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The thesis here, entitled "Magnitude of Adverse Events and Outcome of Foreign Body Aspiration Removal among Pediatric Patients at Tikur Anbessa Specialized Hospital from July 1 to November 30, 2020" is accepted in its present form by the board of examiners as partial fulfillment off the requirement for specialty certificate in Anesthesiology Critical Care and Pain Medicine.

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Magnitude of Adverse Events and Outcome of Foreign Body Aspiration Removal among Pediatric Patients at Tikur Anbessa Specialized Hospital from July 1 to November 30, 2020

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A Research Thesis to be Submitted to Addis Ababa University School Of Medicine in Partial Fulfillment of the Requirement for Specialty Certificate in Anesthesiology, Critical Care and Pain Medicine.

December, 2020

Addis Ababa, Ethiopia

Acknowledgment

I would like to thank the department of Anesthesiology, critical care and pain medicine for giving me this opportunity to do this thesis which is very important for my clinical experience and career development. I also want to forward my gratitude to my advisors Dr. Tsegnesh Berhanu and Dr. Ananiya Abate from the department of Anesthesiology, critical care and pain medicine for their valuable comments, advises and encouragement starting from the topic selection through analysis and result writing . I also would like to acknowledge all members of the department especially the research committee for their help and encouragement in the preparation of this thesis. Last but not the least my thankful heart geos to my family.

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ABSTRACT

Background: *Foreign body Aspiration is a life threatening emergency situation among pediatric age group worldwide. Early intervention is crucial to save lives.*

Objective*: The aim of this study is to determine magnitude of adverse events and outcome of foreign body aspirations removal among pediatric patients at TASH.*

Materials and Methods*: Institution based Prospective; observational study was conducted among 60 foreign body aspiration cases with census sampling technique. Standard structured observational tool was used. Data cleaned and entered to Epi data version 3.1 and exported to SPSS version 26. Descriptive and Chi square and Fisher Exact test were done.*

Result- *A total of 60 FBA cases were studied in 56 patients. Four of the cases were repeat procedure. The commonest adverse event encountered was desaturation 51(85%) followed by one lung ventilation 45 (75%), persistent hypoxia 34(56.7%), air way mucosal bleeding 34(56.7%), laryngospasm 14 (23.3%), air way or laryngeal edema 13(21.7%), bradycardia 9(15%), esophageal intubation 5(8.3%) and inadequate depth of anesthesia 2(3.3%). There were 2 cases of tracheobronchial fistula with tension pneumothorax. Among the study participants 7 patients needed PICU admission. There was no death. Mode of ventilation, duration of surgery, surgeon experience, and occurrence of adverse events such as Laryngeal edema, persistent hypoxia and bradycardia had statistically significant association with PICU admission.*

Conclusion- *The incidence of adverse events, DOS and DOA were higher in comparison to any other researches. The incidence of serious complication is also higher than other researches and surgeon experience also had significant risk factors for patient disposition of PICU transfer.*

Key words*: Foreign body Aspiration, FBA Removal, Bronchoscopy, hypoxia, adverse event*

Acronyms

ACCPM – Anesthesiology, Critical Care and Pain Medicine

AE – Adverse events

ASA - American society of Anesthesiologists

DOS- Duration of surgery

DOA -Duration of anesthesia

ETB - Ethiopian Birr

FBA - Foreign Body Aspirations

FBAR – Foreign Body Aspiration Removal

TB FBA – Trachea-bronchial Foreign Body Aspiration

GC - Gregorian calendar

PACU - Post Anesthetic Care Unit

PICU - Pediatric Intensive Care Unit

EOR - Emergency Operating Room

SPSS - Statistical Package for the Social Sciences

TASH- Tikur Anbesa Specialized Hospital

1. INTRODUCTION

1.1. Background:

Foreign body aspiration is inhaling or breathing of foreign body or any object into the trachea-bronchial tree which can be in the course of mouth or nose.([1]) Roughly around 80% of TB-FBA cases are seen in children aged 0-3 years.([2,1])It is one of the most common causes of accidental or sudden pediatric emergencies in all parts of world.([3])Young children are vulnerable and complications such as asphyxia can lead to death so that rapid intervention should be done.([2,4,5,6,7])

Tracheobronchial foreign body aspiration removal is generally life-saving procedure but complications can happen with either the foreign body or the process of bronchoscopy.([8]) Damage to the tracheobronchial tree is unusual but it may include pneumothorax, pneumo-mediastinum surgical emphysema and minor Hemorrhage.([8]) Common adverse events that are associated with rigid bronchoscopy are desaturation (hypoxia), hypercarbia, hypotension, coughing and bucking, laryngospasm, bronchospasm, laryngeal edema, cardiac arrhythmia like bradycardia and ventricular tachycardia, the need for postoperative oxygen supplementation**,** cardiac arrest, aspirations, convulsions and death.([9,10,11,12,13,6])

Desaturation is the oxygen saturation level of 94% or lower which defines the patient is hypoxic. ([14])In addition a saturation of less than 90% is a clinical emergency.([14])Hypoxia is one of the most common complications that occur during tracheobronchial foreign body removal. Without proper treatment, desaturation could lead to a life-threatening outcome. ([10,15])

There are different reasons for complications like hypoxia to occur such as inadequate depth of anesthesia, and inadequate ventilation.([15])The occurrence of intra-operative hypoxia may also depend on a variety of factors including age, the property of the FB, the surgeon's experience, anesthetic method, and patient's condition.([15])on the other hand, the placement of the scope in one of the bronchus's may lead to hypoxia.([16])The diagnostic delay of FBA for more than 24 h and concomitant infections are also important risks for intra- operative complications.([16,17])Other

risk factors for complications are urgent and emergent procedures, ASA score > 3, repeated therapeutic bronchoscopy, and use of moderate Sedation for anesthesia.([18,19])

The habits of decreasing complications of foreign body aspiration removal should be developed. It involves improvement of knowledge of physician starting from diagnostic accuracy which reduces treatment delays and also family education for prevention of FBA. Training ofoto-rhino-laryngologists, pulmonologists, anesthesiologists and thoracic surgeon on how to perform proper bronchoscopy is vital. Availability of appropriate size functional bronchoscopes, nebulizers and presence of different anesthesia drugs also help to reduce complications.([9])

1.2. Statement of the problem

FBA itself and the process of removal are the major causes of mortality in pediatric age groups. The majority of complications were mild, major complications accounting for less than 2% of the cases and mortality during bronchoscopy was around 0.42% in western countries.([18,3]) Even though no research done in our set up, we observe mortality of 3 patients per year with 98 patients from TASTH reports review. This may partly be explained by the absence of adequate number of experienced surgeons and anesthesiologists in our set up which may increase the risk of complications because most of the procedure done by residents. General anesthesia is the standard anesthesia technique used but the type of ventilation technique that should be used during the procedure i.e. either spontaneous or controlled is still a controversial issue. So we need this research to see the magnitude of adverse events and patients outcomes of disposition in our set up to act on the identified gaps to improve patient outcomes, quality of care and the health system at large.

