomical and pathological factors affecting the teeth, and jaw. Occurrence of any tracheal intubation associated events and severe tracheal intubation associated events were more common with difficult intubation(4,5).

Pediatric patients underwent surgery with trachea intubation were developed different trachea intubation related adverse events. Esophageal intubation, gum injury, lip injury, and pulmonary aspiration, as well as other major complications, were reported. Higher occurrence of tracheal

intubation related adverse events was observed during emergency pediatric surgery as compared with elective pediatric surgical procedure (6).

Premedication and use of paralytic medications were associated with improved success rates of intubation during pediatric surgery. Injury to the mouth, pharynx and larynx may occur when direct laryngoscopy was placed with inadequate muscular relaxation and reflex suppression medication. Therefore, to use of premedication, paralytic , and analgesic drugs before trachea intubation may provide to minimizing discomfort and adverse physiologic response in pediatric surgery (7).

Neonatal endotracheal intubation is a challenge for trainees. Intubation success rates progressively improve with experience. Modifiable risk factors associated with TIAEs identified include anesthesia training level. Adverse TIAEs and severe oxygen desaturation events are common in less experienced anesthetist. Furthermore, intubation attempted by inexperienced providers has been related with an increased incidence of trachea intubation related adverse events. Poor tracheal intubation technique may necessitate multiple attempts or prolong procedural duration, which are associated with airway trauma, desaturation, or bradycardia(8).

Number of attempts and adverse effects of intra tracheal intubation were significantly related number of intubation attempted. Meanwhile, trachea intubation related adverse effects were common with increasing number of intubation attempts. Successful airway management is a critical intervention to stabilize children in operation room. Children are known to have a limited physiologic reserve. Intubation attempts are often unsuccessful, and successful attempts frequently require multiple attempted. Greater experienced is associated with greater success rates and less attempting of intubation. Therefore, identifying factors associated TIAEs (Endotracheal intubation associated events) in children who are vulnerable population are essential(9,10).

1.2. Statement of the problem

Pediatric tracheal intubation is hazardous and commonly associated with recognized potential adverse outcomes in high-risk patients. During intubation, several complications can occur ranging from dental trauma to cardiac arrest. Adverse tracheal intubation associated events and severe desaturation events during tracheal intubation were common in pediatric surgery(11).

Due to low first attempt success rates, neonates are often subjected to a second, third, or even fourth intubation attempt before the endotracheal tube is successfully placed. These factors conspire to make intubation one of the most dangerous procedures in neonatal surgery. Despite the risks, little attention has been paid to neonatal intubation safety(12).

Adverse events are common in the neonatal intensive care unit, occurring in 4 of 10 intubations. The odds of an adverse event doubled with increasing number of attempts and quadrupled in the emergency setting. The American Academy of Pediatrics recommends using premedication to improve non-urgent intubating conditions. Awake intubation is associated with apnea, hypoxia, bradycardia, esophageal intubation, main-stem bronchial intubation, and aspiration of gastric content(13, 14).

Difficult trachea intubation was reported in 9 % of all trachea intubations and was associated with increased adverse trachea intubation events. History of difficult airway and sign of upper airway obstruction were associated with difficult trachea intubations. Adverse trachea intubation adverse events may lead to increased morbidity and mortality in children(15, 16).

Patients undergoing pediatric cardiac surgery or oromaxillo facial surgery have the highest incidence of difficult laryngoscopy. The general incidence of difficult intubation in pediatric ENT surgery was higher than in general pediatric surgery to developed trachea intubation related adverse effects(17).

Adverse tracheal intubation associated events (TIAEs) and hypoxemia below 80% of oxygen saturation during tracheal intubation occur in approximately 15% and 13% of trachea intubations, respectively(18).

1.3. Significance of the study

Despite many research in the past, trachea intubation related adverse effects remains a common clinical problem that is associated with morbidity among pediatric at operation room. The prevention and treatment of trachea intubation related adverse effects during pediatric surgery remains a problem(19).

The cost of managing this complication is huge burden on the country's economy. Hence, it is highly recommended to conduct such research in our set up to see the incidence and identifying associated factor for trachea intubation related adverse effects. The incidence of adverse tracheal intubation associated events and associated factors in Pediatric surgery setting are unknown. Protocols that aim to prevent trachea intubation related adverse effects during pediatric surgery may result better outcomes than protocols of treatment after trachea intubation related adverse effects occurred (20).

However , most of the study done in abroad showed that, because of low first attempt success rates, pediatric are often subjected to multiple intubation attempts before the endotracheal tube is successfully placed. These factors conspire to make intubation one of the most dangerous procedures in pediatric surgery(21).

There are different etiologies of trachea intubation related adverse effects during pediatric surgery(22). Identifying the associated factors for trachea related adverse effects is mandatory which will increase the vigilance for anesthetist in those pediatric patients at risk of develops trachea related adverse effects, enabling a guide in clinical decision. Therefore, this study was carried out aiming to evaluate the associate factors and adverse effects of intra-tracheal intubation.

2. LITERATURE REVIEW

2.1. Magnitude of Trachea related adverse events

A prospective observational study in USA at Neonatal intensive care unit (NICU) by Hatch et al. (2013) conducted that during the study period, 304 intubations occurred in 178 infants. Data were available for 273 intubations 90% in 162 patients. Trachea intubation related adverse events occurred in 39% intubations with non-severe and severe events in 35% and 8.8% intubations, respectively(21).

A prospective study done from Turkey by Bahar et al. at 2014 which showed the magnitude of trachea intubation related adverse events (TIRAEs) which was done at ICU was 36%. Similarly, a prospective interventional study done by Nishisaki et al. 2016 in Spain at PICU found the incidence of TIRAEs was about 6%. Another study by observational study from France by Samir Jaber, et al, 2016 in PICU conducted that among 253 trachea intubations of pediatrics, complication occurred 28%(6, 22).

A prospective study from India by Divatia, et al at Pediatric intensive care unit (PICU) in 2017 conducted the incidence of trachea intubation complication among pediatric patients was 26%. They also found that more than one attempt was required in more than 25% patients. Similarly, a prospective cohort study done at ICU from India by Divatia, et al at 2018 determined that, the incidence of trachea intubation related complication was 24%(9, 23).

