



**College of Medicine and Health Sciences
School of Medicine and Pharmacy**

Procedural sedation and analgesia at emergency department CHUK: Effectiveness and adverse events.

Submitted in partial fulfillment of requirements for degree of
Master of medicine in Emergency medicine and Critical Care 2019

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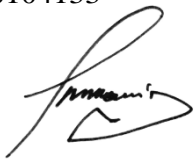
Declaration

I, hereby declare that this is my own work: **“Procedural sedation and analgesia at emergency department CHUK: Effectiveness and adverse events.”** under supervision and guidance of my professors in Emergency Medicine and critical care.

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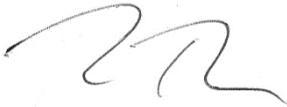
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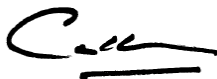
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Acronyms and Abbreviation

ABCDs: Airway, Breathing, Circulation, Disability

ATB: Antibiotics

CHUK: Centre Hospitalier Universitaire de Kigali

UTHK: university teaching hospital of Kigali

ECCM: Emergency and Critical Care

ED: Emergency Department

GCS: Glasgow Coma Scale

IRB: Institutional Review Board

IVF: Intravenous fluid

SpO₂: Oxygen saturation

PI: Principal investigator

SD: Standard deviation

RTA: Road traffic accident

UTH-K: University Teaching Hospital-Kigali

PSA: procedure sedation and analgesia

BP: Blood pressure

HR : Heart rate

HTN: Hypertension

DM : diabetis mellitus

CKD: chronic kidney injury

I&D: Incision and drainage

RASS: Richmond analgesia - sedation scale

RTA: Road traffic accident

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Abstract

Procedural sedation and analgesia at emergency department CHUK: Effectiveness and adverse events.

Introduction

The emergency department is a place where procedures to save life are performed frequently first. Procedural Sedation and Analgesia (PSA) has to be used well and one who is performing the procedural sedation has to be able to handle adverse events. Different medications are used according their availability and based on performers experience and preference. Most reported adverse effects are hypotension, tachypnea, hypoxia, bradycardia, agitation, aspiration, vomiting, and apnea.

Methods

This study is a prospective observational study evaluating procedural sedation done in the university teaching hospital Kigali (CHUK) emergency department. We evaluate the effectiveness of sedation using the Richmond Agitation Sedation Score while under sedation, and pain scale before and after the procedure. We have evaluated the common adverse events related to PSA and associated them with the medications used as and the success or failure of the procedure.

Results

251 patients were recruited. The majority were male (72 %) and female (28 %). The participants median age was 32 years (IQR23-40), youngest 8 years and oldest 88 years. The most commonly used analgesics included Morphine (78%), tramadol (17%), and ketamine least used at 1%. Commonest used for sedation included Ketamine (68%), Propofol (26%). Of procedures done in ED, 29% were for wash out with reduction of open fracture, followed by wound wash out only at 18%, shoulder dislocation (16%), abscess incision and drainage and burn were (7%). Common adverse event was hypoxia (36%) followed by hallucination (8%), 47 % didn't develop adverse events. There was no significant difference in success and failure rates between propofol and ketamine groups ($P=0.518$). There were no significant falls in HR, RR, SBP and SpO₂ in either of the ketamine or propofol groups, or overall ($P= 0.04-0.9$). There were no significant falls in HR, RR, SBP and SpO₂ in either of the ketamine or propofol groups, or overall ($P= 0.04-0.9$). All adverse events were managed successfully by operator or with the help of a supervisor.

Conclusion

The results found was similar to other studies done in developing country where hypoxia was the leading cause of adverse events. Procedural sedation can be done in low-income setting with good preparation to manage adverse events.

Key words: Procedure sedation and analgesia, Emergency medicine, adverse events

Chapter I. INTRODUCTION

Procedural sedation and analgesia (PSA), according to the American College of Emergency Physicians, is “a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardio-respiratory function. PSA is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently” [1]. For safe PSA, resuscitation materials and medication are needed for the rescue of patients from adverse events.

Medications used in low income countries are different from those used in high income countries where most of the studies analyzing adverse events took place. In this study we have used medications available in most developing countries.

1.1 BACKGROUND

The emergency department is a place where life-saving procedures requiring PSA are frequently performed. PSA has to be used carefully, and the person performing the procedural sedation has to be able to handle adverse events. The patient's level of sedation may differ depending on his physiology and comorbidities. Medication choice for procedural sedation may depend on availability as well as the medical provider's experience and preference [2]. Prior research has suggested that adverse events can occur in approximately 11% of cases [3, 5]. Most reported adverse events include hypoxia, hypotension, tachypnea, bradycardia, agitation, aspiration, laryngospasm, intubation, vomiting and apnea [6]. Serious adverse event like intubation laryngospasm, and aspiration are very rare [5,6].

The most common drugs used for PSA are dissociative (Ketamine), sedative/hypnotics (propofol), opioids (morphine, fentanyl), and benzodiazepines (diazepam, midazolam). Sometimes combinations of fentanyl /midazolam or ketamine / propofol can be used [3,4,5]. In our hospital we use primarily ketamine, propofol, diazepam or midazolam for sedation and morphine, tramadol, diclofenac or paracetamol for analgesia, they are more available.

The mode of delivering medications and dosage of these drugs depends on age, weight and medical conditions and available mode of monitoring [2,3]. Guidelines recommend that sedation be given in presence of a physician, and that a physical examination and history of previous medical condition of the patient be taken before authorizing the sedation [5]. For the patient in need of deep procedural sedation close monitoring is required, including capnography and with an experienced physician able to provide cardio pulmonary resuscitation if needed [1].

Our study aimed to evaluate the medication used, how procedural sedation is done, the frequency of adverse events, and pain control before and after the procedure also, It was aimed to evaluate the RASS (Richmond Agitation Sedation Score) for each patient before starting the procedure. The motivation to do this study was because there is no similar study that have been done in Rwanda and few even in Africa. Two descriptive studies on procedural sedation have been done in South Africa [8,9] and one retrospective study in the same country [10]. Our study is to show how we can do safe PSA using available medication

This study will help other researchers who want to explore the same topic by providing an understanding of the current baseline adverse events in our population in the emergency department. Prior studies have shown that propofol, ketamine, morphine, fentanyl, and midazolam are effective, available in most health facilities, and have been shown to be safe and effective in appropriate patients [7]. In our study fentanyl and midazolam were excluded, as they are not available in our setting.

Chapter II. AIMS AND OBJECTIVES

2.1 Research question

- ✓ What are the common adverse events found in patients on different medication used in ED for procedure sedation and analgesia?
- ✓ How effective was the medication that was used?

2.2. Hypothesis

Procedural sedation can be safely and effectively performed in the emergency department, even in a low-resource setting.

2.3 Aims

The primary aims of this study are to identify the most adverse effect of medication used in ED during PSA.

Aim 1: To compare effectiveness of medication used in PSA

Aim 2: To evaluate the adverse events of medication used in PSA

2.4 Objectives:

- ✓ To examine which of the medications mostly used for PSA are associated with the highest rate of successful of procedure.
- ✓ To assess the association between patient demographics, PSA medications used and adverse events.

Chapter III. METHODOLOGY

3.1. Study Description

This study is a prospective observational study evaluating procedural sedation done in the emergency department at CHUK, their effectiveness and evaluation of RASS while under sedation and pain scale before and after procedure. We have evaluated the common adverse events of medication used in PSA and the success or failure of those procedures. Our patients have been categorized according to their profession or what they were doing while being injured to cause PSA.