1.3. Significance of the study

Foreign body aspiration is one of the most common pediatric emergencies worldwide and it's recommended to do immediate intervention to decrease adverse events that can occur due to delays in management. The aim of this study is to assess the magnitude of procedural adverse events and outcome of FBA removal which may help to decrease adverse events that can occur during the procedure, improve patient's outcomes and decrease the morbidity and mortality of these group of patients in our country.

2. LITRATURE REVIEW

When a well trained personnel is doing the foreign body aspiration removal, serious complications are infrequent (<2%) and these complications can be either due to anesthesia or the procedure itself. In one retrospective study of 775 rigid bronchoscopes performed in a tertiary-care university hospital, the overall complication rate was 13.4%. The majority of complications were mild and major complications were rare (mortality rate, 0.4%). In another large series, only 2 deaths were recorded in 11,000 rigid bronchoscopes. ([18])

Intraoperative desaturation or hypoxia is the most common event in foreign body aspiration removal. A retrospective study done on 36 consecutive patients in Indian 2004, showed that there were a total of 26 episodes of desaturation in 17 patients in controlled ventilation and 21 episodes of desaturation in 19 patients in spontaneous ventilations. ([13])On the other hand, in a study done on 772 patients in Turkey university which was published in 2006 found that 30 hypoxia and bradycardia on bronchoscopy procedure.([6]) In another Study of china which was published 2014, by Meta-analysis including 423 subjects of 5 studies, all of the five studies reported the incidence of intraoperative desaturation but no significant difference found in the incidence of desaturation between controlled ventilation and spontaneous respiration (odds ratio, 0.70; 95% CI, 0.30–1.63).([10])A retrospective study done in Northwestern China, which was published in 2015 involving 1, 843 patients, there was no adverse event detected.([20])In another prospective observational study done in India which was published in 2017 with 71 children, desaturation was observed in 18 (25.0%) of children.([2])Finally, a retrospective study done in 81 patients in Pakistan which was published in 2019 showed that peri-operative complications with desaturation was 19.7% (n=16; 19.7%).([1])

Other adverse events may also be present during foreign body aspiration removals. In a study done on 36 patients in India which was published in 2004, the intra-operative bucking and coughing were 13; ventricular arrhythmias were 4, laryngospasm were 4, convulsions were 4 and postoperative laryngeal edemas were 9 and severe cough were 7. Incidence of intraoperative coughing and bucking in spontaneous group was statistically highly significant (P ¼ 0.0012) in this study.([13])In a study done in Turkeys on 772 patients, there were 37 laryngeal edema, laryngeal spasm and/or bronchospasm which required ventilator support; in 6 of patients tracheobronchial

system bleeding occurred; in 2 of patients' pneumothorax occurred.([6]) The 2014 China's study of 423 pediatric patients showed the incidence of laryngospasm was lower when controlled ventilation was used (OR, 0.27; 95% CI, 0.10–0.76). In addition the incidence of bucking and coughing (odds ratio, 0.08; 95% CI, 0.03–0.26) and body movement (odds ratio, 0.07; 95% CI, 0.01–0.59) was significantly decreased in the controlled ventilation group. This study collective results did not notify a significant difference in the incidence of laryngeal edema (odds ratio, 0.36; 95% CI, 0.01–10.76) or breath holding (odds ratio, 0.18; 95% CI, 0.003–1.17).([10])The other Indian study done in 2017showed that airway mucosal bleeding was observed in 14 (19.4%), movement during procedure was found in 8 (11.1%) cases, whereas airway edema was found in 6 (8.3%) cases. Both bradycardia and bronchospasm were found in 2 (2.8%) cases and laryngospasm was found in only 1 (1.4%) case.([2])In addition a study in Pakistan which was done in 2019 on 81 patients showed that bradycardia was found in 8 children (9.8%), mucosal bleeding were seen in 6 (7.4%), laryngeal edema was in 11 (13.6%), laryngospasm found in 13 (16.3%), and bronchospasm was seen in 4 (4.6%).([1])

There are different factors affecting intra operative hypoxia during foreign body aspiration removal in pediatric age group.

In a study of India that was published in 2004 showed that the episodes of desaturation in the spontaneous ventilation group were clinically associated with hypoventilation, breathe holding or apnea whereas those in the controlled ventilation group were clinically associated with inability to ventilate because of gross leak at the proximal end and/or apnea when the surgeon was trying to remove or localize the foreign body in the airway. All the patients breathing spontaneously had to be assisted to maintain adequate oxygen saturation.([13]) In addition Littman et al4 and Soodan et al found that cases initially started with spontaneous ventilation had to be converted to controlled ventilation due to increased intraoperative complications.([8])

Another study done in china from January 2007 to December 2008, 384 children younger than 5-yr-of age subjected to rigid bronchoscopy for FB removal published at 2009 with retrospective analysis of medical charts observed that factors that strongly correlated with intraoperative hypoxemia included age ($P = 0.039$), type of FB ($P = 0.025$), duration of surgical procedure ($P = 0.044$), pneumonia before procedure ($P = 0.067$), and ventilation mode ($P < 0.001$). ([15])

In this study the extent of airway obstruction (P = 0.104) was not significant risk factor for intra operative hypoxemia and no correlation was found between hypoxemia and the presence of an organic FB versus inorganic FB. When the types of plant seed were listed individually, the risk of intra-operative hypoxemia increased significantly (P = 0.027, OR = 2.654). A longer duration of surgery (20 min) and pneumonia before operation also increased the risk of intra-operative hypoxemia significantly (P = 0.001, OR = 1.150) for surgical duration; (P = 0.003, OR = 3.837) for pneumonia. ([15])

In another study of India in 2017 showed that there was no statistically significant relationship between complications and type of anesthetic agents used for induction.([2]) Children of less than 3 years of age were more prone to complications than children of older age group which was showed by Indian study in 2020.([21])

