JIMMA UNIVERSITY

INSTITUTE OF HEALTH FACULTY OF MEDICAL SCIENCE

DEPARTMENT OF ANESTHESIOLOGY

ASSESSMENT OF LEVEL OF SEDATION AND ASSOCIATED FACTORS AMONG INTUBATED CRITICALLY ILL CHILDREN IN PEDIATRIC INTENSIVE CARE UNIT OF JIMMA UNIVERSITY MEDICAL CENTER: A FIVE MONTHS PROSPECTIVE OBSERVATION STUDY, 2022.

BY: MOGES SAHLE (MD, ANESTHESIOLOGY RESIDENT)

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

JIMMA, ETHIOPIA

JANUARY, 2022

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Abstract

Background: Sedation can be provided to facilitate a procedure or to stabilize patients admitted in PICU. Sedation is often necessary to maintain optimal care for critically ill children requiring mechanical ventilation. However, if sedation is too deep or too light it has its own adverse effects, and hence it is important to monitor level of sedation and maintain an optimal level.

Objectives: assess level of sedation and associated factors among intubated critically ill children admitted to PICU of JUMC, Jimma.

Methods: Prospective observation study which was conducted in PICU of JUMC from August, 2021 to December, 2021. Data was collected by residents and nurses working in PICU, after they were given training. Data entry was done using Epi data manager (version 4.6.0.2). Statistical analysis and the creation of charts was performed using SPSS version 26. Data was presented as mean, percentage and standard deviation. To see if level of sedation has any change on patient outcomes was examined using repeated measure ANOVA test. To understand the associated factors of level of sedation chi square test was used. A probability of $p<0.05$ was defined as statistically significant.

Results: Of a total of 49 patients admitted to PICU, level of sedation was assessed for 28 critically ill intubated children. Of a total of 84 sedation scores observed, 45.2% was optimal and 54.8% was suboptimal. The mean age of children was 37.7 months. Patients were taking morphine as a sedative in 78.6% of the cases. There was a change on mortality rate based on the level of sedation, wilk's Lambda value of 0.725, p-value of 0.018. There was an association between comorbidity and level of sedation, Pearson chi square 0.68, p-value of 0.0132.

Conclusion: this small preliminary study showed a high proportion of suboptimal level of sedation in PICU. It is mandatory to study level of sedation and associated factors on a large scale using large sample size.

Key words: Level of sedation, critically ill children, Pediatric intensive care unit.

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List of Abbreviation and Acronyms

CBS- COMFORT Behavior Scale

SBS- State Behavioral Scale

FLACCS- Face, Legs, Activity, Cry, Consolability scale

BIS- Bi Spectral Index

EEG- Electroencephalogram

IQR- Inter Quartile Range

PICU- Pediatrics Intensive Care Unit

ICU- Intensive Care Unit

JUMC- Jimma University Medical Centre

MV- Mechanical Ventilators

LOS- Length of Stay

MI- Myocardial Infarction

TOF- Tetralogy of Fallot

HR- Heart Rate

MAP- Mean Arterial Pressure

GCS- Glasgow Coma Scale

MOH- Ministry of Health

SPSS- Statistical Package for the Social Sciences

TBI- Traumatic Brain Injury

UK- United Kingdom

ETT- Endotracheal Tube

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1. Introduction

1.1. Background information

Sedation in the PICU; Sedation in a sick child encompass anxiolysis, amnesia, analgesia, and facilitation of care. It can be given to facilitate a procedure or to attain optimum comfort and patient ventilator synchrony in critical care units. The ideal sedation management plan for any patient who is mechanically ventilated encompasses analgesia to treat pain from the noxious stimuli of the endotracheal tube and sedation to provide adequate comfort and safety as required for the child's critical illness, while optimising patient-ventilator synchrony and minimising the risk of delirium and sleep disturbances(1). Sedation and analgesia in the PICU are often needed for prolonged periods of time, and optimal agents for long term sedation differ from those used for procedural sedation. Scoring methods have been designed to assess for pain, depth of sedation and delirium(2).

Sedation Assessment; Sedation in the PICU should be titrated depending on the underlying clinical condition and nature of required therapeutic, or invasive procedures. Administration of sedative agents is associated with substantial patient morbidity and mortality. Due to this reason optimal sedation management is needed which requires assessing a child's level of sedation at regular intervals by using any of the validated scores(3).

The commonly used sedation assessment tools include; the SBS defines the sedation-agitation continuum to guide goal-directed therapy using a patient's response to voice, gentle touch, and noxious stimuli such as suctioning.

The COMFORT Scale measures 5 behavioural variables (alertness, facial tension, muscle tone, agitation, and movement) and 3 physiologic variables (heart rate, respiration, and blood pressure).

The COMFORT-B scale is modified from the COMFORT scale by omitting the physiologic variables heart rate and BP.

The RASS score provides a single tool that is intuitive, easy to use, and includes both agitation and sedation. Agitation is scored from +1 to +4 and sedation is scored from -1 to -5 with 0 being alert and calm(4).

1.2. Statement of the problem

In most of PICUs level of sedation is evaluated by an informal method by the patients' nurses and physicians. There is also significant inter patient variability of a sedative to achieve the same effect. Which makes it difficult to attain the desired optimal level of sedation(5). This study will address the problem of suboptimal level of sedation in PICU.

Suboptimal level of sedation is more often correlated with adverse patient outcomes. Over sedation will cause delayed recovery and longer duration of mechanical ventilation. Under sedation will cause patient ventilator desynchrony, risk of myocardial and cerebral ischemia and accidental ETT dislodgement and removal(6).

Three studies showed high proportions of suboptimal level of sedation. The one done in PICU in Netherlands ascertained optimal level of sedation in 57.6% and suboptimal level in 42.4% of observations made using validated sedation scores. The other study done in a general PICU in Nottingham, UK found an optimal level of sedation in 79% of observations and suboptimal level in 21% of observations. The third study done in university of Pennsylvania, Philadelphia showed about 70% of cases with suboptimal sedation(7–9). Nonetheless, these studies didn't determine associated independent factors that may affect the level of sedation.

According to a study done in Singapore, the use of sedation protocol using validated scores has been a focus of increased interest and practice. However, the quality of Paediatric studies done thus far remains poor. Future research in this aspect of critical care is urgently needed in PICU(10). Another study done in Baltimore, USA found correlation of suboptimal level of sedation with worth clinical outcomes of prolonged duration of ICU stay, prolonged duration of MV and high mortality. Which warrants timely study of sedation practice in middle and low income countries(11).

A variety of studies were done to determine the correlation between suboptimal level of sedation and worse patient outcomes(12–14). However, they didn't find a consistent and clear association between those variables. In addition to this, there are little studies done about the quality of level of sedation and its impact on patient outcomes in critically ill children, in the developing countries.