2.2. Associated factors of Trachea related adverse events

A cohort study from California in 2012 by Susan R Wilcox showed that the use of neuromuscular blocking agents was associated with a lower prevalence of hypoxemia (10.1% vs. 17.4%) and a lower prevalence of procedure-related complications (3.1% vs. 8.3%). To use of neuromuscular blocking agents was associated with significantly improved intubating conditions(24).

A retrospective analysis study done at 2013 in USA by T. Sawyer et al reported that over the four year study period; there were 1,828 oro-tracheal intubations. In cases requiring two attempts, the incidence of one or more adverse event was 47.2% (95% CI = 41.8% to 52.7%); in

cases requiring three attempts, the incidence of one or more adverse events was 63.6% (95% CI 53.7% to 72.6%); and in cases requiring four or more attempts, the incidence of one or more AEs was 70.6% (95% CI = 56.2.3% to 82.5%). Multivariable logistic regression showed that more than one attempt at tracheal intubation was a significant predictor of one or more adverse events (AOR= 7.52, 95% CI = 5.86 to 9.63)(25).

A Prospective Study by Hatch et al in Colorado in 2014 reported that adverse events occurred in 39% intubations with non-severe and severe events in 35% and 8.8% intubations respectively. Increasing number of intubation attempts (COR=2.1, 95% CI=1.6–2.6) and emergency surgery (AOR= 4.7, 95% CI= 1.7– 13) were predictors of adverse events(26).

A retrospective cohort study from USA by CN Le et al conducted that adverse TIAEs occurred in 153 of 22% trachea intubation encounters. Factors that were independently associated with lower incidence of TIAEs in logistic regression included use of paralytic medication (AOR 0.45, 95% CI 0.25, 0.81). Another study done at 2015 in USA showed that the median success rate was double with premedication 43% versus 22%. Similarly, A prospective observational cohort study from USA by Jeanne Krick et al (2015) showed that premedication with a paralytic was associated with fewer TIAEs ($p < 0.001$) and less bradycardia compared to the other two regimens compared to premedication without a paralytic(27, 28).

A retrospective study from German by S. Heinrich et al (2016) suggested that the overall incidence of difficult intubation was 1.35%. The occurrence of TIAE or desaturation was significantly associated with difficult intubation. In patients younger than one year, the incidence of trachea intubation was significantly higher than in the older patients(29).

A Cross-Sectional study at Iran in 2017 by Iraj Golikhatir suggested that attempts for intra-tracheal intubation were successful in all cases and 81 patients were intubated on first attempt, 15 on second attempt and 4 on third attempt. Number of attempts and adverse effects of intra-tracheal intubation were significantly related in this study as 88% cases of the observed adverse effects were seen in those who were intubated on the first attempt. Meanwhile, adverse effects were seen in only 7% cases that were intubated on the second or third attempt(30, 31).