When we observed the morbidity associated with foreign body aspiration removal, there were some researches documented. One of which is the Turkish study which included 1035 patients and among which 911patients studied. When we observe the morbidity of foreign body aspiration removal there are some research documented that a study of turkey showed 37 required ventilator supports due to laryngeal edema, laryngeal spasm and/or bronchospasm. In this series there were 8 deaths.([8]) In Pakistan's study of the 81 patients, 18 (22.2%) were transferred to the ICU postoperatively, five of whom required mechanical ventilation. Of the 18 patients transferred to the ICU postoperatively, 12 (66.7%) patients had organic and 4 (22.2%) patients had inorganic FBs, whereas 2 (11.1%) patients were detected with no FBs. Of the 16 FBs extracted in the patients transferred to the ICU, 8 (44.4%) of them were localized in the right bronchus, 6 (33.3%) in the left bronchus, and 2 (11.1%) in the trachea-larynx.([1]) The incidence of laryngeal edema, laryngospasm, desaturation, and mucosal bleeding was significantly higher in the patients transferred to the ICU compared to those transferred to the ward ($p<0.05$).[1]

A study of death as a consequence of FBA in children in Tuzla; university clinical center Tuzla in 2018 showed that although asphyxia at presentation or initial emergency bronchoscope causes some deaths, hypoxic cardiac arrest during retrieval of the object, bronchial rupture, and unspecified intraoperative complications in previously stable patients constitute the majority of in-hospital fatalities.([6])Cardiac arrest was the cause of death of three children during bronchoscopy

(0.5%) in study of Senkaya et.([6])Improvements in surgical techniques, instruments, and modern anesthesia have allowed bronchoscopy to be effective in greater than 95% of the patients, with a complication rate of less than 1%.([9]) Before the advent of bronchoscopy in the early 1900s, the mortality rate for foreign body aspiration approached 50%. Today, successful treatment with bronchoscopy has reduced this to less than 1%.([9])

The review of Boston published in 2010 involving 12,979 cases found that the leading cause of accidental death under 4 years old is asphyxiation from an inhaled foreign body. Mortality during bronchoscope was 0.42%. Even though asphyxia is the major cause of death at presentation, bronchoscope causes some death due to hypoxic cardiac arrest during removal of the object, bronchial rupture, and unspecified intra-operative complication in previously stable patients constitute the majority of in-hospital mortality.([3])

In the study of Northwestern China done in 2015, there were 15 deaths (all aged less than 2 years).([20])They found that the causes of death were acute obstructive asphyxia (seven cases) and residual FB-induced chronic asphyxia and respiration-circulation failure (eight cases).([20])

Finally in the study done in India in 2017, one child died postoperatively. The child had preoperative history of cardiac arrest, was revived after 2 cycles of CPR, shifted in operation theatre on inotropes, and on assisted ventilation.([2])

3. OBJECTIVES OF THE STUDY

3.1. General objective

To determine the magnitude of adverse events and outcome of foreign body aspiration removal among pediatric patients at Tikur Anbessa specialized hospital.

3.2. Specific objectives

- To calculate the magnitude of intra operative adverse events in foreign body aspiration removal in pediatric age group at TASH.
- To determine the factors affecting the occurrence of adverse events during FBAR.
- To determine the disposition outcome of FBAR.

4. METHODOLOGY

4.1 Study design

Institutional based prospective, observational study was employed.

4.2 Study Area and period

The study was conducted at emergency operating room of TASH from July – November 30, 2020. TASH is one of the largest referral and teaching governmental hospital in Ethiopia located in Addis Ababa, capital city of Ethiopia, accommodating referred patients from all over the country and has most specialties apart from transplantation surgery. There are three operating theaters dedicated to elective surgery with 14 operating rooms. One is designated to obstetric OR with 2 operating tables. The other is orthopedic operating room previously 4 tables but currently the 3 table is functioning. The third operating room is the main operating room of TASH which has 9 tables. It has 3 emergency tables one for urology surgery, the other for neurosurgery and the third one is main Emergency Operating Room. It is for all emergency procedure except for obstetric, neurosurgery, urology surgery and orthopedic surgery for whom they have a separate table each. Pediatric emergency surgery is done at main EOR room in collaboration with Anesthesiologists and Anesthesiology resident as anesthesia provider and pediatric surgeon and pediatric surgery residents for bronchoscope procedure. At TASH, there is one main ICU and one cardiac ICU. The cardiac ICU has 4 beds. The main ICU has 16 beds which includes Medical ICU which has 6 beds and run by pulmonologist, Surgical ICU which has 6 beds and run by anesthesiologist and PICU which has 4 beds and run by pediatrician.

4.3. Population

4.3.1 Source population

All pediatric patients who visited TASH EOR during the study period.

4.3.2 Study population

All pediatric patients who came with FBA within the study period who met the inclusion criteria.

4.4. Eligibility criteria

4.4.1. Inclusion criteria

All pediatric patients who had undergone rigid bronchoscope procedure for suspected FBA and who consented to participate in the study during the study period at EOR of TASH.

4.4.2. Exclusion criteria

1. Pediatric Patients with FBA who were intubated and put on mechanical ventilation and admitted to ICU pre procedurally.

2. ASA >= 5

3. Pediatric patients who had rigid bronchoscope procedure done for other indication than suspect of foreign body aspiration

4.5. Sample size determination and procedure

4.5.1 Sample size determination

All patients who had undergone FBA removal in the study period were included in the study.

4.5.2 Sampling procedures

Institutional based census sampling was used.

4.6 variables of the study

4.6.1 Dependent variable

Adverse events

Outcome (post-operative admission to the ward, PICU, DEATH)

4.6.2 Independent variable

Socio-demographic variable: age, sex

Patient factor: ASA status, co-existing diseases or co morbidities, type of foreign body aspiration, duration of initial presentation after FBA

Procedural factors: Adverse events, type of ventilation (controlled, spontaneous or both), number of bronchoscope attempt, duration of surgery, duration of anesthesia, aerosilization with Lidocaine before the procedure one lung ventilation, inadequate depth of anesthesia and the experience of the surgeon and anesthesia provider.