Therefore, due to the scarcity of data on level of sedation and the influence on patient outcomes in paediatrics, there's a growing need to study this area.

The purpose of this study was to assess the level of sedation in intubated critically ill children in JUMC as a primary outcome and its associated factors, and to determine the effect of level of sedation on adverse patient outcomes as a secondary outcome measure.

1.3. Significance of the study

This research would benefit the community, in that there would be better service quality, improved patient outcomes and decreased medical costs.

This research would benefit the institution in that policy makers will create and revise protocols in paediatric critical care.

This research would benefit critically ill children in the PICU, in that they would get improved critical care services which will improve their outcomes.

Through the data and analysis that this research would provide, it would serve as a foundation for future researchers.

This research study is a great experience to me in the field of research and is my final paper to be submitted to the department of anaesthesiology in JUMC.

There are limited studies in the developing countries regarding the quality of level of sedation and its impact on patient outcomes. So that knowing the effect of quality of level of sedation on adverse patient outcomes could shift physicians practice from empirical intensivist based sedation to protocol-based sedation.

2. Literature review

Methods of Assessment of level of sedation in intubated critically ill children

There were five cohort studies in which sample size ranged from 10 to 1,326 patients. Data were collected through medical chart reviews in all studies except one study which used purposive sampling. Sedation assessment tools used included the COMFORT scale, COMFORT-B scale, and hospital-developed tools(13,15,16). Italian Society of Neonatal and Paediatric Anaesthesia and Intensive Care recommends sedation measurement has to be performed using SBS and COMFORT Scale(17).

The UK Paediatric Intensive Care Society Sedation, Analgesia and Neuromuscular Blockade Working Group recommends; level of sedation should be regularly assessed and documented using a sedation assessment scale, COMFORT scale(18).

Impact of level of sedation on incidence of delirium and VAP

One before and after quasi experimental study showed that the intervention has an effect on the rate and incidence of ventilator associated pneumonia but not statistically significant. The study was done in a 23 bed PICU of university affiliated hospital(19). There are limited studies regarding delirium incidence but one large prospective cohort study showed that regardless of the level of sedation, benzodiazepine exposure is associated with the development of longer duration of delirium and lower likelihood of PICU discharge(20,21).

Impact of level of sedation on duration of mechanical ventilation

Two studies(14,22) reported significant decrement in duration of mechanical ventilation after implementation of sedation protocol using the COMFORT scale. The former is a Quasi-experimental study done in Asian medical centre, in Korea. The latter is a before and after protocol implementation study done in one of university affiliated teaching hospital in France.

Another two phase observational study(23) which was done in post cardiac surgery patients with TOF at the PICU of tertiary referral hospital in Germany which showed that after implementation of the analgesia and sedation protocol using COMFORT scale , the median time on a ventilator was shorter, but not statistically significant.

Impact of level of sedation on PICU LOS

Three studies reported on the association between initiation of sedation protocol and reduced PICU LOS. However, this difference was only statistically significant in one study. Although this study did not performed multivariable analysis to control for severity of illness scores, there were no significant differences between the demographic characteristics, severity scores, and diagnosis between the control and intervention groups(16,23,24).

Another study done in a 14 bed medical surgical paediatric intensive care unit showed decrement in the median LOS in the PICU after implementation of sedation protocol using COMFORT scale(23).

Impact of level of sedation on PICU mortality

Two studies that examined the impact of sedation protocol on PICU mortality showed that there was a difference between the intervention and control groups but was not statistically significant. This studies also reported a significant decrease in the frequency of unplanned extubating(16,24).

Impact on sedation duration and use

Five studies described the impact of sedation protocol on sedatives duration and total dose used. Three studies were prospective cohort with historical control and two of them were retrospective cohort with historical control. Two of them reported significant reduction in total duration of sedative use (both IV and enteral). In another study median duration of sedation was reduced in the sedation implementation group compared with the control group. When sedation protocol was used in conjunction with continuous fentanyl or clonidine infusion the total dose required for each drug was significantly less. However, there was no significant difference in total dose used when sedation protocol involved continuous IV sedative infusions of midazolam, morphine and ketamine(13,20,22,24,25).

Impact on clinical practice

One study Showed that the use of protocol brought positive changes in the clinical practice in that there is improved quality of analgesia and sedation and supports nurses decision making(25).

2.1. Conceptual framework

There are several factors, which can affect and be associated with level of sedation. In this study, factors that we will assess include demographic factors (age, sex, and weight), diagnosis at admission, comorbid illness, type of sedative, and infusion/intermittent bolus. This conceptual framework is developed by the principal investigator after reviewing different literatures(12,22,26).

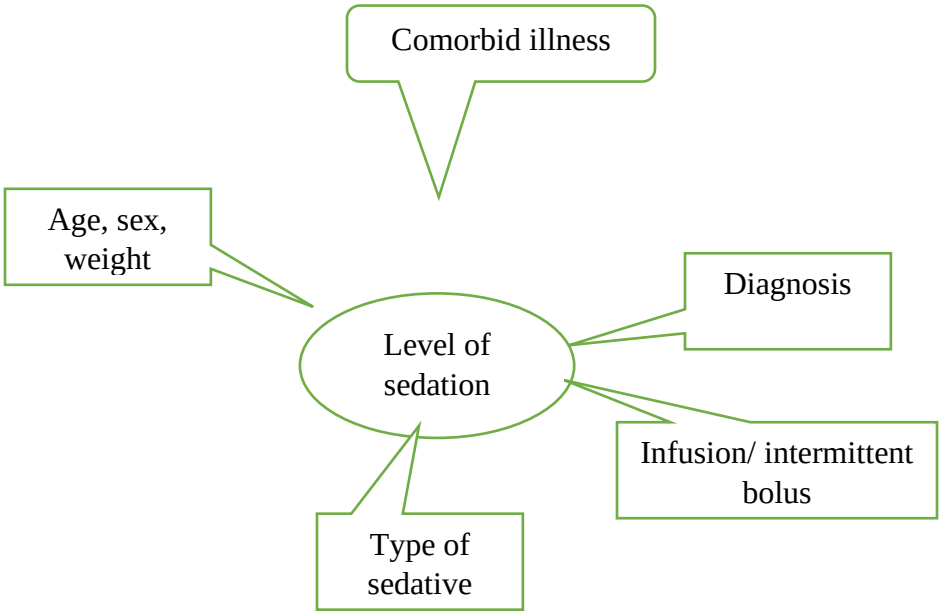

Figure 1. Conceptual framework

3. Objectives

3.1. General objective

To assess level of sedation and its associated factors among intubated critically ill children admitted to paediatrics intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August 2021 to December 2021.