1.1. Conceptual Framework

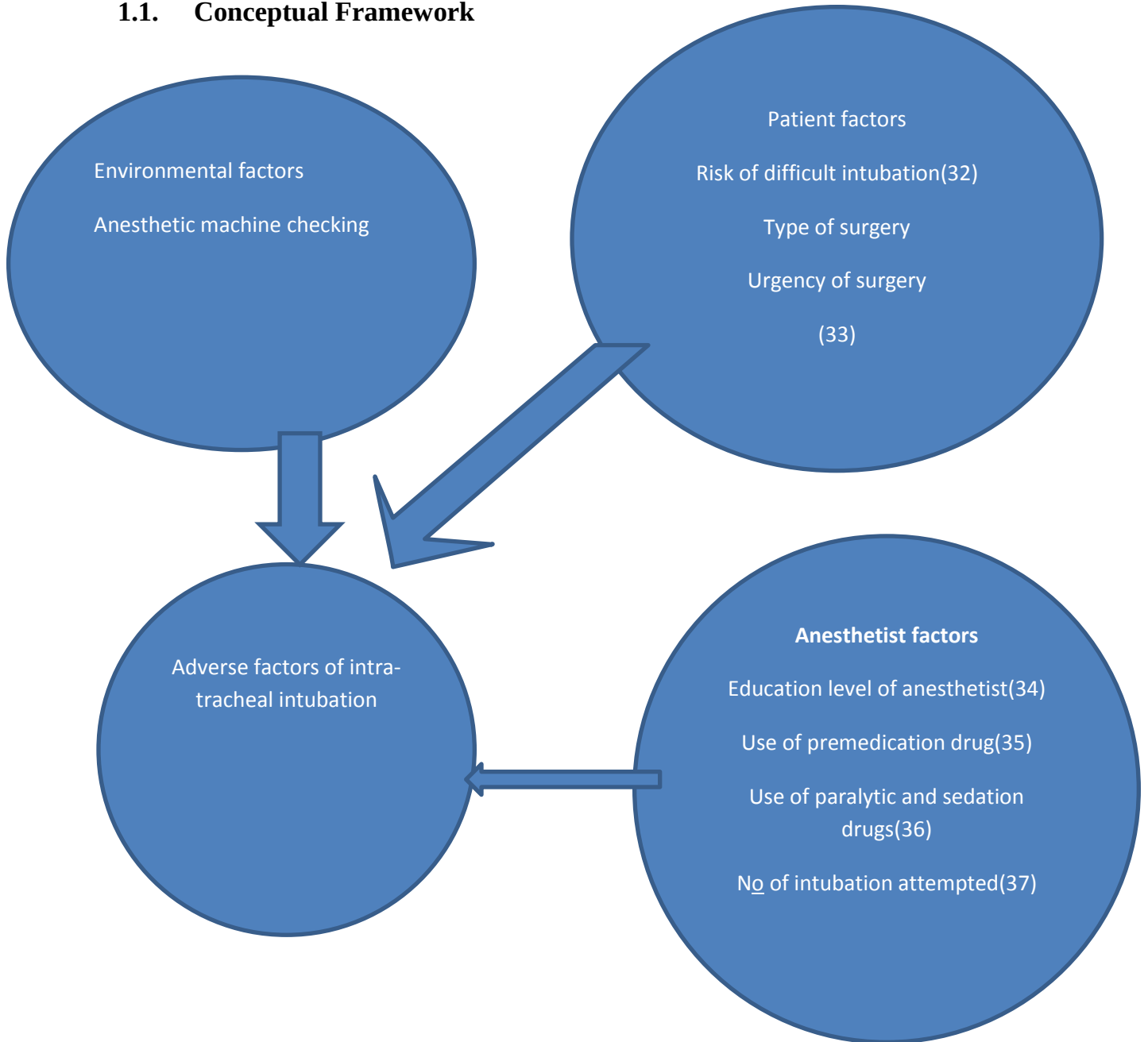


Figure 1: Conceptual framework showing factors related with intubation related adverse effects among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C

3. OBJECTIVE

3.1. General objective

- To determine magnitude and associated factors of tracheal intubation related adverse effects in Pediatric patients who undergo surgery at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia from December 30, 2019 to February 30, 2020 G.C.

3.2. Specific objectives

- To determine the magnitude of the tracheal intubation related adverse events in Pediatric patients who undergo surgery 0
- To identify type of tracheal intubation related adverse events in Pediatric patients who undergo surgery February 30 2020 G.C.
- To identify the associated factors of tracheal intubation related adverse events in Pediatric patients who undergo surgery

4. METHODOLOGY

4.1. Study Area:

The study was conducted in operating theatre of Tikur Anbessa specialize hospital (TASH). The hospital is found in the capital city of the country, Addis Ababa. It was established in 1972 and has 13 operation room with different surgical specialty room like Open Urology, Gynecologic, Gastro-intestinal, Pediatric, Cardiac, Neuro surgery, and ENT surgery. TASH is the largest referral hospital in the country, with 700 beds. It was transferred to the school of medicine by Federal Ministry of Health. The Tikur Anbessa Specialized Hospital is now the main teaching hospital for both clinical and pre-clinical training of most disciplines.

4.2. Study design and period:

A cross-sectional study was conducted from December 30, 2019 to February 30, 2020 G.C at TASH

4.3. Population

4.3.1. Source population:

All pediatric patients who were undergoing schedule surgery under tracheal intubation at TASH

4.3.1. Study population:

Pediatric patients scheduled and underwent surgery under tracheal intubation at TASH during study period who fulfilled the inclusion criteria

4.4. Inclusion and exclusive criteria:

4.4.1. Inclusion criteria:

- All pediatric patients scheduled for surgery
- Patient age between 0-14 years old

4.4.2. Exclusive criteria:

- Pediatric patients who were undergoing surgery with face mask or sedation at operation room

- Pediatric patients who were undergo surgery with LMA.
- Pediatric patients with reactive airway
- Pediatric patients who had recent URTI
- Pediatric patients who intubated with nasal intubation

4.5. Study variables

4.5.1. Dependent variables:

- Trachea intubation related adverse events —Yes/No

4.5.2. Independent variables:

- | | |
|--|--------------------------------|
| ➤ Socio demographic characteristics:
age, weight, sex | ➤ Use of sedation medications |
| ➤ Anesthetic machine checking | ➤ Qualification of anesthetist |
| ➤ Vital sign of patients (Bp, HR, PSo2) | ➤ Difficult intubation |
| ➤ Use of paralytic medications | ➤ Type of surgery |
| ➤ Use of premedication drugs | ➤ Urgency of surgery |

4.6. Operational definition

Trachea intubation: it is the placement of a flexible plastic tube into the trachea to maintain an open airway(21).

Children: age less than 14 years

An attempt: a single advanced airway maneuver (laryngoscopy, ETT), beginning with the insertion of a device (e.g. ETT, Laryngoscopy) into a patient's mouth and ending when either the device is removed or the advanced airway is placed(22).

OP: Operating Room: it is a room in a hospital in which surgical operations are performed

Hypertension: 20% increase of blood pressure from base line

Hypotension: 20% decrease of blood pressure from base line

Bradycardia: 20% decrease of heart rate from base line

Difficult intubation: Is when proper insertion of the trachea tube with a conventional laryngoscopy requires more than three attempts or more than ten minutes(15)

Trachea intubation related adverse events(36, 37).

Adverse events	Definition
✚ Aspiration of gastric contents	• Presence of vomit at the glottic inlet visualized during intubation in a previously clear airway
✚ Cardiac arrest	• Pulseless dysrhythmia occurring during intubation
✚ Dental injury	• Fracture or avulsion of tooth during intubation
✚ Esophageal intubation with delay detection	• Inadvertent placement of the ETT in the esophagus, requiring removal
✚ Dysrhythmia	• Bradycardia or any ventricular dysrhythmia during intubation
✚ Hypotension	• Decrease in systolic blood pressure by 20% of base line
✚ Laryngospasm	• Adduction of vocal cords, preventing passage of the ETT through the glottic inlet
✚ Mainstem bronchial intubation	• Identification of the tip of the ETT in a mainstem bronchus
✚ Hypoxemia	• A decrease in oxygen saturation greater than or equal to 10%

4.7. Sample size and sampling technique

4.7.1. Sample size

The sample size was computed by using Epi-info version 7.0 by considering the following assumptions; confidence level 95%, and 5% margin of error by considering different factors that had linked with tracheal complications from previous studies.

Previous study in India on 2018 showed that the incidence of complication during tracheal intubations in the ICU was 26% (38). 5% non-response rate was included in the sample.

$$SS = \frac{(Z\alpha)^2 p(1-p)}{d^2} \text{ when, } Z\alpha \text{ is } p=0.26, 1-p = q=0.74, d =0.05$$
$$\text{Then, } \frac{(1.96)^2 (0.26) (0.74)}{(0.05)^2}$$
$$\Rightarrow 295 + 15 = \underline{310}$$

4.7.2. Sampling Technique

Systematic random sampling technique was used to select study participants on daily operation schedule list. Depending on pediatric patients scheduled for pediatric surgical procedure, 6200 patients were done for three months previously, which was taken from logbook. The sampling interval K was determined using the formula: $K=N/n$; where, n = total sample size, N = population per 3 months. Three hundred twenty five participants were recruited with the probability of about 20%. Therefore, the sampling interval was 2 and the first study participant (random start) was selected using lottery method after which data collector recruit 1 patient for every 2 consecutive patients undergoes pediatric surgery.