4.7. Operational definitions

1. **Pediatric patients**: all patients less than 14 years of age.
2. **Type of ventilation** is the ventilation that we use during general anesthesia. It can be

a. Spontaneous ventilation a patient is breathing spontaneously without muscle relaxation and clinician assistance to breathing)

b. Assisted ventilation is patient is not on muscle relaxants but needs clinician assistance on breathing

c. Controlled ventilation a patient is on muscle relaxation and need clinician or machine full support of ventilation

3. **Duration of anesthesia** was defined as the time period from the transfer of the patient to the operating room and put on monitors to the transfer of the patient to PACU or ICU.
4. **Duration of surgery** was defined as the time period from the initial introduction of the rigid bronchoscope tip into the patient's mouth to the final removal of the bronchoscope from the vocal cords.
5. **Laryngospasm** was defined as glottal closure caused by the reactions obstructing ventilation of the lungs which can also defined by the treating physician diagnosis with any need of intervention.

6. **Bronchospasm** was defined as a prolonged expiratory phase accompanied by wheezing and desaturation which can also defined by the managing physician diagnosis with any need of intervention.

7. **Bradycardia** was defined as a resting heart rate of below the base line of beats per minute according to age of the patients. < 1 years old <105 beat/ min, 1- 5 years old <85 beat / min, 6- 10 years < 70 beat / min, >=12 years old <60 beat/min for more than 15 seconds either with ECG or stereoscope.

8. **Desaturation/ Hypoxia** was defined as a SpO2 level of 94% or below for more than 15 sec.

9. **Aspiration** is entrance of foreign body or material or fluid in to trachea-bronchial tree which can also done by physician diagnosis with any need of intervention

10. **Mucosal bleeding** was defined as the presence of bleeding associated with the bronchoscope procedure.

11. **Persistent Hypoxia (clinical emergency hypoxia)** was defined as SPO2 level of less than 90% for greater than or equal to 30 sec

12. **Serious trauma to trachea-bronchial tree** is defined as major air way trauma like pneumo-thorax, pneumo-mediastinum and surgical emphysema which can also done by physician diagnosis with any need of intervention.

13. **Monitor interruption –** defined as any interruption of monitors from continuous ASA standard monitor. Monitor interruption after looking the presence of adverse events like the patients is desaturation and bradycardia considered as presence of that adverse events if the interruption last more than 15 sec.

14. **Duration of hospital stay –** from the time procedure was done for FBA to the time the patient was discharged to home in hrs or days.

15. **Cardiac arrest** is defined as absent of pulse in carotid artery for > or = to 10 sec.

16. **Mortality** was defined as death occurring in association with anesthesia or surgery until hospital discharge.

4.8 Data collection procedure and questioner development

Data collection tool : To identify those patient with intra adverse events during foreign body aspiration removal, Structured standardized observational data collection tool was developed from different published research papers([16,6,15,22,3,21,8,1,23,5,2,7,24,25,13]) and it was tested before use. Data was collected for 5 months by a designated EOR attached residents for all pediatric foreign body aspiration patients who fulfill inclusion criteria after being trained by the principal investigator for one day during each month of EOR attachment. In the night time and during the weekends, residents were assigned as investigators after being trained by the principal investigator. Transfer of data was started by filling the formed questionnaires as soon as the patient came to EOR or as soon as it is feasible. The transfer was completed as the patient was discharged or death confirmed. Anesthetic chart and the surgeons´ notes were reviewed for completeness of questioners for each patient. The ASA scoring, preexisting disease, pre-procedural respiratory distress, hypoxia, pulmonary infection and other complications, ventilation technique, intraoperative and post procedural complication like desaturation, bradycardia, mucosal bleeding, laryngospasm, bronchospasm, hypoxia, cardiac arrest, and other surgical and anesthesia related complications were recorded. Duration of anesthesia and surgery (min) and outcome until hospital discharges (hrs. or days) were recorded.

4.9. Data quality assurance

Overall data collection process and completeness of data collection was monitored and checked by the principal investigator. All completed questionnaires were checked for completeness and consistency during data management, storage and analysis.

4.10. Data analysis technique

The principal investigator checked the collected data. All completed questionnaires were coded. Development of data entry templates, data cleaning, processing, analysis and the overall data

management was done by the principal investigator using Epi data and the Statistical Package for Social Sciences (SPSS) software.

Bivariate correlation method was used with Chi square for 2 by 2 cross tabulation ,Fishers Exact test for count less than 5 expected count in the sample and Kendall's Tau Coefficient for non-parametric or non-uniform continuous samples to determine which independent variables was associated with dependent variable.

4.11. Ethical consideration

The proposal was reviewed and approved by the research and ethics committee of department of Anesthesiology, critical care and pain medicine, AAU. The nature and purpose of the study was explained to family member or to legal guardian of the patient to be included in the study and written informed consent obtained from family or legal guardian. Data collection instrument did not include names, addresses or other identifying information about the study participant.

5. Result

5.1 socio-demographic factors

There were a total 56 patients who had suspect of FBA and removal were done in the TASH EOR table from July1-Nov30, 2020. Among this 4 patients had repeat bronchoscopy procedure. From patients who undergo repeat bronchoscopy 3 patients first bronchoscopy was differed because of persistent hypoxia and laryngeal edema while one patient foreign body was not found in the first bronchoscopy. Majority of them 34 (62.5%) were males and 22(37.5%) were female. The median age was 24 month which ranges from 8 -144 months. Most of the patients 36(64.3%) were ≤ 3 years old while 24(35.7%) were>3 years old.

5.2 Descriptive analysis

Most of the patients 45(80.4%) arrived to the hospital after 24 hr of foreign body aspiration while the rest 11(19.6%) arrived before 24 hours. Among those who came after 24hrs, 30(53.6%) was delayed due to referral delay, 14(25%) were due to family thought that the patient had no FBA. One patient was arrived after 24 hrs because of delay during transportation.

Majority of the patients 54(90%) were ASA I while the remaining 6 (10%) were ASA II. All patients did not have any chronic medical illness.

When patients arrived in the waiting area of EOR 36(60.0%) had respiratory complication which includes; 18(30%) desaturation and respiratory distress, 9(15%) respiratory distress, desaturation and aspirations pneumonia, 7(11.7%) only respiratory distress and 2(3.3%) only aspiration pneumonia while 24(40.0%) of patients did not have any respiratory complications. Most of the patients 33(55%) require supplemental oxygen while others 27(45%) did not require oxygen while came to the EOR.

Most of the procedures 49(81.6%) were done at night time while 11(18.4%) were done daytime. 52(86.7%) of procedure were done by Anesthesiology and Pediatric surgery residents, 5(8.5%) were by consultant Anesthesiologist and Pediatric Surgeon while 3(5.0%) were done by Anesthesiologist and Pediatric surgery residents.