3.2. Specific objectives

- To assess level of sedation among intubated critically ill children in paediatric intensive care unit.
- To assess factors associated with level of sedation
- To assess duration of mechanical ventilation among intubated critically ill children in paediatric intensive care unit.
- To assess duration of stay in paediatric intensive care unit in intubated critically ill children.
- To assess rate of unplanned extubating in intubated critically ill children in paediatric intensive care unit.

4. Methods and material

4.1. Study area and period

The study was conducted in Ethiopia, Oromia regional state, Jimma town at Jimma university medical center located 352 km southwest of the capital Addis Ababa. It was inaugurated as a new medical center on December 08, 2018 as the only teaching and referral hospital in the southwestern part of the country. It is delivering services for almost 15000 inpatients, 160000 outpatient attendants, 11000 emergency cases and 4500 deliveries in a year coming to the hospital from the catchment population of more than 15 million people. It has 1600 staff members and 800 beds.

The hospital has three ICUs (pediatrics, medical and surgical) with 13 beds. The PICU has 4 beds serving critically ill children. One pediatrics intensivist, anesthesiology residents, and nurses run the PICU. Study period was from August, 2021 to December, 2021.

4.2. Study design

Institution based prospective observational study was conducted.

4.3. Population

4.3.1. Source of population

All patients who were admitted to PICU of JUMC, Jimma, Ethiopia.

4.3.2. Study population

All critically ill intubated children admitted to PICU of JUMC, Jimma, Ethiopia, from August to December 2021.

4.4. Inclusion and Exclusion criteria

4.4.1. Inclusion criteria

All Patients age from 0 to 14years old who were critically ill and intubated from August 2021 to December 2021.

4.4.2. Exclusion criteria

Comatose patients, neuromuscular disorders and patients who took neuromuscular blockers.

4.5. Sample size determination and Sampling technique

4.5.1. Sample size determination

The sample size was calculated using single population proportion formula. The following assumptions were considered during determination of the sample size for the study:

- P= 0.5 (the level of sedation among mechanical ventilated children in PICU was not studied in JUMC)
- Z= standard normal distribution value at 95% CI=1.96
- d= margin of error = 5%

Sample size estimate using the following assumption like;

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

Where, n=minimum Sample size

Zα/2=Z Value at (α=0.05) =1.96

d=Margin of error (0.05)

So, minimum sample size n=384.16 ~384 p=50%

Accordingly, the calculated sample size would become 384.

Since, the population was relatively small (less than 10,000) the principal investigator adjusted the sample size by using correction formula as follows

$$n = \frac{n_0}{1+\frac{n_0}{N}} \qquad n = \frac{384}{1+\frac{384}{120}} \quad n= 91.42\sim 91$$

Where, n= new sample size = 91

n_0= initial sample size= 384

N= estimated N in a one-year period from 2020 = 120

By adding 10% non-response rate, the sample size would be 100.

4.5.2. Sampling technique

Participants were all children below the age of 14 years old. Each intubated and mechanical ventilated patients, who met inclusion criteria, during the data collection period were included. Though we assumed to continue sampling until we get the required sample size, we didn't get the required number due to limited number of mechanical ventilators in PICU and short period of time we had.

4.6. Variables

4.6.1. Dependent variables

- Primary outcome: Level of sedation
- Secondary outcomes:
  - Unplanned extubation
  - Duration of mechanical ventilation
  - Length of PICU stay
  - Mortality rate

4.6.2. Independent variables for the primary outcome

- Demographic variables: - Age, sex, and weight
- Patient clinical characteristics at admission: - Reason for mechanical ventilation, presence of comorbid illness, GCS at admission.
- Type of sedative medication used and whether it was infusion form or intermittent bolus form.

4.7. Data collection tool and procedures

After reviewing different literatures, a written structured questionnaire in English language was prepared to assess level of sedation, associated factors and patient outcomes among critically ill children admitted to PICU of JUMC. On the day of admission of each patient, the admitting resident who was in charge of the patient recorded the demographic and clinical characteristics of the patient on the daily PICU follow-up chart. The questionnaire included questions related to demographic data, reason for mechanical ventilation, GCS at admission, type of sedative used,

infusion or intermittent bolus, each component of the COMFORT scale and all secondary outcome variables. Data collectors followed patients daily and data was collected anytime the patient was put on sedative medication until the patient died or discharged from PICU. The patients COMFORT scale was recorded three times, each with an 8 hrs gap. Every day, the partially filled questioners were kept with the responsible data collectors and data collection was continued on consecutive PICU days of stay until the outcome of the individual patient was known.

The principal investigator gave two days of training and explanation for the nurses and residents who were working in PICU. The training was on the objectives of the study, the contents of the questionnaire and on matters related to the confidentiality.

4.8. Data processing and analysis

Clinical data of the patients including age, gender, weight, diagnosis, length of stay on PICU, duration of mechanical ventilation, type of sedative medication used and scoring data of the COMFORT scale was obtained from the questioners. The data obtained was edited, coded and entered on Epi data manager (software version 4.6.0.2). Then that data was exported to Statistical analysis for the Social Science Software (SPSS) version 26 for analysis. Descriptive data was presented as counts and percentages for categorical data. The continuous variables were presented as means, and standard deviations. Continuous explanatory variables were categorized. To determine the association between level of sedation and patient outcomes repeated measure ANOVA test was used. For a p-value <0.05 as statistically significant. The magnitude of association was measured by wilk's lambda value with 95% confidence interval. To determine if there was any association between the independent variables and level of sedation, chi square test was used.

4.9. Data quality control

Three days before the actual start of data collection the principal investigator performed pretesting the questionnaires to make sure that the questions were clear to the data collectors. Then, revision was made on questions that were found to be ambiguous and difficult. To ensure the completeness, accuracy and consistency of data collection, a thirty minutes' session was held with the data collectors each day before the start of data collection. During these sessions, thorough checking was done before using the questionnaires. On-site technical support and close supervision was

done. Data editing was done on a daily basis to check for accuracy, consistency and completeness of the questionnaires. Data was entered and cleaned before analysis.