4.8. Data collection technique

Data collection was initiated for each trachea intubation that occurred in the operation room. Data were collected by using questionnaire which was included; socio-demographic, vital sign, type of surgery, and trachea intubation related adverse events starting from preoperatively before induction of anesthesia and after patient entered operation room to time of the patient was intubated with endotracheal tube successfully. Data collectors were anesthetist and anesthesia students.

4.9. Data quality control

The quality of data was ensured before, during and after data collection. To assure the reliability and validity of the data, questionnaire was pretested on 5% of the sample size from TASH before actual data collection. The pretest was done to ensure clarity, wordings, logical sequence and skip patterns of the questionnaire. The whole process of data collection was provided for data collectors. Informed consent was obtained from each patient's family or related family. During data collection, regular supervision and follow up was undertaken. Supervisor was checked each questionnaire daily with further cross check by principal investigator for completeness and consistency of data. Incomplete data was not entered on data base prepared on Epi-info. Data clean up and crosschecking of missing data was done by multiple imputation method before analysis on SPSS version 22.

4.10. Data analysis and interpretation

Data was checked manually for completeness and then coded and entered in to EPI info version 7 then transferred to SPSS version 22 computer program for analysis. Descriptive statistics was used to summarize data, tables and figures to display the result. Continuous variables were expressed as mean $\pm$ SD for normally distribute data and median $\pm$ IQR for skewed data. Frequency and cross tabulation was conducted to describe relevant variables in relation to the outcome variables. Analysis was done by binary logistic regression model. Variable with p value less than 0.25 in binary logistic regression analysis were candidate for multivariable logistic regression. Variable of p value <0.05 at multivariable logistic regression were considered as statistically significant.

4.11. Ethical consideration

Ethical clearance was obtained from the department ethical clearance committee. The purposes and the importance of the study was explained and oral informed consent was obtained from each patient's family or related family. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. The participant's involvement in the study was on a voluntary basis, participants who were not willing to participate in the study and

those who wish to quit their participation at any stage was informed they are allowed to do so without any restrictions.

4.12. Dissemination of findings

After the finalization of the study the finding will be communicated and the study results will be submitted to anesthesia department and post graduate office. Efforts will be made to publish the findings of the study through different journals and scientific publications.

5. RESULTS

5.1. Socio demographic and Environmental Related Factors of the study participants

A total of 310 pediatric surgical patients included in a study with 100% response rate. Out of 310 majority were male 184(59.4%), neonate 184(59.4%), weighted between 5-10kg, and 306(98.7%) anesthetic machine was checked. (Table 1)

Table 1: Socio Demographic and Environmental Related Factors among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C. (n=310)

Variables	Category	Frequency
Sex of patient	Female	126 (40.6)
	Male	184(59.4)
Age of patient	Neonate(<1month)	46(14.8)
	Infant (1-12month)	61(19.7)
	Toddlers(1-3 years)	83(26.8)
	Children (3-14 years)	120(38.7)
Weight of patient	< 5	34(11)
	5-10	87(28.1)
	10-15	76(24.0)
	15-20	44(14.2)
	20-25	28(9)
	25-30	24(7.7)
	>30	17(5.5)
Anesthetic machine check	Yes	306(98.7)
	No	4(1.3)

(AMC= Anesthetic machine checking before intubation, kg= kilogram)

5.2. Patient related Factors

The majority of the patients' vital signs were in normal range. Majority of patients' OPV score were classified under inaccessible (46.1%). Whereas, 66(21.3%) of the patient had difficult of

intubation during endotracheal intubation and 244(78.7%) had no difficult intubation. The most common indication for surgery during study period was Gastro-intestinal surgery 137 (44.2 %), followed by urologic surgery 69 (22.3%). (Table 2)

Table 2: Patient related Factors among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C. (n=310)

Variables	Category	Frequency
SPO2 (%)	Desaturation (<90%)	3(1)
	Saturation (>90%)	307(99)
SBP (mmHg)	Hypertension	7(2.7)
	Normal	303(97.7)
HR (bpm)	Tachycardia	57(17.1)
	Normal	253(82.0)
OPV	I	119(38.4)
	II	45(14.5)
	III	3(1)
	Inaccessible	143(46.1)
Difficult intubation	Yes	66(21.3)
	No	244(78.7)
Type of Surgery	Neurosurgery	27(8.7)
	ENT	30(9.7)
	GIT	137(44.2)
	Urology	69(22.3)
	Orthopedics	35(11.3)
	Cardiology	12(3.9)

SPO2=Oxygen saturation, SBP =Systolic blood pressure, HR=heart rate, OPV=Oropharynx view

During the study period 310 out of patients, the majority of the cases were elective Pediatric surgery 271(87.4%) at operation room. (Fig. 3)