Most of the foreign bodies were removed with ≤ 3 attempts while 28 (46.7 %) removed with >3 attempts. In 4 patients foreign body was removed with single attempt and the maximum attempt to remove a FB was 7.

48(80%) of patients was given pre-operative air way lidocaine aerosolization. In 45(75%) of the patients breathing was assisted, in 11(18.3%) of the cases breathings were assisted and then controlled due to some adverse events and the remaining 4(6.7%) were maintained in spontaneous breathings during the procedure.

There were 2 monitor interruptions during the procedure only on pulse oxymetry.

The median DOS and DOA were 73.5 ± 40 with range of 10-175 minutes and 106 ± 60 with range of 20-240 min respectively. Most of the duration of surgery 34(56.6%) were > 60min while the remaining of DOS 26 (43.3%) ≤ 60 min. The majority of duration of anesthesia 46(76.7%) were >60 min while the remaining DOA 14(23.3%) were ≤ 60 min.

The incidence of adverse events during the procedure were desaturation 51(85%), one lung ventilation 45(75%), persistent hypoxia 34(56.7%), air way mucosal bleeding 34(56.7%), laryngospasm 14(23.3%), air way or laryngeal edema 13(21.7%), bradycardia 9(15%), esophageal intubation 5(8.3%), inadequate depth of anesthesia 2(3.3%) and right side tracheobronchial fistula with tension pneumothorax 1(1.7%). One patient developed pneumothorax secondary to left side tracheobronchial fistula in PACU after procedure and transferred to PICU after bilateral chest tube inserted.

22 (39.3%) of patients developed hypoxia that lasts 2-5min while 13(23.2%), 6(10.7%) and 7(12.5%) of patients developed hypoxia that lasts 30 sec - 2 min, 2-5 min, 5-10 min and > 10 min respectively.

FBA were found in 49(87.9%) with 39(69.6%) of aspirated FB being organic and 10(17.9%) inorganic. 36(64.3%) were in right bronchus, 7(12.5%) were in larynx and trachea, 6(10.7%) were in the left bronchus. One patient had organic foreign body on bilateral bronchus was developed hypoxia during the procedure. She was developed pneumothorax where bilateral chest tube inserted which was removed after 7 days and admitted to PICU.

After the procedure most of the patients 53(88.7%) were in a relatively clinically stable of which 52 transferred to ward and 1 patient was transferred to EOPD after 4 hours of observation in the PACU. The remaining 7(11.7%) had severe adverse events, 3 of them were transferred to PICU intubated where as two of them had respiratory failure due to air way edema and pulmonary infection. The second patient had repeat procedure after 7 days due to remnant foreign body.

After procedure 22(36.7%) patients developed complications which includes; 5(8.3%) were pulmonary infections, 4(6.7%) desaturations and laryngeal edema, 4(6.7%) were desaturations, 8 (13.3%) of patients had desaturation, laryngeal edema and pulmonary infection and one patient had left side tracheobronchial fistula with bilateral tension pneumothorax

After the procedure most of the patients 53(88.7%) were in a relatively clinically stable of which 52 transferred to ward and 1 patient was transferred to EOPD after 4 hours of observation in the PACU. The remaining 7(11.7%) had severe adverse events, 3 of them were transferred to PICU intubated where as two of them had respiratory failure due to air way edema and pulmonary infection. The second patient had repeat procedure after 7 days due to remnant foreign body. The 3rd patient transferred intubated to PICU had remnant egg shalt and it removed upon suctioning on 2nd day of transfer.

Most patients 23(41.1%) discharged from hospital from 4 to 24 hr and the remaining were discharged 17(30.7%), 11(19.6%), and 5(8.3%) were after 3 days, with in 2 to 3 days and ≤ 4 hr respectively. All of 56 patients discharged from hospital with improvement with maximum days of stay in the hospital being 14 days.

5.3 Association factors analysis

The dependent variables such as intra operative desaturation (hypoxia), persistent hypoxia, laryngospasm, laryngeal edema, bradycardia, and procedural outcome were assessed with independent variables using chi-square test and fisher exact test.

The results showed that intraoperative desaturation had significant association with oxygen requirement prior to the procedure, post procedural complications, persistent hypoxia, air way mucosal bleeding, one lung ventilation and DOS and DOA in minutes as shown in table 5.1.

Table 5.1 significant association of risk factors for desaturations

Serial No	Variable		frequency	Procedural desaturations		%			P value
				Yes	No	Yes	No	Total	
1	Oxygen requirement prior to the procedure	Yes	32	31	1	55.4	1.8	57.1	<0.01*
		No	24	7	17	12.4	30.4	42.9	
		Total	56	38	18	67.8	32.2	100	
2	Post procedural complications	Yes	22	22	0	34.9	0	34.9	0.02*
		No	38	30	8	58.8	7.1	65.9	
		Total	56	48	8	82.7	14.3	100	
3	p. Hypoxia	Yes	34	34	0	58.8	0	34.9	<0.01*
		No	26	17	9	38.9	14.3	65.9	
		Total	56	51	9	86.7	14.3	100	
3	Air way mucosal bleeding	Present	34	34	0	56.7	0	56.7	<0.01*
		Absent	26	17	9	28.3	15	43.8	
		Total	60	51	9	85	15	100	
4	DOS in min	<= 60	26	18	8	23.2	12.5	35.7	<0.01*
		>60	34	33	1	62.5	1.8	64.3	
		Total	56	48	8	85.7	14.3	100	
5	DOA in min	<= 60	14	9	5	14.3	8.9	23.2	0.02*
		>60	46	42	4	71.4	5.4	76.8	
		Total	56	48	8	85.7	14.3	100	
6	Prolonged One lung ventilation	yes	42	42	0	75	0	75	<0.01*
		No	14	6	8	10.7	14.3	25	
		Total	56	48	8	85.7	14.3	100	

*= p-value < 0.05 of fisher exact test

Persistent hypoxia had statistically significant association with oxygen requirement prior to the procedure, post procedural complications, laryngeal edema, mode of ventilations, persistent hypoxia, airway mucosal bleeding, one lung ventilation and DOS and DOA in minutes as shown in table 5.2.