The pain was assessed using numerical pain scale before procedure along procedure and 30 minutes after procedure.

Vital signs were measured before administration of sedation and 15 minutes post procedure. Hypoxia was reported if SPO₂ is $\leq 90\%$, immediate oxygen was given. Bradycardia was defined as HR ≤ 60 in adults, Hypotension as SBP ≤ 90 . The management of adverse events happened immediately as it occurs, RASS score was evaluated before starting the procedure at least 3 minutes post sedation.

RASS score was used to know the level of sedation (Light sedation briefly awake to voice (eye opening/contact) < 10 sec) and, minimum on -4 (Deep sedation, no response to voice, but movement or eye opening to physical stimulation) the maximum was 0 (Alert and calm)

We have defined our fasting 6 hours with food and 3 hours with clear fluids. No fasting in the study was defined as patients who have taken clear fluids within 2 hours prior to procedure

We have defined the junior doctor as a postgraduate in year one or two and general practitioner, senior doctor as postgraduate in year three or four, and consultant in emergency medicine and critical care.

We have defined success as absence of adverse events and failure as occurrence of adverse events.

The medications used have been given in on standard dosage (Morphine 0.2mg/kg, ketamine 1-2mg/kg, propofol 1-2mg/kg, Diazepam 0.1-0.2mg/Kg, midazolam 0.1-0.2mg/Kg), Ketofol was 50% ketamine and 50% propofol.

3.2. Study Site

The study was conducted at CHUK, the main public referral and teaching hospital in Rwanda and training center for emergency medicine and critical care.

3.3. Study Population

3.3.1 Inclusion criteria

All patients who needed PSA presenting to the CHUK ED during a period of study from 1st October to 31st December 2018 were enrolled in the study after consent and assent for kids.

3.3.2 Exclusion criteria

- If the patient (or relative) refused to be in the study/to sign the consent.
- If a less than 18 years refuse assent.
- If the patient is less than 7 years old.

3.2. Study Procedures

3.2.1. Procedures at enrollment

After explaining the research study and what kind of information was to be obtained, the patient or family member was asked if they were willing to be enrolled in the study. They were assured their information would be kept confidential. Time was given for patients to ask questions for clarification if needed. If agreeable, the patient (or relative) then signed the consent form. After consent had been obtained, the PI or research project staff filled in the questionnaire. During the procedure vital signs were monitored and recorded until 30 minutes post procedure. A part of vital signs before procedure we have assesses RASS scale and recorded on the questionnaire. We have recorded the timeline before the procedure and the medication they have got especially pain killer

3.3. Sample Size

The study included all patients above age 7 who presented to the CHUK emergency and need procedure sedation and analgesia (PSA). The period of 3 months (1st October to 31st December 2018) 251 cases have been consulted and agreed to the consent to be part of the study. This sample was convenient in 3 months of study period.

Chapter IV. ETHICAL CONSIDERATIONS

4.1. Confidentiality

Any identifying information collected in this study was demographic in nature (age, gender, etc.). Names of survey participants were not recorded on data collection, and there was a separate sheet matching the research code to patient's identification.

4.2 Informed Consent

Participants gave written consent (assent for 7-17 year-olds), in order to be included. To ensure informed consent/assent, participants were provided with a scripted description of the survey that includes possible risks and benefits. The potential subject were provided adequate time to read the consent/assent. Additional explanation was provided if the subject didn't understand the purpose of the study. If any subject either did not understand the study or did not want to be in the study, then they were not included in the study. No influence to the care given whether the patient accept or refuse to be part of study.

4.3 Ethical Approval

This study happened after being sought by CMHS ethical committee and CHUK ethical committee because they were a minimal risk to the patients who were involved. Our research have been approved after being reviewed by CMHS ethical committee after being presented , comments given by this organ have been worked on and was approved .

CHUK ethical committee has approved the same protocol after being reviewed by its committee (Approval documents on annex)

3.5. Data analysis

Data collected was entered into an electronic database and analyzed using Microsoft Excel 2010 software (Microsoft Corporation). We described the ranges and interquartile ranges and median. The primary outcome comparator was absence of adverse events of the patient during procedure versus adverse events. Categorical data was analyzed for significant differences using Chi-squared (χ^2) tests and continuous data with Mann-Whitney (MW) tests. Shapiro-Wilk test was used to look for normal distribution of our data.

Chapter V. RESULTS

5. 1. Patient demographics

In total 251 patients were recruited. The majority was male (72 %). The median age was 32 years (IQR 23-40). The youngest patient enrolled was 8 year and the oldest was 88 years. Shapiro-Wilk test for Normal distribution, normality was rejected for age.

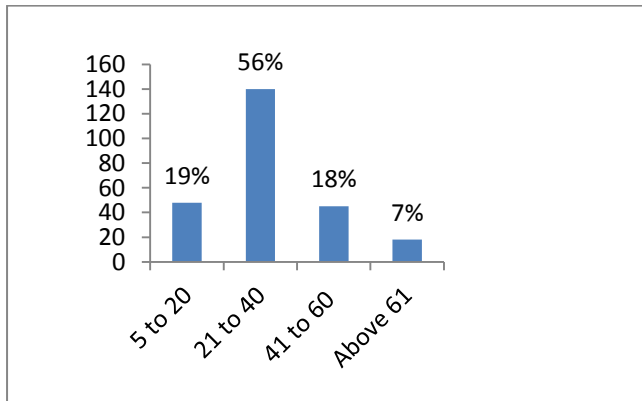


Figure 1 Age trends of study population

5.2 Activity resulting in need of procedure

Moto drivers and passengers made up over half of the patients”.

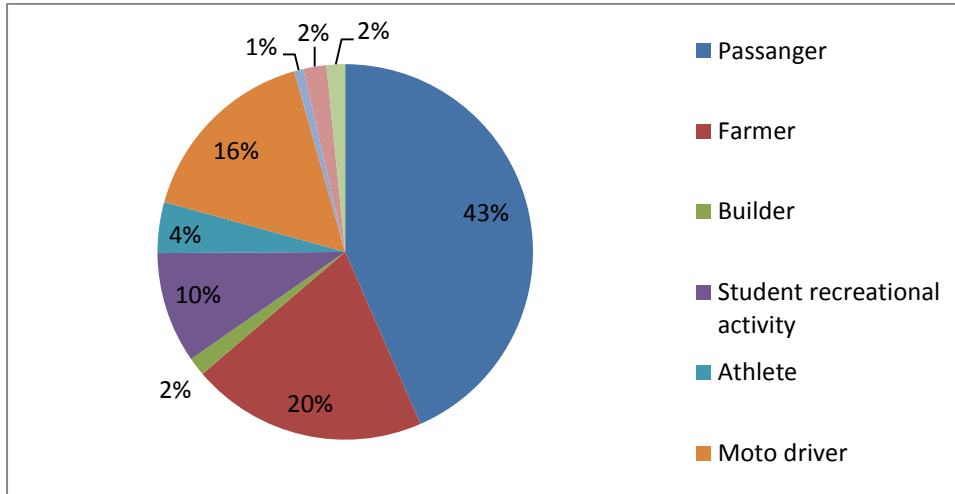


Figure 2 Activity leading to procedure of study population

5.3. Comorbidities

90% were without comorbidities. Commonest comorbidities included hypertension (5%) followed by diabetes (3%).