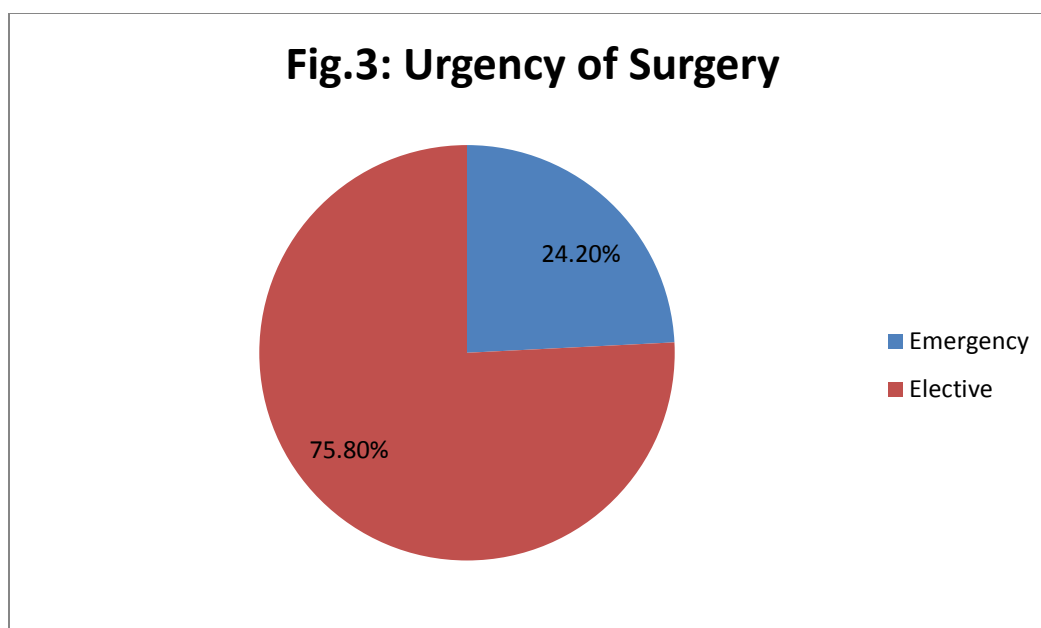


Figure 2: Urgency of surgery performed among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C (n= 310)

5.3. Anesthetist related Factors

Our study revealed that most of the patients were received premedication 174 (56.1%), were received analgesic 241(77.7%), received muscle relaxants 272(87.7%), and intubated by MSc anesthesia students (32.6%). (Table 3)

Table 3: Anesthesia related factors among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C. (n=310)

Variables	Category	Frequency
Use of premedication drugs	Yes	174(56.1)
	No	136(43.9)
Use of analgesic drugs	Yes	241(77.7)
	No	69(22.3)
Use of muscle relaxant	Yes	272(87.7)
	No	38(12.3)
Education level of anesthetist	Undergraduate student	97(31.29)
	MSc student	101(32.58)
	Anesthesiology resident	72(23.23)
	Senior anesthetist	40(32.58)

During the study period 310 of pediatric patients were intubated by anesthetist for pediatric surgery at operation room. One hundred eighty eight (60.6%) of pediatric patients were intubated

with first attempted intubation by anesthetist that takes the most group of tracheal intubation attempted. However, twenty one (6.8%) of pediatric patients was intubated after more than three times attempted. (Fig. 4)

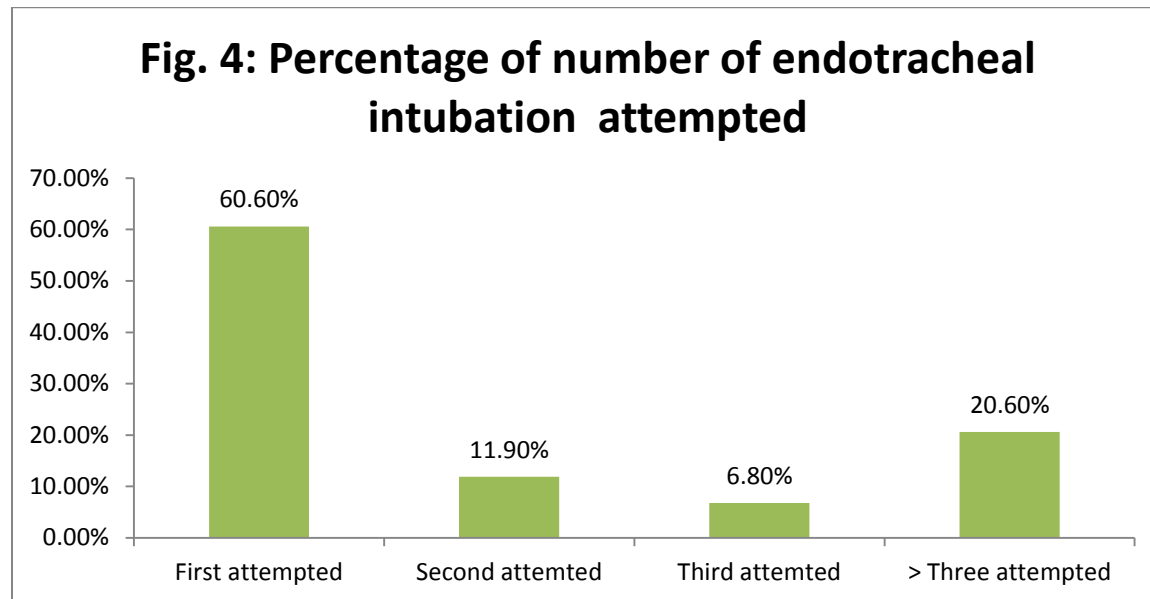


Figure 3: Number of tracheal intubation attempted among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C (n= 310)

5.4. Magnitude of intra-trachea intubation related adverse effects

In this study, the overall incidence of trachea intubation related adverse events was found to be 36.5 % at pediatric surgery of Tikur Anbessa Specailized Hospital. (Figure 5)