Table 5.2. Significant factors for presence of intraoperative persistent hypoxia

Serial No	Variable		frequency	Persistent hypoxia		%			P value	OR, CI95 %
				Yes	No	Yes	No	Total		
1	Oxygen requirement prior to the procedure	Absent	27	10	17	16.7	23.3	45	<0.01#	4.5
		Present	33	24	9	40	15	55		
		Total	60	33	27	56.7	43.3	100		
2	Airway edema	Absent	47	21	26	35.3	43	78.3	<0.01*	
		Present	13	13	0	21.7	0	21.7		
		Total	60	34	26	56.0	43.4	100		
3	Pre-operative complications	Present	36	25	11	47.8	12.2	60	0.01#	3.8
		Absent	24	9	15	15	25	40		
		Total	60	34	26	62.8	37.2	100		
4	Mode of ventilation	S/Assisted	49	24	25	39.3	41.7	81.7	0.02*	
		Controlled	11	10	1	16.6	1.7	18.3		
		Total	60	34	26	55.9	42.4	100		
4		Present	21	18	3	30	5	35	<0.01*	
		Absent	39	16	23	26.7	38.3	65		

	Post procedural complications	Total	60	34	26	56.7	43.3	100		
5	Laryngospasm	Present	14	13	1	21.6	1.7	23.3	<0.01*	
		Absent	46	21	25	35	41.7	76.7		
		Total	60	34	26	56.6	43.4	100		
6	Prolonged one lung ventilation	Present	45	30	15	50	25	75	0.03	
		Absent	15	11	4	18.2	6.8	25		
		Total	60	41	19	68.2	31.8	100		
7	Number of bronchoscope procedure at different time	1	56	34	22	56.6	36.7	93.3	0.03*	
		2	4	0	4	0	6.4	6.4		
		Total	60	34	26	56.6	43	100		
8.	Number of bronchoscopy intubation	<=3	32	14	18	23.3	30	53.3	0.03	3.21
		>=4	28	20	8	33.3	13.3	46.7		
		Total	60	34	26	56.6	43.3	100		
8	Desaturation	Present	51	34	17	56.7	28.3	85	<0.01	
		Absent	9	9	0	15	0	15		
		Total	60	48	8	89..8	11.2	100		
9	Air way mucosal bleeding	Present	34	25	9	41.7	15	56.7	<0.01	5.24
		Absent	26	9	17	15	28.3	43.3		
		Total	60	34	26	56.7	43.3	100		
10		Present	21	18	3	30	5	35	<0.01*	

	Post-operative complications	Absent	39	16	23	26.7	38.3	65		
		Total	60	34	26	56.7	43.3	100		
11	DOS	>60	34	29	5	48.4	8.3	56.7	< 0.01*	
		<=60	26	5	21	8.3	35	43.3		
		Total	60	34	26	56.7	43.3	100		
12	DOA	<=60	14	4	10	6.7	16.6	23.3	0.03*	
		>60	46	30	16	50	26.7	76.7		
			60	34	26	56.7	43.3	100		
13	PICU need	Other	53	27	26	45	43.3	88.3	0.02*	
		PICU	7	7	0	11.7	0	11.7		
		Total	60	34	26	56.7	43.3	100		
		Total	60	34	26	56.7	43.3	100		
* = p value < 0.05 for fisher exact # = p value <0.05 for chi-square										

Mode of ventilation (<0.01), airway edema (0.001), bradycardia (0.003) and persistent hypoxia (<0.01) had significant association with laryngospasm.

Air way or laryngeal edema had strong association with number of bronchoscope intubation trial (p value <0.01) for ≥ 4 trial of intubation, prolonged duration of surgery >60 min (<0.01*) and PICU transfer with p value of (0.047).

Bradycardia had statistically significant association with airway edema (0.02), laryngospasm (0.02), mode of ventilation (<0.01), organic FBA (0.04) and post-operative PICU admission (0.01).

5 (8.3%) of 13 laryngeal edema, 4(6.7%) of bradycardia, 4(6.7%) of controlled ventilation, 4(6.7%) of surgical residents who do the procedure were transferred to PICU. In addition, all patients transferred to PICU were duration of surgery greater than 60 min, persistent hypoxia intra-operatively and post-operative complications**.**

Laryngeal edema (<0.01), persistent hypoxia (0.02), bradycardia (<0.01), mode of ventilation (0.02), surgeon experience (0.02), and duration of surgery in minutes (0.02) had statistically significant association with PICU admission. Please look at table 5.3 showed below.

Table 5.3 significant factors for ICU transfers

Serial No	Variable		Frequency	Outcome					P value
				PICU	Ward	PICU%	Smooth %	Total	
1	Airway edema	Absent	47	2	47	3.3	77	80.3	<0.01*
		Present	13	5	8	8.3	11.4	19.7	
		Total	60	7	53	11.6	88.4	100	
2	Persistent hypoxia	Present	34	7	27	11.7	45	56.7	0.02*
		Absent	26	0	26	0	43.3	43.3	
		Total	60	7	53	11.7	88.3	100	
3	Bradycardia	Present	9	4	5	6.7	8.3	15	<0.01*
		Absent	51	3	48	5	80	85	
		Total	60	7	53	11.7	88.3	100	
4	Post procedural complications	Present	22	7	15	8.4	28.3	36.7	<0.07*
		Absent	38	0	38	0	71.3	71.3	
		Total	60	7	53	8.4	91.9	100	
5	Mode of ventilation	Spont/assested	49	3	46	42.9	86.8	81.7	0.02*
		controlled	11	4	7	57.1	13.2	18.3	
		Total	60	7	53	100	100	100	

6	Surgeon + anesthesia provider	S. Residents	52	4	48	6.7	79.6	86.7	0.02*	
		S. Consultants	8	3	5	5	8.4	13.3		
		Total	60	7	53	11.7	89.3	100		
7	DOS in minutes	<=60	26	0	26	0	43.3	43.3	0.02*	
		>60	34	7	27	11.7	45	56.7		
		Total	60	7	53	11.7	88.3	100		
* = p value < 0.05 Fisher Exact Test										

6. Discussion

Most of tracheobronchial FBA cases were seen in children aged less than or equal to 3 years, which are predominantly seen in males. As consistent with the other literature's, our study results were aged below three years and the incidence of FBA was higher in males compared to females.[1]

Among 56 pediatric patients, FBA were successfully extracted in 49(87.9%) and the remaining 7(12.3%) had no FB which is similar finding as Pakistan's where successfully extracted FB were 71 (87.7%) patients and no FBs were detected in the remaining 10 (12.3%) patients.([1,7])

FBA found in 49 (87.9%) patients of which 39(69.6%) were organic and 10(17.9%) inorganic, that showed lager number of organic FBA.