4.10. Operational definition

- **Comorbidity:** any medical conditions that a patient had in addition to the the primary diagnosis that led to PICU admission and mechanical ventilation.
- **GCS:** it is the summation of scores for eye, verbal, and motor responses. The minimum score is a three, and the maximum is 15. GCS </=8 is coma.
- **COMFORT scale:** Each score is from 1 to 5, the total score ranging from 8 to 40. Patients are optimally sedated if COMFORT scale is between 17 and 26, under sedated if COMFORT scale is above 26, and over sedated if COMFORT scale is below 17. Under sedation and over sedation are suboptimal levels of sedation.
- **PICU:** is an abbreviation for pediatric intensive care unit, an area with in a hospital specialized in the care of critically ill infants, children and adolescents.
- **Duration of MV**: the number of days in which an intubated critically ill children stayed intubated and on mechanical ventilator until discharged improved or died.
- **Prolonged Duration of mechanical ventilation:** there is no standard definition in pediatrics. We used continuous mechanical ventilation for more than 7 days based on our clinical knowledge.
- **Duration of PICU stay**: the number of days that a critically ill child stayed in PICU until discharged improved or died.
- **Prolonged LOS in PICU:** if child stayed greater than or equal to 14 days.
- **Unplanned extubation:** if a patient removed an ETT while fighting, without PICU physicians or nurses' decision to do so.
- **Removal of invasive lines:** if a patient removed any invasive line while fighting, without PICU physicians or nurses' decision to do so.

- **Mortality rate:** the number of deaths among critically ill children in the PICU, who met the inclusion criteria, after undergoing mechanical ventilation and sedation over the data collection period.
- **Infusion form:** the continuous IV administration of sedatives throughout an 8-hour, 12-hour or 24-hour period depending on the physician's order.
- **Intermittent Bolus:** the stat IV administration of sedatives divided into doses on a daily basis.

4.11. Ethical considerations

An ethical approval was obtained from the institutional ethical review board of Jimma University. The purpose of the data collection, the nature of the study and all the necessary information about the study was explained and a formal written consent was obtained from the team of nurses, physicians, patients and legal guardians who were willing to participate in the study. All data obtained in the course of the study was kept and used confidentially solely for the purpose of the research. The name of respondents or study participants was never used by any means throughout the research and participants were told they have the right to withdraw themselves from study anytime they want.

4.12. Dissemination plan

This research will be presented for partial fulfillment of specialty certificate in anesthesiology and critical care. The Soft copy and hard copy of finding of this research will be disseminated kindly to the department of anesthesiology and for selected department of the hospital. Finally, the result of the study will be disseminated to the scientific community through seminars, workshops, and conferences of health professionals' association and publications in peer-reviewed scientific journals.

5. Result

5.1. Socio-demographic characteristics

The mean age of children was 37.7 month with (SD±13). Twenty-one (75%) were below the age of sixty months. Whereas, 15(53.6%) were male. The mean weight of children during admission was 13 kg (SD±13). (See table one given below).

Table 1: Socio-demographic characteristics among intubated critically ill children admitted to paediatrics intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August to December 2021(n=28).

Variables	Categories	Frequency (n= 28)	Percent (%)
Age	<12 months	9	32.1
	>=12 months	19	67.9
Sex	Male	15	53.6
	Female	13	46.7
Weight in kg	<20 kg	26	92.9
	>=20 kg	2	7.1

5.2. Clinical characteristics at admission

Whereas, the mean GCS level during admission was 13.8 (SD±1.4). IRF secondary to severe pneumonia + first episode wheezing accounted for 4(14.3%) of diagnosis during admission. Regarding comorbidity, 4(14.3%) had co-morbidity. Of those with co-morbidity, CHD secondary to VSD, CHF + AKI + hypokalemia and hypernatremia, hyperkalemia and hypernatremia and septic shock each accounted for one case. (See table 2 given below).

Table 2: Clinical characteristics at admission among intubated critically ill children admitted to paediatrics intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August to December 2021(n=28).

Variables	Categories	Frequency (n=28)	Percentage (%)
GCS	12-14	12	42.9
	15	16	57.1
Co-morbidity	Yes	4	14.3
	No	24	85.7

5.3. Sedative medication related characteristics

All i.e. 28(100%) of the children were taking sedative medications. Twenty-two (78.6%) were taking morphine as a sedative medication. Twenty-five (89.3%) were taking the sedative medication as an infusion form.

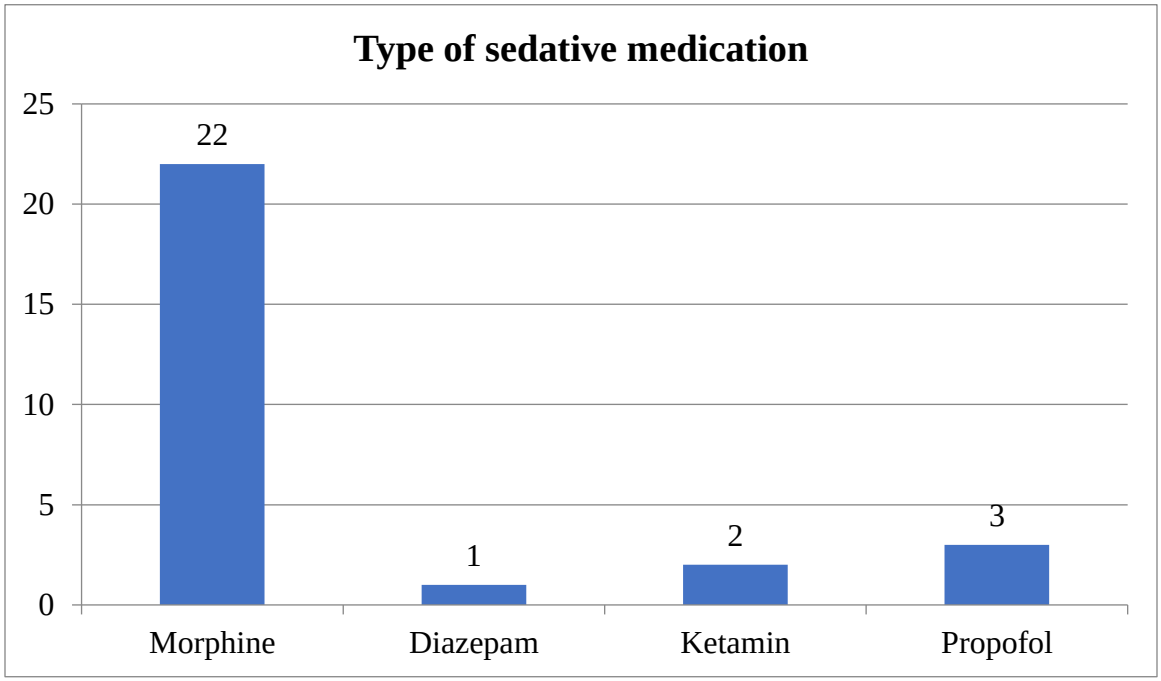

Figure 2: Type of sedative medication used among intubated critically ill children admitted to paediatrics intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August to December 2021(n=28).