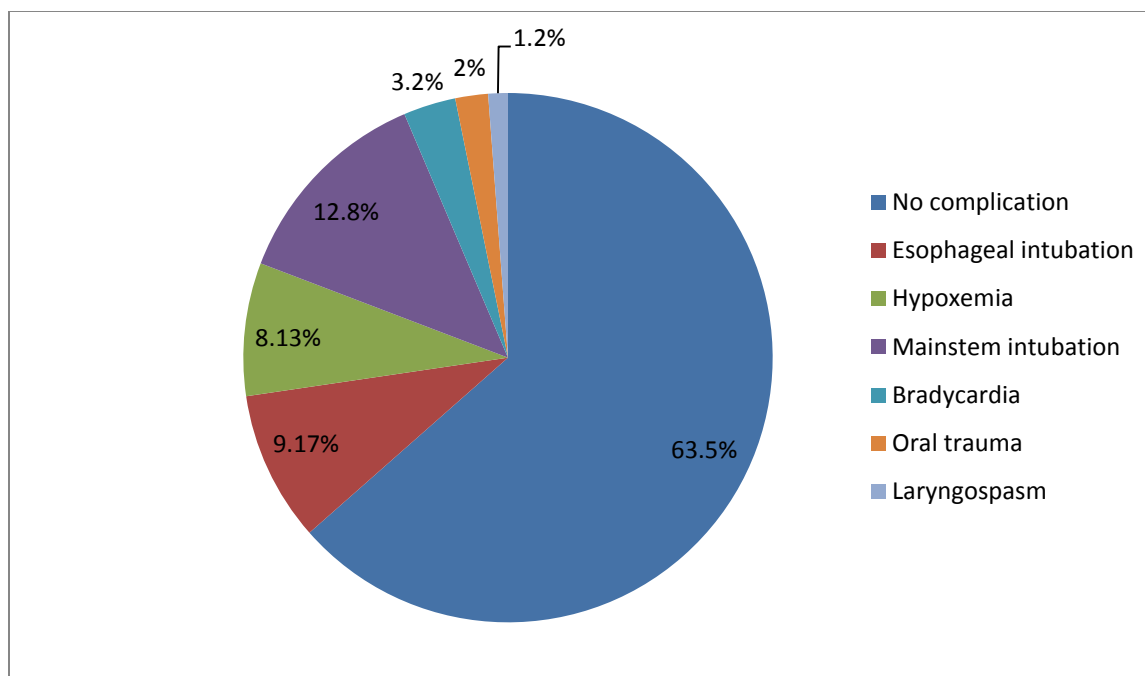


Figure 4: Magnitude of TIRAE among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C (n= 310)

5.5. Result of bivariate analysis

Binary logistic regression analysis was conducted to see the association between independent variables and dependent variable which is trachea intubation related adverse effects during pediatric surgery.

During bivariate analysis, being neonate had four times (COR= 4, CI=1.375-6.340) higher odds of developing TIRAEs compared to children. Weight groups of <5 kg had 2 times (COR=2.401, CI=1.239-12.019) higher odds of developing TIRAEs compared to weight greater than 30kg. Pediatric with difficult intubation had three times (COR=3.083, CI=2.017-7.501) higher odds of developing TIRAEs compared to no difficult intubation. Pediatric patient during neuro-surgery had two times (COR=2, CI=2.692-13.380) higher odds of developing TIRAEs compared to cardiothoracic surgery. Emergency surgery had three times (COR=3.123, CI=1.234-4.501) higher odds of developing TIRAEs compared to elective surgery. (Table 4)

Table 4: Patient factors associated with Trachea intubation related adverse events among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C. (n=310)

Variables	Category	Complication		COR(95%CI)	P Value
		Yes N (%)	No N (%)		
Age	Neonate	44 (38.9)	2 (1)	4(1.375-6.34)	<.001*
	Infant	28 (24.8)	33 (16.8)	.971(2.484-896)	.031
	Toddlers	15 (17)	66 (33.5)	.925(1.150-15.78)	.933
	Children	24 (21.2)	96 (48.7)	1	
Weight	<5kg	33 (29.2)	1 (.5)	2.401(1.29-12.019)	.021*
	5-10kg	32 (28.3)	57 (27.9)	.716(1.231-12.21)	.563
	10-15kg	21 (18.6)	55 (17.7)	1.091(1.343-13.47)	.882
	15-20kg	7 (6.2)	55 (27.9)	2.202(2.589-15.24)	.241
	20-25kg	4 (3.5)	24 (12.3)	1.500(1.66-11.051)	.227
	25-30kg	11 (9.7)	13(6.6)	.492(1.32-9.837)	.292
	>30kg	5 (4.4)	12(6.1)	1	
DI	Yes	65 (57.5)	1 (.5)	3.083(2.017-7.501)	<.001*
	No	48 (42.5)	196(99.5)	1	
IOS	Neurosurgery	5 (4.4)	22 (11.2)	2(2.629-13.380)	.012*
	ENT	10 (8.8)	20 (10.2)	1(1.832-14.596)	.028
	GIT	57 (50.4)	80 (40.6)	1.018(1.4811-3.38)	.142
	Urology	23 (20.4)	46 (23.4)	1(1.022-54.59)	.653
	Orthopedics	8 (7.1)	27 (13.7)	1.875(1.049-13.38)	.071
	Cardiothoracic	10 (8.8)	2 (1)	1	
UOS	Emergency	56 (49.6)	19 (9.6)	3.123(1.234-4.501)	<.001*
	Elective	57 (50.4)	178(90.8)	1	

TIRAE-trachea intubation related adverse events, COR-Crude odd ratio, significantly associated variables that are candidate multivariate analysis at P value less than 0.25

During bivariate analysis, Pediatric who not received premedication had two times (COR=2.05, CI=1.016-11.320) higher odds of developing TIRAEs compared to who received premedication drugs. Pediatric patients who not received analgesic drugs had two times (COR=2.225, CI=1.660-12.25) higher odds of developing TIRAEs compared to who received analgesic drugs. Pediatric patients who not received paralytic drugs had three times (COR=3.048, CI=1.017-10.402) higher odds of developing TIRAEs compared to who received paralytic drugs. Pediatric who attempted intubation greater than three had four times (COR=4.114, CI=2.049-15.263) higher odds of developing TIRAEs compared to first attempted intubation. (Table 5)

Table 5: Anesthesia factors associated with Trachea intubation related adverse events among pediatric surgery at TASH, from December 30, 2019 to February 30, 2020 G.C. (n=310)