The FBs were located in the right bronchus 36(64.3%),in larynx and trachea 7(12.5%) , in left bronchus 6(10.7%) and in both bronchus 1(1.8%) which was inconsistent with Pakistan's results which showed that right bronchial tree 35 (43.3%) , the left bronchial tree 16(19.7%),laryngeal-tracheal tract 20 (23.3%) and no FB 10 (12.3%).([1])

The ASA score was I in 51(91.1%), II in 5 (8.9%), and there were no ASA III and ASA IV patients in contrast to the study of Pakistan with ASA I 18(22.2%), ASAII 62(76.5%) and ASAIII1(1.2%) in our case lower ASA classification.([1]) Our patients were less risk patients.

The experiences of the surgeons and anesthesia providers had statistically significant association with patient outcomes with p value of 0.04 which is consistent with study of China 2009. ([15])

The median DOS and DOA were 73.5 ± 40 with range of 10-175 minutes and 106 ± 60 with range of 20-240 min respectively, which is much larger compared to study of Pakistan (DOS 27.35 ± 14.20, DOA 44.30 ± 14.72) or Indians study.([1])The number of bronchoscopy insertion were 1-7 with median and mean of 3 which is slightly higher mean and median compared to the Indian with 1-8 trial and mean and median of 2.([2])

The duration of surgery had statistically significant association with desaturation, persistent hypoxia, laryngeal edema and patients outcome time with p value of (<0.01, <0.01, <0.02 and 0.01) respectively which is consistent with study of China,2009 and Switzerland 2006.([15,16]) The

duration of anesthesia had no clinically significant association with intraoperative complications in study of china but in our study it had clinically significant association with hypoxia and persistent hypoxia with p value of (0.02, 0.03) respectively which may be explained by prolonged surgical time requiring prolonged time for recovery from anesthesia too.([15]) In addition, this may be explained by the fact that we used only halothane and ketamine, and sometimes propofol if available but they used sevoflorane and dexemetodomidine in their set up. ([16],[26])

The magnitude of procedural adverse events were desaturation/hypoxia 51(85%),one lung ventilation 45(75%), persistent hypoxia 34(56.7%),airway mucosal bleeding 34(56.7%) ,laryngospasm 14(23.3%), air way or laryngeal edema 13(21.7%), bradycardia 9(15%), esophageal intubation 5(8.3%), inadequate depth of anesthesia 2(3.3%) and tracheobronchial fistula with tension pneumothorax 2(3.3%) which were larger compared to the study done in Pakistan in 2019 with results of desaturation 16(19.7%), air way edema 11(13.6%), laryngospasm 11(16.3%) and air way mucosal bleeding 6(7.4%).([1]) Comparing the presence of serious tracheobronchial fistula on many reviews showed < 2 % and study of Indian shows only pneumothorax in 1 patient from 71 patients and in Pakistan no pneumothorax from 81 patients.([2,9]) The tracheobronchial fistula with tension pneumothorax 3.3% were higher than others thesis even large scale studies and reviews showed <2%.

Post operatively 53 (89.7%) were in a relatively smooth post procedural condition and the remaining 7(11.3%) were transferred to PICU with 3(5%) intubated, Pakistan's study of the 81 patients, 63 (77.8%) of them were transferred to the ward and the remaining 18(22.2%) transferred to PICU with 5(6.1%) intubated.([1]) We cannot compare our result with Pakistan's because their patients were higher ASA classifications risk and lower intraoperative adverse events than ours.

Laryngeal edema (<0.01), persistent hypoxia (0.02), bradycardia (<0.01), mode of ventilation (0.02), presence of post procedure complication(<0.01) surgeon experience (0.02), and duration of surgery in minutes (0.02) had significant association with PICU admissions, which had difference with the study done in Pakistan 2019 which showed the incidence of laryngeal edema, laryngospasm, desaturation, and mucosal bleeding were significantly higher in the patients transferred to the ICU postoperatively ($p<0.05$).([1])

7. Limitation of the study

The limitation of the study was the number of patients included in the study was small due to constraints of time; I believe that inclusion of more patients would have changed the results in terms of kind, percentage of complications and better analysis.

The other limitation was that it was done only at TASH due to constraints of time and fund. Only two centers left where the procedure done. Therefore we could not concluded the situation country wide to see the magnitude of foreign body and its complications to set solution nationally.

The type of anesthesia during bronchoscopy procedure used was not included in this study due to our limited drug available, which might have some impact on the results even if in other study it had no impact.

We did not use exclusion and inclusion criteria for surgeons and anesthesiologists based on level of experience unlike other researches done in other set ups use 5 years experiences as inclusion criteria.

8. Strength of the study

There was no researches done on this topic in Ethiopia and Africa that makes this study a stepping stone to various small and large scale studies in this area.

The structured observational tool were adopted and modified from different studies to avail the data.

The study was prospective, observational study which is the primary data that we used for the study.

Even if small sample size we had many statistically significant association with hypoxia, persistent hypoxia and outcome of disposition.

We able to identify risks for adverse events and outcome of patients like delay referral that can be solved by simple communication.

9. Conclusion

The magnitude of adverse events were higher than any other researches. The incidence of serious tracheobronchial trauma with bronco-pleural fistula 2(3.3%) were also higher than other results and even large scale studies and reviews showed <2%. Our patients ASA classification were much less risk patients than others but we encountered more complications.

Even though further studies are needed to clarify more and identify the factors affecting for PICU admission, the incidence of PICU transfer were 7(11.3%) with low ASA classified patients and higher incidence 2(3.3%) of bronco-pleural fistula with tension pneumothorax.

The study showed the surgeon experience, prolonged duration of surgery >60 min and presence of procedural adverse events such as airway or laryngeal edema, persistent hypoxia and bradycardia were modifiable risk factors associated with the patient disposition to the PICU.

10. Recommendation

For researchers, do research on this area in the larger scale country wide to get more inclusive findings.

For TATSH, improve communications with other institutions to facilitate early referral that can decreases delay which is one of the risk factor for adverse outcome.

For ACCPM department, working to reduce procedural adverse events will show significant reduction to post procedural PICU admission.

For ACCPM department, Work closely with pediatrics surgery department to decrease procedure time, to decide who could do the procedure, to improve surgical outcome of patients and to develop guideline on FBA removal procedure.