5.4. Patient's level of sedation using COMFORT scale

Patient's level of sedation was assessed based on COMFORT scale assessment method. The COMFORT level was evaluated three times a day. Accordingly, in the baseline 15(3.5%) had optimum level of COMFORT scale. While, in the 8th hrs. COMFORT level measurement, 15(3.5%) had sub optimum level of COMFORT scale. Also, 18(64.3%) had sub optimum level of COMFORT scale in the 16th hrs. (See figure 2 below). Overall, of the total 84 observations made 45.2% of COMFORT scale was optimal and 54.8% was sub optimal level of sedation.

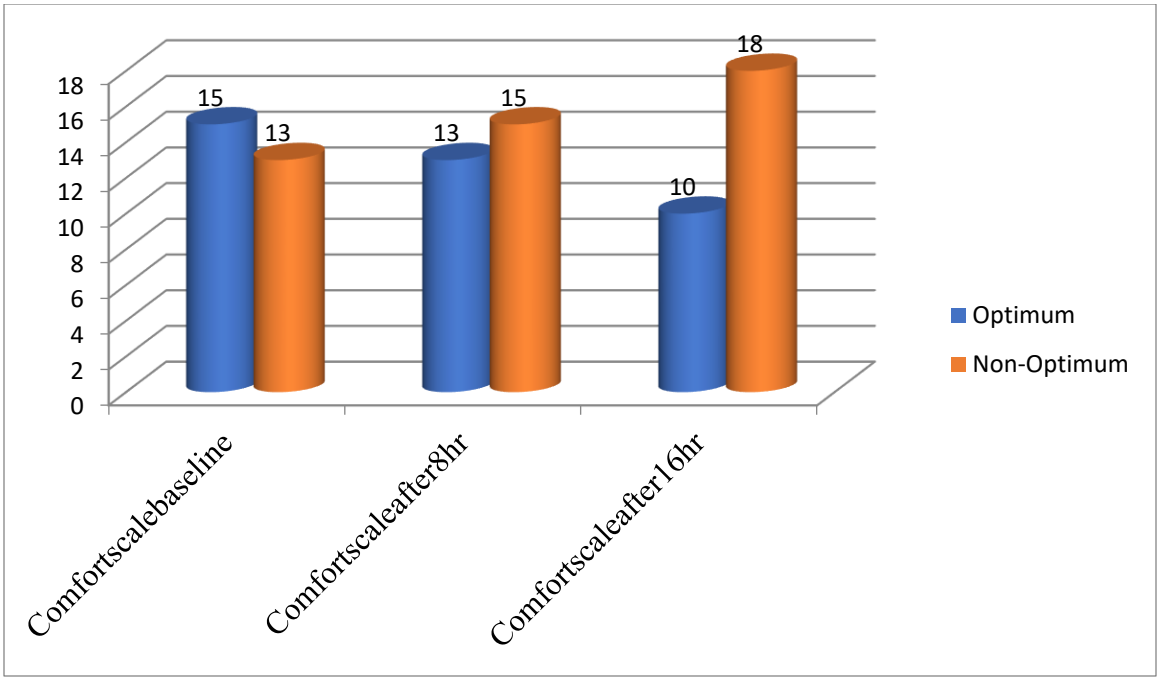

Figure 3: Patient's level of sedation using COMFORT scale among intubated critically ill children admitted to paediatrics intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August to December 2021(n=28).

5.5. Patient Outcome

The mean duration of mechanical ventilation in days and the duration of PICU stay in days was 3 and 5 respectively. Sixteen (57.1%) stayed with MV for 1-3days. Nonetheless, 17(60.7%) stayed in PICU for >3days. Two (5.5%) had unplanned extubation. Regarding mortality rate, 8(28.6%) of patients died and 20 (71.4%) were discharged improved (See table 3 and Figure 3).

Table 3: Patient outcome among intubated critically ill children admitted to pediatric intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August to December 2021(n=28).

Variables	Categories	Frequency (n=28)	Percentage (%)
Duration of MV in days	< 7	27	96.4
	7- 14	1	3.6
Duration of PICU stay in days	< 14	27	96.4
	>=14	1	3.6
Unplanned extubating	Yes	2	7.1
	No	26	92.9
Removal of invasive lines	Yes	0	0
	No	28	100

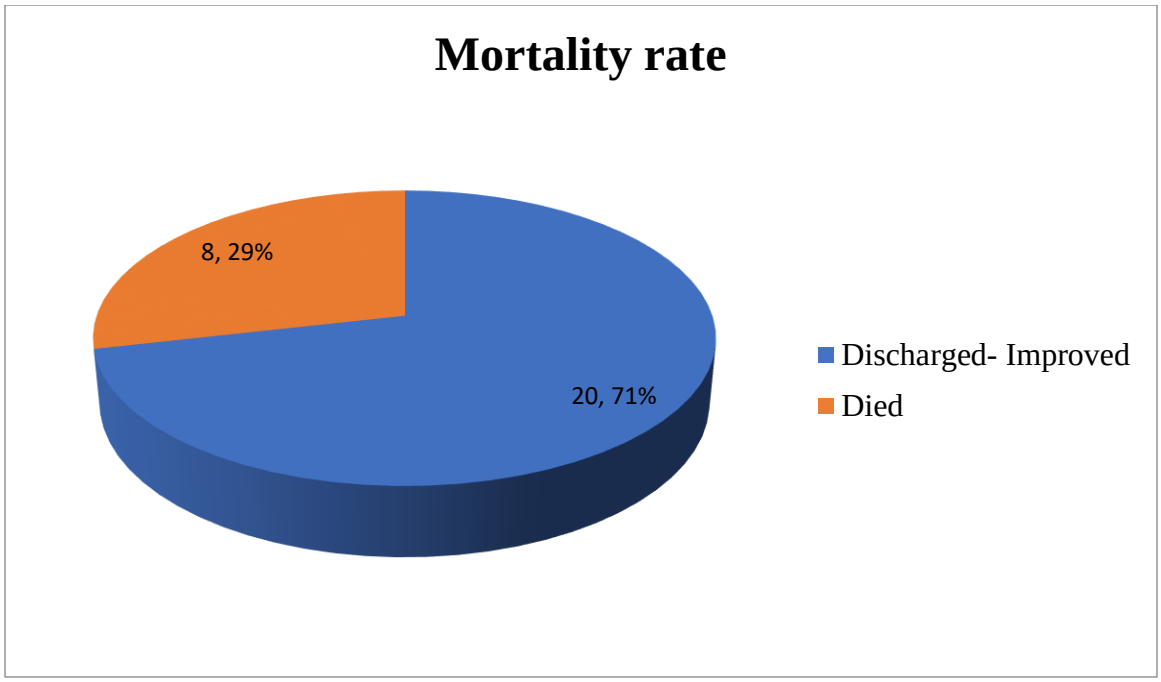

Figure 4: Patients' outcome among intubated critically ill children admitted to paediatrics intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August to December 2021(n=28).