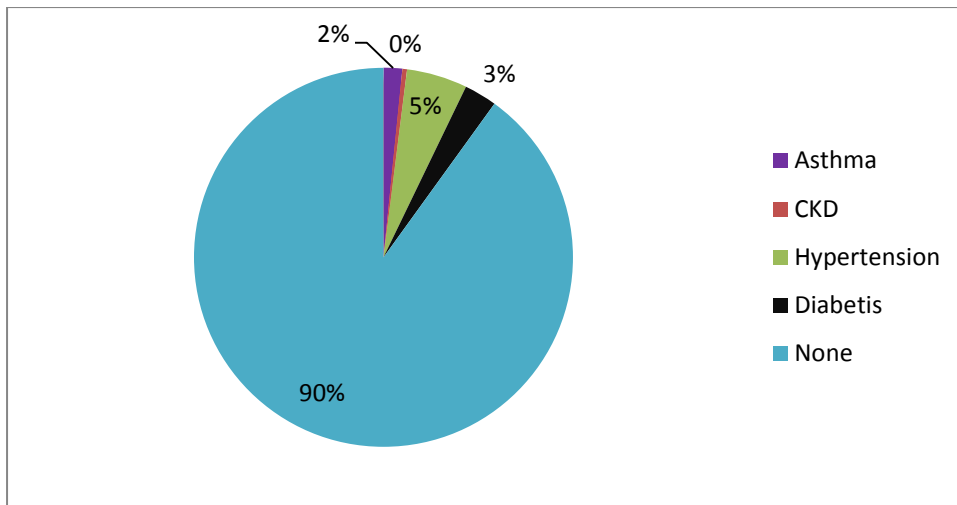


Figure 3 Comorbidities in study population

5.4 Fasting

NPO prior to procedures and the results 53% were fasting and 47% no fasting

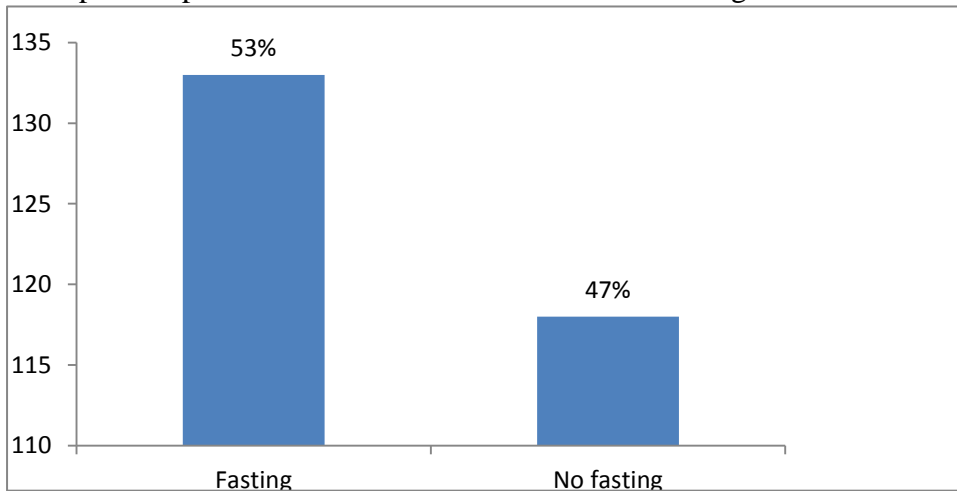


Figure 4 Fasting pattern in study population

5.5. Analgesia

The commonest analgesics used were morphine (78%), and tramadol (17%).

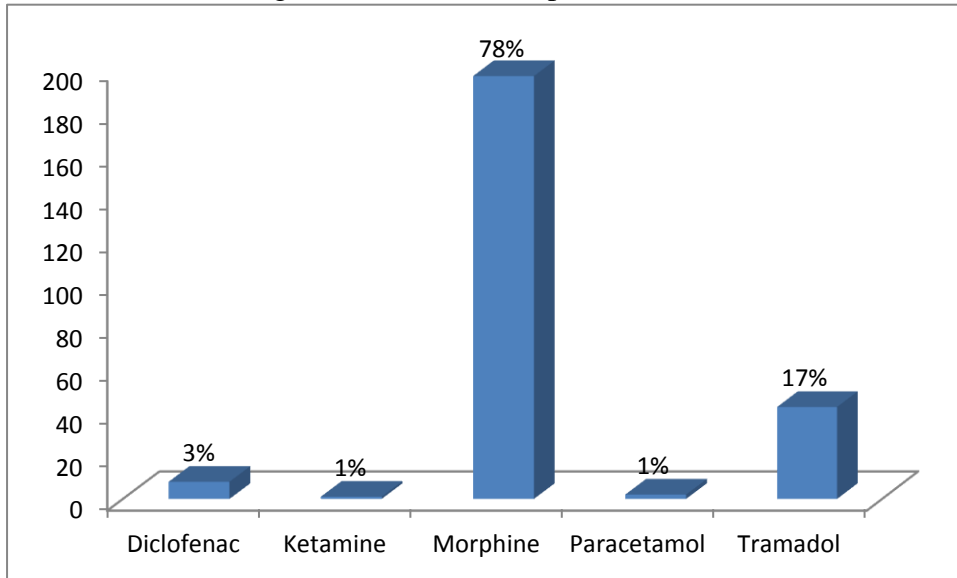


Figure 5 Analgesia in study population

5.6. Sedative

The commonest sedative agents used were ketamine (68%), and propofol (26%).

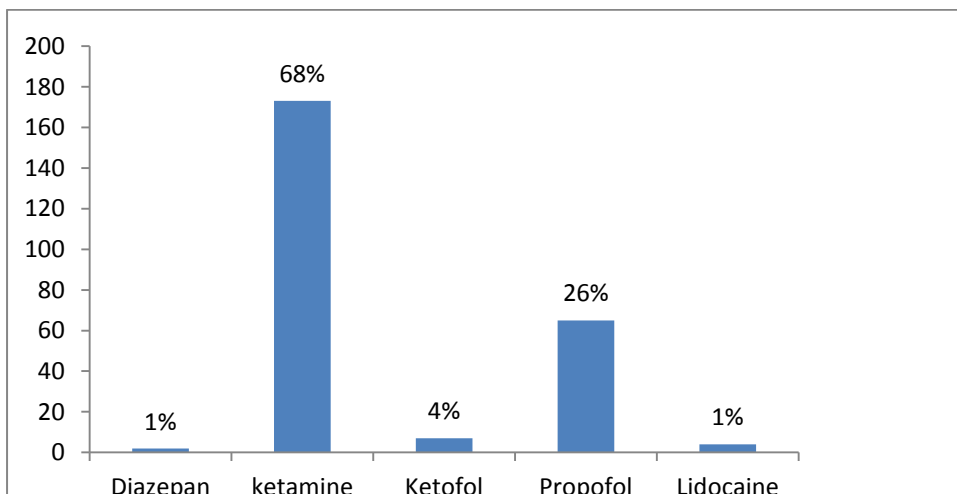


Figure 6 Sedation in study population

5.7. Procedures

Wash out was defined as patients coming with wounds contaminated or not without association of bones fractures , either they have immediately sutured or left if contaminated we had 18%, among study population other were having open fracture wash out and fracture immobilization , 29%