Variables	Category	Complication		COR(95% CI)	P value
		Yes N (%)	No N (%)		
Use of premedication	Yes *	11 (9.7)	163 (82.7)	1	
	No	102 (90.3)	34 (17.3)	2.05(1.016-11.320)	<.033*
Use of analgesic drugs	Yes	62(54.9)	179 (90.9)	1	
	No	51 (45.1)	18 (9.1)	2.225(1.660-12.25)	<.001*
Use of muscle relaxants	Yes	79 (69.9)	193(98.0)	1	
	No	34 (30.1)	4 (2)	3.048(1.017-10.402)	<.001*
Number of trachea attempted	First	15(13.5)	173(87.9)	1	
	Second	16(14.2)	21(10.7)	.391(1.002-4.033)	.022
	Third	19(16.8)	2(1)	.761(1.21-8.011)	.014
	> Three	63(20.3)	1(.3)	4.114(2.049-15.263)	<.001*

TIRAE-trachea intubation related adverse events, COR-Crude odd ratio, significantly associated variables that are candidate multivariate analysis at P value less than 0.25

5.6. Multivariable logistic regression analysis

According to results of bivariable binary logistic regression analysis, weight of the patients, being neonate, emergency surgery, difficult intubation, intubating without using premedication

and paralytic, multiple attempted intubation, use of analgesic drugs, and type of surgery were associated with trachea intubation related adverse events.

In the final model (multivariable binary logistic regression analysis), after excluding variables which doesn't fit for the model using P-value >0.25 in Likelihood ratio test, multivariate analysis was performed for those variables; being neonate, emergency surgery, difficult intubation, intubating without using premedication and paralytic, multiple attempted intubation were associated with trachea intubation related adverse events.

Being neonate were four times (AOR= 4.134, CI=1.266-13.498) more likely to develop TIRAEs in comparison with children. Pediatric patients during emergency surgery had three times (AOR=3.392, CI=1.415-8.132) higher odds of developing TIRAEs compared to during elective surgery. Pediatric patients who had difficult intubation had four times (AOR=4.083, CI=1.017-7.501) higher odds of developing TIRAEs compared to with who had no difficult intubation. Pediatric who not received premedication had two times (AOR= 1.759, CI=1.452-10.83) higher odds of developing TIRAEs compared to who received premedication drugs. Pediatric patients who not received paralytic drugs had three times (AOR=3.921, CI=2.164-7.396) higher odds of developing TIRAEs compared to who received paralytic drugs. Pediatric who attempted intubation greater than three had four times (AOR=3.921, CI=2.164-7.396) higher odds of developing TIRAEs compared to first attempted intubation. (Table 6)

Table 6: Factors associated with TIRAEs among pediatric surgery patients at TASH, from December 30, 2019 to February 30, 2020 G.C. (n=310)

Covariate	Category	Complication		COR(95%CI)	AOR(95% CI)	P Value
		Yes (%)	No (%)			
Age	Neonate	44 (38.9)	2 (1)	4(1.375-6.34)	4.134(1.266-13.498)	.040*
	Infant	28 (24.8)	33 (16.8)	.971(2.484-896)	1.234(1.002-3.184)	.086
	Toddlers	15 (17)	66 (33.5)	.925(1.150-15.78)	1.045(.906-4.132)	.321
	Children	24 (21.2)	96 (48.7)	1	1	
Difficult Intubation	Yes	65 (57.5)	1 (.5)	3.083(2.0176-7.501)	4.083(1.0176-7.501)	.019*
	No	48 (42.5)	196(99.5)	1	1	
Urgency of surgery	Emergency	56 (49.6)	19 (9.6)	3.123(1.234-4.501)	3.392(1.415-8.132)	.035*
	Elective	57 (50.4)	178(90.8)	1	1	
Use of premedication	Yes	11 (9.7)	163 (82.7)	1	1	
	No	102 (90.3)		2.05(1.016-11.320)	1.759(1.452-10.83)	<.001*
Use of muscle relaxant drugs	Yes	79 (69.9)	193(98.0)	1	1	
	No	34 (30.1)	4 (2)	3.048(1.017-10.402)	3.921(2.164-7.396)	.019*
Number of trachea attempted	First	15(13.5)	173(87.9)	1	1	
	Second	16(14.2)	21(10.7)	.391(1.002-4.033)	.514(.205-8.290)	0.401
	Third	19(16.8)	2(1)	.761(1.21-8.011)	.859(1.35-11.5)	.025
	>Three	63(20.3)	1(.3)	4.114(2.049-15.263)	3.921(2.164-7.396)	.012*

(TIRAEs – Trachea intubation related adverse events, COR- Crude odd ratio AOR – Adjusted Odds Ratio, CI-Confidence Interval, * - independent predictors of TIRAEs at P value less than 0.05)

6. DISCUSSION

In our study the overall magnitude of trachea intubation related adverse events among pediatrics patients who underwent surgery was 36.5 %. These findings are in line with a prospective study done by Bahar et al. 2014 in Turkey which showed the incidence of TIRAE which was done at ICU was 36%.

Our finding was high when compared with a prospective interventional study done by Nishisaki et al. 2010 in Spain at PICU found the incidence of TIRAEs was about 6% and other study done observational study by Samir Jaber, et al. in 2006 in France found that the incidence of TIRAEs was 28%(6).

Our finding was also low when compared with a prospective observational study done in India by Divatia, et al. in 2011 in intensive care unit which was found to be 26% and other study in Japan in 2016 done showed that children aged less than 18 years who underwent emergency department intubation reported that age greater than 10 years was significantly associated with a lower incidence of TIRAEs(23). This might be due to techniques used in their studies to measure TIRAEs, clinical setup and method of data collection.

In our study, the incidence of TIRAE over the entire period studied were higher in the neonate patients. Similarly, a prospective observational study by Lee et al. in USA at 2016 suggested that higher TIRAEs were associated with young age(9, 24).

Our finding showed that repeatedly attempted of trachea intubation was also strongly associated with TIRAEs. This finding is similar to a prospective observational study by Lee et al. in USA at 2016 suggested that TIRAEs rates increased from with increasing number of trachea intubation attempted(20). Similarly, a prospective observational study done by Sakles et al. (2013) in a Spain showed that the risk of adverse trachea intubation events increases with increasing number of attempts, increasing when a second attempted(21). Similarly, a prospective observational study done by Simpson et al. 2018 in a Spain, observed that the frequency of severe TIRAEs increased 14 fold in patients who required more than two attempts at tracheal intubation(25).