5.6. Association between COMFORT scale in baseline, after 8 hours and after 16 hr. with patient outcome

To test for whether patient COMFORT scale has an effect on patient outcomes i.e. (Duration of PICU stay, duration of MV, unplanned extubation, and mortality rate) they were examined using repeated measure ANOVA test. Accordingly, there was strong statistically significant change in mortality rate depending on the COMFORT scale measures. Nonetheless, there was no statistically significant change in patient outcome measures: unplanned extubation, duration of PICU stay, duration of MV. (See table below).

Table 4: Repeated Measure ANOVA analysis between COMFORT scales at different time on patient outcome among intubated critically ill children admitted to pediatric intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August to December 2021(n=28).

Independent Variables	Dependent Variables							
	Duration of stay in PICU (in days)		Duration of MV		Unplanned extubation		Mortality rate	
	Wilk's Lambda value	P-Value	Wilk's Lambda value	P-Value	Wilk's Lambda value	P-Value	Wilk's Lambda value	P-Value
Comfort scale Measured at (Baseline, after 8 and after 16hr)	0.925	0.357	0.956	0.57	0.967	0.857	0.725	0.018*

5.7. Factors associated with COMFORT score

The existence of association between the independent variables (like age, comorbidity, type and form of sedatives used) and the aggregate COMFORT scale were assessed using chi square test. With this sense, there was strong statistical association between COMFORT score and comorbidity. In spite, there was no statistically significant association between COMFORT score and age, type of sedative and infusion/intermittent bolus. (See tables given below) (n=28).

Table 5: Factors associated with COMFORT scales at different time on patient outcome among intubated critically ill children admitted to pediatric intensive care unit of Jimma University Medical Centre in Jimma, Ethiopia from August to December 2021(n=28).

Variables	Categories	Aggregate COMFORT scale category		Pearson Chi square	P-value
		Optimal	Sub-Optimal		
Age	< 12 months	4 (44.4%)	5 (55.6%)	0.014	0.907
	>= 12 months	8 (42.1%)	11 (57.9 %)		
Comorbidities	Yes	1 (25.0%)	3 (75.0%)	0.68	0.0132*
	No	11 (45.8%)	13(54.2%)		
Type of sedative medication	Morphine	9 (40.9%)	13 (59.1%)	3.5	0.35
	Diazepam	0(0.0%)	1 (100.0%)		
	Ketamine	2 (100.0%)	0(0.0%)		

	Propofol	1(33.3%)	2(66.7%)		
Form of sedative medication	Continuous infusion	10 (40.0%)	15 (60.0%)	0.77	0.37
	Intermittent bolus	2 (66.7%)	1(33.3%)		

6. **Discussion**

The finding from this study shows that the level of sedation in critically ill children is often suboptimal during their stay in PICU on mechanical ventilation. Patients were optimally sedated in only 45.2% of observations. Whereas the proportion of suboptimal sedation was 54.8%. This goes in line with the large meta-analysis done in Norway(7) which showed an optimal level of sedation in 57.6% and suboptimal level of sedation in 42.4% of observations. This prospective observation shows that there is evidence of a strong statistically significant effect of level of sedation on mortality rate, wilk's lambda value of 0.725, p-value of 0.018. Which implies that the mean of group of patients with optimal level of sedation who were discharged improved was greater than those with suboptimal level of sedation with an error rate of 27.5%. Which means that optimal level of sedation plays an important role to reduce mortality rate in critically ill children. Furthermore, the other finding from this study shows that there is evidence of a statistically significant association between comorbidity, as an independent variable and level of sedation.

Somewhat surprisingly, in this study there is no evidence of statistically significant effect of level of sedation on duration of mechanical ventilation, duration of PICU stay and rate of unplanned extubation. Nonetheless, two of the patients who extubated their ETT unplanned had inadequate level of sedation, based on the COMFORT scale, before they extubated. Researches showed that there was evidence of significant effect of level of sedation on those variables. The effects were optimal level of sedation resulted in decreased duration of mechanical ventilation, decreased duration of PICU stay and decreased rate of unplanned extubation(14,16,19,23,24). This difference may have happened due to the small sample size and the designed nature of this study. Interestingly, however the other researches done showed there was no statistically significant effect of level of sedation on the above dependent variables(12,13).

Quite surprisingly there was no statistically significant correlation between type of sedative medication and form of administration, and level of sedation. One study showed that sedation by continuous infusion was an independent risk factor for over sedation(11). Another study showed that benzodiazepines were significantly associated with over sedation and increased mortality rate(21). This unmatched finding might be due to the smaller sample size and unequal proportion of sedative medications used and the form of administration during this study.

One must ask the reason by which suboptimal level of sedation is common. It is possible that it happens due to first, there is no adherence to sedation protocols so that dosage not decreased or increased when needed to be, second fear of removal of invasive lines and ETT nurses and physicians give additional bolus doses, and third fear of hemodynamic perturbations nurses have a tendency not to increase dose when needed to be(7). Other possible explanations include infusers which are not properly functional, and respiratory causes as an admission diagnosis. One study showed an increased incidence of inadequate level of sedation in mechanical ventilated bronchiolitis patients(26).

One must also ask the explanation for the correlation of mortality rate and level of sedation. It is a probability that over sedation may be one cause of cardio respiratory depression and worse patient outcomes including death, the other mechanism might be related with an over sedation resulting in prolonged mechanical ventilation and increased hospital acquired infections and increased risk of mortality. Under sedation might be a cause for unplanned extubation and risk of airway injury and hypoxemia if not recognized timely(27). In both conditions there is a probability of death due to suboptimal level of sedation. Even though it was done in adults, there was an evidence of increased ICU mortality rates due to over sedation(21,28).

Another question to be raised is why there is an association between comorbidity and level of sedation. Comorbidities might increase the sensitivity of a patient to sedative medications which might result in over sedation. For instance, in the presence of liver disease there is decreased drug metabolism and in the presence of renal disease there is decreased drug clearance which might lead to an over sedation.

7. Strengths and limitations of the study

7.1. Strength

This is the first prospective study done in JUMC on this topic and it lays a foundation for future researchers. In addition to its prospective nature, incomplete and poor data recording were managed appropriately.

7.2. Limitations

The sample size was small due to the limited availability of mechanical ventilators in the PICU of JUMC, which decreased the influx of cases to undergo mechanical ventilation.

This study is only an observational study done in a referral hospital with a small sample size, which makes it difficult to apply to the general population of critically ill children.