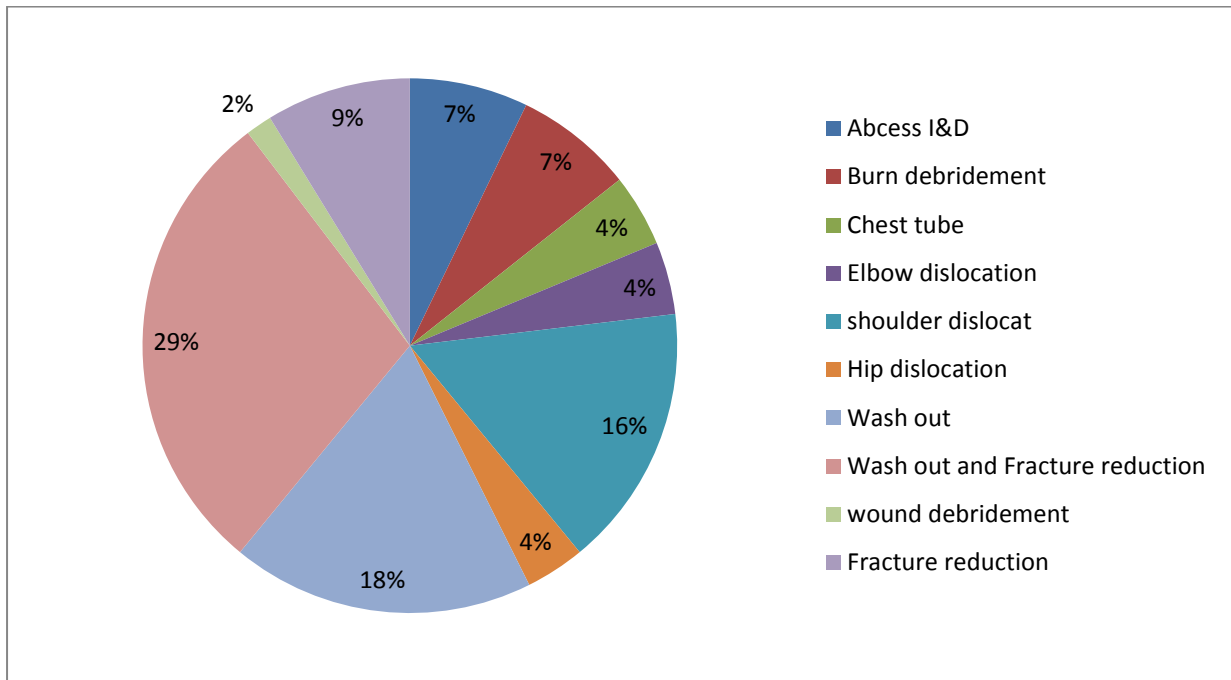


Figure 7 Procedures in study population

5.8. Pain before procedure and after procedure

Prior to procedural sedation the median of pain score was 5, (IQR5-6-After the procedure the median pain score was 2 (IQR= 1-2)

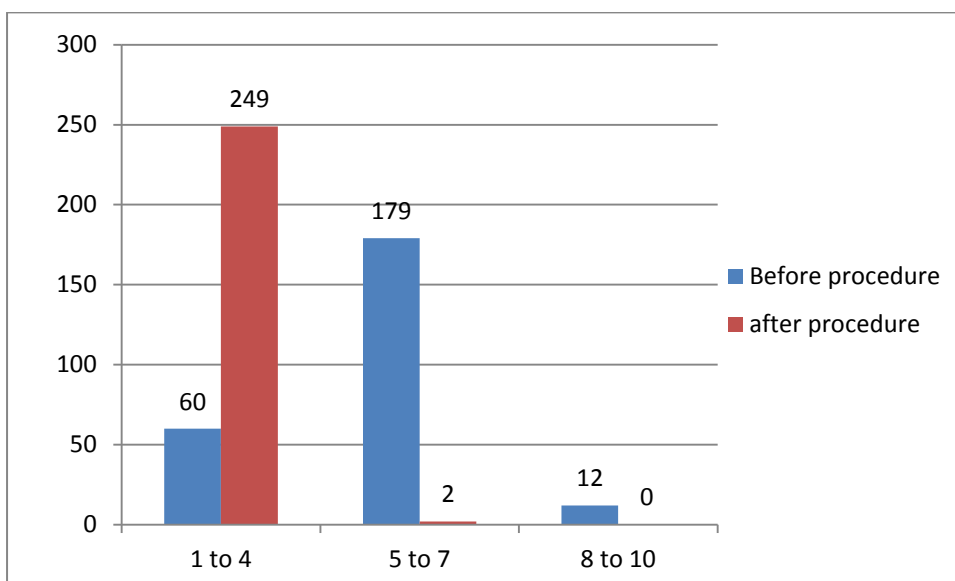


Figure 8 Pain numerical scale in study population

5.9. Sedation level with RASS

Median RASS score was -2 (IQR -2 to -2)

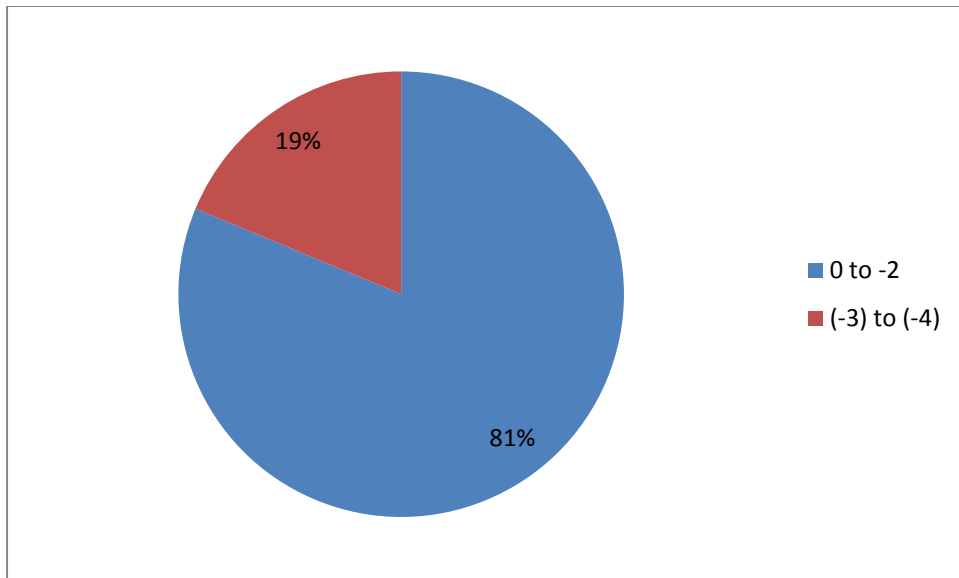


Figure 9 Sedation level

5.10. Adverse events

The most common adverse events were hypoxia 36% and hallucinations 8%. 47% didn't develop adverse events