For FMOH, work on capacity building on physicians and health institutions (those usually refer patients to TASH) to do bronchoscopy procedure for foreign body aspiration at their institutions.

For FMOH and Regional health bureaus, give continuous Health Education on Foreign body aspiration prevention methods and its risks for the community integrated with health Education Program.

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Annex - Observational tool

First I would like to thank you for participating in this research and inform you that the procedure to be done for your child will not be affected. We will just observe while the procedure done and document it in systematic manner so that will help us for future improvement. Your name, or your kid's name, your address, phone number or any identification will not be documented. Thank you again, if you have any question you are welcome. Do you want to proceed?

A. yes B. no signature _____

Socio-demographic factors and patients related factors

1. Questionnaire no. _____
2. Age (in month)_____
3. Weight _____
4. Sex A. male B. Female
5. Preoperative coexisting medical diseases such as cardiovascular, respiratory, hepatic, renal, neurologic and endocrinology (circle above if any) A. no B. yes (please specify) _____
6. Was the patient on O2 prior to the procedure A. yes B. no
7. Was the patient presented with respiratory distress A. yes B. no
8. Was there any pulmonary infection before the procedure A. No B. yes (please specify) _____
9. Any preoperative FBA complications seen before the procedure
10. NO B. YES (Please specify) _____

Surgical factors

11. The number of bronchoscope procedure done at different time A. 1st B. 2nd
12. The foreign body removed or differed after how many trial of bronchoscope is done in the current procedure _____

13. Duration of surgery in minutes(defined as the time period from the initial introduction of the rigid bronchoscope tip in the patient's mouth to the final removal of the bronchoscope from the vocal cords) _____

Anesthesia related factors

14. ASA score A. I B. II C. III D. IV
15. Any interruption on the Monitors A. No B. YES if yes please specify _____
16. Use of topical lidocaine aerosolization before rigid bronchoscope A. Yes B. No
17. Mode of ventilation a. spontaneous (no muscle relaxation) b. controlled(muscle relaxation) c. assisted (no muscle relaxation and need assistance on spontaneous breath)

Associated complications and intervention

18. Any intra operative complications A. Yes B. No
19. If yes to Q no. 20 what was the intra operative complications (more than 1 option can be selected)

A. Hypoxia (SpO2 level of 94% or below for more than 15 sec) a. Present b. Absent

B. Airway mucosal bleeding (presence of any bleeding seen in the airway associated with the bronchoscope procedure) a. Present b. Absent

C. Airway edema(the presence of acute swelling in the airway or if intubated failure of leak test) a. Present b. Absent

D. Bradycardia (if < 1 years old <105 beat/ min, if 1- 5 years old <85 beat / min, if 6- 10 years < 70 beat / min, if >=12 years old <60 beat/min for greater than 15 second and either by ECG or pericardial stereoscope or both) a. Present b. Absent

E. Broncospasm (prolonged expiratory phase accompanied by wheezing on bilateral lung associated with difficult ventilation and desaturation or hypoxia) a. Present b. Absent

F. Laryngeospasm (defined as glottal closure caused by the reactions obstructing ventilation of the lung partially or completely with the clinical feature of unable to ventilation which responds to

positive pressure ventilation or deepening of anesthesia or require muscle relaxation) a. Present b. Absent

G. Aspiration (entrance of foreign body in to trachea-bronchial tree from gastrointestinal contents on the procedure due to incomplete fasting protocol or not) a. Present b. Absent

H. Persistent hypoxemia (saturation <90% for >2 min) a. Present b. Absent

I. Nausea and Vomiting a. Present b. Absent

Serious trauma to trachea-bronchial tree (major air way trauma like pneumo-thorax, pneumo-mediastinum and surgical emphysema according to the clinician definition of pneumo-thorax, pneumo-mediastinum and surgical emphysema) a. present b. absent

J. Cardiac arrest (absent of pulse in carotid artery for > or = to 10 sec) a. present b. absent

K. Mortality (death occurring in association with anesthesia or surgery during the procedure or with 7 days of procedure) a. present b. absent

L. Other please specify_____

20. How long the hypoxia lasts

a. <1min c. 6-10 min

b. 1-5 min d. >10 min _____

21. When is the hypoxia happen

A. The scope was placed in a right bronchus

B. The scope was placed in a left bronchus

C. The scope was placed above the carina

D. Esophageal intubation

E. Inadequate depth of anesthesia

F. Other please specify _____

22. Procedure done to improve hypoxia

A. Two lung ventilation

B. Increase depth of anesthesia

C. Muscle relaxation

D. Bronchodilators (inhalational)

E. Other please specify _____

23. Duration of anesthesia in minutes (was defined as the time period from the transfer of the patient to the operating room and first monitor apply to the transfer of the patient to PACU or ICU)_____

Other factors

24. Duration of aspiration before arriving to FBAR

A. < 24 hr B. > 24 hr

25. Reason for delay

A. Referral from other hospital

B. The family did not think FBA

C. The patient had no symptoms

D. Did not delay

E. other specify _____

26. Site of foreign body found (more than 1 option can be selected)

A. FB in right bronchial tree

B . FB in left bronchial tree

C . FB in larynx and trachea

D. Specific location not identified

E. No FB F. Other please specify _____

27. Aspirated things

A. Organic materials (pleases specify)_____

B. Inorganic material (please specify)_____

C. No foreign body found _____

28. How was the procedure done

A. urgent and emergent procedures done at night

B. urgent and emergent procedures done at daytime

C. all the vital sign are normal range per age, no respiratory distress defined by clinician and stable done at night

D. stable performed on the next available day time operating list rather than doing it late at night

29. Procedure done by

A. Anesthesiologist and Pediatric surgeon

B. Anesthesiology resident and Pediatric surgeon

C. Anesthesiologist and Pediatric surgery resident

D. Anesthesiology resident and Pediatric surgery resident

E. MSC or anesthetist

30. Patients transferred to

A. Intubated to the ICU
B. Exrtubated to the ICU
C. PACU and then to the ward
D. PACU and then to EOPD and discharged after 4 hr

31. Is there any post procedural complications

A. No B. Yes

32. What was the complications

a. Hypoxia d. Laryngeal edema

b. Laryngospasm e. Pulmonary infections

c. Other (please specify)_____

33. The patients discharge on

a. Less than 24 hr c. Greater than 3 days

b. 2 to 3 days

THANKY