The most important confounding factor which affects mortality rate is severity of illness which could be assessed using PRISM lll score, which was not done in this study due to absence of blood gas analysis.

8. Conclusions and recommendations

8.1. Conclusion

This small preliminary study showed a high proportion of suboptimal level of sedation among intubated critically ill children. There is evidence of strong statistically significant change in mortality rate based on level of sedation. The mean of group of patients discharged improved was greater with optimal level of sedation. There was also an association between comorbidity, as an independent factor, and level of sedation, but we didn't identify the specific association.

8.2. Recommendations

To Researchers: large scale study to clearly determine the effect of level of sedation on each of the specific patient outcomes, is needed in the low-income countries. This study can be an excellent foundation for future researches to be done on this topic.

To anesthesiology department: This preliminary study is part of an ongoing research being done in PICU, and hence one resident must take over to continue the data collection.

To health professionals: level of sedation must be assessed regularly in critically ill children using a validated score.

To JUMC: sufficient number of functional mechanical ventilator must be available in PICU.

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Annexes

Annex 1: Information sheet & consent form

Assessment of level of sedation as under, optimal and over sedation using COMFORT scale and its impact on duration of mechanical ventilation and duration of PICU stay among patients admitted to PICU of JUMC from August to December, 2021 at, Jimma town, Ethiopia.

Introduction: Good day! I am _____ from JUMC and working with investigator Moges Sahle (MD) who is doing his thesis for partial fulfillment of the requirement for a specialty certificate in anesthesiology. I kindly request you to lend me your attention to explain about the issue raised here below.

Purpose: The study will be, helpful to assess level of sedation and its impact on duration of mechanical ventilation and duration of PICU stay among patients admitted to PICU from august 1 to December 30, 2021at JUMC. The Information collected during this study could be used by the MOH, JUMC, organizations supporting the services, and researchers, for planning health service improvement or for conducting further studies on quality health services. Furthermore, the main aim of this study is to write a thesis as a partial requirement for the fulfillment of specialty certificate in anesthesiology.

Procedure, risk and duration: First of all, the patient will be selected to take part in this study because of convenience. There are some questions to be filled on the questioner by checking on the patient card, daily PICU follow-up chart, and patient's legal guardian. The data will be collected starting on the day of admission until the patient outcome from the PICU is known. The risks of being participated in this study are very minimal, only taking few minutes from your day. Other than this, the study will not cause any physical harm on anybody or the organization.

Confidentiality: The information provided will be confidential. There will be no evidence that will identify you. The findings of the study will be general for the study population and will not reflect anything particular of individual person. The questioner will be coded to exclude showing names; no references will be made on reports that could link participants to the research.

Risks and discomforts: No subject is obliged to take part in this study and you may withdraw from the study any time you want.

Would you be willing to participate in the study?

1. Agree_____

2. Disagree _____

Signature of the data collector: _____

Annex 2: Informed consent form Amharic version

የመጠይቅ ፈቃድ

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

የመጠይቅ ፈቃደኛነት ቅጽ

ስሜ_____ይባላል፡፡ እኔ በጂማዩኒቨርሲቲ በአንስቴሽሎጂ ትምህርት ክፍል የምርምር ቡድን ዉስጥ አንድ አባል ነኝ፡፡ የዚህ መጠይቅ አላማ.

የ ጽኑ ህሙማን ክፍል ታካሚዎች ውጤት እና ተያያዥ ነገሮችን ለማዎቅ ለሚደረገው ምርምር/ጥናት /መረጃ ለመሰብሰብ ነው፡ ፡እርስዎ አንድ የጥናቱ ክፍል አድርጌ ስመርጥ አስፈላጊ የሆኑ መረጃዎችን እንደሚሰጡኝ በማሰብ ነው፡፡ በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ ከእርስዎ የሚገኘው ማንኛውም መረጃ በሚስጥር ይጠበቃል፡፡ ለዚህም ሲባል የእርስዎ ሥም እና አድራሻ አይገለጽም፡፡ እንዲሁም ከጥናቱ በኃላም ጽኑ ህሙማን ክፍል ታካሚዎች ውጤት እና ተያያዥ ምክንያቶችን ለማዎቅ እና ተገቢ የሆኑ እርምጃዎን ለመዉሰድ ይረዳል፡፡

የቃል ሥምምነት

የዚህ ጥናት ዓላማው ገብቶኝ በጥናቱ ለመሣተፍ

ሀ. ፈቃደኛ ሆኛለሁ ለ. ፈቃደኛ አይደለሁም

በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ ቃለመጠይቁን መቀጠል ይቻላል፡፡

ፈቃደኛ ከሆኑ የመጠይቁ መለያ ቁጥር _____ መጠይቁ የተካሄደበት ቀን _____

የጠያቂው ስምና ፈርማ _____

የሱፐርቫይዘር ስምና ፈርማ _____ ጥናቱን በተመለከተ ማንኛዉም አይነት ጥያቄ ካላችሁ የሚከተለዉን አድራሻ ተጠቀሙ፡: mogessahle@yahoo.com

Annex 3: Informed consent form Afaan Oromo version

Walii galitee

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

Qoranoo Kun kan inni irratti xiyeefatee, waa'ee yaalamtota kutaa namoota gar malee dhibamani itti ciisani kessa yaalaman irratti. kanaafuu qorannoo kana irrattii wanta isin irraa eegamu akka nuufgotan kabajaan isin gaafanna. Kunis ammoo fayyaa yaalamtota garmalee dhukkubsatan irratti fayidaa fi jijjiirama guddaa ni fida. Waliigaltee fi eyyama kessaniin malee iccitii kessan nama biraaf yookin ammoo waajira tokkoofuu akka dabarsinee hin kenninee waadaa isiniif galla.

Yoo qorannoo kana irratti hirmachuu kessan waliigallee, gaaffii waliigalaa irraa isiniif jaliqabna. Deebii kessan kan dhugaa irratti hundahee yoo kennitan fayidaa jijjiirama fayyaatif nuf gargaara. Qorannoon Kun karaa univarsitii Jimma irraa fudhatama argatee jira. Kanafuu qorannoo kanarratti hirmaachuuf fedhii qabduu?

1. naan qaba ……. Deebiin nanqaba yoo jette gaafii itti anutti fufi.

2. Hin qabu …… deebiin hinqabu yoo jette, galatomaa jedhiiti gaafii addaan kuti.

Fedhii qorannoo adeemsisuuf yaada namarraa kan fuudhu.

Maqaa_____

guyyaa gaaffii itti gaafatame ……/…../..... mallattoo…….

Hordofa isaatin mirkana'u kan muli'isu

Maqaa……guyyaa……../……. /……mallattoo…….