In our study we found that presence of difficult intubation during intubation was significantly associated with TIRAEs as compared to those patients have no difficult intubation. Our study is in line with a prospective observational study by Thomas C. Mort in USA (2016) which

demonstrated that there was a significant increase in the rate of airway related complications in patients with difficult intubation compared to patient without difficult intubation(1, 26).

Our study revealed that intubation without using premedication was significantly associated with TIRAEs as compared to using premedication for intubation. Our study was in line with study by Jeanne Krick et al. in USA (2017) demonstrated that intubation without premedication was associated with fewer intubation attempts, fewer TIAEs, and less bradycardia(3) and a retrospective cohort study by CN Le et al showed that there were increasing rate of intubation if premedication used before trachea intubation(11).

In our study we found that intubation without using muscle relaxant was significantly associated with TIRAEs as compared to using muscle relaxant for intubation. Our study was similar with study done by LiJ, Murphy C, et al in USA(5)which demonstrated that complications were greater in number and severity in the non-paralyzed group and prospective observational cohort study done by Foglia et al. in USA (2015)) which found adverse TIAEs occurred high in non-paralyzed patients(12).

We observed that pediatric patients intubated for emergency surgery procedure in the operation room were associated with worsened intubation conditions and an increase of complications compared with elective surgery procedures. Similarly a prospective observational study done by Martin et al, 2012 in USA reported emergency surgeries at operation room complications is high(7, 21).

6.2. Limitations of the Study

Lack of similar published topic literature in Ethiopia and Africa. We did not attempt to collect data on any long-term complications that may have manifested themselves after the patient left the OR. These data were obtained from a single institution. The study design followed was cross-sectional study design which is used to investigate on a single point in time. Due to this it is impossible to determine the cause and effect of the topic understudy.

6.3. Strength of the study

The strength of this study will be helpful as baseline information for other researchers.

Most units of pediatric surgeries were included: General surgery, orthopedic, urologic, Cardio-thoracic and ENT surgery.

7. CONCLUSION AND RECOMMENDATION

7.1. Conclusion

In our study the incidence of trachea intubation related adverse effect in the pediatric surgical patients is high. We found different associated factors for incidence of trachea intubation related adverse effects those are being neonate, presence of difficult intubation, intubating the patient without using premedication and muscle relaxant, emergency surgery, and multiple attempts of trachea intubation. Having this knowledge of the associated factors for TIRAEs might help in the day to day routine to increase the anesthetist's vigilance.

7.2. Recommendation

Based on the findings of the present study, the following recommendations are forwarded

For anesthetist

- To use premedication and paralytic drugs before intubating the patient to improve the patient safety
- To be vigilant, have pre-planned strategy, and optimize vital sign of patient is required before trachea intubation
- To identification of patients at risk and their standard management

For Tikur Anbessa Hospital

- The institutions have a written protocol on premedication
- To develop difficult intubation management protocols and guidelines
- Emphasize on providing material used for difficult intubation management

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ANNEX I: QUESTIONAREE

**ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES SCHOOL
OF MEDICINE AND DEPARTMENT OF ANESTHESIA**

Oral Consent Form

Greeting:

Hello, my name is Bayisa Garbessa. I am Msc Anesthesia student. I am going to do a research on ‘Magnitude and associated factors of Tracheal Intubation related adverse events in the Pediatric Surgery at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia’ I want to ask your permission to observe and record your vital sign while your anesthetist intubate you with a flexible tube via your trachea. I did’t intervene the way your anesthetist intubate you rather than observing while anesthetist perform the intubation.

Your name will not be written in this form and will never be used in connection with any information you tell us. Your responses will be kept confidentially. Your participation will be based on your interest and you are not obligated to answer any question if you do not wish to answer. If you feel discomfort with the participation, it is your right to leave it.

Are you willing to participate in this study?

- a) Yes
- b) No

Thank you in advance for your cooperation

Instruction: For each of the questions, please circle the number of alternative(s) that fit the response or fill the blank space provided.

1. Questions on socio-demographic characteristics of the patients

Code	Socio-demographic characteristics of the patient	
001	Sex	a. Male b. Female
002	Age in years	
003	Weight in kg	

2. Questions on environmental associated factors

Code	Environmental associated factors	
004	Is there enough space in the operation room?	a. Yes b. No
005	Is anesthetic machine checked before intubation?	a. Yes b. No

3. Questions on patient associated factors

Code	Questions on patient associated factors	
005	What are the Vital signs of patient before trachea intubation?	BP_____mmHg HR_____bpm RR_____bpm PSO2_____%
006	What are Vital signs of patient after tube placement?	BP_____mmHg HR_____bpm RR_____bpm PSO2_____%
007	What is the patient Mallampati classification?	I II III IV

008	Does difficult of intubation there during intubation?	a) Yes b) No
009	What is the indication of surgery?	a) GIT b) ENT c) Othopedics d) Urology e) Cardiothoracic f) Emergency

4. Questions on Anesthetist's associated factors

Code	Anesthetist's associated factors	
010	Does premedication drugs used?	a. No Yes
011	Does induction agents used?	a. No Yes
012	Is analgesic drugs administered?	a. No Yes
013	Does paralytic agent used for intubation?	No Yes
014	What is anesthetist education level?	a. Undergraduate student b. MSc student c. Anesthesiology resident d. Senior anesthetist
015	How many attempts were done for intubation?	a. First attempts b. Second attempts c. Third attempts d. >Three attempts

5. Questions on trachea intubation related adverse events

Code	Trachea intubation related adverse events
016	No
017	If the answer is yes: a. Esophageal intubation with delay detection

	b. Hypoxemia (oxygen saturation less than 80%) c. Aspiration of gastric contents d. Emesis without aspiration e. Arrhythmia f. Dental injury g. Cardiac arrest h. Mainstem bronchial intubation with early detection i. Esophageal intubation with early detection j. Laryngospasm/bronchospasm k. Gum, lip trauma or oral trauma l. Medication error m. Emesis without aspiration n. Hypertension o. Epistaxis p. Hypotention needs intervention
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