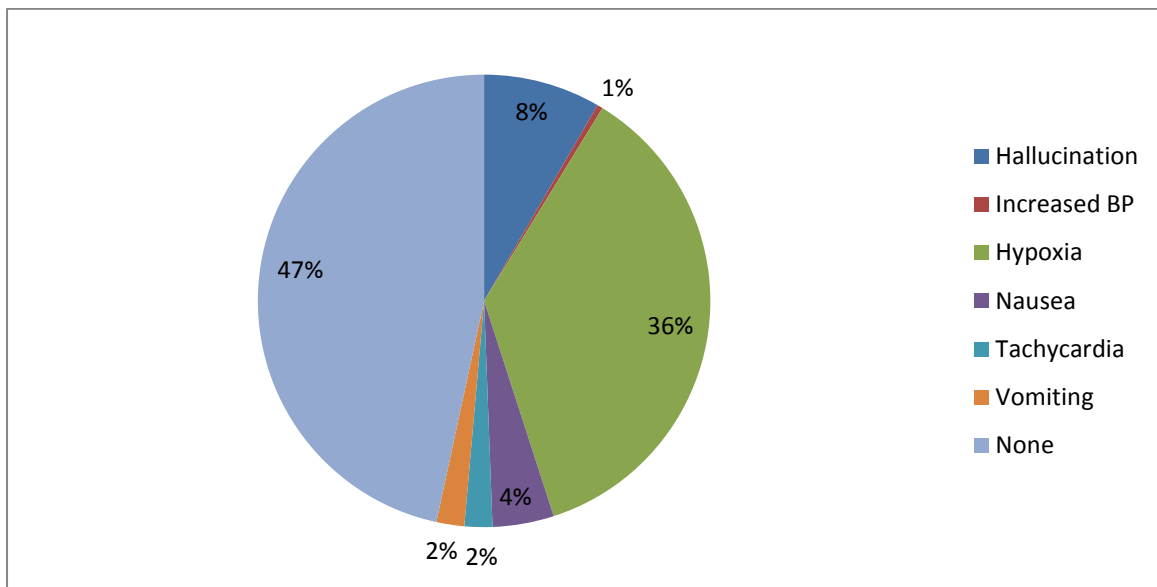


Figure 10 Adverse events in study population

5.11. Management of adverse events

All adverse events were managed accordingly and no advanced management, such as intubation, was required. Among hypoxic patients none needed BVM, patients who had hallucinations were managed with diazepam.

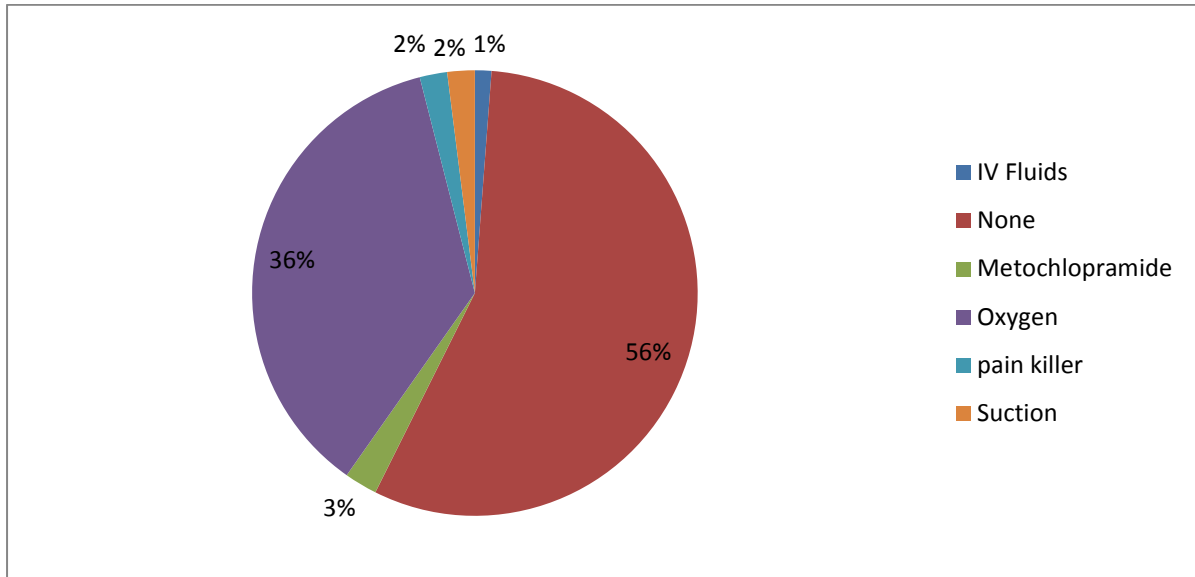


Figure 11 Adverse event in study population

5.12. Comparison of propofol and ketamine groups (Tables 1 and 2).

We compared propofol and ketamine groups as these made up the large majority of all sedatives used (94%). There was no significant difference in failure rates between propofol and ketamine groups. There was a non-significant trend towards senior residents being more likely to use propofol than juniors. There were no significant falls in HR, RR, SBP and SpO₂ in either of the ketamine or propofol groups, or overall. There was a non-significant trend to propofol causing a higher fall in SBP than ketamine.

	Total	n=251	Propofol	n=65	Ketamine	n=173	Chi square test
	n	%	n	%	n	%	p value
Failure	128	51.0	35	53.8	85	49.0	0.518
Success	123	49.0	30	46.2	88	51.0	
Hypoxia (SPO ₂ <90 on RA)	91	36.3	26	40	61	35.2	0.435
None	160	63.7	39	60	112	64.8	
Hallucination	21	8.3	3	4.6	18	10.5	0.162
None	230	91.6	62	95.4	155	89.5	
Nausea	11	4.4	3	4.6	7	4.0	0.846
None	240	95.6	62	95.4	166	96	
Male	181	72.1	48	73.8	124	71.7	0.74
Female	70	27.9	17	26.2	49	28.3	
Comorbidities	25	10	4	6.2	20	11.6	0.218
No comorbidities	226	90	61	93.8	153	88.4	
Senior (PGY3&PGY4)	75	29.9	24	36.9	46	26.6	0.12
Junior (PGY1&PGY2)	176	70.1	41	63.1	127	73.4	
Fasted	133	53	33	50.8	92	53.2	0.741
Not fasted	118	47	32	49.2	81	46.8	

Table 1 Comparison of propofol and ketamine groups (categorical data, p values according to Chi square test

		Overall		Pre vs post	Propofol		Pre vs post	Ketamine		Pre vs post	Mann-Whitney test for Propofol vs Ketamine
	N	median	IQR	M-W p	median	IQR	M-W p	median	IQR	M-W p	p value
HR pre	251	82	72-98		90	78-98		80	70-98		0.126
HR post	251	75	70-85	<0.0001	76	70-86.25	0.0002	75	70-85	<0.0001	0.487
HR fall	251	6	0-14.75		8	3-15		5	-1.25-13		0.049
RR pre	251	19	18-22		18	18-20		20	18-22		0.388
RR post	250	18	16-18	<0.0001	18	16-20	<0.0001	18	17-18	<0.0001	0.65
RR fall	250	2	0-4		2	0-3.25		2	0-4		0.49
SBP pre	249	128	117.75-135		130	117.5-135.25		125	118-135		0.498
SBP post	249	122	115-130	0.001	120	115-126	0.0115	122.5	115-130	0.0271	0.281
SBP fall	247	5	-5-10.75		7.5	-1.5-12		3	-5-10		0.103
SpO2 pre	250	100	98-100		100	98-100		100	98-100		0.371
SpO2 post	251	98	97-98	<0.0001	98	97-98	<0.0001	98	97-98	<0.0001	0.983
SpO2 fall	250	2	0-3		2	0-2		2	0-3		0.463
Age	250	32	23-40		31	23.75-40		32.5	23-40		0.761
Pain pre	251	5	5-6		5	4-6		5	5-6		0.18

Table 2 Comparison of propofol and ketamine groups (continuous data, p values according to Mann Whitney test).

5.13. Comparison of success and failure groups (Tables 3 and 4).

Post procedure SBP was higher in failures than in successes. Otherwise, there were no significant differences between groups. There were non-significant trends towards: pre procedure HR higher in failures; pre-procedure pain score lower in failures; senior doctors having more success; fasted patients having more success.