Annex 4: Questionnaires

Part one: sociodemographic characteristics

Directions: please circle the appropriate number or fill in the blank

Questioner Code----------

1. Age in years ----------
2. Sex of the patient
   A. Male
   B. Female
3. Weight of the patient (in Kg)

Part two: clinical data of the patient

4. What is the Date of admission of the patient to the PICU (Gregorian calendar)?
   A. date
   B. month
   C. year
5. What is the main reason/diagnosis that led the patient to be admitted to PICU?
   A. P-1----------
   B. P-2 ----------
   C. P-3----------
   D. P4----------

6. Prior to PICU admission of the patient, does the patient had any identified co-morbidities?

   A. Yes
   B. No

7. If the answer yes for the above question, specify the comorbidities
   A. Cardiovascular disease (specify) _____

B. Respiratory disease (specify) _____
C. Neurologic disease (specify) _____
D. Endocrine disease (specify) _____
E. Infectious disease (specify) _____
F. Renal disorders (specify) _____
G. Gastrointestinal diseases (specify)
H. Malignancy (specify) _____
I. Other (specify) _____

8. What is the GCS/ mental status of the patient at arrival for admission to PICU? ----------

Part three: sedative medication used

9. Is the patient taking sedative medications?
A. yes
B. no
10. If the answer for the above question is yes, which sedative medication is he/she taking?
A. Ketamine
B. Propofol
C. Diazepam
D. Morphine
E. Other (specify)

11. If the patient is taking any of the sedative medications, in which form?
A. Intermittent bolus
B. Continuous infusion

Part four: patients level of sedation using COMFORT scale

12. What is patient's baseline COMFORT scale?
A. Alertness

1, deeply asleep 2, lightly asleep 3, Drowsy 4, fully awake 5, Hyper alert

B. Calmness/agitation

1, Calm 2, slightly anxious 3, Anxious 4, Very anxious 5, Panicky

C. Respiratory response

1, No coughing and no spontaneous respiration

2, spontaneous respiration with little or no response to ventilation.

3, occasional coughing or resistance to ventilator.

4, actively breaths against ventilator or coughs regularly.

5, fights ventilator, coughing or choking

D. Physical movement

1, No movement 2, Occasional, slight movement 3, Frequent, slight movement

4, vigorous movement of only extremities 5, vigorous movement including head & torso

E. Blood pressure (MAP)

1, below baseline 2, consistently at baseline 3, Infrequent elevation >=15% 4, Frequent elevation >=15% 5, Sustained elevation>=15%

F. Heart rate

1, below baseline 2, consistently at baseline 3, Infrequent elevation >=15%

4, Frequent elevation >=15% 5, Sustained elevation >=15%

G. Muscle tone

1, Totally relaxed 2, Reduced 3, Normal 4, Increase tone & finger flexion

5, Extreme rigidity & finger flexion

H. Fascial expression

1, Totally relaxed

2, Normal; no tension evident

3, Tension evident some fascial muscle

4, tension evidence throughout Fascial muscles

5, fascial muscles contorting and grimacing

13. What is patients COMFORT scale after 8 hrs of baseline?

A. Alertness

1, Deeply asleep 2, Lightly asleep 3, Drowsy 4, Fully awake 5, Hyper alert

B. Calmness/agitation

1, Calm 2, Slightly anxious 3, Anxious 4, Very anxious 5, Panicky

C. Respiratory response

1, No coughing and no spontaneous respiration

2, spontaneous respiration with little or no response to ventilation.

3, occasional coughing or resistance to ventilator.

4, actively breaths against ventilator or coughs regularly.

5, fights ventilator, coughing or choking

D. Physical movement

1, No movement 2, Occasional, slight movement 3, Frequent, slight movement

4, vigorous movement of only extremities 5, vigorous movement including head & torso

E. Blood pressure (MAP)

1, Below baseline 2, Consistently at baseline 3, Infrequent elevation >=15% 4, Frequent elevation >=15% 5, Sustained elevation>=15%

F. Heart rate

1, Below baseline 2, Consistently at baseline 3, Infrequent elevation >=15%

4, Frequent elevation >=15% 5, Sustained elevation >=15%

G. Muscle tone

1, Totally relaxed 2, Reduced 3, Normal 4, Increase tone & finger flexion

5, Extreme rigidity & finger flexion

H. Fascial expression

1, Totally relaxed

2, Normal;no tension evident

3, Tension evident some fascial muscle

4, tension evidence througuout Fascial muscles

5, fascial muscles contorting and grimacing

14. What is patients COMFORT scale after 16 hours of baseline?

A. Alertness

1, Deeply asleep 2, Lightly asleep 3, Drowsy 4, Fully awake 5, Hyper alert

B. Calmness/agitation

1, Calm 2, Slightly anxious 3, Anxious 4, Very anxious 5, Panicky

C. Respiratory response

1, No coughing and no spontaneous respiration

2, spontaneous respiration with little or no response to ventilation.

3, occasional coughing or resistance to ventilator.

4, actively breaths against ventilator or coughs regularly.

5, fights ventilator, coughing or choking

D. Physical movement

1, No movement 2, Occasional, slight movement 3, Frequent, slight movement

4, vigorous movement of only extremities 5, vigorous movement including head & torso

E. Blood pressure (MAP)

1, Below baseline 2, Consistently at baseline 3, Infrequent elevation >=15% 4, Frequent elevation >=15% 5, Sustained elevation>=15%

F. Heart rate

1, Below baseline 2, Consistently at baseline 3, Infrequent elevation >=15%

4, Frequent elevation >=15% 5, Sustained elevation >=15%

G. Muscle tone

1, Totally relaxed 2, Reduced 3, Normal 4, Increase tone & finger flexion
5, Extreme rigidity & finger flexion

H. Fascial expression
1, Totally relaxed
2, Normal; no tension evident
3, Tension evident some fascial muscle
4, tension evidence throughout Fascial muscles
5, fascial muscles contorting and grimacing

Part five: patient out come

15. The duration of mechanical ventilation of the patient in the PICU in days

16. The duration of PICU stay in days

17. Does the patient have delirium? A, yes B, no

18. Did the patient develop VAP? A, yes B, no

19. Was there an unplanned ETT extubation? A. Yes B. No

20. Was there removal of any invasive lines? A. Yes B. No

21. What is the patient outcome? A, discharged improved B, died

Annex 4: Declaration

I, the undersigned, declare that this thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been fully acknowledged.

Name: _____

Signature: _____

Name of the institution: _____

Date of submission: _____

This thesis has been submitted for examination with my approval as university advisors.

Name and Signature of the first advisor

_____

Name and Signature of the second advisor

_____

Name and Signature of the internal examiner

_____