Categorical data	Overall		Success		Failure		Chi square test
	n	%	n	%	n	%	
Male	181	72.1	89	72.4	92	71.9	0.932
Female	70	27.9	34	27.6	36	28.1	
Comorbidities	25	10	15	12.2	10	7.8	0.247
No comorbidities	226	90	108	87.8	118	92.2	
Senior	75	70.1	42	65.9	33	25.8	0.149
Junior	176	29.9	81	34.1	95	74.2	
Fasted	133	53	73	59.3	60	46.9	0.124
Not fasted	118	47	50	40.7	68	53.1	
Diazepam	2	0.8	1	0.8	1	0.8	0.83
Ketamine	173	68.9	85	69.1	88	68.7	
Ketofol	7	2.8	4	3.3	3	2.3	
Lidocaine	4	1.6	3	2.4	1	0.8	
Propofol	65	25.9	30	24.4	35	27.3	

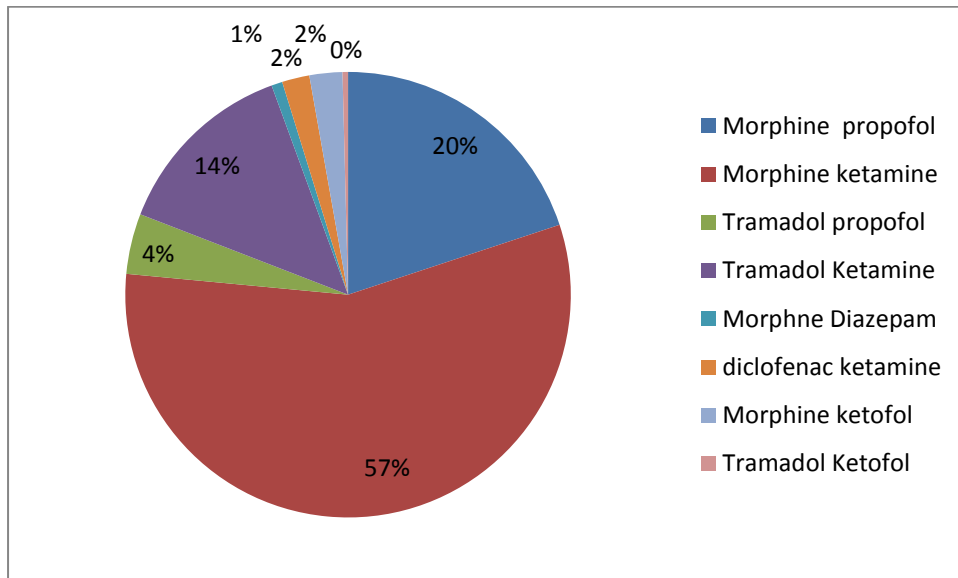
Table 3 Comparison of success and failure groups (categorical data, p values according to Chi Square test).

	Overall			Success			Failure			Mann-Whitney test
Continuous data										
	n	Median	IQR	n	Median	IQR	n	Median	IQR	p
Age	250	32	23-40	122	31.5	23-41	128	32	23-39.5	0.561
HR pre	251	82	72-98	123	80	70-95	128	90	75.5-98	0.106
HR post	251	75	70-85	123	75	70-83.75	128	78	70-90	0.148
HR fall	251	6	0-14.75	123	5	0-13	128	8	0-15	0.624
RR pre	251	19	18-22	123	20	18-22	128	18.5	18-22	0.459
RR post	250	18	16-18	123	18	16-18	127	18	16-18	0.447
RR fall	250	2	0-4	123	2	0-4	127	2	0-4	0.862
SBP pre	249	128	117.75-135	121	125	115.75-135	128	130	118-135	0.227
SBP post	249	122	115-130	123	120	115-125	126	125	118-130	0.0213
SBP fall	247	5	-5-10.75	121	4	-5-10.25	126	5	-5-11	0.8437
SpO2 pre	250	100	98-100	122	100	98-100	128	100	98-100	0.836
SpO2 post	251	98	97-98	123	98	97-98	128	98	97-99	0.158
SpO2 fall	250	2	0-3	122	2	0-3	128	2	0-3	0.55
Pain pre	251	5	5-6	123	5	5-6	128	5	4-6	0.0673

Table 4 Comparison of success and failure groups (continuous data, p values according to Mann Whitney test)

5.14. Analgesia and sedation given

Majority of our population have got Morphine and ketamine at the rate of 57% , Morphine propofol 20% and tramadol Ketamine 14%.



Chapter VI. DISCUSSIONS

Successfully procedural sedation and analgesia in ED is expectation of ED resident or physician even if adverse events may occur, he has to be able to handle them.

Studies to medications used have been extensively done in different corner of the world; our study propofol and ketamine have been used 94% because they are available. Propofol is known to cause hypotension and can't be used on patient with hypotension, ketamine as a dissociative agents it can cause hallucinations, laryngospasm has an incidence of 0.4 percent in patients receiving ketamine, but it is generally transient, and patients can be ventilated manually via bag-valve mask when necessary if not intubation. The adverse events we had in this study was simple we didn't get events requiring advanced care. The timeline to this study was short so that we didn't have those adverse events.

Overall residents performed most of the procedure in ED, with senior residents (PGY3 and PGY4) and consultant playing a supervising role for junior residents during PSA, and ready to intervene if adverse events.

Our study cohort was unique compared to other similar studies in that patients there were no significant difference in failure rates between propofol and ketamine groups. Miner et al showed that respiratory depression in patients in the ketamine group than the propofol group, and recovery agitation was seen more frequently in patients receiving ketamine than in those receiving propofol, same study showed no significant different for those medication to cause hypotension.

Study done in Australia and published in Emergency medicine in Australasia 2011(Bell et al 2011). The common procedure done in this study was shoulder dislocation reduction at 26.7% , the fasting rate was 53%. Our study showed that the pre medication given mostly was morphine in the same study showed that Morphine was given 34.1% as pre medication before PSA.

Taylor et al study showed that the adverse events related to airway was 20.8% , vomiting was reported at 1.6% (Taylor et al 2011)

The common procedure done in this study was shoulder dislocation reduction at 26.7% , while our study the shoulder dislocation count 16%

Metanalysis done looking the incidence of adverse events in PSA where 55 articles have been reviewed including 9,562 PSA , showed that hypoxia was common 40.2 , vomiting 16.4 ,and hypotension 15.2 per 1000 sedations . In same metanalysis ketamine was the leading cause of agitation and vomiting 164.1 and 170.0 per 1000 sedations, apnea with midazolam 51.4 per 1000 sedations. The severe adverse events requiring emergency medical intervention were rare with 1.2 per thousand sedations of aspiration and 1.6 per thousand sedations of intubation [6].

The study done from 2003 to 2013 and published in EMJ in February 2016 by Dr Gael et al in Netherland showed that the adverse events occurred 11%, the commonest was hypoxia and apnea .the medication used were Propofol, Midazolam and ketamine at the rate of 63%, 29% and 8% The same study they were no significant difference in percentage of adverse events

between medications used ($p=0.88$). Majority of procedure were hip and shoulder dislocation 29.2%, 26.1% respectively [3].

6.1.Limitations

The recording of Pulse oxymeter were not reported with the time of occurrence of hypoxia after giving procedure. If it was done , may give us how many minutes we have to wait to predict the adverse events of hypoxia . Airway examination and reporting was necessary even if it was not done to predict if we were facing a difficult airway.

The study timeline was short (3 months) and the sample were not enough (251) to know if we don't have severe adverse events like bronchospasm , apnea ...that need aggressive management

The study for 1 year may be fruitful to show us those severe adverse events. Independent observer is needed to collect the data on adverse events thereby eliminating the possibility of biased underreporting.

We didn't assess other risk factor to failure of procedure but we saw that pre-procedure pain score lower in failures, further studies to explore this are recommended.

Chapter VII. Conclusion & recommendation

These data suggest that, although some adverse events may be unavoidable in any setting, a comparably level of safety can be achieved even in low resource settings. Preparation of severe adverse events even if is rare will help to save patients without harm. Avail emergency trolley in procedure room will improve the PSA; adding capnography on the monitor can help to minimize the hypoxia.

Further studies should use a larger sample size powered to evaluate rare events such as laryngospasm from ketamine. When resources are available future studies should also employ an independent observer to collect data on adverse events thereby eliminating the possibility of biased underreporting.

Multivariate evaluations of analgesia, procedure sedation and adverse events have to be studied in next research on PSA.

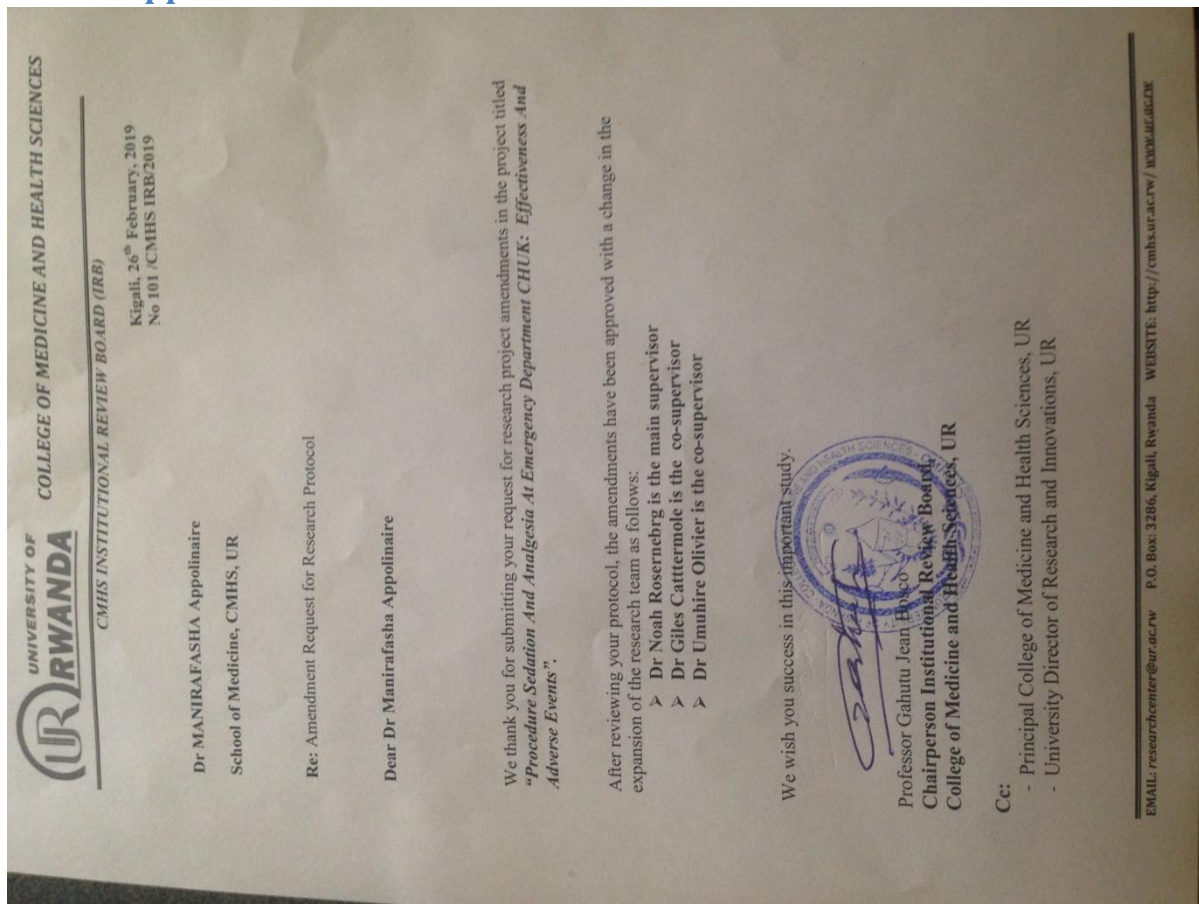
Chapter VIII. REFERENCES

- [1] s. A, J. Hurton and C. Gerardo, et al. "Clinical Policy: Procedural Sedation and Analgesia in the Emergency department," *Annals of emergency medicine*, vol. 63, no. 2, pp. 247-258, 2014.
- [2] R. F. Pinto and M. Bhimani, "Procedural sedation and analgesia in rural and regional emergency departments," *Canadian Journal of rural medicine*, vol. 4, no. 18, pp. 130-136, 2013.
- [3] G. G. Smith and M. Kuypers, "Procedural sedation in the emergency department by Dutch emergency physicians: a prospective multicentre observational study of 1711 adults," *BMJ emergency medicine journal* Vol 34 pp:237–242, 2017.
- [4] P. G. S and F. Angeli, "Pediatric Procedural Sedation and analgesia," *Emerg Med Clin N Am* vol. 31, pp. 831-852, 2013.
- [5] Paul. Atkinson. and F. James, "Procedural sedation and analgesia for adults in the emergency department," *BMJ*, vol. 348, pp. 1-5, 2014.
- [6] M. Fernanda Bellolio, M D, M S, Waqas I. Gilani, MD et al, "Incidence of Adverse Events in Adults Undergoing Procedural Sedation in the Emergency Department: A Systematic Review and Meta-analysis" *academic emergency medicine journal*; vol.23, pp 119 –134 , 2016
- [7] Alan J. Smally, Thomas A. Nowicki ,and Bernard H. Simelton "Procedural sedation and analgesia in the emergency department" *Current Opinion in Critical Care* Vol17, pp.317 – 322 , 2011
- [8] P. W. Hodkinson & M. F. M. James & L. A. Wallis "Emergency department procedural sedation practice in Cape Town, South Africa" *international journal of emergency medicine* Vol.2, pp91 –97 , 2009
- [9] C.C. Meyer , A. Engelbrecht "Procedural sedation and analgesia: Auditing the practice at Steve Biko Academic Hospital Emergency Centre from May to October 2014" *African Journal of Emergency Medicine* ,Vol.5, pp 108–113, 2015
- [10] G Wenzel-Smith, B Schweitzer "Safety and efficacy of procedural sedation and analgesia (PSA) conducted by medical officers in a level 1 hospital in Cape Town" *The south African medical journal* Vol 101, no 12, pp 895-898 , 2011.
- [11] Taylor, David McD Bell, Anthony Holdgate, Anna MacBean Risk factors for sedation-related events during procedural sedation in the emergency department , *Emergency Medicine Australasia* vol 23 no 12 pp 466-473 ,2011
- [12] Bell, Anthony Taylor, David McD Holdgate, Anna MacBean : Procedural sedation practices in Australian Emergency Departments, *Emergency Medicine Australasia* vol 23 no 12 pp 458-465 ,2011
- [13] Holdgate, Anna Taylor, David McD Bell, Anthony MacBean, Catherine : Factors associated with failure to successfully complete a procedure during emergency department sedation , *Emergency Medicine Australasia* vol 23 no 12 pp 474-478 ,2011

[14] James R. Miner, MD, et al : Randomized Clinical Trial of Propofol Versus Ketamine for Procedural Sedation in the Emergency Department , ACADEMIC EMERGENCY MEDICINE 2010; 17:604–611 a 2010 by the Society for Academic Emergency Medicine

ANNEX

UR IRB approval



Dr. MANIRAFASHA Apollinaire
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No. 020 /CMHS IRB/2018

Your Project Title "*Procedure Sedation And Analgesia At Emergency Department CHUK: Effectiveness And Adverse Events*" has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	Withdrawn from the proceeding
Prof. Kato J. Njunwa	UR-CMHS		X	
Prof. Jean Bosco Gahutu	UR-CMHS	X		
Dr. Brenda Asimwe-Kateera	UR-CMHS	X		
Prof. Ntanganira Joseph	UR-CMHS	X		
Dr. Tumusiime K. David	UR-CMHS	X		
Dr. Kayunga N. Egide	UR-CMHS	X		
Mr. Kanyoni Maurice	UR-CMHS	X		
Prof. Muryanshore Cyrien	UR-CMHS	X		
Mrs. Ruzindana Landrine	Kicukiro district		X	
Dr. Gishoma Darius	UR-CMHS	X		
Dr. Donatilla Mukamana	UR-CMHS	X		
Prof. Kyamunyuwa Patrick	UR-CMHS	X		
Prof. Condo Umutesi Jeannine	UR-CMHS	X		
Dr. Nyirazinyoye Laetitia	UR-CMHS	X		
Dr. Nkeramihigo Emmanuel	UR-CMHS	X		
Sr. Mailiboli Marie Josee	CHUK	X		
Dr. Mudenye Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 31st January 2018, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for 12 months.

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrollment of participants. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

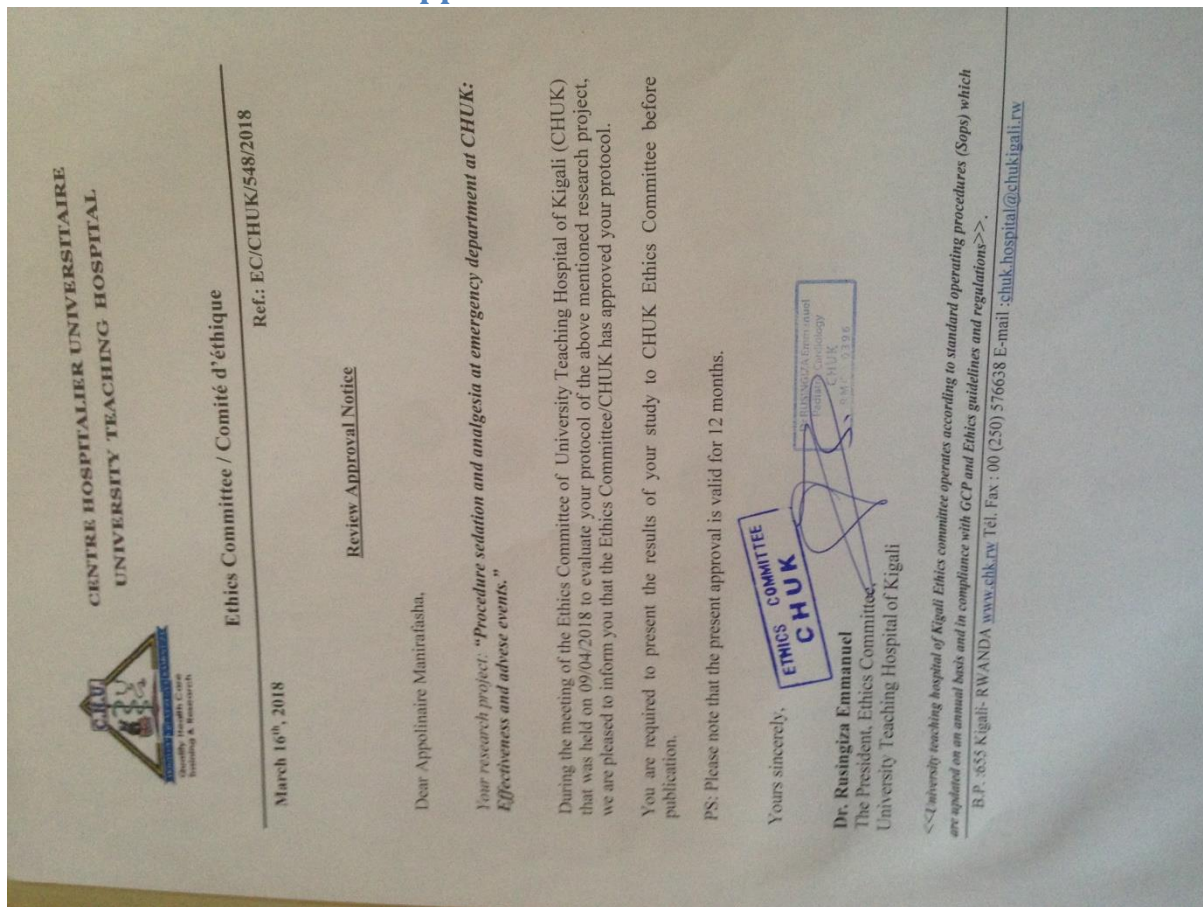
Date of Approval: The 2nd February 2018

Expiration date: The 2nd February 2019

For Professor Kato J. NIUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc: - Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

CHUK ethical committee approval



Questionnaire

A. Demographic data

Patient code PSAS (Procedure sedation and analgesia study).....

Age:

Sex: Male female

Activity leading to procedure : motor driver car driver builder passenger farmer
other.....

B. Clinical information

Duration of /symptoms/injury (If trauma)

Date of consultation/...../.....

Reason of consultation: Medical surgical Trauma Iatrogenic

Fasting yes no

Pain controlled by and dose : Morphine tramadol. Diclofenac. Paracetamol fentanyl
Other

Sedative + dose used : propofol Ketamine Midazolam Diazepam
Other.....(dosage.....)

Procedure ...Chest tube wash out , burn , shoulder dislocation , hip dislocation ,
elbow dislocation fracture reduction Abscess incision and drainage other

Pain before procedure 0 1 2 3 4 5 6 7 8 9 10

.RASS score after sedation 4 3 2 1 0 -1 -2 -3 -4 -5

Pain 30 min after procedure 0 1 2 3 4 5 6 7 8 9 10

Vitals signs: Before procedure	BP: .../...	HR	RR....	SPO ₂
In procedure	BP:/...	HR.....	RR	SPO ₂
After procedure	BP:/...	HR.....	RR	SPO ₂

Adverse event : Hypotension Hypertension Hypoxia Bradycardia
tachycardia , Nausea , Vomiting , hallucinations , Apnea , other.....

Management of adverse events: intubation IVFluid Oxygen Suction Atropine
other.....

Outcome of procedure: successful failed helped by another one for success

Procedure performer... Nurse GP PGY1 PGY2 PGY3 PGY4
Consultant

Supervisor: GP PGY1 PGY2 PGY3 PGY4 Consultant

Richmond sedation-agitation scale (RASS)

Richmond Agitation Sedation Scale (RASS)

Target RASS	RASS Description
+ 4	Combative, violent, danger to staff
+ 3	Pulls or removes tube(s) or catheters; aggressive
+ 2	Frequent nonpurposeful movement, fights ventilator
+ 1	Anxious, apprehensive , but not aggressive
0	Alert and calm
- 1	awakens to voice (eye opening/contact) >10 sec
- 2	light sedation, briefly awakens to voice (eye opening/contact) <10 sec
- 3	moderate sedation, movement or eye opening. No eye contact
- 4	deep sedation, no response to voice, but movement or eye opening to physical stimulation
- 5	Unarousable, no response to voice or physical stimulation

Numerical pain scale

